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PREVENTION, PESTICIDES
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MEMORANDUM

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From: Bill Smith,
Health Effects Division/Reregistration Branch 2 (7509C)

Through: Alan Nielsen, Branch Senior Scientist
Health Effects Division/Reregistration Branch 2 (7509C)

To: Elissa Reaves, Risk Assessor
Health Effects Division/Registration Action Branch 2 (7509C)

The attached assessment is the occupational exposure and risk estimates for fluometuron to support HED's reregistration eligibility decision (RED) document.

The assessment was reviewed by HED's Science Council for Exposure (ExpoSAC) to ensure compliance with current HED policy for conducting occupational and residential exposure (ORE) assessments.

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Fluometuron is a widely used herbicide in the United States. It is currently registered only for use in agricultural settings on cotton. Fluometuron is formulated as dry flowable, wettable powder (including water-soluble packets), and flowable liquid concentrate end-use formulations. The methods of application are aerial and groundboom.

Exposure Data Used In Assessment

Occupational handler exposure was addressed using the Pesticide Handlers Exposure Database (PHED ver. 1.1). Fluometuron is registered solely for use by professional applicators in agricultural settings. Therefore, this assessment only evaluates handler and postapplication risks for occupational handlers, both full-time and part-time applicators.

All of the studies used by the Agency to assess occupational risks were considered to be the best source of data available for the scenario where it was used.

Hazard Concerns

The short-term dermal and inhalation toxicological endpoint of concern (10 mg/kg/day) is based on a developmental oral toxicity study in rats. The intermediate-term dermal and inhalation toxicological endpoint of concern (10 mg/kg/day) is based on a subchronic oral dog study. Since oral studies were selected, a dermal absorption factor of 10 percent was selected and an inhalation absorption factor of 100 percent was selected.

The adverse effects for the short-term dermal and inhalation endpoints are based on oral studies, where the effects were observed in females, therefore, the average body weight of an adult female handler (i.e., 60 kg) is used to complete the short-term dermal and inhalation noncancer risk assessment. Since the NOAEL selected for intermediate-term dermal and inhalation non-cancer assessments is numerically identical (i.e., 10 mg/kg/day) to the short-term NOAEL, no separate intermediate-term noncancer risks are assessed. The dermal and inhalation margins of exposure were combined for the fluometuron risk assessment, because the toxicity endpoints for the dermal and inhalation routes of exposure are the same.

Fluometuron is currently classified as a "Group C: Possible Human Carcinogen". The Q_1^* for fluometuron, based upon male mouse combined lung (adenomas and or carcinomas) tumor rates is 1.80×10^{-2}.

The Agency's level of concern for noncancer risks (i.e., target level for MOEs or Margins of Exposure) is defined by the uncertainty factors that are applied to the assessment. The Agency applies a 10X factor to account for inter-species extrapolation and a 10X factor to account for intra-species sensitivity. The total uncertainty factors that have been applied to noncancer risk assessments is 100 for occupational scenarios.

Occupational Handler Non-cancer Risks

The noncancer handler risk assessment indicates that some scenarios are below HED's level of concern with baseline mitigation, including:

- mixing/loading dry flowables to support groundboom applications,
- applying sprays with groundboom equipment, and
- flagging to support aerial spray applications.

With the addition of personal protective equipment, risks from mixing/loading liquid concentrates to support groundboom applications fall below HED's level of concern. In addition, the risks for mixing/loading liquid concentrates to support aerial applications fall below HED's level of concern with double layer body protection, gloves, and a quarter-face dust/mist filtering respirator. However, the baseline inhalation risk for this scenario indicates that inhalation exposures are not significantly contributing to the total risk, and that dermal exposure is the route of concern.

With engineering control mitigation, the remaining handler scenarios fall below HED's level of concern. These include:

- mixing/loading liquid concentrates, dry flowables, and wettable powders to support aerial applications,
- mixing/loading wettable powders to support groundboom applications, and
- applying sprays via aerial equipment.

Occupational Handler Cancer Risks

The cancer handler risk assessment indicates that the risks for mixing/loading dry flowables for aerial and groundboom application, applying sprays with groundboom equipment and flagging to support aerial spray applications are all less than 1×10^{-4} with baseline mitigation for both private and commercial growers. With the addition of personal protective equipment, mixing/loading liquid concentrations for aerial and groundboom applications and mixing/loading wettable powders for groundboom applications are all less than 1×10^{-4}.

For private growers, the cancer risks are less than 1×10^{-4} with baseline attire plus gloves plus a respirator and with double-layer attire plus gloves plus a respirator for mixing/loading wettable powders for aerial applications. For private growers, the cancer risks are less than 1×10^{-6} with baseline attire plus gloves plus a respirator and with double-layer attire plus gloves plus a respirator for applying sprays with groundboom equipment.

For mixing/loading wettable powder for aerial applications and for applying sprays via aerial equipment (for commercial growers), the cancer handler risk assessment indicates that the risks are less than 1×10^{-4} with engineering control mitigation. For mixing/loading liquid concentrates (*private growers only)*, dry flowables (*private growers only)*, and wettable powders (*private growers only)* for groundboom applications; applying sprays with groundboom equipment (*private growers);* and flagging to Support Aerial Spray Applications (private growers only), the cancer handler risk assessment indicates that the risks are less than 1×10^{-6}

with engineering controls.

Occupational Postapplication Risks

For the non-cancer risk assessment, the MOEs for low- and medium-exposure tasks exceed the target MOE of 100 on the day of application. For the cancer risk assessment, the postapplication cancer risks are less than 1×10^{-4} for both early and later season postapplication activities. Early-season cancer risks are less than 1×10^{-6} on day 0. Later-season cancer risks are 1×10^{-5} on day 0 and are less than 1×10^{-6} starting on day 12 following application.

Residential Handler Risks

There are no residential handler uses of fluometuron and, therefore, residential handler exposures have not been addressed in this risk assessment.

Residential Postapplication Risks

There are no residential postapplication exposures to fluometuron and, therefore, residential postapplication exposures have not been addressed in this risk assessment.

Overall Risk Summary

This risk assessment applied the latest exposure data, toxicology information, and use data. The overall results indicate that handler and postapplication risks are below HED's level of concern at some level of risk mitigation for all scenarios assessed.

1.0 Occupational Exposure/Risk Assessment

1.1 Purpose

This document is the occupational non-dietary exposure and risk assessment for fluometuron for its use as an herbicide. In this document, which is for use in EPA's development of the HED chapter of the fluometuron RED Document, EPA presents the results of its review of the potential human health effects of occupational exposure to fluometuron.

1.2 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is a potential for exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites or exposed to vapors after application is complete. Toxicological endpoints were selected for short- and intermediate-term dermal and inhalation exposures to fluometuron. In addition, a cancer Q_1^* was selected as an endpoint of concern. There is a potential for fluometuron exposure from mixing/loading, applying, flagging, and other handling tasks involved in applications to cotton and from postapplication activities after applications to cotton. Therefore, risk assessments are required for occupational handlers as well as for occupational postapplication exposures that can occur as a result of fluometuron use.

1.3 Summary of Hazard Concerns

HED's Hazard Identification Assessment Review Committee (HIARC) met to determine appropriate toxicological endpoints of concern for fluometuron. The toxicological endpoints that were used to complete the occupational risk assessments are summarized below. Adverse effects were identified at all durations of exposure ranging from short-term (up to 30 days) to intermediate-term durations (1 to 6 months). Cancer risks were calculated for fluometuron, since it is currently classified as a "Group C: Possible Human Carcinogen".

1.3.1 Fluometuron

Fluometuron is an herbicide where the use patterns can vary widely ranging from short-term through intermediate-term exposure durations. As such, when the HIARC evaluated the fluometuron hazard database (see Table 1), endpoints were selected to address each duration of exposure. Fluometuron exposures are expected to occur to occupational users.

Dermal Route (non-cancer)

The short-term toxicological endpoint of concern selected for the dermal (non-cancer) fluometuron risk assessment is based on a NOAEL of **10 mg/kg/day** from a developmental oral toxicity study in rats. The intermediate-term toxicological endpoint of concern selected for the dermal (non-cancer) fluometuron risk assessment is based on a NOAEL of **10 mg/kg/day** from

a subchronic oral dog study. Long-term exposures to fluometuron (i.e., greater than 6 months) are not expected for current registered uses. A dermal absorption factor of 10 percent was selected based on an oral developmental rabbit study and a 21-day rabbit dermal study.

Inhalation Route (non-cancer)

The short-term toxicological endpoint of concern selected for the inhalation (non-cancer) fluometuron risk assessment is based on a NOAEL of **10 mg/kg/day** from a developmental oral toxicity study in rats. The intermediate-term toxicological endpoint of concern selected for the inhalation (non-cancer) fluometuron risk assessment is based on a NOAEL of **10 mg/kg/day** from a subchronic oral dog study. Long-term exposures to fluometuron (i.e., greater than 6 months) are not expected for current registered uses. An inhalation absorption factor of 100 percent was selected.

Non-cancer Level of Concern (LOC)

HED's level of concern (LOC) for fluometuron is 100 (i.e., a margin of exposure (MOE) less than 100 exceeds HED's level of concern) for occupational scenarios. The level of concern is based on 10x to account for interspecies extrapolation to humans from the animal test species and 10x to account for intraspecies sensitivity.

Non-cancer Aggregation

The dermal and inhalation margins of exposure were combined for the fluometuron risk assessment, because the toxicity endpoints for the dermal and inhalation routes of exposure are the same.

Body Weight

Since the adverse effects for the studies utilized in the fluometuron short-term noncancer dermal and inhalation risk assessments are based on a developmental toxicity study, the adverse effects are considered female-specific. Therefore, the average weight of a female adult (i.e., 60 kg) was used to estimate short-term risks. Note: the intermediate-term NOAEL is based on an oral dog feeding study and the effects are not considered sex-specific. Therefore, the average weight of an adult (i.e., 70 kg) would be selected to estimated intermediate-term risks. However, since the intermediate-term NOAEL is the numerically the same (i.e., 10 mg/kg/day) as the short-term NOAEL, using a 70 kilogram body weight would result in slightly lower risks for intermediate-term exposures than for short-term exposures. Since this outcome is scientifically improbable, noncancer risks were assessed solely using the 60 kilogram body weight.

Cancer

HED's Carcinogenicity Peer Review Committee (CPRC) met on October 11, 1995 and classified fluometuron as a "Group C: Possible Human Carcinogen". This classification was based on statistically significant increases in combined adenomas/carcinomas of the lungs in male mice and malignant lymphocytic lymphomas in female mice at a dose which was less than adequate for fully assessing the carcinogenic potential of fluometuron (L. Taylor Memorandum 8/28/96, TXR 012049). The Q_1^* for fluometuron is 1.80×10^{-2} in human equivalents (converted from animals to humans by the use of the 3/4's scaling factor).

Table 1. Toxicology Endpoints for Fluometuron

Exposure Scenario	Dose (mg/kg/day)	FQPA Safety Factor and Level of Concern for Risk Assessment	Endpoint for Risk Assessment
Dietary Risk Assessments			
Acute Dietary females 13+	NOAEL= 10 UF= 100 **Acute RfD**= 0.1	**FQPA SF =1** acute RfD FQPA SF = 0.1 mg/kg/day	**Acute-** Fluometuron LOAEL=100 mg/kg/day, based on reduced food consumption, darkened spleens, and increased incidence of abortions and decreased maternal body-weight gain.
Chronic Dietary all populations	NOAEL = 0.55 UF = 100 **Chronic RfD** = 0.0055	**FQPA SF = 1** **cPAD** = chronic RfD FQPA SF = **0.005** mg/kg/day	**Chronic-**Fluometuron LOAEL=100 mg/kg/day, based on decreased body weight gain (9%), and increased splenic hemosiderin pigment deposition.
Incidental Oral:	No Residential Uses are Proposed for Fluometuron.		
Dermal Exposure: Short-Term	**Oral NOAEL**= 10 **AF=10**	**FQPA SF=1** **LOC for MOE=100**	**Developmental oral toxicity study in rats.** LOAEL = 100 mg/kg/day, based on delayed urinary system development.
Dermal Exposure: Intermediate-Term	**Oral NOAEL**= 10 **AF=10**	**FQPA SF=1** **LOC for MOE=100**	**Subchronic oral dog study. LOAEL**=100 mg/kg/day, based on inflammatory reactions in the liver and kidney.
Dermal Exposure: Long-Term	No uses currently support a long-term dermal endpoint.		
Inhalation Exposure: Short-Term	**Oral NOAEL=** 10 **AF=100**	**FQPA SF=1** **LOC for MOE=100**	**Developmental oral toxicity study in rats.** **LOAEL =** 100 mg/kg/day, based on decreased food consumption and darkened spleens.
Inhalation Exposure: Intermediate-Term	**Oral NOAEL=** 10 **AF=100**	**FQPA SF=1** **LOC for MOE=100**	**Subchronic oral dog study. LOAEL** =100 mg/kg/day, based on inflammatory reactions in the liver and kidney.
Inhalation Exposure: Long-term	No uses currently support a long-term inhalation endpoint.		
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).		

Acute Toxicity

Fluometuron is classified as category III for acute oral and dermal and as category III for 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.

Table 2. Summary of Acute Toxicity Data for Fluometuron (80%)

Test	MRID	Results	Category
Oral LD_{50}-rat	41216802 40409302 258202 114673	LD_{50}= 3880 (3020-4980) [M] & >1000 <1500 mg/kg [F] LD_{50}= 5223 (4111-6636) mg/kg [M&F] LD_{50}=3949 [M] and 3209 [F] mg/kg LD_{50}= 8.9 [M] and 7.8 [F] gm/kg	III
Dermal LD_{50}-rabbit	41216803	LD_{50}>2020 mg/kg	III
Inhalation LC_{50}-rat	40409304 41216804	LC_{50}>0.6 mg/L LC_{50}>2.25 mg/L	III
Eye Irritation-rabbit	24505	corneal opacity, iris irritation, redness, chemosis, discharge; all cleared by day 10.	II
Dermal irritation-rabbit	24505 41216806	severely irritating w/eschar formation [24 & 72 hrs] PIS= 5.65 slightly irritating, PIS = 0.96	II
Dermal sensitization	41216807 40409307	Non-sensitizing: guinea pig Non-sensitizing: rat	Not applicable

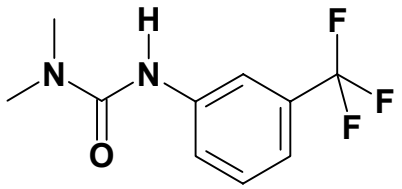
1.4 Incident Reports

An analysis of incidence reports will be included in a separate memo by Jerome Blondell.

1.5 Summary of Physical and Chemical Properties of Fluometuron

Fluometuron (CAS registry number 2164-17-2) has a molecular formula of $C_{10}H_{11}F_3N_2O$ and a molecular weight of 395.4 g/mole.

The nomenclature and physiochemical properties of Fluometuron are in Table 3.

Table 3. Fluometuron Nomenclature and Physical/Chemical Properties	
Chemical structure	
Molecular Formula	$C_{10}H_{11}F_3N_2O$
Molecular Weight	395.4
CAS name	1,1-dimethyl-3-(alpha, alpha, alpha-trifluoro-m-toly) urea
CAS #	2164-17-2
PC Code	035503

1.6 Summary of Use Patterns and Formulations

1.6.1 End-Use Products

Fluometuron is registered for use as a pre-emergence and post-emergence herbicide for effective control of certain annual grasses and broadleaf weeds in cotton. Broadleaf weeds controlled include: Buttonweed, Cocklebur, Florida pusley, Jimsonweed, Morningglory, Pigweed, Prickely aids, Puncturevine, Puslane, Ragweed, Seebania, Sicklepod, Smartweed, Tumbleweed, and Wright groundcherry. Grasses and other monocots controlled include: Barnyardgrass, Crabgrass, Crowfootgrass, Fall panicum, Foxtail, Goosegrass, Ryegrass, and Signalgrass. Cotton accounts for all of the reported use and 90 percent of the reported use is in the Delta area, which includes Mississippi, Louisiana, Arkansas, and Tennessee.

Fluometuron is applied by broadcast, or banded treatment with up to three applications per season in cotton. In cotton it can be applied as a pre-emergence and post-emergence directed or over-the-top spray, and as a preplant soil incorporated and at layby as a directed spray.

Fluometuron needs rainfall that is sufficient to germinate the weed seeds for its activation. Fluometuron is available as a technical material, at 96 percent active ingredient, and at varying percentages as end-use products. Fluometuron is available in dry flowable, wettable powder and flowable liquid concentrate end-use formulations and one of the wettable powder formulations is packaged in water-soluble packets.

1.6.2 Registered Use Categories and Sites

An analysis of the current labeling and available use information was completed by Biological and Economic Analysis Division. Fluometuron is registered for use in occupational

scenarios (see Table 4). It is also possible for occupational populations to be exposed to fluometuron during postaplication time periods.

Table 4: Summary of Maximum Application Rates for Registered Fluometuron Agricultural Uses

Crop Type/Use Site	Target of Application	Application Equipment	Maximum Application Rate	Application Rate Range
Cotton	soil/foliage	aerial, groundboom	2.0 lb ai/A	1.0 to 2.0 lb ai/A

1.6.3 Application Methods

Fluometuron is applied either via aerial or groundboom applications.

2.0 Occupational Exposures and Risks

There is a potential for exposure to fluometuron in occupational scenarios from handling fluometuron products during the application process (i.e., mixer/loaders, applicators, and flaggers) and a potential for postapplication worker exposure from entering into areas previously treated with fluometuron. As a result, risk assessments have been completed for occupational handler scenarios as well as occupational postapplication scenarios.

2.1 Occupational Handler Exposures and Risks

HED uses the term "handlers" to describe those individuals who are involved in the pesticide application process. HED believes that there are distinct job functions or tasks related to applications and that exposures can vary depending on the specifics of each task. Job requirements (e.g., amount of chemical to be used in an application), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event.

Exposure scenarios can be thought of as ways of categorizing the kinds of exposures that occur related to the use of a chemical. The use of scenarios as a basis for exposure assessment is very common as described in the *U.S. EPA Guidelines For Exposure Assessment* (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992). Information from the current labels; use and usage information; toxicology data; and exposure data were all key components in the development of the exposure scenarios.

The first step in the handler risk assessment process is to identify the kinds of individuals that are likely to be exposed to fluometuron during the application process. In order to do this in a consistent manner, HED has developed a series of general descriptions for tasks that are associated with pesticide applications. Tasks associated with occupational pesticide use (i.e., for "handlers") can generally be categorized using one of the following terms:

- **Mixers and/or Loaders:** these individuals perform tasks in preparation for an

application. For example, prior to application, mixer/loaders would mix the fluometuron and load it into the holding tank of the airplane or groundboom;

- **Applicators:** these individuals operate application equipment during the release of a pesticide product into the environment. These individuals can make applications using equipment such as airplanes or groundboom; and

- **Occupational Flaggers:** these individuals guide aerial applicators during the release of a pesticide product onto an intended target.

Next, assessors must understand how exposures to fluometuron occur (i.e., frequency and duration) and how the patterns of these occurrences can cause the effects of the chemical to differ (referred to as dose response). Wherever possible, use and usage data determine the appropriateness of certain types of risk assessments (e.g., a chronic risk assessment is not warranted for fluometuron uses because chronic duration exposure patterns are not expected to occur). Other parameters are also defined from use and usage data such as application rates and application frequency. HED always completes non-cancer risk assessments using maximum application rates for each scenario because what is possible under the label (the legal means of controlling pesticide use) must be evaluated, for complete stewardship, in order to ensure there are no concerns for each specific use.

A chemical can produce different effects based on how long a person is exposed, how frequently exposures occur, and the level of exposure. It is likely that fluometuron exposures can occur in a variety of patterns. HED believes that occupational fluometuron exposures can occur over a single day or up to weeks at a time for many use-patterns and intermittent exposures over several weeks are also anticipated. Some applicators may apply fluometuron over a period of weeks because they are custom or full-time applicators who are completing a number of applications for a number of different clients. HED classifies exposures up to 30 days as short-term and exposures greater than 30 days up to several months as intermediate-term. HED completes both short- and intermediate-term assessments for occupational scenarios in essentially all cases, because these kinds of exposures are likely and acceptable use/usage data are not available to justify deleting intermediate-term scenarios. Long-term handler exposures are not expected to occur for fluometuron.

Occupational handler exposure assessments are completed by HED using different levels of personal protection. HED typically evaluates all exposures with a tiered approach. The lowest tier is represented by the baseline exposure scenario (i.e., long-sleeve shirt, long pants, shoes, and socks) followed by increasing the levels of personal protective equipment or PPE (e.g., gloves, double-layer body protection, and respirators) and engineering controls (e.g., enclosed cockpits, enclosed cabs, and closed mixing/loading systems). This approach is always used by HED in order to be able to define label language using a risk-based approach. In addition, the minimal level of adequate protection for a chemical is generally considered by HED to be the most practical option for risk reduction (i.e., over-burdensome risk mitigation measures are not considered a practical alternative).

2.1.1 Data and Assumptions For Handler Exposure Scenarios

2.1.1.1 Assumptions for Handler Exposure Scenarios

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor is detailed below on an individual basis. The assumptions and factors used in the risk calculations include:

- Occupational handler exposure estimates were based on surrogate data from the Pesticide Handlers Exposure Database (PHED).

- The adverse effects for the short-term dermal and inhalation endpoints are based on oral studies, where the effects were observed in females, therefore, the average body weight of an adult female handler (i.e., 60 kg) is used to complete the short-term dermal and inhalation noncancer risk assessment. Since the NOAEL selected for intermediate-term dermal and inhalation non-cancer assessments is numerically identical (i.e., 10 mg/kg/day) to the short-term NOAEL, no separate intermediate-term noncancer risks are assessed.

- Generic protection factors (PFs) were used to calculate exposures when data were not available. For example, an 80 percent protection factor was assumed for the use of a dust/mist filtering (quarter-face) respirator.

- Cancer risk assessments were completed using the Q_1^* (1.8×10^{-02}) selected for fluometuron.

- For cancer assessments, it was assumed that fluometuron handlers who are employed either by small/typical cotton growers or small commercial operations (i.e., private growers) may be exposed 6 days per year – using estimates that typically two applications are applied per year to a cotton field and it might take three days per application to treat all cotton fields on an establishment. For cancer assessments, it was assumed that fluometuron handlers who are employed either by large-scale cotton growers or typical/large commercial operations (i.e., full-time applicators) may be exposed 18 days per year – assuming they are exposed on three times as many days as the private growers. All handlers were assumed to have a 35 year career and a 70 year lifespan for the cancer assessment.

- For non-cancer assessments, HED assumes the maximum application rates allowed by labels in its risk assessments (see table 1). For the cancer assessment, HED uses typical application rates, when available, rather than maximum application rates. Since the label directions allow for a range of application rates between one and two pounds active ingredient per acre and the label indicates that the higher application rate is for use only when weeds are a particular problem, HED assumed that a typical application rate over a number of years would be 1.5 pounds active ingredient per acre. This 1.5 pound rate is

used to assess cancer risks to handlers.

- The average occupational workday is assumed to be 8 hours. The daily areas treated were defined for each handler scenario (in appropriate units) by determining the amount that can be reasonably treated in a single day (e.g., acres per day). The assumptions for daily areas treated is taken from the Health Effects Division Science Advisory Committee on Exposure SOP #9: Standard Values for Daily Acres Treated in Agriculture which was completed on July 5, 2000.
  - Aerial applications: 1200 acres for high acreage crops (i.e., cotton)
  - Groundboom: 200 acres for high acreage crops (i.e., cotton)
  - Flaggers: 350 acres for cotton crops.

2.1.1.2 Exposure Data for Handler Exposure Scenarios

For fluometuron handler exposure assessments, all analyses were completed using data that were deemed to be a source of acceptable surrogate exposure data for the scenario in question.

HED uses a concept known as *unit exposure* as the basis for the scenarios used to assess handler exposures to pesticides. *Unit exposures* numerically represent the exposures one would receive related to an application. They are generally presented as (mg active ingredient exposure/pounds of active ingredient handled). HED has developed a series of unit exposures that are unique for each scenario typically considered in our assessments (i.e., there are different unit exposures for different types of application equipment, job functions, and levels of protection). The *unit exposure* concept has been established in the scientific literature and also through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization For Economic Cooperation and Development). The concept of unit exposures can be illustrated by the following example. If an individual makes an application using a low-pressure sprayer with either 10 pounds of chemical A or 10 pounds of chemical B using the same clothing and personal protective equipment, the exposures to chemicals A and B would be similar.

Pesticide Handler Exposure Database (PHED) Version 1.1 (August 1998): PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates)

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g.,

mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Appendix A, Table A1. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments. Unit exposures are used which represent different levels of personal protection as described above. Protection factors were used to calculate unit exposure values for varying levels of personal protection if data were not available.

2.1.2 Fluometuron Handler Exposure Scenarios

It has been determined that exposure to pesticide handlers is likely during the occupational use of fluometuron in a variety of occupational environments. The anticipated use patterns and current labeling indicate several occupational exposure scenarios based on the types of equipment and techniques that can potentially be used to apply fluometuron. The quantitative exposure/risk assessment developed for occupational handlers is based on the following scenarios. [Note: The scenario numbers correspond to the tables of risk calculations included in the occupational risk calculation aspects of the appendices. Fluometuron dermal and inhalation exposure was estimated using PHED]

Mixer/Loaders:

(1a) Liquids for Aerial Applications
(1b) Liquids for Groundboom Applications
(2a) Dry Flowables for Aerial Applications

(2b) Dry Flowables for Groundboom Applications
(3a) Wettable Powders for Aerial Applications
(3b) Wettable Powders for Groundboom Applications

Applicators:
(4) Aerial Applications (Sprays)
(5) Groundboom Applications

Flaggers:
(6) Flagging for Aerial- Sprays

2.1.3 Non-cancer Fluometuron Handler Exposure and Assessment

The occupational handler exposure and non-cancer risk calculations are presented in this section.

2.1.3.1 Non-cancer Fluometuron Handler Exposure and Risk Calculations

Non-cancer risks were calculated using the Margin of Exposure (MOE), which is a ratio of the daily dose to the toxicological endpoint of concern. Daily dose values are calculated by first calculating exposures by considering application parameters (i.e., rate and area treated) along with unit exposure values (see Appendix Table A2 for unit exposure values). Exposures were then normalized by body weight and adjusted for absorption factors, as appropriate, to calculate dose levels. MOEs were then calculated.

Daily Exposure: The daily exposure and daily dose to handlers were calculated as described below. The first step was to calculate daily exposure (dermal or inhalation) using the following formula:

$$Daily\ Exposure\left(\frac{mg\ ai}{day}\right) = Unit\ Exposure\left(\frac{mg\ ai}{lb\ ai\ handled}\right) \times Application\ Rate\left(\frac{lbs\ ai}{area}\right) \times Daily\ Area\ Treated\left(\frac{area}{day}\right)$$

Where:

Daily Exposure	=	Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;
Unit Exposure	=	Unit exposure value (mg ai/lb ai) derived from August 1998 PHED data;
Application Rate	=	Normalized application rate based on a logical unit treatment, such as acres, square feet, gallons, or cubic feet. Maximum values are generally used (lb ai/A, lb ai/sq ft, lb ai/gal, lb ai/cu ft); and
Daily Area Treated	=	Normalized application area based on a logical unit treatment such as acres (A/day), square feet (sq ft/day), gallons per day (gal/day), or cubic feet (cu ft/day).

Daily Dose: Daily dose (inhalation or dermal) was calculated by normalizing the daily dermal exposure value by body weight and accounting for dermal or inhalation absorption. Daily dose was calculated using the following formula:

$$\text{Average Daily Dose\_mg /kg /day\_} = \text{Daily Exposure} \left(\frac{\text{mg ai}}{\text{day}} \right) x \left(\frac{\text{Absorption Factor (\% /100)}}{\text{Body Weight (kg)}} \right)$$

Where:

Average Daily Dose	=	Absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure	=	Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;
Absorption Factor	=	A measure of the amount of chemical that crosses a biological boundary such as the skin or lungs (% of the total available absorbed); and
Body Weight	=	Body weight determined to represent the population of interest in a risk assessment (kg).

Margins of Exposure: Finally, the calculations of daily dermal dose and daily inhalation dose received by handlers were then compared to the appropriate endpoint (i.e., NOAEL) to assess the total risk to handlers for each exposure route within the scenarios. All MOE values were calculated separately for dermal and inhalation exposure levels using the formula below:

$$MOE = \frac{\text{NOAEL\_mg/kg/day}}{\text{Average Daily Dose\_mg/kg/day}}$$

Where:

MOE	=	Margin of exposure, value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless);
ADD	=	Average Daily Dose or the amount as absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and
NOAEL	=	Dose level in a toxicity study, where no observed adverse effects occurred (NOAEL) in the study

It is important to present risk values for each route of exposure (i.e., dermal or inhalation) in each scenario because it makes determining appropriate risk mitigation measures easier. For example, if overall risks are driven by dermal exposures and not inhalation, it is inadvisable to require respirators even though they may marginally reduce overall risks. A total MOE was calculated for fluometuron because common toxicity endpoints were used to calculate dermal and inhalation risks for each exposure duration.

2.1.3.2 Fluometuron Non-cancer Risk Summary (using PHED)

All of the non-cancer risk calculations for occupational fluometuron handlers completed in this assessment are included in Tables 4, 5, and 6.

Baseline Mitigation: The noncancer handler risk assessment indicates that these scenarios are not of concern with baseline mitigation:

- Mixing/Loading Dry Flowables to Support Groundboom Applications;
- Applying Sprays via Groundboom Equipment; and
- Flagging to Support Aerial Spray Applications.

Personal Protective Equipment Mitigation: The noncancer handler risk assessment indicates that the following scenario is not of concern with personal protective equipment mitigation:

- Mixing/Loading Liquid Concentrates to Support Groundboom Applications.

Note that risks are not a concern (i.e., MOE = 130) for mixing/loading liquid concentrates to support aerial applications with double layer body protection, gloves, and a quarter-face dust/mist filtering respirator. However, the baseline inhalation risks (MOE = 210) for this scenario indicates that inhalation exposures are not significantly contributing to the total risk, and that dermal exposure is the route of concern. Therefore, HED recommends that engineering controls be used to mitigate dermal exposures in this scenario.

Engineering Control Mitigation: The noncancer handler risk assessment indicates that the following scenarios are not of concern with engineering control mitigation:

- Mixing/Loading Liquid Concentrates to Support Aerial Applications;
- Mixing/Loading Dry Flowables to Support Aerial Applications;
- Mixing/Loading Wettable Powders to Support Aerial Applications;
- Mixing/Loading Wettable Powders to Support Groundboom Applications; and
- Applying Sprays via Aerial Equipment.

Table 5. Summary of Dermal, Inhalation, and Total Handler NonCancer Risks for Fluometuron									
Exposure Scenario	Application Rate (lb ai/acre) [a]	Area Treated Daily (acres) [b]	Combined MOEs						
			Baseline	PPE-G-NR	PPE-G, DL-NR	PPE-G-80% R	PPE-G, DL-80% R	Eng Controls	Eng Controls Dermal + Baseline Inhalation
Mixer/Loader									
Mixing/Loading Emulsifiable Concentrates (Liquids) for Aerial Applications (1a)	2	1200	0.86	71	86	98	130	260	**120**
Mixing/Loading Emulsifiable Concentrates (Liquids) for Groundboom Applications (1b)	2	200	5.2	**430**	520	590	770	1600	720
Mixing/Loading Dry Flowables for Aerial Applications (2a)	2	1200	34	34	46	37	52	**210**	**NA**
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	2	200	**200**	200	270	220	310	1200	NA
Mixing/Loading Wettable Powders for Aerial Applications (3a)	2	1200	0.61	4.2	4.5	9.8	12	**210**	**NA**
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	2	200	3.6	25	27	59	69	**1200**	NA
Applicator									
Applying Liquid Sprays via Aerial Equipment (4)	2	1200	No Data	No Data	No Data	No Data	No Data	**440**	No Data
Applying Liquid Sprays via Groundboom Equipment (5)	2	200	**700**	700	820	970	1200	2800	1200
Flagger									
Flagging for Liquid Sprays via Aerial Equipment (6)	2	350	**590**	No Data	630	No Data	800	1600	1000

– MOEs shown in bold indicate the lowest risk mitigation level that does not exceed HED's level of concern.

a Application rates are the maximum application rates determined from EPA registered labels for fluometuron.

b Amounts handled per day are HED estimates of acres, square feet, or cubic feet treated or gallons applied based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry sources, and HED estimates.

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

2.1.4 Cancer Fluometuron Handler Exposure and Risk Assessment

This section presents the occupational handler exposure and cancer risk assessment from fluometuron.

2.1.4.1 Cancer Fluometuron Handler Exposure and Risk Calculations

Cancer risks resulting from exposures to fluometuron were calculated using a linear low-dose extrapolation approach in which a *Lifetime Average Daily Dose* (LADD) is first calculated and then compared with a Q_1^* that has been calculated for fluometuron based on dose response data ($Q_1^* = 1.80 \times 10^{-2}$ (mg/kg/day)$^{-1}$). Absorbed average daily dose (ADD) levels were used as the basis for calculating the LADD values. Section 2.1.3.1 describes how the ADD values were first calculated for the non-cancer MOEs. These values also serve as the basis for the cancer risk estimates. Dermal and inhalation ADD values were first added together to obtain combined ADD values. LADD values were then calculated and compared to the Q_1^* to obtain cancer risk estimates.

Lifetime Average Daily Dose: To calculate the carcinogenic risk from absorbed average daily dose, the values must be amortized over the working lifetime of occupational handlers. Current use patterns indicate that application can occur typically two times during a crop cycle. HED considered two distinct handler populations (private growers versus commercial growers) for the cancer risk assessment. HED assumed that private growers would handle fluometuron approximately 6 days per year and that commercial growers would handle fluometuron approximately 18 days per year. Finally, a 35 year career and a 70 year lifespan were used to complete the calculations.

Since fluometuron labels permit a range of application rates between one and two pounds active ingredient per acre, HED assumed that the typical application rate for cancer assessments would be 1.5 pounds active ingredient per acre.

LADD values were calculated using the following equation:

$$LADD = ADD \times \frac{Exposure\ Frequency}{365\ Days\ per\ Year} \times \frac{Exposure\ Duration}{Lifetime}$$

Where:

Lifetime Average Daily Dose	=	The amount as absorbed dose received from exposure to a pesticide or degradate in a given scenario over a lifetime (mg/kg/day, also referred to as LADD);
Average Daily Dose	=	The amount as absorbed dose received from exposure to a pesticide or degradate in a given scenario on a daily basis (mg/kg/day, also referred to as ADD);
Exposure Frequency	=	The annual frequency of exposure to an individual (days/year);

Exposure Duration	=	The amount of a lifetime that an individual is exposed (35 years for Occupational); and
Lifetime	=	The average life expectancy of an individual (70 years).

Cancer Risks : Finally, cancer risk calculations were completed by comparing the LADD values to the Q_1^* for fluometuron (Q_1^* = 1.80 x 10^{-2} $(mg/kg/day)^{-1}$). Cancer risks were calculated using the following equation:

$$Cancer\ Risk = LADD \times Q1^*$$

Where:

Cancer Risk	=	Probability of excess cancer cases over a lifetime (unitless);
Lifetime Average Daily Dose	=	The amount as absorbed dose received from exposure to a pesticide or degradate in a given scenario over a lifetime (mg//kg/day); and
Q_1^*	=	Quantitative dose response factor used for linear, low-dose response cancer risk calculations $(mg/kg/day)^{-1}$.

HED has defined a range of acceptable cancer risks based on a policy memorandum issued in 1996 by then Office of Pesticide Programs director, Mr. Dan Barolo. This memo refers to a predetermined quantified "level of concern" for occupational carcinogenic risk. In summary, this policy memo indicates occupational carcinogenic risks that are 1 x 10^{-6} or lower require no risk management action. For those chemicals subject to reregistration, HED is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks. If carcinogenic risks are in this range for occupational handlers, increased levels of personal protection would be warranted as is commonly applied with non-cancer risk estimates (e.g., additional PPE or engineering controls). Carcinogenic risks that remain above 1.0 x 10^{-4} at the highest level of mitigation appropriate for that scenario remain a concern.

2.1.4.2 Fluometuron Cancer Risk Summary

Fluometuron cancer risks for handlers are summarized below in Tables 7-9. All the cancer risk calculations for occupational handlers exposed to fluometuron completed in this assessment are included in the appendices.

Baseline Mitigation: The cancer handler risk assessment indicates that these scenarios are less than **1 x 10^{-4}** with baseline mitigation for both part-time and commercial growers:

- Mixing/Loading Dry Flowables to Support Aerial Applications;
- Mixing/Loading Dry Flowables to Support Groundboom Applications;
- Applying Sprays via Groundboom Equipment; and
- Flagging to Support Aerial Spray Applications.

No scenarios are less than **1 x 10^{-6}** with baseline mitigation.

Personal Protective Equipment Mitigation: The cancer handler risk assessment indicates that the following scenarios are less than **1 x 10^{-4}** with any personal protective equipment mitigation for both private and commercial growers:

- Mixing/Loading Liquid Concentrates to Support Aerial Applications;
- Mixing/Loading Liquid Concentrates to Support Groundboom Applications; and
- Mixing/Loading Wettable Powders to Support Groundboom Applications.

For private growers, the cancer risks for mixing/loading wettable powders to support aerial applications are less than **1 x 10^{-4}** either with baseline attire plus gloves plus a respirator or with double-layer attire plus gloves plus a respirator.

For private growers, the cancer risks for applying sprays with groundboom equipment are less than **1 x 10^{-6}** either with baseline attire plus gloves plus a respirator or with double-layer attire plus gloves plus a respirator.

Engineering Control Mitigation: The cancer handler risk assessment indicates that the following scenarios are less than **1 x 10^{-4}** with engineering control mitigation:

- Mixing/Loading Wettable Powders to Support Aerial Applications; and
- Applying Sprays via Aerial Equipment for *commercial growers*.

The cancer handler risk assessment indicates that the following scenarios are less than **1 x 10^{-6}** with engineering control mitigation:

- Mixing/Loading Liquid Concentrates to Support Groundboom Applications (*private growers only)*;
- Mixing/Loading Dry Flowables to Support Groundboom Applications (*private growers only)*;
- Mixing/Loading Wettable Powders to Support Groundboom Applications (*private growers only)*;
- Applying Sprays with Groundboom Equipment *(private growers)*; and
- Flagging to Support Aerial Spray Applications (*private growers only)*.

Table 6. Summary of Fluometuron Private Grower Handler Cancer Risks									
Exposure Scenario	Typical Application Rate (lb ai/acre) [a]	Area Treated Daily (acres) [b]	Private Grower Treatments/Yr	Private Grower Cancer Risks [c]					
				Baseline	PPE-G-NR	PPE-G, DL-NR	PPE-G-80% R	PPE-G, DL-80% R	Eng Controls
Mixer/Loader									
Mixing/Loading Emulsifiable Concentrates for Aerial Applications (1a)	1.5	1200	6	1.1E-03	**1.3E-05**	1.1e-05	9.7E-06	7.4E-06	3.6E-06
Mixing/Loading Emulsifiable Concentrates for Groundboom Applications (1b)	1.5	200	6	1.8E-04	**2.2E-06**	1.8e-06	1.6E-06	1.2E-06	6.0E-07
Mixing/Loading Dry Flowables for Aerial Applications (2a)	1.5	1200	6	**2.8E-05**	2.8E-05	2.1e-05	2.6E-05	1.8E-05	4.6E-06
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	1.5	200	6	**4.7E-06**	4.7E-06	3.5e-06	4.3E-06	3.1E-06	7.7E-07
Mixing/Loading Wettable Powders for Aerial Applications (3a)	1.5	1200	6	1.6E-03	2.3E-04	2.1e-04	**9.7E-05**	8.2E-05	4.6E-06
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	1.5	200	6	2.6E-04	**3.8E-05**	3.6e-05	1.6E-05	1.4E-05	7.7E-07
Applicator									
Applying Liquid Sprays via Aerial Equipment (4)	1.5	1200	6	No Data	No Data	No Data	No Data	No Data	**2.2E-06**
Applying Liquid Sprays via Groundboom Equipment (5)	1.5	200	6	**1.4E-06**	1.4E-06	1.2e-06	9.8E-07	7.9E-07	3.4E-07
Flagger									
Flagging for Liquid Sprays via Aerial Equipment (6)	1.5	350	6	**1.6E-06**	No Data	1.5e-06	No Data	1.2E-06	6.0E-07

– Handler exposure was considered to be 6 days per year for 35 years over a 70 year lifetime.

a Application rates are the average of the rates from the fluometuron labels (ranged from 1.0 to 2.0 lb ai/acre).

b Amount handled per day values are HED estimates of acreage treated or gallons applied based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry input, and HED estimates.

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

Table 7. Summary of Fluometuron Commercial Grower Handler Cancer Risks									
Exposure Scenario	Typical Application Rate (lb ai/acre) [a]	Area Treated Daily (acres) [b]	Commercial Grower Treatments/Yr	Commercial Grower Cancer Risks [c]					
				Baseline	PPE-G-NR	PPE-G, DL-NR	PPE-G-80% R	PPE-G, DL-80% R	Eng Controls
Mixer/Loader									
Mixing/Loading Emulsifiable Concentrates for Aerial Applications (1a)	1.5	1200	18	3.3E-03	**4.0E-05**	**3.3e-05**	**2.9E-05**	**2.2E-05**	1.1E-05
Mixing/Loading Emulsifiable Concentrates for Groundboom Applications (1b)	1.5	200	18	5.5E-04	**6.7E-06**	**5.5e-06**	**4.8E-06**	**3.7E-06**	1.8E-06
Mixing/Loading Dry Flowables for Aerial Applications (2a)	1.5	1200	18	**8.4E-05**	8.4E-05	6.2e-05	7.7E-05	5.5E-05	1.4E-05
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	1.5	200	18	**1.4E-05**	1.4E-05	1.0e-05	1.3E-05	9.2E-06	2.3E-06
Mixing/Loading Wettable Powders for Aerial Applications (3a)	1.5	1200	18	4.7E-03	6.8E-04	6.4e-04	2.9E-04	2.5E-04	**1.4E-05**
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	1.5	200	18	7.9E-04	**1.1E-04**	**1.1e-04**	**4.9E-05**	**4.1E-05**	2.3E-06
Applicator									
Applying Liquid Sprays via Aerial Equipment (4)	1.5	1200	18	No Data	No Data	No Data	No Data	No Data	**6.5E-06**
Applying Liquid Sprays via Groundboom Equipment (5)	1.5	200	18	**4.1E-06**	4.1E-06	3.5e-06	2.9E-06	2.4E-06	1.0E-06
Flagger									
Flagging for Liquid Sprays via Aerial Equipment (6)	1.5	350	18	**4.8E-06**	No Data	4.5e-06	No Data	3.6E-06	1.8E-06

– Handler exposure was considered to be 18 days per year for 35 years over a 70 year lifetime.

a Application rates are the average of the rates from the fluometuron labels (ranged from 1.0 to 2.0 lb ai/acre).

b Amount handled per day values are HED estimates of acreage treated or gallons applied based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry input, and HED estimates.

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

2.1.5 Summary of Risk Concerns and Data Gaps for Occupational Handlers

2.1.5.1 Summary of Risk Concerns

There are no occupational handler scenarios for fluometuron that have risks associated with them that are above HED's level of concern for non-cancer and cancer risk assessments at some level of risk mitigation.

2.1.5.2 Summary of Data Gaps

Surrogate unit exposures from the Pesticide Handler Exposure Database (PHED ver. 1.1) were used to assess risks to handlers. There are no handler data gaps of concern for fluometuron.

2.1.6 Recommendations For Refining Occupational Handler Risk Assessment

In order to refine this occupational risk assessment, data on actual use patterns including rates, timing, and areas treated would better characterize fluometuron risks.

2.2 Occupational Postapplication Exposures and Risks

HED uses the term "postapplication" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide (also referred to as reentry exposure). HED believes that there are distinct job functions or tasks related to the kinds of activities that occur in previously treated areas. Job requirements (e.g., the kinds of jobs to cultivate a crop), the nature of the crop or target that was treated, and the how chemical residues degrade in the environment can cause exposure levels to differ over time. Each factor has been considered in this assessment.

2.2.1 Occupational Postapplication Exposure Scenarios

Fluometuron is used on agricultural crops (i.e., cotton). As a result, individuals can potentially be exposed by working in areas that have been previously treated. HED is concerned about these kinds of exposures one could receive in the workplace. Fluometuron is applied to cotton with aerial (spray) and groundboom equipment.

HED uses a concept known as the *transfer coefficient* to numerically represent the post-application exposures one would receive (i.e., generally presented as cm^2/hour). The transfer coefficient concept has been established in the scientific literature and through various exposure monitoring guidelines published by the U.S. EPA and international organizations such as Health Canada and OECD (Organization For Economic Cooperation and Development). The establishment of transfer coefficients also forms the basis of the work of the Agricultural Reentry

Task Force. The transfer coefficient is essentially a measure of the contact with a treated surface one would have while doing a task or activity. These values are defined by calculating the ratio of an exposure for a given task or activity to the amount of pesticide on leaves (or other surfaces) that can rub off on the skin resulting in an exposure. For postapplication exposures, the amounts that can rub off on the skin are measured using techniques that specifically determine the amount of residues on treated leaves or other surfaces (referred to as transferable residues) rather than the total residues contained both on the surface and absorbed into treated leaves. HED has developed a series of standard *transfer coefficients* that are unique for variety of job tasks or activities that are used in lieu of chemical- and scenario-specific data.

As with the handler risk assessment process, the first step in the postapplication risk assessment process is to identify the kinds of individuals that are likely to be exposed to fluometuron after application. In order to do this in a consistent manner, has developed a series of general descriptions for tasks that are associated with post-application exposures. also considers whether or not individuals are exposed to pesticides as part of their employment (referred to as occupational risk assessments). Common examples include: agricultural harvesters, scouting activities in agriculture, and crop maintenance tasks (e.g., irrigating, hoeing and weeding).

The next step in the risk assessment process is to define how and when chemicals are applied in order to determine the level of transferable residues to which individuals could be exposed over time. Wherever available, use and usage data are included in this process to define values such as application rates and application frequency. HED always completes risk assessments using maximum application rates for each scenario because what is possible under the label (the legal means of controlling pesticide use) must be evaluated, for complete stewardship, in order to ensure HED has no concern for the specific use. In order to define the amount of transferable residues to which individuals can be exposed, HED relies on available chemical- and crop-specific studies – as described in HED guidelines for exposure data collection (*Series 875, Occupational and Residential Exposure Test Guidelines: Group B - Postapplication Exposure Monitoring Test Guidelines*).

There are no fluometuron-specific dislodgeable foliar residue studies. In this situation, HED uses a standard modeling approach that can predict transferable residues over time (best described in HED's *SOPs For Residential Exposure Assessment*). Dermal exposures during postapplication activities were estimated using dermal transfer coefficients from the Science Advisory Council for Exposure Policy Number 3.1: Agricultural Transfer Coefficients, August 2000 and using dislodgeable foliar residue values estimated using the standard default assumption that 20 percent of the application rate is initially deposited on foliar surfaces and the residues dissipate at a rate of 10 percent per day.

Next, assessors must understand how exposures to fluometuron occur (i.e., frequency and duration) and how the patterns of these occurrences can alter the effects of the chemical in the population after being exposed (referred to as dose response). This is supported by the fact that several areas within a work environment may be treated at different times. For example, parts of

agricultural fields in a localized area might be treated over several weeks because of an infestation with a concurrent need for hand labor activities. Therefore, individuals working in those fields might be exposed from contact with treated foliage over an extended period of time that could be categorized as an intermediate-term exposure as they work on different sections of fields. The durations of exposure that were considered for noncancer toxicity were short-term (≤30 days) and intermediate-term (>30 days up to several months). However, since the short- and intermediate-term dermal NOAELs are numerically identical, only one assessment was needed.

Cancer risks were also calculated using a linear, low-dose extrapolation model (i.e., Q_1*). Inhalation exposures are thought to be negligible in outdoor postapplication scenarios because of the low vapor pressure and due to the infinite dilution expected outdoors. As such, inhalation postapplication exposures are not considered in this assessment.

The use of personal protective equipment or other types of equipment to reduce exposures for postapplication workers is not considered a viable alternative for the regulatory process. This is described in some detail in HED's Worker Protection Standard (40CFR170). As such, an administrative approach is used by to reduce the risks and is referred to as the *Restricted Entry Interval* or REI. The REI is time period follow a pesticide application during which entry into the treated area is restricted. Postapplication risk levels are generally calculated in the risk assessment process on a chemical-, crop-, and activity-specific basis. To establish REIs, HED considers postapplication risks on varying days after application.

HED has used the basic approach described above since the mid 1980s for calculating postapplication risks to pesticides. From that time to the present, several revisions and modifications were made to Agency policies as data which warranted such changes became available. In 1995, issued a Data Call-In for postapplication agricultural data that prompted the formation of the Agricultural Reentry Task Force (ARTF). This task force has generated a number of exposure studies and associated documents that are currently under review by . The work of the ARTF is not yet complete, however, sufficient data were available from the group that warranted a significant interim change in Agency policy related to the data which were already available as the efforts of the ARTF paralleled push for tolerance reassessment stipulated by the timelines established by FQPA. As a result of the need for the revision and using the latest data, developed a revised policy on August 7, 2000 entitled *Policy 003.1 Science Advisory Council For Exposure Policy Regarding Agricultural Transfer Coefficients*. The revision to this policy entailed linking worker activities to more specific crop/agronomic groupings and making better use of the available occupational postapplication exposure data. In the new policy, transfer coefficients were selected to represent the activities associated with 18 distinct crop/agronomic groupings based on different types of vegetables, trees, berries, vine/trellis crops, turf, field crops, and bunch/bundle crops (e.g., tobacco). In this new scheme, which HED uses to develop scenarios for occupational postapplication exposures, fluometuron uses were identified in the following crop groupings from the policy:

- Field/row crops, low/medium (e.g., cotton)

Within each agronomic group, a variety of cultural practices are required to maintain the included crops. These practices are varied and typically involve light to heavy contact with immature plants as well as with more mature plants. The Agency selected transfer coefficient values in its revision of Policy 003 to represent this range of exposures within each agronomic group. In the policy, transfer coefficients were placed in 1 of 5 generic categories based on the exposures relative to that group. These 5 categories include: very low exposure, low exposure, medium exposure, high exposure, and very high exposure. Numerical values were not necessarily assigned to each category for each crop group. Selections depended upon the actual agronomic practices that were identified by for each group (i.e., some groups had 2 assigned transfer coefficients while others had 5). For fluometuron postapplication assessment, transfer coefficients for the **Low Exposure** and **Medium Exposure** categories were included. The low exposure category represents postapplication exposures while performing hand weeding, scouting, or irrigating *while the crop is very small* – as in an early season application. The medium exposure category represents postapplication exposures while performing those same tasks, but assumes that *the crop is well developed* – as in a later season application. HED did not assess postapplication risks using the high exposure category for cotton, since it represents hand harvesting tasks and fluometuron is applied at least 60 days before harvest.

2.2.2 Data/Assumptions for Postapplication Exposure Scenarios

A series of assumptions and exposure factors served as the basis for completing the occupational postapplication worker risk assessments. Each assumption and factor is detailed below on an individual basis. In addition to these values, transfer coefficient values were used to calculate risk estimates. Several chemical-specific residue dissipation studies were also submitted which were used in the development of the risk values. The transfer coefficients were taken from HED's revised policy entitled *Policy 003.1 Science Advisory Council For Exposure Policy Regarding Agricultural Transfer Coefficients* (August 7, 2000). The assumptions and factors used in the risk calculations are presented below:

- There are many factors that are common to handler and postapplication risk assessments such as body weights, duration, and ranges of application rates. Please refer to the assumptions and factors in Section 2.1.1.1 for further information concerning these values which are common to both handler and postapplication risk assessments. In the noncancer postapplication risk assessment, the maximum application rate (i.e., 2.0 pounds active ingredient per acre) was considered. For the cancer postapplication risk assessment, the typical application rate (i.e., 1.5 pounds active ingredient per acre) was used.

- **Levels of Concern:** HED has established the following levels of concern (LOC) for occupational postapplication risks:
  - margin of exposure of less than 100 for occupational non-cancer risks; and
  - cancer risk greater than 1×10^{-4} (and reasonable mitigation to reach 1×10^{-6}) for occupational cancer assessments.

- **Days of Exposure:** Since the postapplication tasks of concern for fluometuron uses in cotton include hand weeding, scouting, and irrigating (and not harvesting), HED estimated that workers typically would spend 6 days per season performing tasks in fluometuron treated areas.

2.2.3 Occupational Postapplication Exposure and Noncancer Risk Estimates

The occupational postapplication exposure and non-cancer risk calculations are presented in this section. Postapplication risks diminish over time because fluometuron residues eventually dissipate in the environment. As a result, risk values were calculated over time based on changing residue levels.

Postapplication exposures to agricultural workers are summarized in Table 10 below. The following assumptions are used in the postapplication exposure assessment:

- Application Rate: maximum label rate for each crop
- Exposure Duration: 8 hours
- Body Weight: 60 kg for short-term exposures
- Dermal absorption: 10%
- Fraction of active ingredient retained on foliage: 20 percent
- Fraction of active ingredient dissipating per day: 10 percent
- Transfer coefficients from Policy 3.1

Equations/Calculations

The following equations were used to calculate risks for workers performing postapplication activities:

$$DFR_t\ (\mu g/cm^2) = Application\ Rate\ (lb\ ai/acre) \times F \times (1-D)^t \times 4.54E8\ \mu g/lb \times 2.47E\text{-}8\ acre/cm^2$$

Where:

DFR_t	=	dislodgeable foliage residue on day "t" (µg/cm^2)
Rate	=	application rate (lb ai/acre)
F	=	fraction of ai retained on foliage (unitless)
D	=	fraction of residue that dissipates daily (unitless)

$$Daily\ Dermal\ Dose_t = \frac{DFR_t\ (\mu g/cm^2) \times 1E\text{-}3\ mg/\mu g \times Tc\ (cm^2/hr) \times DA \times ET\ (hrs/day)}{BW\ (kg)}$$

Where:

t	=	number of days after application day (days)
DFR_t	=	dislodgeable foliage residue on day "t" (µg/cm^2)
Tc	=	transfer coefficient (cm^2/hr)
DA	=	dermal absorption factor (unitless)
ET	=	exposure time (hr/day)
BW	=	body weight (kg)

Noncancer Risk Summary: The MOEs for low- and medium-exposure tasks exceed the target MOE of 100 on the day of application (see table 10).

2.2.3 Occupational Postapplication Exposure and Risk Estimates for Cancer

The occupational exposure and cancer risk calculations for postapplication workers are presented in this section. [**Note:** Inhalation exposures are thought to be negligible in outdoor postapplication scenarios because of the low vapor pressure and due to the infinite dilution expected outdoors. As such, inhalation postapplication exposures are not considered in this assessment.]

LADD and Cancer Risk Calculations: The use of dissipation data and the manner in which daily postapplication dermal exposure values were calculated are inherently different than with handler exposures. However, once daily exposure values are calculated, the calculation of LADD (Lifetime Average Daily Dose) and the resulting cancer risks use the same algorithms that are described above for the handler exposures (see Section 2.1.4).

To reiterate, occupational carcinogenic risks that are 1×10^{-6} or lower require no risk management action based on the 1996 Barolo memo. For those chemicals subject to reregistration, EPA is to carefully examine uses with estimated risks in the 10^{-6} to 10^{-4} range to seek ways of cost-effectively reducing risks.

Cancer Risk Summary

Cancer risks were calculated as described above and summarized in Table 10 below. Postapplication workers were assumed to be exposed 6 days per year. Different transfer coefficients were used to represent early-season and later-season exposures. The default dissipation assumptions were used along with the transfer coefficients to calculate the LADDs. The postapplication cancer risks are less than 1×10^{-4} for both early and later season postapplication activities. Early-season cancer risks are less than 1×10^{-6} on day 0. Later-season cancer risks are 1×10^{-5} on day 0 and are less than 1×10^{-6} on day 12 following application.

Table 8: Summary of Fluometuron Postapplication Activities and Risks					
Crops	Transfer Coefficients (cm^2/hr)[a]	Activities[a]	Short-Term MOE at Day 0 (12 hours after application)[b,c,d]	Cancer Risk at Day 0	Cancer Risk at 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	6.6E-07	NA
	1500 (later season - mature crop)	Irrigation, Scouting, Hand Weeding	110	1.0E-05	9.02E-07

Footnotes:

a Crop-specific activities and transfer coefficients from Science Advisory Council for Exposure Policy Number 3.1, Agricultural Transfer Coefficients adopted May 7, 1998, and revised August 7, 2000.

b The DFR is based on default assumption that 20% of the application rate is available for transfer on day 0.

c Daily Dermal Dose = DFR ($\mu g/cm^2$) x conversion factor (1E-3 mg/µg) x Tc (cm^2/hr) x DA x ET (8 hrs/day) / BW (60 kg)

d Short-Term Dermal MOE = Short-term NOAEL (10 mg ai/kg/day) ÷ Daily Dermal Dose (mg ai/kg/day)

2.2.4 Off Target Non-Occupational Exposure

Spray drift is always a potential (postapplication) source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for fluometuron. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

2.2.5 Summary of Occupational Postapplication Risk Concerns and Data Gaps

Noncancer postapplication risks do not exceed HED's level of concern (i.e., risks are greater than the target MOE of 100) at day 0, approximately 12 hours following application.

Cancer postapplication risks were calculated with the assumption that postapplication workers typically would be exposed 6 days per year. The postapplication cancer risks for early season entry are less than 1×10^{-6} on day 0, approximately 12 hours following application. The

postapplication cancer risks for later season entry are less than 1 x 10^{-4} on day 0 and are less than 1 x 10^{-6} on day 12.

HED has used the latest information to complete this postapplication risk assessment for fluometuron. Several data gaps exist such as a lack of postapplication studies in different crop groupings (e.g., cole crops, tall field crops) and lack of exposure data on mechanized or partially mechanized cultural practices where there is a potential for exposure. Additionally, because of the number and breadth of fluometuron uses, there may be many exposure pathways where the transfer coefficient is not an appropriate model that have not been quantitatively addressed due to a lack of data.

2.2.6 Recommendations For Refining Occupational Postapplication Risk Assessment

To refine this occupational risk assessment, data on actual use patterns including rates, timing, and the kinds of tasks that are required to produce agricultural commodities and other products would better characterize fluometuron risks. Exposure studies for many cultural practices that lack data or that are not well represented in the revised transfer coefficient policy should also be considered based on the data gaps identified above. Risk managers should consider that the risks associated with the current label REI generally meet HED's risk targets.

Appendix A: Handler Risk Calculations and Data

Appendix A/Table A1: Sources of Exposure Data Used In The Occupational Permethrin Handler Exposure And Risk Calculations

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day) [a]	Comments[b, c]
Mixer/Loader Descriptors			
Mixing/Loading Liquid Formulations (1a through 1b)	PHED V1.1	**Aerial:** 1,200 acres (high acreage) **Groundboom:** 200 acres (high acreage)	**Baseline:** Dermal, hand, and inhalation = acceptable grades. Hands = 53 replicates; Dermal = 72 to 122 replicates; and Inhalation = 85 replicates. High confidence in hand, dermal, and inhalation data. No protection factor was needed to define the unit exposures. **PPE:** The same dermal data are used as for baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hands = acceptable grades. Hands = 59 replicates. High confidence in hand data. A respirator protection factor of 5 is applied to estimate the use of a quarter-face respirator (dust/mist filtering only). **Engineering Controls:** Hands, dermal, and inhalation = acceptable grades. Hands = 31 replicates; Dermal = 16 to 22 replicates; and Inhalation = 27 replicates. High confidence in hand, dermal, and inhalation data. **Gloves were used coupled with engineering controls since empirical data without gloves were not available and back calculation of gloves to a no glove scenario is believed to give erroneously high estimates.**
Mixing/Loading Wettable Powder Formulations (2a through 2b)	PHED V1.1	**Aerial:** 1,200 acres (high acreage) **Groundboom:** 200 acres (high acreage)	**Baseline:** Dermal, hand, and inhalation = ABC grades. Hands = 7 replicates; Dermal = 22 to 45 replicates, and Inhalation = 44 replicates. Low confidence in the dermal/hands data due to the low number of hand replicates. Medium confidence in inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** Hands = ABC grades. Hands = 24 replicates. The same dermal data are used as for baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hands = ABC grades. Hands = 24 replicates. Medium confidence in hand data A respirator protection factor of 5 is applied to estimate the use of a quarter-face respirator (dust/mist filtering only). **Engineering Controls**: Dermal and hands = AB grades. Inhalation = all grades. Dermal = 6 to 15 replicates; Hands = 9 replicates; and Inhalation = 15 replicates. Low confidence in hand, dermal, and inhalation data. **Gloves were used coupled with engineering controls since empirical data without gloves were not available and back calculation of gloves to a no glove scenario is believed to give erroneously high estimates.**
Mixing/Loading Wettable Dry Flowable Formulations (3a through 3b)	PHED V1.1	**Aerial:** 1,200 acres (high acreage) **Groundboom:** 200 acres (high acreage)	**Baseline:** Dermal = AB grades; Hand = AB grades; and Inhalation = AB grades. Dermal = 16 to 26 replicates; Hands = 7 replicates; and Inhalation = 23 replicates. Low confidence in the hands data due to low replicate number. High confidence in inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** The same dermal data are used as for baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hand = AB grades. Hands = 21 replicates. High confidence in the dermal/hands data. A respirator protection factor of 5 is applied to estimate the use of a quarter-face respirator (dust/mist filtering only). **Engineering Controls**: The same engineering control data from the wettable powder scenario - water soluble bags - are used for this scenario.

Appendix A/Table A1: Sources of Exposure Data Used In The Occupational Permethrin Handler Exposure And Risk Calculations

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day) [a]	Comments[b, c]
Applying Descriptors			
Applying Sprays via Fixed-wing Aircraft (4)	PHED V1.1	1,200 acres (high acreage)	**Engineering Controls:** Dermal and hands = AB grade and Inhalation = ABC grade. Dermal = 20 to 28 replicates; Hands = 34 replicates; and Inhalation = 23 replicates. High confidence in dermal and hand data. Medium confidence in inhalation data. No protection factor was needed to define the unit exposure value. **EPA has no data for this scenario, other than enclosed cockpits – the engineering control.**
Applying Sprays via Groundboom Sprayer (5)	PHED V1.1	200 acres (high acreage)	**Baseline**: Dermal, hand, and inhalation = AB grades. Dermal = 23 to 42 replicates; Hands =29 replicates; and Inhalation = 22 replicates. High confidence in hand, dermal, and inhalation data. No protection factors were needed to define the unit exposure values. **PPE:** The same dermal data are used as for baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hands = ABC grades. Hands = 21 replicates. Medium confidence in hand data. A respirator protection factor of 5 is applied to estimate the use of a quarter-face respirator (dust/mist filtering only). **Engineering Controls**: Dermal and Hands = ABC grade. Inhalation = AB grades. Dermal = 20 to 31 replicates; Hands = 16 replicates; and inhalation = 16 replicates. Medium confidence in the hand and dermal data. High confidence in inhalation data. No protection factor needed to define the unit exposure value. Protective gloves not used.
Flagging Descriptors			
Flagging for Aerial Spray Applications (6)	PHED V1.1	350 acres	**Baseline:** Dermal, hands, and inhalation = AB grades. Dermal = 18 to 28 replicates; Hands = 30 replicates; and Inhalation = 28 replicates. High confidence in dermal, hand, and inhalation data. No protection factor was required to calculate unit exposures. **PPE**: The same dermal data are used as for baseline coupled with a 50% protection factor to account for an additional layer of clothing. Hand = AB grades. Hands = 6 replicates. Low confidence in hand data due to the small number of replicates. A respirator protection factor of 5 is applied to estimate the use of a quarter-face respirator (dust/mist filtering only). **Engineering Controls**: The same data are used as for baseline coupled with a 98% protection factor to account for the use of an engineering control (e.g., sitting in a vehicle).

a All Standard Assumptions are based on an 8-hour work day as estimated by the Agency.

b All handler exposure assessments in this document are based on the "Best Available" data as defined by the HED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows:
High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = grades A, B, C, D and E or any combination of grades with less than 15 replicates.

c **PHED grading criteria do not reflect overall quality of the reliability of the assessment. Sources of the exposure factors should also be considered in the risk**

Appendix A/Table A2. Summary of PHED Unit Exposure Values Used in the Occupational Handler Assesment							
Exposure Scenario	PHED Unit Exposure Values						
	Baseline Dermal (mg/lb ai)	Baseline Inhalation (µg/lb ai)	SL + G (mg/lb ai)	DL +G (mg/lb ai)	80% Respirator (µg/lb ai)	Engineering Controls Dermal (mg/lb ai)	Engineering Controls Inhalation (µg/lb ai)
Mixer/Loader							
Mixing/Loading Emulsifiable Concentrates (Liquids) for Aerial Applications (1a)	2.9	1.2	0.023	0.017	0.24	0.0086	0.083
Mixing/Loading Emulsifiable Concentrates (Liquids) for Groundboom Applications (1b)	2.9	1.2	0.023	0.017	0.24	0.0086	0.083
Mixing/Loading Dry Flowables for Aerial Applications (2a)	0.066	0.77	0.066	0.047	0.154	0.0098	0.24
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	0.066	0.77	0.066	0.047	0.154	0.0098	0.24
Mixing/Loading Wettable Powders for Aerial Applications (3a)	3.7	43	0.17	0.13	8.6	0.0098	0.24
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	3.7	43	0.17	0.13	8.6	0.0098	0.24
Applicator							
Applying Liquid Sprays via Aerial Equipment (4)	No Data	No Data	No Data	No Data	No Data	0.005	0.068
Applying Liquid Sprays via Groundboom Equipment (5)	0.014	0.74	0.014	0.011	0.148	0.005	0.043
Flagger							
Flagging for Liquid Sprays via Aerial Equipment (6)	0.011	0.35	No Data	0.01	0.07	0.005	0.043

Appendix A/Table A3. Dermal, Inhalation, and Total Handler Noncancer Risks for Fluometuron

Exposure Scenario	Max App Rate (lb ai/A) [a]	Area Treated Daily (acres/day) [b]	Baseline [c]					Personal Protective Equipment [c]										Engineering Controls [c]					
			Dermal Dose	Dermal MOE	Inh Dose	Inh MOE	Combined MOE	Dermal (G) Dose	Dermal (G) MOE	Dermal (G, DL) Dose	Dermal (G, DL) MOE	Inh (80% R) Dose	Inh (80% R) MOE	Combined (G-80%R) MOE	Combined (G,DL-80% R) MOE	Combined (G-Base) MOE	Combined (G,DL-Base) MOE	Dermal Dose	Dermal MOE	Inh Dose	Inh MOE	Combined MOE	Combined (Eng Con-Base) MOE
Mixer/Loader																							
Mixing/Loading Emulsifiable Concentrates (Liquids) for Aerial Applications (1a)	2	1200	12	0.86	0.048	210	0.86	0.092	110	0.068	150	0.0096	1000	98	130	71	86	0.034	290	0.0033	3000	260	120
Mixing/Loading Emulsifiable Concentrates (Liquids) for Groundboom Applications (1b)	2	200	1.9	5.2	0.008	1300	5.2	0.015	650	0.011	880	0.0016	6300	590	770	430	520	0.0057	1700	0.00055	18000	1600	720
Mixing/Loading Dry Flowables for Aerial Applications (2a)	2	1200	0.26	38	0.031	320	34	0.26	38	0.19	53	0.0062	1600	37	52	34	46	0.039	260	0.0096	1000	210	140
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	2	200	0.044	230	0.0051	1900	200	0.044	230	0.031	320	0.001	9700	220	310	200	270	0.0065	1500	0.0016	6300	1200	850
Mixing/Loading Wettable Powders for Aerial Applications (3a)	2	1200	15	0.68	1.7	5.8	0.61	0.68	15	0.52	19	0.34	29	9.8	12	4.2	4.5	0.039	260	0.0096	1000	210	5.7
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	2	200	2.5	4.1	0.29	35	3.6	0.11	88	0.087	120	0.057	170	59	69	25	27	0.0065	1500	0.0016	6300	1200	34
Applicator																							
Applying Liquid Sprays via Aerial Equipment (4)	2	1200	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.02	500	0.0027	3700	440	ND
Applying Liquid Sprays via Groundboom Equipment (5)	2	200	0.0093	1100	0.0049	2000	700	0.0093	1100	0.0073	1400	0.00099	10000	970	1200	700	820	0.0033	3000	0.00029	35000	2800	1200
Flagger																							
Flagging for Liquid Sprays via Aerial Equipment (6)	2	350	0.013	780	0.0041	2400	590	ND	ND	0.012	860	0.00082	12000	ND	800	ND	630	0.0058	1700	0.0005	20000	1600	1000

– MOEs shown in bold indicate the lowest risk mitigation level that does not exceed HED's level of concern.

a Application rates are the maximum application rates determined from EPA registered labels for fluometuron.

b Amounts handled per day are HED estimates of acres, square feet, or cubic feet treated or gallons applied based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry sources, and HED estimates.

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

Appendix A/Table A4. Summary of Fluometuron Private Grower Handler Cancer Risks

Exposure Scenario	Typical Application Rate (lb ai/A)	Area Treated Daily (acres/day)	Treatments/ Yr	Total Baseline LADD (mg/kg/day)	Baseline Cancer Risk	PPE-G-NR LADD (mg/kg/day)	PPE-G-NR Cancer Risk	PPE-G, DL-NR LADD (mg/kg/day)	PPE-G, DL-NR Cancer Risk	PPE-G-80% R LADD (mg/kg/day)	PPE-G-80% R Cancer Risk	PPE-G, DL - 80% R LADD (mg/kg/day)	PPE-G, DL - 80% R Cancer Risk	Eng Controls Total LADD (mg/kg/day)	Eng Control Cancer Risk
Mixer/Loader															
Mixing/Loading Emulsifiable Concentrates (Liquids) for Aerial Applications (1a)	1.5	1200	6	6.2E-02	1.1E-03	0.00074	1.3E-05	0.00061	1.10E-05	0.00054	9.7E-06	0.00041	7.4E-06	2.0E-04	3.6E-06
Mixing/Loading Emulsifiable Concentrates (Liquids) for Groundboom Applications (1b)	1.5	200	6	1.0E-02	1.8E-04	0.00012	2.2E-06	0.0001	1.84E-06	0.000089	1.6E-06	0.000068	1.2E-06	3.3E-05	6.0E-07
Mixing/Loading Dry Flowables for Aerial Applications (2a)	1.5	1200	6	1.6E-03	2.8E-05	0.0016	2.8E-05	0.0012	2.08E-05	0.0014	2.6E-05	0.001	1.8E-05	2.6E-04	4.6E-06
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	1.5	200	6	2.6E-04	4.7E-06	0.00026	4.7E-06	0.00019	3.47E-06	0.00024	4.3E-06	0.00017	3.1E-06	4.3E-05	7.7E-07
Mixing/Loading Wettable Powders for Aerial Applications (3a)	1.5	1200	6	8.7E-02	1.6E-03	0.013	2.3E-04	0.012	2.13E-04	0.0054	9.7E-05	0.0046	8.2E-05	2.6E-04	4.6E-06
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	1.5	200	6	1.5E-02	2.6E-04	0.0021	3.8E-05	0.002	3.55E-05	0.0009	1.6E-05	0.00076	1.4E-05	4.3E-05	7.7E-07
Applicator															
Applying Liquid Sprays via Aerial Equipment (4)	1.5	1200	6	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	1.2E-04	2.2E-06
Applying Liquid Sprays via Groundboom Equipment (5)	1.5	200	6	7.5E-05	1.4E-06	0.000075	1.4E-06	0.000065	1.17E-06	0.000055	9.8E-07	0.000044	7.9E-07	1.9E-05	3.4E-07
Flagger															
Flagging for Liquid Sprays via Aerial Equipment (6)	1.5	350	6	8.9E-05	1.6E-06	No Data	No Data	0.000083	1.50E-06	No Data	No Data	0.000066	1.2E-06	3.3E-05	6.0E-07

– Handler exposure was considered to be 6 days per year for 35 years over a 70 year lifetime.

a Application rates are the average of the rates from the fluometuron labels (ranged from 1.0 to 2.0 lb ai/acre).

b Amount handled per day values are HED estimates of acreage treated or gallons applied based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry input, and HED estimates.

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

Appendix A/Table A5. Summary of Fluometuron Commercial Grower Handler Cancer Risks

Exposure Scenario	Typical Application Rate (lb ai/A)	Area Treated Daily (acres/day)	Treatments /Yr	Total Baseline LADD (mg/kg/day)	Baseline Cancer Risk	PPE-G-NR LADD (mg/kg/day)	PPE-G-NR Cancer Risk	PPE-G,DL-NR LADD (mg/kg/day)	PPE-G, DL-NR Cancer Risk	PPE-G-80% R LADD (mg/kg/day)	PPE-G - 80% R Cancer Risk	PPE-G,DL - 80%R LADD (mg/kg/day)	PPE-G,DL - 80% R Cancer Risk	Eng Control Total LADD (mg/kg/day)	Eng Control Cancer Risk
Mixer/Loader															
Mixing/Loading Emulsifiable Concentrates (Liquids) for Aerial Applications (1a)	1.5	1200	18	1.8E-01	3.3E-03	0.0022	4.0E-05	0.0018	3.31E-05	0.0016	2.9E-05	0.0012	2.2E-05	6.0E-04	1.1E-05
Mixing/Loading Emulsifiable Concentrates (Liquids) for Groundboom Applications (1b)	1.5	200	18	3.1E-02	5.5E-04	0.00037	6.7E-06	0.00031	5.52E-06	0.00027	4.8E-06	0.00021	3.7E-06	1.0E-04	1.8E-06
Mixing/Loading Dry Flowables for Aerial Applications (2a)	1.5	1200	18	4.7E-03	8.4E-05	0.0047	8.4E-05	0.0035	6.24E-05	0.0043	7.7E-05	0.0031	5.5E-05	7.7E-04	1.4E-05
Mixing/Loading Dry Flowables for Groundboom Applications (2b)	1.5	200	18	7.8E-04	1.4E-05	0.00078	1.4E-05	0.00058	1.04E-05	0.00071	1.3E-05	0.00051	9.2E-06	1.3E-04	2.3E-06
Mixing/Loading Wettable Powders for Aerial Applications (3a)	1.5	1200	18	2.6E-01	4.7E-03	0.038	6.8E-04	0.036	6.39E-04	0.016	2.9E-04	0.014	2.5E-04	7.7E-04	1.4E-05
Mixing/Loading Wettable Powders for Groundboom Applications (3b)	1.5	200	18	4.4E-02	7.9E-04	0.0063	1.1E-04	0.0059	1.07E-04	0.0027	4.9E-05	0.0023	4.1E-05	1.3E-04	2.3E-06
Applicator															
Applying Liquid Sprays via Aerial Equipment (4)	1.5	1200	18	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	3.6E-04	6.5E-06
Applying Liquid Sprays via Groundboom Equipment (5)	1.5	200	18	2.3E-04	4.1E-06	0.00023	4.1E-06	0.00019	3.50E-06	0.00016	2.9E-06	0.00013	2.4E-06	5.7E-05	1.0E-06
Flagger															
Flagging for Liquid Sprays via Aerial Equipment (6)	1.5	350	18	2.7E-04	4.8E-06	No Data	No Data	0.00025	4.49E-06	No Data	No Data	0.0002	3.6E-06	1.0E-04	1.8E-06

– Handler exposure was considered to be 18 days per year for 35 years over a 70 year lifetime.

a Application rates are the average of the rates from the fluometuron labels (ranged from 1.0 to 2.0 lb ai/acre).

b Amount handled per day values are HED estimates of acreage treated or gallons applied based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry input, and HED estimates.

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