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Agency

Prevention, Pesticides
and Toxic Substances
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September 2005

Reregistration Eligibility Decision (RED) for Fluometuron

REREGISTRATION ELIGIBILITY

DECISION

for

Fluometuron

Case No. 0049

Approved by:

_____
Debra Edwards, Ph.D.
Director, Special Review and
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_____
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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for fluometuron and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of fluometuron that pose risks of concern. As a result of this review, EPA has determined that fluometuron-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

Fluometuron is a phenylurea herbicide that was first registered in 1974 on cotton and sugarcane and is now used only on cotton. Initial risk assessments indicated chronic (non-cancer) and cancer dietary (food and drinking water) risks of concern. Risk estimates were revised based on refinements to the assessments as well as mitigation measures, and the Agency will be requiring groundwater monitoring data. Occupational risks have been mitigated through PPE requirements on the labels, and ecological risks have been addressed through the rate reductions and a requirement for use of a medium droplet size during pesticide application. Further, additional ecotoxicology data are being required.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility of infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider available information concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. However, EPA has not made a common mechanism of toxicity finding as to fluometuron and any other substances, and fluometuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluometuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for fluometuron. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment; Section II provides a profile of the use and usage of the chemical; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the

risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The revised risk assessments for fluometuron are available in the Office of Pesticide Programs (OPP) public docket under docket number OPP-2004-0372 available on the Agency's web page at http://www.epa.gov/oppsrrd1/reregistration/fluometuron/.

II. Chemical Overview

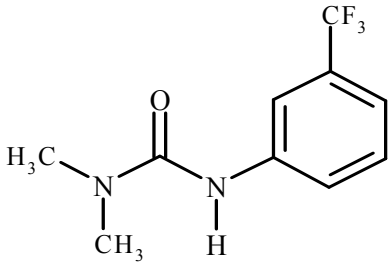
A. Regulatory History

Fluometuron was first registered in 1974 by Ciba-Geigy Corporation for use on cotton and sugarcane as a preplant, pre-emergence, and post-emergence herbicide for the control of broadleaf weeds and annual grasses. The tolerance for sugarcane was voluntarily revoked in 1998 (63 FR 57067). After a series of transfers of ownership, Agan Chemical Manufacturers, Ltd., is the current basic manufacturer of fluometuron.

The Agency issued the Guidance for the Reregistration of Pesticide Products Containing Fluometuron (or the "Registration Standard") in 1986. The Registration Standard summarized available toxicity, product chemistry, ecological, and environmental fate data to determine the adequacy of the fluometuron database to support continued registration. This document also identified generic and product-specific chemistry data required for the reregistration eligibility of fluometuron. Two Data Call-In (DCI) Notices requiring studies to support use patterns were issued in 1991 and in 1995. The data received in response to the DCIs were used to reach the reregistration eligibility conclusions for fluometuron that are presented in this RED document.

B. Chemical Identification - Fluometuron

Chemical Structure:



Common Name:	Fluometuron
Chemical Name:	*N*,*N*-dimethyl-*N*'-(3-(trifluoromethyl)phenyl)urea
Trade Name:	Cotoran®
Chemical Family:	Phenylurea herbicide
Case Number:	0049
CAS Number:	2164-17-2
PC Code:	035503
Molecular Weight:	232.2
Empirical Formula:	$C_{10}H_{11}F_3N_2O$
Basic Manufacturer:	Agan Chemical Manufacturers, Ltd.
Other Technical Registrants:	Loveland Products, Inc. Micro-Flo Company LLC

C. Use Profile

The following is information on the currently registered uses of fluometuron, including an overview of use sites and application methods. A detailed table of the uses of fluometuron eligible for reregistration is available in Appendix A.

Type of Pesticide:	Herbicide
Target Pest:	Broadleaf weeds
Mode of Action:	Inhibition of photosynthesis and bleaching and inhibition of carotenoid biosynthesis
Use Site:	Cotton
Use Classification:	General Use
Formulation Types:	Fluometuron formulations include dry flowable, soluble concentrate/liquid, wettable powder, and emulsifiable concentrate
Application Methods:	Fluometuron is applied by broadcast sprayer, band sprayer, aircraft, or via ground/soil incorporation. It can be applied in broadcast sprays, banding treatments, low volume sprays, directed sprays, basal sprays, or incorporated directly into the soil. About 80% of fluometuron application is by ground.
Application Rates:	Fluometuron is applied at a maximum one-time application rate of 2.0 pounds active ingredient per acre (lb ai/A) with up to 3 treatments per year.
Application Timing:	Fluometuron can be applied pre-plant (7%); at plant (57%); pre-emergence (22%); or post-emergence (14%). Percentages represent percent of fluometuron-treated acres.

D. Estimated Usage of Fluometuron

A screening-level estimate of the usage of fluometuron from 1998 to 2002 indicates that approximately 2,400,000 pounds of fluometuron are used annually in the United States with an average of 10% of cotton acreage and a maximum of 20% of cotton acreage (2000) being treated. Annual usage appears to be declining as a result of the use of glyphosate-resistant cotton.

III. Summary of Fluometuron Risk Assessments

The following is a summary of EPA's human health and ecological effects risk findings and conclusions for the herbicide fluometuron, as presented fully in the following documents: *Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED)* dated February 1, 2005; *Fluometuron: Occupational Exposure Assessment for the Reregistration Eligibility Decision Documen*t dated December 7, 2004; *Revised Environmental Fate*

and Ecological Risk Assessment of Fluometuron dated February 22, 2005; *Fluometuron Revised Drinking Water Assessment for the Health Effects Division (HED) Reregistration Eligibility Decision Document* dated December 8, 2004; *Revised Drinking Water Assessment and EFED's Response…* dated September 28, 2005; *Impacts Assessment for Fluometuron* dated September 26, 2005; *Refined Fluometuron Percent Crop Treated and Percentage of National Soybean, Corn, and Wheat Crops Rotated with Fluometuron-Treated Cotton* dated August 9, 2005; and *Addendum to Refined Fluometuron Percent Crop Treated…* dated September 21, 2005.

The purpose of this section of the document is to summarize the key features and findings of the risk assessments in order to help the reader better understand the conclusions reached in the assessments. While the risk assessments and related addenda are not included in this RED document, they are available from the Office of Pesticide Programs (OPP) public docket: OPP-2004-0372 and may also be accessed on the Agency's website at http://www.epa.gov/oppsrrd1/reregistration/fluometuron/.

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children. For more information on the fluometuron human health risk assessment, see: *Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED)* dated February 1, 2005.

1. Toxicity of Fluometuron

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects such as skin or eye damage, and lifetime or chronic effects such as cancer, developmental effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for fluometuron and has determined that the toxicological database is complete, reliable, and sufficient for reregistration. For more details on the toxicity and carcinogenicity of fluometuron, see *Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED)* dated February 1, 2005, which is available under docket number OPP-2004-0372.

a. Acute Toxicity Profile for Fluometuron

Fluometuron is classified as category III for acute oral and dermal toxicity and as category III for acute inhalation toxicity. It is classified as category II for eye irritation potential and for skin irritation potential. Results were negative for dermal sensitization in guinea pigs and rats. The acute toxicity profile for fluometuron is summarized in Table 1 below.

Table 1. Acute Toxicity Profile for Fluometuron				
Guideline	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute Oral	41216802 40409302 00142844	LD50 > 1000 mg/kg	III
870.1200	Acute Dermal	41216803 40409303 00142844	LD_{50} > 2000 mg/kg	III
870.1300	Acute Inhalation	40409304 41216804 00142844	LC_{50} > 0.6 mg/L	III
870.2400	Primary Eye Irritation	41216805 00142846 40409305	Moderate to severe eye irritant (irritation to cornea and iris)	II
870.2500	Primary Skin Irritation	41216806 40409306 00142847 00068040	Slight to severe skin irritant	II
870.2600	Dermal Sensitization	40409307 41216807 00160762 00142848	Non-sensitizing in guinea pig or rat	Not Applicable

LD_{50} or LC_{50} = Median Lethal Dose or Concentration. A statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).

b. FQPA Safety Factor Considerations for Fluometuron

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional ten fold (10x) safety factor (SF) to account for potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the 10x FQPA SF only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

For fluometuron, based on the hazard data and the exposure data, the FQPA SF was reduced to 1x. There are low concerns and no uncertainties with regards to pre- and post-natal toxicity, and there is no evidence of increased susceptibility of infants and children. Moreover, there is no evidence that fluometuron is associated with significant reproductive or developmental toxicity. In addition, the moderately refined dietary food assessment uses field trial data and percent crop treated estimates for all commodities that will not underestimate exposure. The dietary drinking water assessment uses values generated by models and associated modeling parameters that are designed to provide health protective, high-end estimates of water concentrations. See *Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED)* dated February 1, 2005, for additional details.

c. Toxicological Endpoints for Fluometuron

The toxicological endpoints used in the human health risk assessment for fluometuron are listed in Table 2 below, as well as the estimated dermal and inhalation absorption factors used in the risk assessment. For dermal absorption, a factor of 10% was estimated by comparing the oral developmental rabbit Lowest Observed Adverse Effect Level (LOAEL) of 100 mg/kg/day and the

rabbit 21-day dermal No Observed Adverse Effect Level (NOAEL) (because no LOAEL was established) of 1000 mg/kg/day. For the inhalation absorption, a default factor of 100% was used. The uncertainty factors (UF) and safety factors used to account for interspecies extrapolation, intraspecies variability, and special susceptibility of infants and children (FQPA SF) are also described in Table 2.

Table 2. Toxicology Endpoints for Fluometuron

Exposure Scenario	Dose, Uncertainty Factors	FQPA Safety Factor and Level of Concern	Study and Endpoint for Risk Assessment
Acute Dietary females 13-49 years	NOAEL=10 mg/kg/day UF= 100X (inter and intraspecies) Acute RfD= 0.1 mg/kg/day	FQPA SF =1 aPAD = Acute RfD / FQPA SF aPAD = 0.1 mg/kg/day	Developmental, Rat LOAEL=100 mg/kg/day, based on delayed urinary system development.
Chronic Dietary all populations	NOAEL = 0.55 mg/kg/day UF = 100X (inter and intraspecies) Chronic RfD = 0.0055 mg/kg/day	FQPA SF = 1 cPAD = Chronic RfD / FQPA SF cPAD = 0.005 mg/kg/day	Chronic/Carcinogenicity, Rat LOAEL=100 mg/kg/day, based on decreased body weight gain (9%), and discoloration in the spleen.
Dermal and Inhalation Exposure: Short-Term (1 to 30 days)	Oral NOAEL= 10 mg/kg/day Absorption Factors Dermal=10% Inhalation=100%	FQPA SF=NA (occupational) LOC for MOE=100	Developmental, Rat LOAEL=100 mg/kg/day, based on delayed urinary system development.
Dermal and Inhalation Exposure: Intermediate-Term (1 to 6 months)	Oral NOAEL= 10 mg/kg/day Absorption Factors Dermal=10% Inahalation=100%	FQPA SF=NA (occupational) LOC for MOE=100	Subchronic, Dog LOAEL=150 mg/kg/day, based on inflammatory reactions in the liver and kidney.
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, 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

2. Carcinogenicity of Fluometuron

As described in Table 2 above, the Agency classified fluometuron as Group C, possible human carcinogen. This was based on statistically significant increases in combined adenomas/carcinomas of the lungs in male mice and malignant lymphocytic lymphomas in

female mice. For the purpose of risk characterization, a low dose extrapolation model (Q_1^*) was used. The Q_1^* is 1.8 x 10^{-2} $(mg/kg/day)^{-1}$ was derived from the incidence of combined lung tumors. For more information, see the document *Carcinogenicity Peer Review of Fluometuron* dated August 28, 1996.

3. Metabolites and Degradates

The Agency reviewed the metabolism of fluometuron, and concluded that there are several residues of concern in food. In plants, the residue of concern consists of parent fluometuron and metabolites determined as trifluoromethylaniline (TFMA); in animals, the residue of concern consists of fluometuron, TFMA, and the hydroxylated metabolites and their conjugates. The drinking water assessment summarized in this document is for fluometuron and the only major degradate identified in soil metabolism studies, desmethyl fluometuron (CGA-41686; 1-methyl-3-(α,α,α-trifluoro-m-tolyl)urea). All of the metabolites and degradates are assumed to be of equal toxicity to the parent compound, and all metabolites of concern are calculated as fluometuron equivalents. See *Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED)* dated February 1, 2005, for additional details.

4. Dietary Risk (Food and Drinking Water)

Acute dietary risk assessments were only considered for the population subgroup females 13-49 years old. For the general population, no acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data. Chronic dietary analyses were conducted for the general U.S. population and various population subgroups. A cancer dietary risk assessment was conducted for the general U.S. population. Please note that the dietary risk estimates presented in Section III of this document have subsequently been refined. The refined estimates are presented in Section IV.

a. Exposure Assumptions

The Agency conducted acute, chronic and cancer dietary (food and drinking water) risk assessments for fluometuron and its metabolites using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03). To conduct the assessments, both food consumption data from USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994-1996 and 1998, and screening-level model results for drinking water exposure were incorporated in the DEEM-FCID™ to estimate combined food and drinking water dietary risks.

Drinking water exposure to pesticides can occur through surface and groundwater contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or monitoring data, if available and of sufficient quality, to estimate those exposures. Fluometuron and its metabolites are mobile and persistent in the environment. The primary route of degradation of fluometuron and its main major degradate is microbial metabolism. However, since fluometuron and its degradates are not volatile, and these degradative processes are not rapid, these compounds will be available for leaching to groundwater and runoff to surface water in many use conditions. Once in groundwater or surface water, fluometuron is expected to persist due to its stability to hydrolysis and photolysis.

Parent fluometuron is also very stable to aerobic soil metabolism, anaerobic soil metabolism, and anaerobic aquatic metabolism with half-lives of 181, 378, and 177 days respectively.

Estimated Drinking Water Concentrations (EDWCs) of fluometuron (parent and major degradate CGA-41686) were calculated in groundwater and surface water sources of drinking water for use in the dietary risk assessment. EDWCs for fluometuron were calculated, based on maximum application rates, and using screening-level PRZM and EXAMS models (Tier II) with the Index Reservoir and Percent Crop Area adjustment for surface water and the Screening Concentration in Groundwater (SCI-GROW) model (Tier I) for groundwater, and are presented in Table 3 below.

Table 3. Total EDWCs (ppb) in surface water and groundwater for fluometuron and its major degradate

	CA	TX	MS	NC
Surface water/ peak (90th percentile annual daily max. - acute)	26.8	47.5	81.8	45.0
Surface water/average (90th percentile annual mean - chronic)	21.9	20.1	18.9	16.9
Surface water/36-year overall mean (cancer)	19.4	12.4	8.2	12.0
Groundwater (all exposures)	241			
Use modeled	3 aerial applications @ 2.0 lb ai/acre to cotton*			
Percent Cropped Area (cotton)	20%			

Please note that U.S. Geological Survey National Water Quality Assessment Program (NAWQA) monitoring data are available for fluometuron. The NAWQA data show maximum (peak) concentrations of 37.8 ppb sampled in surface water and 4.7 ppb in groundwater. However, the vast majority of groundwater samples present substantially lower values (<0.1 ppb). In addition, over the course of the monitoring program, only two groundwater detections showed concentrations greater than 2.5 ppb. However, these data are limited because the majority of the NAWQA sampling sites are not located in high fluometuron use areas, and the frequency of sampling and the length of the sampling period are insufficient. In the absence of robust monitoring data, the Agency generally relies on modeling to estimate potential pesticide exposure from drinking water.

b. Population Adjusted Dose

A population adjusted dose, or PAD, is the reference dose (RfD) adjusted for the FQPA SF. A risk estimate that is less than 100% of the acute PAD (aPAD), the dose at which an individual could be exposed over the course of a single day and no adverse health effects would be expected, does not exceed EPA's level of concern. Likewise, a risk estimate that is less than 100% of the chronic PAD (cPAD), the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, does not exceed EPA's level of concern. For the cancer dietary risk assessment, risks in the negligible risk range of one in a million (1×10^{-6}) are generally below the Agency's level of concern.

c. Acute Dietary Risk (Food and Drinking Water)

A moderately refined probabilistic (Monte-Carlo) acute dietary exposure assessment was conducted to estimate the dietary (food and drinking water) risks associated with the registered use of fluometuron on cotton. This assessment also considers exposure from residues in rotational crops (i.e., crops planted in a field that has previously grown fluometuron-treated cotton). No monitoring data for residues of fluometuron in/on food are available from the FDA 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, and incorporate maximum (20%) percent crop treated estimates for cotton. This assessment likely overestimates the food risk because food monitoring data are not available and because the percent crop treated factor is based on 2000 data and is currently believed to be significantly less (10% crop treated). For more information, see the document *Refined Fluometuron Percent Crop Treated*… dated August 9, 2005; and *Addendum to Refined Fluometuron Percent Crop Treated*… dated September 21, 2005.

The acute risk estimate of 34% of the aPAD does not exceed the Agency's level of concern (i.e., it is less than 100% of the aPAD) at the 99.9th exposure percentile for females 13-49 years old. The acute dietary risk estimate is based on screening-level modeled groundwater EDWCs. Because EDWCs for drinking water derived from surface water sources are less than groundwater EDWCs (see Table 3), the risk estimates for food and surface water would be less than risk estimates for food and groundwater. The acute dietary risk estimates are shown in Table 4 below.

Table 4. Results of Acute Dietary (Food + Drinking Water from Groundwater Sources) Exposure Analysis Using DEEM FCID.

Population Subgroup	aPAD (mg/kg/day)	99.9th Percentile	
		Exposure (mg/kg/day)	% aPAD
Females 13-49 years old	0.1	0.033720	34

d. Chronic Dietary Risk (Food and Drinking Water)

A moderately refined chronic dietary (food and drinking water) exposure assessment was conducted to estimate the dietary risks associated with the registered uses of fluometuron. No monitoring data for residues of fluometuron are available. The AR residue estimates in this assessment are based on available field trial and field accumulation data, and incorporated maximum (20%) percent crop treated estimates for cotton. Feeding and metabolism studies along with percent crop treated information on feed items were used to calculate AR estimates for livestock commodities. Processing data were also used when available. Chronic dietary risk estimates are provided for the general U.S. population and various population subgroups. This assessment likely overestimates the food risk because food monitoring data are not available and the percent crop treated factor for cotton is based on 2000 data, as above.

The chronic risk estimates exceed the Agency's level of concern for 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 (see Table 5 below).

The significant contributor to chronic dietary risk is potential drinking water exposure from groundwater sources. For food alone (excluding drinking water), the chronic risk estimates are less than 4% of the cPAD for each population subgroup. In addition, risk estimates for food plus drinking water from surface water sources do not exceed the Agency's level of concern. The unrefined groundwater EDWC was calculated using a Tier 1, screening-level model and likely overestimates the chronic drinking water exposure and resulting risk. Please note that the chronic dietary risk estimates presented in this section have subsequently been refined, and are further discussed in Section IV.

Table 5. Results of Chronic Dietary (Food + Drinking Water from Groundwater Sources) Exposure Analysis Using DEEM FCID.

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
All populations	0.0055	0.005147	94
All infants (< 1 year old)		0.016807	306
Children 1-2 years old		0.007726	141
Children 3-5 years old		0.007221	131

e. Cancer Dietary (Food and Drinking Water)

The cancer dietary assessment was conducted for the general U.S. population. To estimate cancer risk, the 70-year lifetime average daily exposure is multiplied by the cancer potency factor (Q_1*) to yield a unitless number that represents the excess number of cancers potentially attributed to exposure to the pesticide over a lifetime. For the cancer dietary risk, risk estimates within the range of an increased cancer risk of one in a million (1×10^{-6}) are generally below EPA's level of concern. A Q_1* is an estimate of the upper bound on risk.

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 combined cancer risk estimate of 9.27×10^{-5} for food and drinking water from groundwater sources. As stated previously, the conservative predicted groundwater concentration used in this assessment may have overestimated the cancer dietary risk of fluometuron. See Table 6 below for cancer dietary risk estimates.

Table 6. Fluometuron Cancer Dietary (Food + Drinking Water) Risk Estimates		
Dietary Exposures Assessed	**Q_1***	**Cancer Risk Estimate**
Food alone	1.80×10^{-2} $(mg/kg/day)^{-1}$	1.22×10^{-6}
Groundwater alone		9.14×10^{-5}
Food + drinking water from groundwater sources		9.27×10^{-5}
Surface water alone		7.36×10^{-6}
Food + drinking water from surface water sources		8.58×10^{-6}

The estimated exposure of the general U.S. population to fluometuron in surface water 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 combined cancer risk estimate of 8.58×10^{-6} for food and drinking water from surface water sources.

For comparison, the cancer risk estimates for exposure through groundwater and surface water sources of drinking water individually (excluding food) are 9.14×10^{-5} and 7.36×10^{-6}, respectively. The estimated cancer risk for food alone (excluding drinking water) is 1.22×10^{-6}. Each of these risk estimates individually exceeds the Agency's level of concern, except for the estimated cancer risk for food alone.

The significant contributors to the cancer risk estimates have been identified as drinking water (direct, all sources and indirect, all sources), and several rotational crops, with wheat (flour), soybean (oil), and rice (white) having the highest contributions. The AR estimates are considered moderately refined, although they are also 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 use of fluometuron. Also, in the risk estimates above, a maximum percent crop treated estimate of 20% was used for application to cotton. When the Agency considered potential residues in rotational crops, the Agency used the conservative percent crop treated value of 20% as well. Both the use of a maximum percent treated estimate for cotton and the application of the maximum value to rotational crops likely overestimated the cancer dietary risk of fluometuron. Moreover, the unrefined EDWCs were based on screening-level models and likely overestimated the cancer dietary risk of fluometuron. Please note that the cancer dietary risk estimates presented in this section have subsequently been refined, and are further discussed in Section IV.

5. Residential Exposure and Risk

Fluometuron has no residential uses. In addition, no residential post-application exposure is expected as a result of currently labeled uses. Therefore, a residential risk assessment was not conducted.

6. Aggregate Risk

In accordance with the FQPA, the Agency must consider the potential for aggregate risk from all sources of pesticide exposures including food, drinking water, and, if applicable, residential exposure to homeowners. In the case of fluometuron, the aggregate risk estimates are the same as those presented in the dietary (combined food and drinking water) risk section of this document (see Tables 4, 5, and 6), because there are no registered residential uses and no residential exposures are expected to occur.

7. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying the pesticide, or re-entering a treated site. For dermal and inhalation exposures, worker risk is estimated by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the No Observed Adverse Effect Level (NOAEL) selected from animal studies. Please see Table 2 for the toxicological endpoints used in the fluometuron occupational assessment. The dermal and inhalation MOEs were combined for fluometuron because the toxicity endpoints for the dermal and inhalation routes of exposure were derived from the same study. In addition, short- and intermediate-term risk estimates are the same because the NOAELs for both exposure durations are identical. Long-term MOEs were not calculated since long-term exposure is not expected as a result of the currently registered uses. Since fluometuron is currently classified as a Group C carcinogen with a Q_1* of 1.80×10^{-2} $(mg/kg/day)^{-1}$, the Agency assessed both cancer and non-cancer risks for occupational handlers and postapplication workers.

For fluometuron, MOEs that are greater than 100 and cancer risks within the range of an increased cancer risk of 1×10^{-6} generally do not exceed the Agency's level of concern. However, when occupational MOEs are less than 100 or occupational cancer risks exceed 1×10^{-6}, EPA strives to reduce worker cancer risks through the use of personal protective equipment and engineering controls. The Agency generally considers occupational cancer risks within the range of 1×10^{-6} (1 in 1 million persons) or less to be negligible, but will consider risks as high as 1×10^{-4} (1 in 10,000 persons) when all mitigation measures that are practical and feasible have been applied and when there are critical pest management needs associated with the use of the pesticide.

Nine occupational exposure scenarios based on active registered labels were assessed for fluometuron, as follows:

1a mixing/loading emulsifiable concentrates (ECs, liquids) for aerial applications
1b mixing/loading ECs for groundboom applications
2a mixing/loading dry flowables (DF) for aerial application
2b mixing/loading DF for groundboom application
3a mixing/loading wettable powders (WP) for aerial application
3b mixing/loading WP for groundboom application

4 applying liquid sprays via aerial equipment
5 applying liquid sprays via groundboom equipment
6 flagging for liquid sprays via aerial equipment

The Agency considered the following levels of personal protective equipment (PPE) or engineering controls in the exposure assessments:

- Baseline, or long-sleeve shirt, long pants, no gloves, and no respirator. (Baseline)
- Baseline plus chemical-resistant gloves, and no respirator. (PPE-G-NR)
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and no respirator. (PPE-G-DL-NR)
- Baseline plus chemical-resistant gloves and an 80% PF (quarter-face dust/mist) respirator. (PPE-G-80%R)
- Coveralls worn over long-sleeve shirt and long pants, chemical-resistant gloves, and an 80% PF (quarter-face dust/mist) respirator. (PPE-G-DL-80%R)
- Engineering Controls, or closed mixing/loading system, enclosed cab, or enclosed cockpit. (EC)

a. Handler Exposure and Risk

Risks for occupational handlers addressed the following scenarios: mixer/loader, applicator, and flagger. These scenarios were used to estimate exposures based on application of a variety of formulations (wettable powder, emulsifiable concentrate or liquid, and dry flowable) via aircraft or by groundboom sprayer.

There were no chemical-specific handler data, so unit exposures from the Pesticide Handlers Exposure Database (PHED) Version 1.1 (August 1998) were used to estimate exposures for a variety of clothing scenarios and combinations of PPE as listed above and engineering controls. Standard assumptions were used for the number of acres treated, body weight, hours worked, etc., for most handler scenarios.

Exposure assumptions for handler non-cancer exposure are based on a one-time maximum application rate of 2.0 lb ai/A determined from EPA registered labels for fluometuron. PPE and engineering controls, as described above, were considered in the assessment. Both dermal and inhalation MOEs for all occupational handler exposure scenarios are above 100 at some level of PPE or engineering controls (see Table 7 below), and therefore below EPA's LOC.

Table 7. Predicted Handler Non-Cancer Risks for Fluometuron at the Maximum Application Rate of 2 lb ai/A

Exposure Scenario	Acres Treated per Day	Dermal + Inhalation MOEs at Varying Levels of PPE						
		Baseline	PPE-G-NR	PPE-G-DL-NR	PPE-G-80%R	PPE-G-DL-80%R	Eng. Cont.	Eng. Cont. (dermal only)
Mixer/Loader								
Mixing/Loading EC for Aerial Applications (1a)	1200	0.86	71	86	98	130	260	120
Mixing/Loading EC for Groundboom Applications (1b)	200	5.2	430	520	590	770	1600	720
Mixing/Loading DF for Aerial Applications (2a)	1200	34	34	46	37	52	210	NA

Table 7. Predicted Handler Non-Cancer Risks for Fluometuron at the Maximum Application Rate of 2 lb ai/A								
Exposure Scenario	**Acres Treated per Day**	**Dermal + Inhalation MOEs at Varying Levels of PPE**						
		Baseline	**PPE-G-NR**	**PPE-G-DL-NR**	**PPE-G-80%R**	**PPE-G-DL-80%R**	**Eng. Cont.**	**Eng. Cont. (dermal only)**
Mixing/Loading DF for Groundboom Applications (2b)	200	200	200	270	220	310	1200	NA
Mixing/Loading WP for Aerial Applications (3a)	1200	0.61	4.2	4.5	9.8	12	210	NA
Mixing/Loading WP for Groundboom Applications (3b)	200	3.6	25	27	59	69	1200	NA
Applicator								
Applying Liquid Sprays via Aerial Equipment (4)	1200	No Data					440	No Data
Applying Liquid Sprays via Groundboom Equipment (5)	200	700	700	820	970	1200	2800	1200
Flagger								
Flagging for Liquid Sprays via Aerial Equipment (6)	350	590	No Data	630	No Data	800	1600	1000
G=gloves; NR=no respirator; DL=double layer, R=respirator, Eng. Cont.=engineering controls EC=emulsifiable concentrate, WP=wettable powder, DF=dry flowable								

Exposure assumptions for handler cancer risks included the average application rate of 1.5 lb ai/A. It is assumed that private handlers would handle fluometuron approximately 6 days per year and that commercial handlers would handle fluometuron approximately 18 days per year, based on the use pattern of the chemical. Finally, a 35 year career and a 70 year life span were used to complete the calculations. PPE and engineering controls were also used in the assessment. Estimated cancer risks for most commercial grower scenarios are less than 1×10^{-4} at various levels of PPE, but are in the range of 1×10^{-6} with engineering controls (except for handlers mixing and loading for aerial applications). Table 8 below presents the predicted cancer risk estimates for commercial handlers at varying levels of PPE. Risk estimates for private applicators are not presented here; however, risk estimates are less than risk estimates for commercial handlers due to the handling of less material, and mitigation to address commercial handlers will be protective of private applicators.

Table 8. Predicted Handler Cancer Risks for Fluometuron for Commercial Handlers Applying at the Average Rate of 1.5 lb ai/A							
Exposure Scenario	**Acres Treated per Day**	**Cancer Risks at Varying Levels of PPE**					
		Baseline	**PPE-G-NR**	**PPE-G-DL-NR**	**PPE-G-80%R**	**PPE-G-DL-80%R**	**Eng. Cont.**
Mixer/Loader							
Mixing/Loading EC for Aerial Applications (1a)	1200	3.2x10-3	4.0x10-5	3.3x10-5	2.9x10-5	2.2x10-5	1.1x10-5
Mixing/Loading EC for Groundboom Applications (1b)	200	5.5x10-4	6.7x10-6	5.5x10-6	4.8x10-6	3.7x10-6	1.8x10-6
Mixing/Loading DF for Aerial Applications (2a)	1200	8.4x10-5	8.4x10-5	6.2x10-5	7.7x10-5	5.5x10-5	1.4x10-5
Mixing/Loading DF for Groundboom Applications (2b)	200	1.4x10-5	1.4x10-5	1.0x10-5	1.3x10-5	9.2x10-6	2.3x10-6
Mixing/Loading WP for Aerial Applications (3a)	1200	4.7×10^{-3}	6.8x10-4	6.4x10-4	2.9x10-4	2.5x10-4	1.4x10-5

Table 8. Predicted Handler Cancer Risks for Fluometuron for Commercial Handlers Applying at the Average Rate of 1.5 lb ai/A							
Exposure Scenario	**Acres Treated per Day**	**Cancer Risks at Varying Levels of PPE**					
		Baseline	**PPE-G-NR**	**PPE-G-DL-NR**	**PPE-G-80%R**	**PPE-G-DL-80%R**	**Eng. Cont.**
Mixing/Loading WP for Groundboom Applications (3b)	200	7.9x10-4	1.1x10-4	1.1x10-4	4.9x10-5	4.1x10-5	2.3x10-6
Applicator							
Applying Liquid Sprays via Aerial Equipment (4)	1200	No Data	No Data	No Data	No Data	No Data	6.5x10-6
Applying Liquid Sprays via Groundboom Equipment (5)	200	4.1x10-6	4.1x10-6	3.5x10-6	2.9x10-6	2.4x10-6	1.0x10-6
Flagger							
Flagging for Liquid Sprays via Aerial Equipment (6)	350	4.8x10-6	No Data	4.5x10-6	No Data	3.6x10-6	1.8x10-6
G=gloves; NR=no respirator; DL=double layer, R=respirator, Eng. Cont.=engineering controls EC=emulsifiable concentrate, WP=wettable powder, DF=dry flowable							

b. Post-Application Exposure and Risk

Post-application exposure scenarios including irrigation, scouting, and hand weeding were assessed. No chemical-specific dislodgeable foliar residue data were available for fluometuron, so the Agency used dislodgeable foliar residue estimates based on standard default assumptions. These values are presented in the Table 9 below.

Table 9. Summary of Fluometuron Post-Application Activities and Predicted Risks					
Crop (Rates)	**Transfer Coefficients (cm^2/hr)[a]**	**Activities**	**MOE at Day 0 (12 hours after application)**	**Cancer Risk**	
				Day 0	**Day 12**
Cotton (2.0 lb ai/A for short-term & 1.5 lb ai/A for cancer)	100 (early season - low crop)	Irrigation, Scouting, Hand Weeding	1700	7×10^{-7}	not needed
	1500 (later season - mature crop)	Irrigation, Scouting, Hand Weeding	110	1×10^{-5}	9×10^{-7}

Based on the maximum application rate of 2.0 lb ai/A, short-term non-cancer post-application risks do not exceed the Agency's level of concern (i.e., risks are greater than the target MOE of 100) at day 0, approximately 12 hours following application.

Exposure assumptions for handler cancer risks included the average application rate of 1.5 lb ai/A. Since the post-application tasks of concern for fluometuron uses in cotton include hand weeding, scouting, and irrigating (but not harvesting), the Agency estimated that workers typically would spend 6 days per season performing tasks in fluometuron treated areas. The post-application risks for early season entry are less than 1×10^{-6} on day 0, approximately 12 hours following application. However, post-application cancer risks for later season entry are 1×10^{-5} on day 0 and are not in the negligible risk range until several days after treatment.

c. Incident Reports

Available sources of incident data in humans were reviewed for fluometuron. Data were available from the following sources: 1) Incident Data System consisting of reports submitted to EPA by registrants, other federal and state health and environmental agencies and the public since 1992; 2) Poison Control Centers for 1993 through 1998; 3) California Department of Pesticide Regulation for pesticide poisonings since 1982; and 4) National Pesticide Telecommunications Network (NPTN) for ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive. Two of the four available sources had information relevant to this review. The Incident Data System reported two incidents. The first of which consisted of burns on the arm of an individual from a dermal exposure and another individual reported dizziness, nausea, tingling face, and a locked jaw. No further information on the disposition of the cases was reported. Poison Control Centers reported five cases. Four of these five cases resulted from exposure to environmental residue rather than direct contact. Symptoms reported differed from case to case indicating effects reported were coincidental rather than fluometuron exposure. Fluometuron was not listed of the top 200 chemicals for which the National Pesticide Information Center received calls from 1984-1991. Therefore, no conclusions can be drawn from this very limited number of reported exposures.

B. Environmental Fate and Effects Risk Assessment

A summary of the Agency's environmental fate and effects risk assessment is presented below. For detailed discussion of all aspects of the environmental risk assessment, please see the *Revised Environmental Fate and Ecological Risk Assessment of Fluometuron* dated February 22, 2005, which is available on the internet and in the public docket.

1. Environmental Fate and Transport

Fluometuron and its metabolites are both mobile and persistent in the environment. The primary route of degradation of fluometuron and its main degradate, CGA-41686, is microbial metabolism. However, since fluometuron and its degradates are not volatile, and these degradative processes are not rapid, these compounds will be available for leaching to groundwater and runoff to surface water under many use conditions. Once in groundwater or surface water, fluometuron is expected to persist due to its stability to hydrolysis and photolysis. Since there is limited fate data on the major metabolite, CGA-41686, and fluometuron is persistent and mobile, it is assumed that CGA-41686 is equipotent to the parent compound. Therefore, it is assumed that the environmental risk from the metabolite would be the same as from the parent.

2. Ecological Exposure and Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing acute and chronic exposure estimates (EECs) by ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs), and when the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern to that category. In general, the higher the RQ, the greater the potential risk (see Table 10 below

for the Agency's LOCs). Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed. To the extent feasible, the Agency seeks to reduce environmental concentrations in an effort to reduce the potential for adverse effects to non-target organisms.

Table 10. EPA's Levels of Concern (LOCs) and Risk Presumptions

If a calculated RQ is greater than the LOC presented, then the Agency presumes that…	LOC terrestrial animals	LOC aquatic animals	LOC plants
Acute Risk …there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification	0.5	0.5	1.0
Acute Restricted Use …there is potential for acute risk, but may be mitigated through restricted use classification	0.2	0.1	NA
Acute Endangered Species …endangered species may be adversely affected	0.1	0.05	1.0
Chronic Risk …there is potential for chronic risk	1	1	NA

a. Terrestrial Organisms

Birds and Mammals

To assess potential risks to terrestrial organisms, the Agency derives estimated environmental concentrations (EECs) from the Kenaga nomograph based on a large set of actual field residue data. For fluometuron, the Agency determined EECs based on 3 applications of 2 lb ai/A fluometuron to cotton. EECs are then compared to the most sensitive toxicity endpoints to calculate RQs (e.g., LC_{50} or LD_{50} for acute effects, or a NOAEC for chronic effects). Avian chronic RQs could not be calculated for fluometuron because no chronic toxicity data are available. The Agency intends to require these data to support reregistration.

As presented in Table 11 below, acute RQs based on maximum EECs for birds do not exceed the Agency's acute LOC of 0.5. However, acute RQs for birds feeding on short grass, tall grass, broadleaf plants, and small insects slightly exceed the Agency's acute endangered species LOC of 0.1

Also as seen in Table 11, acute RQs based on maximum EECs for smaller mammals feeding on short grass slightly exceed the Agency's acute LOC of 0.5; acute RQs for all other mammals do not exceed the Agency's acute LOC. However, acute RQs for smaller mammals feeding on short grass, tall grass, broadleaf plants, and insects, and large mammals feeding on short grass exceed the Agency's endangered species acute LOC of 0.1. All chronic mammalian RQs exceed the Agency's chronic LOC of 1.

Table 11. Acute and Chronic Risk Quotients for Terrestrial Organisms Exposed to Fluometuron as a Result of Use on Cotton

Food Item	Maximum EEC (ppm)	Mean EEC (ppm)	Bird Acute RQs*	Mammal Acute RQs** by Body Weight			Mammal Chronic RQs***	
				15g	35 g	1000 g	Based on Max EECs	Based on Mean EECs
Short grass	1119	396	0.36	0.71-1.06	0.49-0.74	0.11-0.17	112	40
Tall grass	513	168	0.16	0.33-0.49	0.23-0.34	0.05-0.08	51	17

Table 11. Acute and Chronic Risk Quotients for Terrestrial Organisms Exposed to Fluometuron as a Result of Use on Cotton								
Food Item	**Maximum EEC (ppm)**	**Mean EEC (ppm)**	**Bird Acute RQs***	**Mammal Acute RQs** by Body Weight**			**Mammal Chronic RQs*****	
				15g	**35 g**	**1000 g**	**Based on Max EECs**	**Based on Mean EECs**
Broadleaf plants small insects	630	210	0.20	0.44-0.60	0.28-0.42	0.06-0.09	63	21
Fruits, pods large insects	70	33	0.02	0.04-0.07	0.03-0.05	0.01	7	3
Seeds				0.01	0.01	<0.01		
* Based on maximum EECs and ring-necked pheasant LC_{50} of 3150 ppm ** Based on maximum EECs and laboratory rat LD_{50} of >1000 ppm and <1500 ppm *** Based on NOAEC of 10 ppm based on discoloration of the spleen in a rat chronic dietary/carcinogenicity study (MRID 0163772).								

Non-Target Insects

EPA currently does not estimate RQs for terrestrial non-target insects. However, fluometuron is practically non-toxic to honeybees with an acute contact LD_{50} of 193.38 ug/bee. The Agency does not expect fluometuron exposure to pose acute risk to non-target insects because fluometuron is practically non-toxic to honeybees and because there are no incident data reporting adverse effects to honeybees.

Non-Target Plants

EECs for terrestrial and semi-aquatic plants were derived for dry and wetland (semi-aquatic) areas adjacent to a potential treatment site that may be affected by fluometuron via runoff and spray drift. Acute non-endangered species RQs were derived by dividing the EEC by the EC_{25} plant toxicity value. For endangered species, the RQs were derived by dividing the EEC by the selected NOAEC. Table 12 below summarizes the estimated RQs for non-target terrestrial and semi-aquatic plants; all acute non-endangered and endangered RQs for non-target terrestrial and semi-aquatic plants are greater than the LOC of 1.

Note that the predicted risks to semi-aquatic plants appears to be significantly greater than the risk to plants in dry areas or the risk to plants exposed to spray drift. The model input for the watershed for semi-aquatic areas adjacent to the field being treated is 10 times that of the input for adjacent dry areas. Unlike runoff from an adjacent dry area, wetlands tend to be low-lying and would typically collect field runoff from a larger area.

Table 12. Acute Risk Quotients for Terrestrial and Semi-Aquatic Plants Exposed to Fluometuron			
Area	**EEC (lb ai/A)**	**Non-Endangered Species RQs***	**Endangered Species RQs****
Dry Area Adjacent to the Treatment Site	0.1600	27	80
Wetland (Semi-Aquatic Area) Adjacent to the Treatment Site	0.7000	117	350
Drift	0.1000	11	50
* Based on terrestrial plant EC_{25} of 0.006 lb ai/A ** Based on terrestrial plant NOAEC of 0.002 lb ai/A			

b. Aquatic Organisms

Freshwater and Estuarine/Marine Fish and Invertebrates

To assess potential risks to aquatic animals, the Agency considers predicted EECs in surface water using the Tier II model PRZM/EXAMS. Unlike the drinking water assessment described in the human health risk assessment section of this document, the exposure values used in the ecological risk assessment do not include the Index Reservoir (IR) and Percent Cropped Area (PCA) factor refinements. These factors represent a drinking water reservoir, not the variety of aquatic habitats relevant to a risk assessment for aquatic animals, such as ponds adjacent to treated fields. Therefore, the EEC values used to assess exposure and risk to aquatic animals are not the same as those used to assess exposure and risk to humans from pesticides in drinking water.

For fluometuron, the Agency modeled EECs for four cotton growing states, Mississippi, North Carolina, Texas, and California, based on 3 aerial applications of 2 lb ai/A. Peak EECs were compared to acute toxicity endpoints to derive acute RQs. Generally, 60-day EECs are compared to chronic toxicity endpoints (NOAEC values) to derive chronic RQs for freshwater organisms and 21-day EECs are compared to chronic toxicity endpoints to derive chronic RQs for estuarine/marine organisms; however, in the case of fluometuron, chronic RQs could not be calculated because no chronic toxicity data are available. The Agency intends to require these data to support reregistration.

Acute RQs for freshwater fish based on EECs modeled for Mississippi and freshwater invertebrates based on EECs modeled for Mississippi, Texas, and North Carolina slightly exceed the Agency's acute LOC of 0.5, as shown in Table 13 below. Acute RQs for freshwater fish and freshwater invertebrates for all locations modeled exceed the Agency's endangered species LOC for aquatic animals of 0.05.

Acute RQs for estuarine/marine fish and invertebrates do not exceed the Agency's acute LOC of 0.5; however, for endangered species, the predicted RQs are equal to or slightly exceed the LOC of 0.05 for aquatic animals based on peak EECs modeled for Mississippi, Texas, and North Carolina.

Table 13. Acute Risk Quotients for Aquatic Organisms Exposed to Fluometuron

Crop	Modeled Location	Peak EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs		
			Fish LC_{50} = 640 ug/L	Invertebrates LC_{50}= 220 ug/L	Fish LC_{50} = 55300 ug/L	Invertebrates LC_{50} = 3800 ug/L	Mollusks LC_{50} = 6530 ug/L
Cotton	Mississippi	324	0.51	1.47	0.006	0.09	0.05
	Texas	191	0.29	0.87	0.003	0.05	0.03
	North Carolina	246	0.38	1.12	0.004	0.06	0.04
	California	52	0.08	0.24	0.001	0.01	0.01

Non-Target Plants

For aquatic vascular and non-vascular plants, peak EECs were compared to acute EC_{50} toxicity endpoints to derive acute non-endangered species RQs. Peak EECs were compared to NOAEC toxicity endpoints to derive acute endangered species RQs. The most sensitive endpoint (EC_{50} or NOAEC) from the most sensitive species was used for both endangered and non-endangered species; therefore, the acute RQ for nonvascular plants is based on green algae, *Selenastrum*

capricornatum. The most sensitive EC_{50} for *Selenastrum capricornatum* was 30 ug/L from a supplemental study in which no NOAEC was determined. Thus the NOAEC of 180 ug/L from a core study on *Selenastrum capricornatum* was chosen for as the risk assessment endpoint for endangered nonvascular aquatic plants.

The RQs are presented in Table 14 below. Almost all acute non-endangered species RQs exceed the LOC of 1 except for vascular plants based on Texas and California use scenarios. Endangered species RQs exceed the plant LOC of 1 for plants based on Mississippi, Texas, and North Carolina use scenarios.

Table 14. Acute Risk Quotients for Aquatic Vascular and Non-Vascular Plants Exposed to Fluometuron as a Result of Use on Cotton

Modeled Location	Peak EECs (ppb)	Non-Endangered RQs		Endangered RQs	
		Vascular Plant EC_{50} = 220 ug/L	Non-Vascular Plant EC_{50}= 30 ug/L	Vascular Plant NOAEC = 115 ug/L	Non-Vascular Plant NOAEC = 180 ug/L
Mississippi	324	1.47	10.81	2.82	1.80
Texas	191	0.87	6.35	1.66	1.06
North Carolina	246	1.12	8.19	2.14	1.37
California	52	0.24	1.73	0.45	0.29

c. Endangered Species

The preliminary risk assessment for fluometuron indicates a potential for acute effects on listed species as noted below, should exposure actually occur at modeled levels:

- Freshwater fish and invertebrates (acute): Cotton (all scenarios modeled - MS, NC, TX, and CA).
- Estuarine/marine invertebrates (acute): Cotton (scenarios modeled - MS, NC, and TX).
- Aquatic plants (acute): Cotton (MS, TX, and NC scenarios).
- Birds (acute): Cotton (short grass, tall grass, and broadleaf plants/small insects).
- Mammals (acute): Cotton (short grass, tall grass, broadleaf plants/small insects) for small (15 g) and medium (35 g) mammals and cotton (short grass) for large mammals (1000 g).
- Mammals (chronic): Cotton (short grass, tall grass, broadleaf plants/small insects, and fruits/pods/large insects/seeds).
- Terrestrial and semi-aquatic plants (acute): Cotton (dry areas, wetland areas, and drift).

EPA does not currently have enough chronic toxicity data to quantify risks for fluometuron at the screening level and therefore cannot preclude potential chronic effects to the following taxonomic groups: birds, freshwater fish and invertebrates, and estuarine/marine fish and invertebrates. These data will be required by the Agency as part of this RED.

Further, indirect effects cannot be precluded based upon the screening level assessment for listed species dependent upon a taxa that may experience effects from the use of fluometuron.

These conclusions are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species.

3. Ecological Incidents

A review of the Ecological Incident Information System (EIIS) database for ecological incidents involving fluometuron was completed on August 3, 2004. There were two fluometuron incidents in the database, both involving cotton. Fluometuron can have detrimental effects on the cotton crop if it is applied directly to the foliage after cotton emergence. The first incident occurred in North Carolina, and involved 45 adversely affected acres of cotton out of a total acreage of 80. The second incident occurred in North Carolina and involved a liquid formulation of fluometuron. Three acres out of 26 acres were adversely affected. It was unclear in this incident if fluometuron was applied directly to cotton foliage leading to decimation of the crop.

IV. Risk Management, Reregistration, and Tolerance Reassessment

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing fluometuron as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing fluometuron.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient fluometuron. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient fluometuron, the Agency has sufficient information on the human health and ecological effects to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that fluometuron-containing products are eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted and (ii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of fluometuron that are eligible for reregistration (i.e., cotton). Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of fluometuron, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of fluometuron, the Agency has determined that fluometuron products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of fluometuron. If all changes outlined in this document are incorporated into the product labels, then all current risks for fluometuron will be adequately mitigated for the purposes of this determination under FIFRA. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III. B.2.c. of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for fluometuron. EPA released its fluometuron preliminary risk assessments for public comment on April 6, 2005, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period on the risk assessments, which closed on June 6, 2005, the Agency received comments from the registrant and one individual. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (OPP-2004-0372) at the address given above and in the EPA's electronic docket at http://www.epa.gov/edockets.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to fluometuron are within acceptable levels. In other words, EPA has concluded that the tolerances for fluometuron meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to fluometuron from all possible sources.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for fluometuron, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of fluometuron. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of fluometuron and its degradate.

As discussed in Section III, the acute dietary (food and drinking water) risks from fluometuron are not of concern. Chronic and cancer risks from fluometuron are not of concern provided that mitigation measures outlined in this document are adopted and labels are amended.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for fluometuron, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the

specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of fluometuron residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of fluometuron, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the Special FQPA SF has been removed (i.e., reduced to 1X) for fluometuron. The rationale for the decisions on the FQPA SF can be found in Section III and the following document: *Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED)* dated February 1, 2005.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). In the available toxicity studies on fluometuron, there was no evidence of estrogen, androgen, and/or thyroid-mediated toxicity.

3. Cumulative Risks

Section 408(b)(2)(D)(v) of FIFRA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluometuron and any other substances, and fluometuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluometuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

4. Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as appropriate. If the Agency determines that the use of fluometuron "may affect" listed species or their designated critical habitat, EPA will employ provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is complete, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposure to fluometuron at levels of concern.

D. Tolerance Reassessment Summary

A tolerance is established for negligible residues of the herbicide fluometuron [1,1-dimethyl-3-(α,α,α,-trifluoro-m-tolyl)urea] in or on the raw agricultural commodity cotton, undelinted seed (40 CFR §180.229).

The tolerances listed in 40 CFR must be reorganized in order to: (i) incorporate the recommendations made by the Agency concerning the fluometuron residues of concern that need to be regulated for plant and animal commodities; (ii) include tolerances that are needed to cover fluometuron residues of concern in/on the raw agricultural commodities and processed commodities of rotational crops; and (iii) conform with the requirements of FQPA. FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a single section of the statute, Section 408. The FQPA authorizes the conversion of all existing Section 409 tolerances for pesticide residues in processed food/feed into Section 408 tolerances. The reorganization of fluometuron tolerances should be conducted as depicted below in Table 15. A summary of fluometuron tolerance reassessments is presented in Table 16.

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) for fluometuron.

Table 15. Reorganization of Fluometuron Tolerances Required Under 40 CFR.		
40 CFR Section	**Section Reserved For**	**Tolerance Expression**
§180.229 (a)(1)	Plant commodities	Fluometuron and its metabolites determined as TFMA.
§180.229 (a)(2)	Livestock commodities	Fluometuron and its metabolites determined as TFMA, and the hydroxylated metabolites CGA-236431, CGA-436432, CGA-13211, and their conjugates.
§180.229 (d)	Rotational crop commodities	Fluometuron and its metabolites determined as TFMA.
§180.229 (d)	Food/feed commodities processed from rotational crops	Fluometuron and its metabolites determined as TFMA.

Tolerances Required Under 40 CFR §180.229 (a)(1):

The interim cottonseed field trial data suggest that the established 0.10 ppm tolerance for cottonseed is too low to adequately cover fluometuron residues of concern that may result following applications of WP and EC formulations according to the maximum use pattern eligible for reregistration. The existing data indicate that an appropriate tolerance would be 1.0 ppm. However, additional field trial data reflecting use of the DF formulation are required, and these data may indicate a need to further adjust the tolerance. An adequate cotton gin byproducts field trial study has been submitted and reviewed. Residues of fluometuron are not expected to exceed 3.1 ppm in cotton gin byproducts, therefore, an appropriate tolerance value would be 3.5 ppm.

Tolerances Required Under 40 CFR §180.229 (a)(2):

The data from ruminant feeding studies suggest that an appropriate tolerance level of 0.10 ppm should be established for milk and 0.10 ppm for ruminant and hog meat byproducts. This recommendation is tentative pending submission and evaluation of the requested storage stability data for the hydroxylated metabolites (CGA-236431, CGA-436432, CGA-13211, and their conjugates).

The aggregate of data from poultry metabolism and poultry feeding studies suggest that an appropriate tolerance level of 0.10 ppm should each be established for eggs, poultry fat, poultry meat, and poultry meat byproducts. This recommendation is tentative pending submission and evaluation of the requested storage stability data for the hydroxylated metabolites (CGA-236431, CGA-436432, CGA-13211, and their conjugates).

Tolerances Required Under 40 CFR §180.229 (d):

Data from extensive field rotational trials suggest the need for tolerances for fluometuron residues of concern in/on several raw agricultural commodities of rotational crops. The recommended tolerances are listed below in Table 16.

Data from processing studies on rotational crops suggest the need for tolerances for

fluometuron residues of concern in/on several processed commodities; the recommended tolerances are listed below in Table 16.

Table 16. Tolerance Reassessment Summary for Fluometuron.			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comments**
Tolerances Required Under 40 CFR §180.229 (a)(1)			
Cotton, gin byproducts	None	3.5	Based on field trial data
Cotton, undelinted seed	0.1	1.0[1]	
Tolerances Required Under 40 CFR §180.229 (a)(2)			
Cattle, meat byproducts	None	0.1	These recommendations are based on feeding studies, but tentative pending submission of supporting storage stability data for the hydroxylated metabolites.
Goat, meat byproducts	None	0.1	
Hog, meat byproducts	None	0.1	
Horse, meat byproducts	None	0.1	
Sheep, meat byproducts	None	0.1	
Milk	None	0.02	
Egg	None	0.1	
Poultry, fat	None	0.1	
Poultry, meat	None	0.1	
Poultry, meat byproducts	None	0.1	
Tolerances Required Under 40 CFR §180.229 (d)			
Grain, cereal, group 15	None	0.5	Proposed tolerance levels are based on available data.
Grain, cereal, forage, group 16	None	3.0	
Grain, cereal, fodder, and straw, group 16	None	6.0	
Peanut	None	0.1	
Peanut, hay	None	4.0	
Soybean, seed	None	2.0	
Soybean, forage	None	3.0	
Soybean, hay	None	3.0	
Peanut, meal	None	0.2	

Table 16. Tolerance Reassessment Summary for Fluometuron.			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comments**
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 adjustment.

E. Regulatory Rationale

The following is a summary of the rationale for mitigation measures necessary for managing risks associated with the use of fluometuron for fluometuron to be eligible for reregistration. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V.

1. Human Health Risk Management

a. Dietary (Food and Drinking Water) Risk Mitigation

Acute

Acute dietary risk is below the Agency's level of concern; risk estimates are 34% of the aPAD for women of childbearing age, the only population subgroup for which the acute endpoint applies. Therefore, no mitigation is needed to address acute dietary risks. Further, acute risk estimates decrease to 5% of the aPAD when revised to incorporate the mitigation measures and refinements described below.

Chronic and Cancer

Estimated chronic and cancer dietary risks are above the Agency's level of concern. Chronic dietary risk estimates presented in Section III are driven by screening-level, modeled drinking water exposure from groundwater sources, and cancer dietary risk estimates are driven by predicted drinking water exposures (from both groundwater and surface water sources) and food exposures from several rotational crops with wheat (flour), soybean (oil), and rice (white) having the highest contributions.

To address these predicted risk concerns, the Agency used a number of approaches which included a combination of risk assessment refinements and risk mitigation measures. The Agency used an updated value of 10% percent crop treated for cotton and updated information on the percent of national acreage of soybeans, corn, and wheat rotated in following fluometuron-treated cotton. These updated values were incorporated into the Agency's dietary risk assessment to refine the potential food exposure estimates. For details, see also the following document: *Refined Fluometuron Percent Crop Treated and Percentage of National Soybean, Corn, and Wheat Crops Rotated with Fluometuron-Treated Cotton* dated

August 9, 2005 and *Addendum to Refined Fluometuron Percent Crop Treated…* dated September 21, 2005.

In addition, the Agency calculated refined drinking water EDWCs for use in the dietary risk assessment in order to account for mitigation measures (i.e., application rate reductions) proposed by the registrant (see Table 17 below) and to account for differences between the fate characteristics of parent fluometuron and its primary degradate, desmethyl fluometuron. Different application rates are proposed for different soil types to reflect the rate necessary to achieve efficacy of the product. See Table 18 below for refined drinking water EDWCs that were used to revise the dietary (food and drinking water) exposure and risk estimates. See also *Revised Drinking Water Assessment and EFED's Response…* dated September 28, 2005 for additional explanation of the modeling input parameters and results.

Table 17. Proposed Revised Fluometuron Application Rates by Soil Type

Soil Texture	Maximum One-Time Application Rate	Number of Applications	Seasonal Max. Rate	Minimum Application Interval
Sand, Loamy Sand, Sandy Loam	1 lb ai/A	2	2 lb ai/A	20 days
Loam, Silt Loam, Silt, Sandy Clay Loam, Silty clay loam, Clay loam	1.6 lb ai/A	2	3 lb ai/A	20 days
Sandy clay, Silty Clay, Clay	2 lb ai/A	2	3 lb ai/A	20 days

Table 18. Refined Total EDWCs (ppb) in Surface Water and Groundwater for Fluometuron and its Major Degradate (by State)

	CA	TX	MS	NC
Surface water/ peak (90th percentile annual daily max. - acute)	13.8	15.5	31.2	14.1
Surface water/average (90th percentile annual mean - chronic)	10.9	6.38	6.34	4.60
Surface water/36-year overall mean (cancer)	9.3	3.84	2.54	3.56
Groundwater (all exposures)	21.6 (light soils) 32.4 (intermediate soils) 22.8 (heavy soils)			
Use modeled*	3 lb ai/A	2 lb ai/A	3 lb ai/A	2 lb ai/A
Percent Cropped Area (cotton)	20%			

* The use modeled, specifically the application rate, was chosen based on proposed rate by soil type as described in Table 17 above and the predominant soil type in the states modeled.

Revised chronic dietary (food and drinking water) risk estimates incorporating the refinements and mitigation described above are no longer of concern to the Agency with the most highly exposed subpopulation being all infants at 41% of the cPAD. The revised chronic dietary risk estimates are presented in Table 19 below. As stated above, predicted groundwater exposure is the chronic dietary risk driver and surface water estimates are not of concern to the

Agency. For further information, see *Fluometuron. Revised Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document* dated September 27, 2005.

Table 19. Refined results of Chronic Dietary (Food + Drinking Water from Groundwater Sources) Exposure Analysis Using DEEM FCID.

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
All populations	0.0055	0.000688	13
All infants (< 1 year old)		0.002248	41
Children 1-2 years old		0.001028	19
Children 3-5 years old		0.000962	18

Revised cancer dietary risk estimates incorporating the refinements and mitigation described above are presented in Table 20 below. Cancer dietary (food and drinking water) risk estimates are within the negligible risk range of 10^{-6} based on predicted EDWCs from surface water sources for the modeled scenarios and are not of concern to the Agency.

The cancer dietary (food and drinking water) risk estimate is 1×10^{-5}, based on the highest predicted EDWCs from groundwater sources (32. 4 ppb; intermediate soils), with groundwater exposure being the risk driver. For further information, see *Fluometuron. Revised Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document* dated September 27, 2005. However, drinking water exposure estimates are based on conservative, screening-level models which are used to determine if further characterization or monitoring information is needed to evaluate whether risks are of concern. Also, the cancer potency factor is, by nature, a conservative estimate of risk, and exposure estimates from food remain conservative as they are based on field trial data. Moreover, banded application of fluometuron, which is an application practice described on product labels and often employed, would result in significantly less potential drinking water exposure because the amount of active ingredient per acre used in banded applications is much less than that used in broadcast applications.

Further, existing NAWQA drinking water monitoring data on fluometuron showed low concentrations. While these data are spatially and temporally limited in cotton and fluometuron use areas, the maximum groundwater concentration measurement of 4.7 ppb, which is the highest concentration sampled, is well below an average concentration that results in estimated risks of concern to the Agency. Moreover, the vast majority of groundwater samples present substantially lower concentration levels (<0.1 ppb) and, over the course of the monitoring program, only two groundwater detections showed concentrations greater than 2.5 ppb. Also, a limited number of NAWQA groundwater samples from 1995 to 2004 are available from areas of high planted cotton (counties with > 100,000 acres of planted cotton) and historic high use of fluometuron use, which included areas in AR, MS, NC, and TX. Most samples of the parent compound resulted in no detects and only five samples resulted in detects < 0.35 ppb. From the same samples, some detections were available of TFMA, a common analyte for fluometuron degradates including the primary degradate, desmethyl fluometuron. Similarly, TFMA

concentrations from these samples were low, with all being < 0.05 ppb.

Based on the monitoring data and the conservative nature of the assessment as described above, the Agency does not believe that long-term average residues of fluometuron and its degradate in groundwater sources of drinking water will result in cancer risks above the Agency's level of concern. To confirm that exposure is not likely to exceed the Agency's level of concern, the Agency and the registrant have agreed that additional groundwater monitoring data are necessary. A water monitoring program is being required as part of this RED. For further information, the see the document *Revised Drinking Water Assessment and EFED's Response…*dated September 28, 2005.

Table 20. Revise Fluometuron Cancer Dietary (Food + Drinking Water) Risk Estimates

Dietary Exposures Assessed	Q_1*	Cancer Risk Estimate
Food alone	1.80×10^{-2} $(mg/kg/day)^{-1}$	9×10^{-8}
Groundwater alone		1×10^{-5}
Food + groundwater		1×10^{-5}
Surface water alone		1×10^{-6}
Food + surface water		2×10^{-6}

b. Residential Risk Mitigation

Fluometuron has no residential uses. In addition, no residential post-application exposure is expected as a result of currently labeled uses. Therefore, no residential risk mitigation is necessary.

c. Aggregate Risk Mitigation

For fluometuron, the aggregate risk estimates are the same as those presented in the dietary (combined food and drinking water) risk section of this document because there are no registered residential uses of fluometuron. Therefore, no additional mitigation beyond that presented in the dietary risk mitigation section is necessary.

d. Occupational Risk Mitigation

It is the Agency's policy to mitigate occupational risk to the greatest extent practical and feasible. Mitigation measures may include reducing application rates, adding personal protective equipment (PPE) to end product labels, requiring the use of engineering controls, and other measures. A wide range of factors is considered in making risk management decisions for worker risks. These factors include, in addition to the estimated MOEs and cancer risk estimates, incident data, the nature and severity of adverse effects observed in the animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other factors.

Occupational exposure assessments are completed by the Agency considering the use of baseline PPE and, if warranted, for handlers, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The target MOE for fluometuron is 100, based on information provided in Section III of this document. For occupational cancer risks, estimates within the negligible risk range of 10^{-6} do not exceed the Agency's level of concern. When occupational risks are less than 100 or occupational cancer risks exceed the general range of 10^{-6}, EPA strives to reduce worker risks through the use of PPE and engineering controls or other mitigation measures. The Agency generally considers occupational cancer risks in the general range of 10^{-6} or less to be negligible, but may accept risks as high as 1×10^{-4} when all mitigation measures that are feasible and practical have been applied, particularly when there are critical pest management needs associated with the use of the pesticide. For example, fluometuron is a useful tool to address weed resistance and weed shifts that occur as a result of widespread glyphosate use, as well as for growers that do not grow glyphosate-tolerant cotton.

Handler Risk Mitigation

Handler risks were predicted for several fluometuron exposure scenarios as listed in Tables 7 and 8 for both commercial handlers and private handlers. Predicted risk estimates for commercial handlers only are presented in Section III of this document because MOEs for private handlers are much less than MOEs for commercial handlers, and any mitigation to address potential risks to commercial handlers will also address potential risks to private handlers.

Commercial handlers mixing and loading WP for aerial or groundboom application (3a and 3b), and handlers mixing and loading DF for aerial application (2a) have estimated risks above the Agency's level of concern, with MOEs from 12 to 69 and cancer risk estimates ranging from 3×10^{-4} to 4×10^{-5} at the highest level of PPE. To address these risk concerns, the technical registrant has agreed to voluntarily cancel its WP formulation registrations. For a separate WP product (EPA Reg. No. 5905-494), the end-product registrant has agree to package its WP product in water soluble packaging, resulting in an MOE of 210 and a cancer risk estimate of 1×10^{-5}. Further, the technical registrant has agreed to prohibit the application of DF formulations via aircraft.

To mitigate potential risks to commercial handlers mixing and loading EC formulation for aerial application (1a), the Agency is requiring the use of double-layer PPE plus gloves and an apron. With this level of PPE, the MOE is greater than 86 and the cancer risk estimate is less than 3×10^{-5}. The Agency determined that a respirator does not provide significantly greater levels of protection for handlers because the dermal route of exposure to fluometuron is of much greater concern than the inhalation route of exposure, and additional PPE has minimal impact on reducing the cancer risk estimates. Further, aerial application of fluometuron does not occur frequently, as it is considered an emergency treatment if the ground is too wet for an applicator to enter fields on a tractor to apply via groundboom. Agency information indicates that at least 80% of fluometuron is applied via groundboom with less than 20% being applied aerially. Therefore, the risk estimate as a result of limited potential exposure from mixing and loading for aerial application is not of concern to the Agency.

To mitigate potential risks to commercial handlers mixing and loading EC and DF for groundboom application (1b and 2b), the Agency is requiring the use of single-layer PPE plus gloves. With this level of PPE, the MOEs are 430 for EC formulations and 200 for DF formulations and not of concern. Cancer risk estimates are 7×10^{-6} and 1×10^{-5}, respectively. Because additional PPE has minimal impact on reducing the estimated cancer risks for these scenarios, no additional PPE is required.

For commercial handlers applying fluometuron via groundboom (applicators; 5), the Agency does not have short/intermediate-term risk concerns and is requiring baseline PPE, resulting in a MOE of 700. The cancer risk estimate considering this PPE is 4×10^{-6}. To mitigate potential risks to handlers applying fluometuron aerially (applicators; 4), the Agency is requiring the use of engineering controls in the form of enclosed cockpits resulting in a MOE of 440 and a cancer risk estimate of 7×10^{-6}. For handlers acting as flaggers (6), the Agency does not have short/intermediate term risk concerns and is requiring baseline PPE, resulting in a MOE of 590. The estimated cancer risk considering this PPE is 5×10^{-6}; since additional PPE requirements do not have a significant impact on reducing the risk estimates, no additional PPE is required.

Post-Application Worker Risk Mitigation

For workers re-entering treated cotton fields to conduct post-application activities, such as irrigation and hand weeding, the Agency's risk estimates are not of concern for early season activities with MOEs of 1700 and cancer risk estimates of 7×10^{-7}. Predicted cancer risks exceed the Agency's level of concern for workers re-entering treated, mature cotton later in the season (cancer risk estimate of 1×10^{-5}; MOEs are not of concern at 110) as a result of increase foliage; however, the Agency understands that the great majority (>88%) of fluometuron application to cotton occurs early in the season (pre-emergence, pre-plant, or early post-emergence). Because of the limited late season use, repeated exposures are not likely; therefore, the Agency does not have post-application risk concerns for fluometuron and will maintain the current 24 hour REI.

2. Non-Target Organism (Ecological) Risk Management

The Agency's policy is to mitigate ecological risks to the greatest extent practical and feasible. Mitigation measures may include lowering application rates, reducing the number of applications allowed in a year, restricting the timing of applications, extending the time between applications, and changing pesticide use to minimize runoff or spray drift. In some situations, registrants may choose to delete certain uses or application methods to address ecological risk concerns. Fluometuron is expected to be useful for weed resistance and weed shifts that occur as a result of widespread glyphosate use, as well as for growers that do not grow glyphosate-tolerant cotton.

The screening-level risk assessment for fluometuron suggests that exposure to fluometuron could result in acute risks of concern to birds, mammals, terrestrial and aquatic plants, and chronic risks of concern to mammals. The Agency has addressed these risk concerns

to the extent feasible while considering some of the factors listed above. Specific risk mitigation measures are described in the following sections.

EPA does not currently have enough chronic toxicity data to quantify risks for fluometuron for the following taxonomic groups: birds, freshwater fish, estuarine/marine fish, freshwater invertebrates, estuarine/marine invertebrates. The Agency intends to require these data as part of this RED.

To help address ecological risk concerns, the registrant has agreed to label changes to significantly reduce the potential risk to non-target species, including significant reductions in the maximum seasonal application rates (up to 66% of the rate assessed, for some soil types), as presented in Table 17 above, and to require the use of medium to coarse droplet sizes during spray applications. The use of a larger droplet size is expected to significantly reduce off-site drift to nontarget organisms. See the following document for additional information on the effects of these mitigation measures on predicted ecological risk estimates: *Revised Risk Quotient Calculations for Proposed New Application Rates for Fluometuron*, dated September 23, 2005.

a. Terrestrial Organisms

Birds and Mammals

EPA's screening-level risk assessment based on estimated maximum potential rates and aerial application for fluometuron suggests minimal acute risk concerns for birds and mammals, with the highest RQ being approximately 1 (for the smallest mammals feeding on short grass) and all others being 0.6 or less, and only slightly exceeding the LOCs (Table 11). The rate reductions that the registrant has agreed to will reduce these risks so that all acute RQs are less than 0.25.

EPA's screening-level risk assessment for fluometuron suggests chronic risks of concern for mammals, with RQs ranging from 40 to 3 based on mean EECs and aerial application (Table 11). At most, only 20% of fluometuron used is applied aerially, and groundboom application results in less exposure as a result of drift. Further, the significant reductions in seasonal maximum application rates will reduce chronic risks to mammals, resulting in revised chronic RQs of 0.18 to 2.82.

As stated above, the Agency does not have chronic toxicity data with which to estimate potential chronic risks to birds. The mitigation described above will reduce any current, potential chronic risks to birds, and the Agency intends to require the data necessary to evaluate chronic risk as part of this RED decision.

Non-Target Insects

Available data show that fluometuron is practically non-toxic to honeybees. The Agency does not have a risk concern for non-target insects. Therefore, no bee precautionary labelling is required on fluometuron product labels.

Plants

Consistent with its use as an herbicide, fluometuron is toxic to plants. Therefore, as would be expected, EPA's screening-level risk assessment for fluometuron results in RQs for terrestrial and semi-aquatic plants ranging from 11 to 117 (Table 12). As stated above, there are significant reductions in seasonal maximum application rates; however, these reductions will not reduce risks to plants because the maximum one-time application rate is still 2 lb ai/A for heavy soils; thus, RQs for terrestrial non-endangered plants remain 11 to 117. However, fluometuron is useful for weed resistance and weed shifts that occur as a result of widespread glyphosate use, as well as for growers that do not grow glyphosate-tolerant cotton. Further, the implementation of spray drift reduction measures, including a requirement that sprays consist of medium to coarse size droplets will reduce potential off-site drift.

b. Aquatic Organisms

Freshwater Fish and Invertebrates

EPA's screening-level risk assessment for fluometuron based on maximum rates and aerial application suggests minimal acute risk concerns for freshwater fish and invertebrates, with the highest RQ being approximately 1.5, and only slightly exceeding the Agency's LOC (Table 13). The rate reductions for certain soil types that the registrant has agreed to will further reduce these predicted risks. With this mitigation, the maximum acute RQ is reduced to 1. In addition, at most, only 20% of fluometuron used is applied aerially, and groundboom application results in less exposure as a result of drift and lower risk estimates.

As stated above, the Agency does not have chronic toxicity data with which to estimate potential chronic risks to freshwater fish and invertebrates. The mitigation described above will reduce any current, potential chronic risks to freshwater fish and invertebrates that have not been estimated, and the Agency intends to require the necessary data as part of this RED decision.

Estuarine/Marine Fish and Invertebrates

EPA's screening-level risk assessment for fluometuron based on maximum rates and aerial application suggests minimal acute risks concerns for estuarine/marine fish and invertebrates, with the highest RQ being approximately 0.09 and only slightly exceeding the endangered species LOC (Table 13). The rate reductions for certain soil types that the registrant has agreed to will further reduce these predicted risks. With this mitigation, the maximum acute RQ is reduced to 0.06. In addition, at most, only 20% of fluometuron used is applied aerially, and groundboom application results in less exposure as a result of drift.

As stated above, the Agency does not have chronic toxicity data with which to estimate potential chronic risks to estuarine/marine fish and invertebrates. The mitigation described above will reduce any current, potential chronic risks to estuarine/marine fish and invertebrates that have not been estimated, and the Agency intends to require the necessary data as part of this RED decision.

Plants

Consistent with its use as an herbicide, fluometuron is toxic to plants. Therefore, as would be expected, EPA's screening-level risk assessment for fluometuron results in RQs for non-endangered aquatic vascular and non-vascular plants ranging from 0.24 to 11 (Table 14). As stated above, the significant reductions in seasonal maximum application rates will reduce acute risks to aquatic plants, resulting in revised RQs of 0.16 to 6.97. Similarly, revised RQs for endangered plants would also be lower, ranging from 0.31 to 1.82.

3. Summary of Mitigation Measures

The following mitigation measures are necessary for fluometuron to be eligible for reregistration.

- Require wettable powder formulations be packaged in water soluble packaging.
- Prohibit aerial application with dry flowable formulations.
- Reduce application rates, as follows:
    - Sand, loamy sand, and sandy loam soils – the maximum one-time application rate is 1 lb ai/A, with 2 applications per year for a total annual maximum application rate of 2 lb ai/A.
    - Loam, silt loam, silt, sandy clay loam, silty clay loam, and clay loam soils – The maximum one-time application rate is 1.6 lb ai/A, with 2 applications per year. The total annual maximum application rate is 3 lb ai/A.
    - Sandy clay, silty clay, and clay soils – The maximum one-time application rate is 2 lb ai/A, with 2 applications per year. The total annual maximum application rate is 3 lb ai/A.
- Increase the interval between applications to 20 days.
- Add PPE requirements to labels, as follows:
    - Handlers mixing and loading liquids and dry flowable formulations for groundboom application must wear single layer PPE plus gloves,
    - Handlers mixing and loading liquids for aerial application must wear double-layer PPE plus gloves and an apron,
    - Handlers applying via groundboom must wear baseline PPE,
    - Handlers applying via aircraft must be in enclosed cabs, and
    - Handlers acting as flaggers must wear baseline PPE.

F. Other Labeling Requirements

To be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing fluometuron. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

1. Endangered Species Considerations

At this time, the Agency is not requiring label changes specific to the protection of listed species. If, in the future, specific measures are necessary for the protection of listed species, the

Agency will implement them through the Endangered Species Protection Program. While RQs exceeded the Agency's endangered species LOC for several taxa, these results were based on a screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act. As explained earlier, after a species-specific assessment is conducted, a determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to fluometuron at levels of concern.

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, EPA will continue to work with all interested parties on this important issue.

From its assessment of fluometuron, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for fluometuron, including a requirement for medium to coarse droplet size. Label statements implementing these measures are listed in the "spray drift management" section of the label table (Table 21) in Section V of this RED document. In the future, fluometuron product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that fluometuron is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table (Table 21) below. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for fluometuron to be eligible for reregistration.

A. Manufacturing-Use Products

1. Data Requirements

The generic data base supporting the reregistration of fluometuron for the above eligible uses has been reviewed and determined to be substantially complete. However, there are a few

data gaps remaining, and these are listed below. In addition, updated Confidential Statements of Formula (CSFs) are required.

Human Health

- pH (OPPTS Guideline Number 830.7000).

- UV/Visible Absorption (OPPTS Guideline Number 830.7050).

- Directions for Use (OPPTS Guideline Number 860.1200). Certain label revisions are required for cotton and rotational crops. This information will be considered confirmatory, because adequate data are available to reassess tolerances and to conduct a dietary risk analysis.

- Residue Analytical Method (OPPTS Guideline Number 860.1340). The registrant must either improve Method AG-519A or develop a new method capable of determining fluometuron residues that may be converted to TFMA in livestock commodities.

- Storage Stability (OPPTS Guideline Number 860.1380). Study required on the hydroxylated metabolites, as a result of the Agency's decision to regulate the hydroxylated metabolites in animal commodities.

- Magnitude of the Residue (OPPTS Guideline Number 860.1500). Magnitude of the residue data in/on cottonseed from use of the DF formulation are needed.

Ecological Effects

- Avian Chronic Reproduction (Guideline Numbers 71-4a and 71-4b; OPPTS Guideline Number 850.2300). The avian chronic reproduction tests with Northern bobwhite and mallard duck using fluometuron technical grade active ingredient are needed.

- Freshwater Fish Early Life-Stage (Guideline Number 72-4a; OPPTS Guideline Number 850.1400). The freshwater fish early life-stage test using fluometuron technical grade active ingredient is needed.

- Freshwater Invertebrate Early Life-Stage (Guideline Number 72-4 b; OPPTS Guideline Number 850.1300). The freshwater invertebrate early life-stage test using fluometuron technical grade active ingredient is needed.

- Estuarine/Marine Fish Early Life-Stage (Guideline Number 72-4a; OPPTS Guideline Number 850.1400). The estuarine/marine fish early life-stage test using fluometuron technical grade active ingredient is needed.

- Estuarine/Marine Invertebrate Life-Cycle (Guideline Number 72-4b; OPPTS Guideline Number 850.1350). The estuarine/marine aquatic invertebrate life-cycle test using fluometuron technical grade active ingredient is needed.

Special Studies

- Information on the Proximity of Federally Listed Endangered Species to the Fluometuron Use Sites (Special Study). This requirement may be satisfied by 1) having membership in the FIFRA Endangered Species Task Force (PR Notice 2000-2); 2) citing FIFRA Endangered Species Task Force data; or 3) independently producing these data.

- Prospective Groundwater Monitoring Study (Special Study).

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 21.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 21. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

For fluometuron to be eligible for reregistration, all fluometuron labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 21 below describes how language on the labels should be amended.

Table 21. Summary of Labeling Changes for Fluometuron		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an herbicide for use on cotton." Manufacturers of products formulated as dry flowables must prohibit aerial application. End-use products manufactured as a wettable powder must be reformulated into water soluble packaging.	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."	Precautionary Statements
End-Use Products Intended for WPS Use		
PPE Requirements Established by the RED for Dry Flowable (DF) Formulation	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks, and In addition, chemical-resistant gloves are required for all handlers (except applicators)"	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements	"Personal Protective Equipment (PPE)"	Immediately following/below

Table 21. Summary of Labeling Changes for Fluometuron		
Description	**Amended Labeling Language**	**Placement on Label**
Established by the RED for Liquid Concentrate Formulations	"Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers and loaders supporting aerial application must wear: - coveralls over long-sleeved shirt and long pants, - chemical resistant gloves, - chemical-resistant footwear and socks, and - a chemical-resistant apron." "All other mixers, loaders, applicators, flaggers, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks, and - chemical-resistant gloves (except applicators and flaggers)" "See engineering controls for additional requirements and options."	Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements for Wettable Powder (WP) Formulations packaged in water soluble packaging. (Note: all wettable powder products must be packaged in water soluble packaging to be eligible for reregistration.)	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)]. If you want more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and flaggers must wear: - long-sleeved shirt, - long pants, - shoes and socks.	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 21. Summary of Labeling Changes for Fluometuron		
Description	**Amended Labeling Language**	**Placement on Label**
	In addition, mixers and loaders must wear: - chemical-resistant gloves and chemical-resistant apron." "Handlers performing tasks that involve exposure to the concentrate, such as cleaning equipment or spill clean-up must wear: - coveralls over long-sleeved shirt and long pants, - chemical resistant gloves, - chemical-resistant footwear and socks, - chemical-resistant apron, and - a NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or any N, R, P, or HE filter ." "See engineering controls for additional requirements."	
Engineering Controls: Enclosed Cockpits for Aerial Applicators	Enclosed Cockpits "Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Engineering Controls: Wettable Powder Formulations packaged in water soluble packaging	"Engineering Controls: Water-soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides {40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must: - wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders - be provided, and must have immediately available for us in an emergency, such as a broken package, spill, or equipment breakdown: chemical resistant footwear and a NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or any N, R, P, or HE filter."	

Table 21. Summary of Labeling Changes for Fluometuron		
Description	**Amended Labeling Language**	**Placement on Label**
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/ PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.."	Precautionary Statements: Hazards to Humans and Domestic Animals
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, in Agricultural Use Requirements box
Early Reentry Personal Protective Equipment for Products Subject to WPS as required by Supplement 3 of PR Notice 93-7	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: - Coveralls, worn over a short-sleeved shirt and short pants, - Chemical-resistant gloves made of any waterproof material, - Chemical-resistant footwear plus socks, and - Protective eyewear.	Directions for Use, in Agricultural Use Requirements Box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use directly above the Agricultural Use Box

Table 21. Summary of Labeling Changes for Fluometuron		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restrictions Dry Flowable (DF) Formulation	"Aerial application is prohibited."	Directions for Use
Application Restrictions	Application Rates (Cotton) - Sand, loamy sand, and sandy loam soils The maximum one-time application rate is 1 lb ai/A, with 2 applications per year for a total annual maximum application rate of 2 lb ai/A. - Loam, silt loam, silt, sandy clay loam, silty clay loam, and clay loam soils The maximum one-time application rate is 1.6 lb ai/A, with 2 applications per year. The total annual maximum application rate is 3 lb ai/A. - Sandy clay, silty clay, and clay soils The maximum one-time application rate is 2 lb ai/A, with 2 applications per year. The total annual maximum application rate is 3 lb ai/A. - All soils Require a 20 day interval between applications The feeding restriction for cotton gin trash must be removed from product labels (cotton gin trash is a livestock feed item not under control of the grower). Plantback intervals must be as follows: - 3 months for wheat - 8 months for field corn, sweet corn, peanuts - 9 months for rice, grain sorghum, and soybeans	Directions for Use
Spray Drift Label Language for Products Applied as a Spray	"Spray Drift Management" "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product." Wind Speed "Do not apply at wind speeds greater than 15 mph."	Directions for Use under General Precautions or Restrictions and/or Application Instructions

Table 21. Summary of Labeling Changes for Fluometuron		
Description	**Amended Labeling Language**	**Placement on Label**
	Droplet Size "Apply as a medium or coarser spray (ASAE Standard 572)" Temperature Inversions "If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions." Other State and Local Requirements "Applicators must follow all state and local pesticide drift requirements regarding application of fluometuron. Where states have more stringent regulations, they must be observed." Equipment "All application equipment must be properly maintained and calibrated using appropriate carriers or surrogates." *Additional requirements for aerial applications (for liquid and wettable powder formulations only):* 1. "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." 2. "Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety." 3. "When applications are made with a crosswind, the swath must be displaced downwind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind." *Additional requirement for groundboom application:* 1. "Do not apply with a nozzle height greater than 4 feet above the crop canopy."	

Appendix A: Fluometuron Use Patterns Eligible for Reregistration

Table 1. Fluometuron Use Patterns Eligible for Reregistration - Cotton				
Site Application Timing Application Type Application Equipment	**Max. Single Application Rate (ai)[1]**	**Max. # of Apps.**	**Minimum Retreatment Interval**	**Use Limitations**
Cotton				
Early Bloom Broadcast Sprayer	2 lb ai/A	2	20 days	Aerial application is prohibited for dry flowable formulations. Wettable powders formulations must be packaged in water soluble bags 24 hour REI. See application rate limitations based on soil type in table 2 below. 60 day PHI
Foliar Band Treatment/Basal Spray Sprayer				
Layby Broadcast/Directed Spray/Soil Band Treatment Band Sprayer/Sprayer				
Postemergence Band treatment/ Broadcast/ Directed Spray/Low Volume Spray (concentrate)/Soil Band Treatment Aircraft/Band Sprayer/Ground/Soil Incorporation Equipment/Sprayer				
Prebloom Band Treatment/Directed Spray Sprayer				
Preemergence Band treatment/ Broadcast/ /Low Volume Spray (concentrate)/Soil Band Treatment/Soil Incorporated Treatment/Soil Treatment Aircraft/Band Sprayer/ Ground/ Sprayer				
Preplant Band treatment/ Broadcast/ /Low Volume Spray (concentrate)/Soil Band Treatment/Soil Incorporated Treatment Aircraft/Band Sprayer/ Ground/ Soil Incorporation Equipment/ Sprayer				

[1] See additional application rate limitations based on soil type in table 2 below.

Table 2. Fluometuron Use Patterns Eligible for Reregistration – Additional Required Use Rate Restrictions for Application of Fluometuron on Cotton Based on Soil Type				
Soil Texture	**Max. Single Application Rate (ai)**	**Max. # of Apps.**	**Seasonal Max. Rate**	**Minimum Retreatment Interval (Days)**
Cotton				
Sand, Loamy Sand, Sandy Loam	1 lb ai/A	2	2 lb ai/A	20 days
Loam, Silt Loam, Silt, Sandy Clay Loam, Silty Clay Loam, Clay loam	1.6 lb ai/A	2	3 lb ai/A	20 days
Sandy Clay, Silty Clay, Clay	2 lb ai/A	2	3 lb ai/A	20 days

Appendix B: Data Supporting Guideline Requirements for the Reregistration of Fluometuron

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case 0049 covered by this RED. It contains generic data requirements that apply to fluometuron in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed by Guideline Number. The Guideline Numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

A. Terrestrial Food
B. Terrestrial Feed
C. Terrestrial Non-Food
D. Aquatic Food
E. Aquatic Non-Food Outdoor
F. Aquatic Non-Food Industrial
G. Aquatic Non-Food Residential
H. Greenhouse Food
I. Greenhouse Non-Food
J. Forestry
K. Residential
L. Indoor Food
M. Indoor Non-Food
N. Indoor Medical
O. Indoor Residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fluometuron				
Guideline Requirement			Use Pattern	MRID Citation
New	Old	Study Title		
PRODUCT CHEMISTRY				
860.1200	171-3	Directions for Use	A, B	Data Gap (for technical registrants)
830.7000	63-12	pH	A, B	Data Gap (for technical registrants)
830.7050	None	UV/visible absorption	A, B	Data Gap
830.7300	63-10	Dissociation constant in water	A, B	42017302

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fluometuron				
Guideline Requirement			Use Pattern	MRID Citation
New	Old	Study Title		
830.7550	63-11	Octanol/water partition coefficient	A, B	00160757
830.7840	63-8	Water solubility	A, B	00152460
830.7860	63-8	Solvent solubility	A, B	00019017
830.7200	63-5	Melting point/melting range	A, B	00019017
830.7300	63-7	Density	A, B	00019017
830.7950	63-9	Vapor pressure	A, B	00019017
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B	40864401, 40930601
835.2240	161-2	Direct Aqueous Photolysis	A, B	41065101
835.2410	161-3	Soil Photolysis	A, B	40930602
835.4100	162-1	Aerobic Soil Metabolism	A, B	42998702
8354200	162-2	Anaerobic Soil Metabolism	A, B	42998703
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B	43158901
835.1240	163-1	Leaching/Adsorption/Desorption	A, B	42643601, 42643602, 42643603, 42643604
835.110	164-1	Terrestrial Field Dissipation	A, B	40459401, 40459402, 41931501
None	165-4	Bioaccumulation In Fish	A, B	42017304, 42413502
835.2100	166-1, 2	Ground Water Monitoring	A, B	41931501
ECOLOGICAL EFFECTS				
850.2100	71-1 (b)	Avian Acute Oral LD50 - Mallard Duck	A, B	19221
850.2100	71-1 (b)	Avian Acute Oral LD50 - Mallard Duck	A, B	160000
850.2200	71-2 (a)	Avian Subacute Dietary LC50 Bobwhite Quail	A, B	42498001, 42597401, 19222
850.2200	71-2 (b)	Avian Subacute Dietary LC50 Mallard Duck	A, B	19222
850.2300	71-4 (a)	Avian Reproduction Quail – Bobwhite Quail	A, B	Data Gap
850.2300	71-4 (b)	Avian Reproduction Quail – Mallard Duck	A, B	Data Gap
850.1075	72-1	Freshwater Fish LC50 – Channel Catfish	A, B	40098001

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fluometuron				
Guideline Requirement			Use Pattern	MRID Citation
New	Old	Study Title		
850.1075	72-1 (a)	Freshwater Fish LC_{50} – Bluegill Sunfish	A, B	42498002, 40098001
850.1075	72-1 (c)	Freshwater Fish LC_{50} – Rainbow Trout	A, B	42498003, 40098001, 42505001
850.1010	72-2	Freshwater Invertebrate LC_{50} – *Daphnia magna*	A, B	40098001
850.1010	72-2	Freshwater Invertebrate LC_{50} – Chironomus plumosus	A, B	40098001
None	72-3 (a)	Estuarine/Marine Fish LC_{50} – Sheepshead	A, B	42498004, 42505002
None	72-3 (b)	Estuarine/Marine Mollusk – Eastern Oyster	A, B	42498005, 43848101
None	72-3 (c)	Estuarine/Marine Shrimp – Mysid Shrimp	A, B	42498006, 42568501
850.1400	72-4 (a)	Freshwater Fish Early Life Stage Toxicity Test – Fathead Minnow	A, B	Data Gap
850.1400	72-4 (b)	Estuarine/Marine Fish Early-Life Stage Test – Sheepshead Minnow	A, B	Data Gap
850.1350	72-4 (c)	Estuarine/Marine Aquatic Invertebrate Life-Cycle Test - Mysid	A, B	Data Gap
850.1300	72-4 (d)	Freshwater Aquatic Invertebrate Life-Cycle Test – *Daphnia magna*	A, B	Data Gap
850.5400	122-2	Aquatic Plant Growth (Tier I) Vascular plant species	A, B	42564102
850.5400	122-2	Aquatic Plant Growth (Tier I) Non-Vascular plant species	A, B	42564103, 42568502, 42568503, 43025601
850.4225	123-1(a)	Seed Germ./Seedling Emergence (Tier II) - Dicots, Monocots (TGAI)	A, B	42718801, 42718802
850.4250	123-1(b)	Vegetative Vigor (Tier II) Dicots, Monocots (TGAI)	A, B	42718803
None	123-2	Aquatic Plant Growth (Tier II) Vascular plant species (TGAI)	A, B	43421601
None	123-2	Aquatic Plant Growth (Tier II) Non-vascular plant species	A, B	43421602
850.3020	144-1	Acute Contact LD_{50} - Honeybee	A, B	114832
RESIDUE CHEMISTRY				

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fluometuron				
Guideline Requirement			Use Pattern	MRID Citation
New	Old	Study Title		
860.1300	171-4a	Nature of Residue - Plants	A, B	40492411, 40492412, 40492413, 43654402, 43654403, 43654404
860.1300	171-4b	Nature of Residue - Livestock	A, B	40047401, 40047402, 40190704, 40190706, 43413403, 43413404
860.1340	171-4c	Residue Analytical Method - Plant Commodities	A, B	00019009, 00022940, 40190714, 40292001, 42017305, 42017306, 42498008, 43218104, 43654405, 44449401 44449402
860.1340	171-4d	Residue Analytical Method - Animal Commodities	A, B	00019014, 00019160, 40067501, 42017305, 42017306,43413405, 44623201 Data Gap[2]
860.1360	171-4m	Multiresidue Methods	A, B	42498008
860.1380	171-4e	Storage Stability Data	A, B	00019021, 00019099, 41161903, 41161904, 42258701 Data Gap[3]
860.1480 Magnitude of Residue - Meat, Milk, Poultry, and Eggs				
860.1480	171-4j	Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	A, B	40190710, 44623202
860.1480	171-4j	Eggs and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	A, B	40190711
860.1500 Crop Field Trials				

[2] The registrant must either improve Method AG-519A or develop a new method capable of determining floumeturon residues that may be converted to TFMA in livestock commodities.
[3] Study required on the hydroxylated metabolites, as a result of the Agency's decision to regulate the hydroxylated metabolites in animal commodities.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fluometuron				
Guideline Requirement			Use Pattern	MRID Citation
New	Old	Study Title		
860.1500	171-4k	Cottonseed and gin byproducts	A, B	00018930, 00018995, 00018997, 00019020, 00019022, 00019036, 00019085, 00019099, 00031739, 00034005, 00065048, 00106374, 40190712, 43218101 43218102, 44623203 Data gap[4]
860.1520 Magnitude of Residue - Processed Food/Feed				
860.1520	171-4l	Cottonseed processed commodities (meal, hulls, and refined oil)	A, B	402920026, 43218103
860.1850	None	Confined Rotational Crops	A, B	43654401, 43654402, 44084801
860.1900	None	Field Rotational Crops	A, B	43218101, 43218102, 43218103 Data Gap[5]
TOXICOLOGY				
870.1000	81-1	Oral LD_{50} – Rat	A, B	41216802, 40409302, 00142844
870.1100	81-2	Dermal LD_{50} – Rabbit	A, B	00142845
870.1200	81-3	Inhalation LD_{50} – Rat	A, B	40409304, 41216804, 00145431
870.2400	81-4	Eye Irritation – Rabbit	A, B	41216805, 00142846 00145431
870.2500	81-5	Dermal Irritation – Rabbit	A, B	0068040, 41216806, 40409306, 00142847
870.2600	81.6	Dermal Sensitization	A, B	40409307, 41216807, 0160762, 00142848
870.3100	82-1a	90-day Oral Toxicity – Rat	A, B	00019034
870.3150	82-1b	13-week Subchronic Oral Toxicity – Dog	A, B	00019035

[4] Magnitude of the residue in/on cottonseed from use of the DF formulation are needed.
[5] Adequate data are available to support the following intervals: three months for wheat; eight months for field corn, sweet corn, and peanuts; and none months for rice, grain sorghum, and soybeans. If the registrant wishes to support rotational crops and plantback intervals other than those listed above, then additional rotational crop field trials must be conducted.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Fluometuron				
Guideline Requirement			Use Pattern	MRID Citation
New	Old	Study Title		
870.3200	82-2	21-Day Dermal – Rabbit	A, B	00160763
870.4100a	83-1a	Chronic Feeding – Rodent	A, B	83-5 satisfies this guideline
870.4100b	83-1b	Chronic Feeding – Dog	A, B	40779001, 41189501
870.4200	83-2	Carcinogenicity – Rat	A, B	83-5 satisfies this guideline
870.4200	83-2b	Carcinogenicity – Mouse	A, B	00163854, 42413501, 43506601
870.3700a	83-3a	Developmental Toxicity – Rat	A, B	00163710, 42397601
870.3700b	83-3b	Developmental Toxicity – Rabbit	A, B	00163774, 00147554, 42397602
870.3800	83-4	2-Generation Reproduction - Rat	A, B	00163773
870.4300	83-5	Chronic Feeding/Carcinogenicity - Rat	A, B	00163772
870.5100	84-2a	Mutagenicity - Ames	A, B	40802901
None	84-4	Mutagenic - DNA Synthesis	A, B	42017303
870.7485	85-1	Metabolism	A, B	40047403

Appendix C: Technical Support Documents for Fluometuron

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard (South Building), 1777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4:00 pm.

The preliminary risk assessments for fluometuron are available in the public docket and in e-dockets under docket number OPP-2004-0372. This contains risk assessments and related documents as of August 2005. During the comment period, the registrant submitted additional data for fluometuron. EPA reviewed these data and incorporated them into the revised risk assessments for fluometuron. These revised risk assessments form the basis of the regulatory decision described in this RED. These risk assessment and related documents are also available under docket number OPP-2004-0372.

Technical support documents from the Fluometuron RED are as follows:

Federal Register Documents

- Fluometuron; Notice of Availability of Risk Assessments and Opening of Docket. 70 FR 17447; April 6, 2005
- Fluometuron; Reregistration Eligibility Decision; Notice of Availability

Special Review and Reregistration Division Administrative Documents

- Overview of Fluometuron; March 30, 2005
- Fluometuron Use Closure Memorandum; July 9, 2004

Benefits and Economic Analysis Division Documents

- Table 1. Maximum Fluometuron Use Rates and Management Practices by Crop Based on Current Labels ; April 6, 2004
- Table A2. Food/Feed Use Patterns Summary for Fluometuron. April 6, 2004
- Screening Level Estimates of Agricultural Uses of Fluometuron (SLUA); March 15, 2004
- Refined Fluometuron Percent Crop Treated and Percentage of National Soybean, Corn, and Wheat Crops Rotated with Fluometuron-Treated Cotton; August 9, 2005
- Usage Report in Support of Reregistration for the Herbicide Fluometuron; September 14, 2005
- Addendum to Refined Fluometuron Percent Crop Treated; September 21, 2005
- Impacts Assessment for Fluometuron September 26, 2005

Human Health Risk Assessment Documents

- Fluometuron: Occupational Exposure Assessment for the Reregistration Eligibility Decision Document; July 19, 2004
- Fluometuron. Summary of Product Chemistry for the Reregistration Eligibility Decision (RED) Document; November 3, 2004

- Fluometuron. Summary of Analytical Chemistry and Residue Data for the Reregistration Eligibility Decision (RED) Document; November 30, 2004
- Fluometuron. Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document; November 30, 2004
- Fluometuron: Revised HED Risk Assessment for Phase III of the Reregistration Eligibility Decision (RED); February 1, 2005.
- Phase 2 Response to Error Comments for Fluometuron RED (HED Risk Assessment); February 1, 2005
- HED Response to a Proposal to Maintain the 24-Month CD-1 Mouse Oncogenicity Study Supplementary for the Fluometuron RED; July 28, 2005
- Fluometuron: Revised Acute, Chronic, and Cancer Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document; September 27, 2005

Environmental Fate and Ecological Risk Assessment Documents

- Fluometuron Drinking Water Assessment for the Human Effects Division (HED) Reregistration Eligibility Decision Document; December 8, 2004
- EFED response to Registrant's 30 day Error Correction Comments on Fluometuron RED; February 22, 2005
- Revised Environmental Fate and Ecological Risk Assessment of Fluometuron; February 22, 2005
- Revised Risk Quotient Calculations for Proposed New Use Rates; September 23, 2005
- Revised Drinking Water Assessment and EFED's Response; September 28, 2005

Appendix D: Citations Considered to be Part of the Database Supporting the Fluometuron Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

Study Citations

MRID **Citation**

Product Chemistry

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Appendix E: Generic Data Call-In

Appendix F: Product-Specific Data Call-In

The Agency intends to issue both Generic and Product-Specific Data Call-Ins for fluometuron. See Chapter V of the RED for a list of studies that the Agency plans to require.

Appendix G: Batching of Fluometuron Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing FLUOMETURON as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to

participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twenty products were found which contain fluometuron as the active ingredient. These products have been placed into five Batches and a No Batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

Batch 2a: Products in this Batch may cite data generated with products in Batch 2.

Batch 3: EPA Reg. Nos. 352-709 and 66222-32 may cite each other but may not cite data generated by other products in this Batch.

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	11603-31	96.0
	66330-254	96.5
	74694-27	97.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	1812-438	85.0
	66222-33	85.0
	66222-34	85.0

Batch 2a	EPA Reg. No.	Percent Active Ingredient
	352-687	80.0
	5905-494	80.0
	9779-311	80.0
	66330-261	80.0
	66222-30	80.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	1812-285	41.2
	352-709	41.7
	9779-312	41.7
	66330-260	41.7
	56077-79	43.0
	66222-32	41.7

Batch 4	EPA Reg. No.	Percent Active Ingredient
	9779-319	Fluometuron: 13.2% MSMA: 27.6%
	66222-29	Fluometuron: 13.2% MSMA: 27.6%

No Batch	EPA Reg. No.	Percent Active Ingredient
	19713-127	Fluometuron: 13.2% MSMA: 27.6%

Appendix H: List of Registrants Sent The Data Call-In

Appendix H: List of Registrants Sent the Fluometuron DCI		
Company Number	**Company Name**	**Address**
352	E.I. Du Pont de Nemours and Co., Inc.	PO Box 30 Stine-Haskell Research Center Newark, DE 19714
1812	Griffin LLC	PO Box 30 Stine-Haskell Research Center Newark, DE 19714
5905	Helena Chemical Co.	225 Schilling Boulevard, Suite 300 Collierville, TN 38017
9779	Agriliance, LLC	PO Box 64089 St. Paul, MN 55164
11603	AGAN Chemical Mfg., LTD	4515 Falls of Neuse Rd., Suite 300 Raleigh, NC 27609
19713	Drexel Chemical Co.	PO Box 13327 1700 Channel Avenue Memphis, TN 38113
66222	Makhteshim-Agan of North America Inc.	4515 Falls of Neuse Rd., Suite 300 Raleigh, NC 27609
66330	Arysta Lifescience North America Corporation	Park West II 15401 Weston Parkway, Suite 150 Cary, NC 27513

Appendix I: List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions:

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the following address for the Document Processing Desk.:

   Document Processing Desk (distribution code)*
   Office of Pesticide Programs (7504P)
   Environmental Protection Agency
   1200 Pennsylvania Ave, NW
   Washington, DC 20460-0001

   * Distribution Codes are as follows:
   (APPL) Application for product registration
   (AMEND) Amendment to existing registration
   (CAN) Voluntary Cancellation
   (EUP) Experimental Use Permit
   (DIST) Supplemental Distributor Registration
   (SLN) Special Local Need
   (NEWCO) Request for new company number
   (NOTIF) Notification
   (PETN) Petition for Tolerance
   (XFER) Product Transfer

DO NOT fax or e-mail any form containing "Confidential Business Information" or "Sensitive Information."

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at *williams.nicole@epamail.epa.gov*. If you want these forms mailed or faxed to you, please contact Lois White, *white.lois@epa.gov* or Floyd Gayles, *gayles.floyd@epa.gov*.

If you have any questions concerning how to complete these forms, please contact OPP's ombudsperson for conventional pesticide products: Linda Arrington, (703) 305-5446

The following Agency Pesticide Registration Forms are currently available via the Internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit http://www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program-Storage and Disposal Statements
    b. 84-1 Clarification of Label Improvement Program
    c. 86-5 Standard Format for Data Submitted under FIFRA
    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
    b. EPA Form No. 8570-4, Confidential Statement of Formula
    c. EPA Form No. 8570-27, Formulator's Exemption Statement
    d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
    e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

    a. Registration Division Personnel Contact List
    b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
    c. Antimicrobials Division Organizational Structure/Contact List
    d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
    e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
    f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
    g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

    National Technical Information Service (NTIS)
    5285 Port Royal Road
    Springfield, VA 22161

    The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: http://npic.orst.edu

   The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

   - Date of receipt
   - EPA identifying number
   - Product Manager assignment

   Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

   To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.