



United States  
Environmental Protection  
Agency

Prevention, Pesticides  
and Toxic Substances  
(7508C)

EPA 738-R-05-010  
September 2005

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# Reregistration Eligibility Decision for Ethofumesate

Reregistration Eligibility Decision (RED) Document for  
Ethofumesate

List [B]

Case No. 2265

Approved by:

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## Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
IR	Index Reservoir
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model

Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

## **Abstract**

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of the herbicide ethofumesate. The Agency has determined that ethofumesate is eligible for reregistration. There are currently 18 listed tolerances on sugar beets, grass, and livestock commodities.

In the human health risk assessment, dietary (food and drinking water) and residential risks do not exceed the Agency's level of concern. Handler risks are being addressed by a label clarification which will prohibit aerial applications for the highest rate and the requirement of engineering controls for custom applications to fertilizer. There were no post-application concerns noted for agricultural uses; however for the turf uses, a 9 day re-entry interval is imposed for maintenance activity and a 16 day pre-harvest interval is imposed for sod harvesting. This post-application worker assessment may be refined with a submission of an acceptable dermal absorption study which may affect these re-entry restrictions.

The screening level ecological risk assessment indicates slight exceedances of levels of concern for freshwater fish and non-target terrestrial plants. Prohibition of high rate aerial applications will result in lower exposures for fish and plants.



## **I. Introduction**

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

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

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://epa.gov/pesticides/cumulative/>.]

The Agency has found no information indicating ethofumesate shares a common mechanism of toxicity with other substances. Ethofumesate does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has not assumed that ethofumesate shares a common mechanism of toxicity with other compounds. In the future, if additional information suggests ethofumesate shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

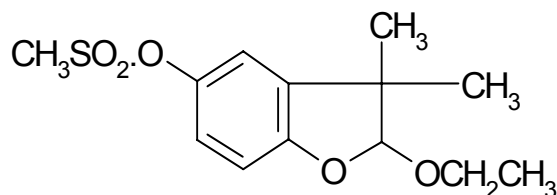
This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for ethofumesate. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The preliminary and revised risk assessments for ethofumesate are available in the Public Docket, under docket number OPP-2004-0346 and on the Agency's web page, <http://www.epa.gov/edockets>.

## II. Case Overview

### A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

- Common Name: Ethofumesate
- Chemical Name: 2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl-methanesulfonate
- CAS Registry Number: 26225-79-6
- OPP Chemical Code: 110601
- Trade and Other Names: Notron, Progress, and Prograss
- Basic Manufacturer: Bayer CropScience and United Phosphorus, Inc.
- Chemical Structure:



Ethofumesate (e.g., 2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate) is a selective herbicide registered for preplant, preemergence and postemergence use to control broadleaf and grass weeds. Products containing ethofumesate were first registered as NORTRON in 1977 and the name was officially changed to ethofumesate upon acceptance of the new common name by the American National Standards Institute (ANSI) in 1978. A Phase IV Data Call-In (DCI) was issued in

June, 1991. Subsequent DCIs were issued in January, 1995 and October, 1995. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data submitted to date.

*Use Sites:*

- Ethofumesate is registered for use on sugar beets, garden beets, table beets, carrots, and turf uses including grass seed, sod production, and ornamental turf. It is also registered for use in seed production for Swiss chard and spinach.

*Mode of Action:*

- The mode of action is related to inhibition of mitosis plus reduced photosynthesis and respiration.

*Formulations:*

- Formulation types registered include flowable concentrate, emulsifiable concentrate, and granular products.

*Methods and Timing of Application:*

- Methods of application include groundboom application, soil incorporation, broadcast spreader, and bellygrinder.
- Timing of application for food and feed crops (sugar beets, carrots, etc.) primarily includes soil-incorporated preplant and pre-emergence, and low rates used for post-emergence.
- Timing of application for turf uses includes both pre- and post-emergence use for cool season and warm season grasses (primarily to suppress Bermuda grass in St. Augustine grass)

*Use rates:*

- Use rates vary from approximately 1.0 lb active ingredient per acre (ai/A) to a maximum application rate of 3.75 lb ai/A. See Table 1.

Table 1: Maximum Use Rates for Ethofumesate

Crop Group	Crop or Treated Area	Maximum Application Rates
Turf	Sod Farms, golf courses, and ornamental uses on residential lawns	1.5 lb ai/acre
Turf (St. Augustine Grass) <sup>a</sup>	Sod Farms, golf courses, and ornamental uses on residential lawns	3 lb ai/acre
Food and Feed	Sugar Beets	3.75 lb ai/acre
	Carrots	2.0 lb ai/acre
	Beets	1.9 lb ai/acre

<sup>a</sup> This rate represents a narrow turf use pattern specific for a particular warm season grass (suppression of Bermuda grass weeds in St. Augustine grass).

*Annual poundage:*

- Based on available pesticide usage information from 1998 through 2002, approximately 200,000 pounds of active ingredient were used on sugar beets. An average of 35% of sugar beets were treated with ethofumesate.

*Tolerance information:*

- There are currently 18 listed tolerances on sugar beets, grass, and livestock commodities. These tolerances are expressed as ethofumesate and two metabolites (2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate) expressed as parent compound.

*Technical registrants:*

- Bayer CropSciences
- United Phosphorus, Inc.

**III. Summary of Ethofumesate Risk Assessment**

The following is a summary of EPA’s human health and ecological risk findings and conclusions for ethofumesate, as presented fully in the documents: “Ethofumesate: Human Health Risk Assessment for Phase 2; Response to Error Only Comments from the Registrant PC Code 110601. DP Barcode DP304056” written by N. McCarroll (8/10/2005), and “Environmental Fate and Effects Division Risk Assessment for the Reregistration Eligibility Document” written by A. Al-Mudallal and L. Brown (8/31/2005).

The purpose of this section is to summarize the key features and findings of the risk assessment in order to help the reader better understand the risk management decisions reached by the Agency. While the full risk assessments and related supporting documents are not included in this document they are available in the public docket (docket # OPP-2004-0346) and the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

## **A. Human Health Risk Assessment**

The Agency has conducted a human health risk assessment for ethofumesate for the purposes of making reregistration eligibility decisions. The Agency evaluated the toxicology, product and residue chemistry and occupational/residential exposure studies submitted for ethofumesate and determined that the data are adequate to support a reregistration decision. Details of the toxicity, residue chemistry and/or occupational/residential exposure data are available in the risk assessment and separate supporting disciplinary documents available in the electronic docket. A summary of the human health risk assessment findings and conclusions are provided in the subsections below.

### **1. Dietary Exposure and Risk from Food and Drinking Water**

#### **a. Acute Dietary (Food and Drinking Water)**

Acute dietary risk is calculated based on quantity of food eaten in one day and maximum residue values in the food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD) (the dose at which an individual could be exposed on any given day with no adverse health effects) does not exceed the Agency's level of concern. EPA evaluated the acute dietary risks using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.30) which incorporates food consumption data from USDA's Continuing Survey of Food Intake by Individuals (CSFII), 1994-1996, and 1998. A summary of the acute dietary exposure and risk for ethofumesate is presented in Table 2. The acute dietary estimates are below the Agency's level of concern at 4% of the aPAD at the 95<sup>th</sup> percentile for the female (age 13-49 years old) subgroup population. No appropriate endpoint was identified for the general population and infants.

An unrefined acute Tier 1 dietary exposure/risk analysis for ethofumesate was conducted using tolerance residue values, default processing factors, a processing factor from sugar beet processing studies, and the assumption of 100% crop treated for all commodities. For dietary risk from ethofumesate residues in drinking water, a point estimate residue value derived from PRZM/EXAMS modeling turf uses, was included in the dietary analyses. The dietary risk assessment used an uncertainty factor (UF) of 100 (10x for interspecies extrapolation, and 10x for intraspecies variability). The Special FQPA safety factor, required by the 1996 Food Quality Protection act (FQPA) as a special protection for infants and children, was reduced from the default 10x to 1x. The toxicity database for ethofumesate includes acceptable developmental and reproductive toxicity studies, and there is no evidence in the developmental toxicity study of susceptibility following *in utero* exposure. Also, the Agency has a low level of concern and no residual uncertainties regarding

exposure or concerns for the effects seen in the developmental toxicity studies after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment.

No acute dietary risk endpoint has been identified for the general population including infants and children. An acute dietary risk endpoint was identified for the population of females (13-49 yrs) based on a developmental toxicity study in rabbits with a No Observed Adverse Effect Level (NOAEL) of 30 mg/kg/day. A LOAEL of 300 mg/kg/day was observed with effects manifested by increased resorptions, post-implantation loss and incomplete ossification of the vertebral arches.

**Table 2: Summary of Acute Dietary (Food + Drinking Water) Exposure and Risk for Ethofumesate**

Population Subgroup	aPAD (mg/kg/day)	% aPAD at 95 <sup>th</sup> Percentile	Exposure (mg/kg/day)
Females (13-49 years old)	0.3	4	0.011722

For additional information, please see Section 6.1 of the human health risk assessment.

#### b. Chronic Dietary (Food and Drinking Water)

An unrefined Tier 1 chronic dietary risk analysis was conducted using the average consumption value for food and average residue values on those foods. A risk estimate that is less than 100% of the chronic Population Adjusted Dose (cPAD) (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's level of concern. An uncertainty factor of 100x was applied for the chronic dietary assessment, and the FQPA safety factor was reduced to 1 (as discussed in the acute dietary assessment section, above). DEEM™ was used to calculate the chronic dietary exposure estimates based on average consumption for the U.S. population and population subgroups including infants and children. As in the acute dietary assessment, the chronic dietary assessment assumed ethofumesate residues in food at 100% of tolerance levels and a point estimate for drinking water residues.

The chronic dietary risk endpoint for the general population including infants and children is based on a chronic oral toxicity/carcinogenicity study in rats with a NOAEL of 127 mg/kg/day and a LOAEL of 469 mg/kg/day; effects were decreased body weight gain in females. The calculated cPAD is 1.3 mg/kg/day.

Estimated chronic dietary exposure (food and drinking water) for ethofumesate is below the Agency's level of concern for the all population subgroups at <1% of the cPAD. For additional information, please see Section 6.1 of the human health risk assessment.

#### c. Drinking Water Estimates

Typically EPA evaluates the potential for human exposure to pesticides in drinking water through an assessment of available surface water and ground water monitoring data and modeling. For ethofumesate, no monitoring data were available for use in this drinking water assessment.

Therefore, potential human exposures to ethofumesate were evaluated through modeling. Estimated exposure concentrations (EECs) in surface water were calculated using PRZM version 3.12 and EXAMS version 2.98.04. Ground water concentrations were modeled using SCIGROW (version 2.3). Drinking water residues were then incorporated into the DEEM-FCID™ into the food categories “water, direct, all sources” and “water, indirect, all sources.”

Based on the modeling results, the estimated surface water-derived drinking water concentration for the use of ethofumesate is 154 µg/L (used for the acute analysis) based on the Florida turf scenario. The 1 in 10 year annual average concentrations are 45.5 µg/L (used for the chronic analysis) for the Florida turf scenario, and 26 µg/L for the 30 year annual mean concentration for the Minnesota sugar beet scenario. The maximum concentration modeled using SCIGROW for ground water is 8.4 µg/L for use on turf. For details regarding modeling inputs and additional information, please see the Drinking Water Assessment Summary in Section V of the Environmental Fate and Effects risk assessment.

## **2. Residential Exposure and Risk**

Residential risk is expressed as a Margin of Exposure (MOE), which measures how close the residential exposure comes to the NOAEL from animal studies. Generally, MOEs that are greater than 100 do not exceed the Agency’s level of concern (the standard target MOE incorporates the standard uncertainty factors of 10x for interspecies variability and 10x for intraspecies variability). EPA determined that the available data supports the removal of the default 10x FQPA factor. Thus, scenarios that yield MOEs that are less than 100 may trigger concern.

An oral NOAEL of 190 mg/kg/day was selected from a 90-day oral study in rats for assessing the dermal exposure route. The LOAEL in this study was 1900 mg/kg/day with the effects of decreased body weight gain and liver microscopic lesions. Data on dermal absorption are unavailable at this time; therefore, a default assumption of 100% absorption was used. Inhalation exposure is not expected because residues are likely to be diluted outdoors in the air and ethofumesate has a low vapor pressure ( $4.9 \times 10^{-6}$  torr).

Some residential (dermal) scenarios were assessed for females 13-49 based on an oral endpoint from a developmental study in rabbits with effects manifested by increased resorptions, post-implantation loss and incomplete ossification of the vertebral arches. While the residential postapplication scenarios resulted in apparent risks of concern (see Table 3), the Agency believes that these scenarios are very conservative and unlikely to occur. The developmental endpoint was based on a study with a NOAEL (30 mg/kg/day) that is 10X lower than the LOAEL (300 mg/kg/day); therefore the NOAEL may be an artifact of dose selection. Additionally, for the residential exposures, the endpoint is oral while the assessed exposures are dermal and conservative SOP-based default assumptions such as 100% dermal absorption, default turf transferable residue dissipation assumptions, contact with turf immediately post-treatment and maximum application rates were used in this assessment. The rate of 1.5 lb ai/A covers the majority of uses; however, the label does permit a 3.0 lb ai/A rate specifically for suppression of Bermuda grass in St Augustine grass turf.

The acute toxicity profile for ethofumesate shows that the dermal LD<sub>50</sub> for ethofumesate was >20,050 mg/kg which was approximately three times higher than the highest dose tested for the oral

route (oral LD<sub>50</sub> = >6,400 mg/kg). Additionally, no effects were seen at the highest dose tested (1000 mg/kg/day) in a 21-day dermal study in rabbits. For more information on the toxicity profile for ethofumesate, please see Section 4.1.7 of the Human Health Risk Assessment. Although the LD<sub>50</sub> studies and the short term dermal study did not reach the desired endpoint and cannot be directly compared, the information from these studies gives the Agency confidence that high dermal exposures such as calculated for the residential risk assessments are unlikely to be a risk concern. However, the Agency intends to call in a dermal absorption (or penetration) study to permit more realistic estimation of dermal absorption.

#### a. Residential Handler Exposure and Risk

Since all ethofumesate products are intended for either agricultural use or require professional application for ornamental turf, no residential handler use is expected. There is, however, potential post-application residential exposure to ethofumesate for adults and children through its use on turf (lawn care applications) and golf courses.

#### b. Residential Postapplication Exposure and Risk

Residential post-application exposure to ethofumesate on treated lawn was assessed for toddlers and adults. The MOEs for residential turf exposures were calculated using conservative assumptions of a screening-level assessment such as maximum application rates, 100% dermal absorption, default assumptions for dissipation of turf transferable residues and a conservative endpoint for females 13-49 years. The total MOE includes the dermal, hand-to-mouth, object to mouth and soil ingestion pathways. Exposures were calculated for short and intermediate term exposures; ethofumesate use is not expected to result in long term residential exposure. As shown in Table 3, estimated risks for all population subgroups except females (13-49 yrs) were well above 100. The short-term total MOEs for females (13-49 yrs) are 73 at an application rate of 1.5 lb ai/acre and 27 at an application rate of 3.0 lb ai/acre. The maximum application rate is solely for suppression of Bermuda grass growth in St. Augustine grass.

To address this concern, the Agency intends to call in a dermal absorption study to permit more realistic estimation of dermal absorption. It should be noted that estimated exposures are extremely conservative due not only to assumption of 100% dermal absorption but also because they assume exposure at levels immediately after application, maximal levels of dermal exposure activity, maximum dermal contact, and maximum dermal surface contact areas. Additionally, ethofumesate has minimal lawncare and commercial turf uses, which is the scenario where high dermal exposure activities would occur. The predominant use is on golf courses and sod farms. High exposure activities would likely not occur on a golf course. Ethofumesate residues resulting from sod farm application would likely dissipate significantly before sod was transplanted to residential or commercial turf.



Table 3. Residential Exposure Estimates & MOEs for Ethofumesate Treated Turf					
Resident	lb ai/A	Activity	Body Weight (kg)	NOAEL(mg/kg/day)	MOE
Toddler	1.5	Playing	15	190	330
Toddler	3.0	Playing	15	190	160
Toddler	1.5	Hand to mouth	15	190	8600
Toddler	1.5	Turf to mouth	15	190	34000
Toddler	1.5	Soil to mouth	15	190	2.5 E6
Adult	1.5	High dermal contact activity	70	190	540
Adult	3.0	High dermal contact activity	70	190	270
Females 13-49 yrs	1.5	High dermal contact activity	60	30**	73
Females 13-49 yrs	3.0	High dermal contact activity	60	30**	27

\*\* based on a developmental toxicity study in rabbits; developmental LOAEL = 300, and assumes 100% dermal absorption.

### 3. Aggregate Exposure and Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii) require “that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information.” An aggregate risk assessment predicts the combined risk from dietary exposure to residues in food and drinking water and, if applicable, residential exposures.

In this assessment, risk assessments for aggregate exposure to food, drinking water, and residential were considered only for the short- and intermediate-term exposure scenarios because use patterns do not suggest a long-term residential exposure. Acute and chronic aggregate risks (food and drinking water) exposures are below the level of concern for all population subgroups. Short and intermediate term aggregate risks for food, drinking water, and residential exposures estimated for all population subgroups (general population, infants and adult 50+ male), with the exception of females (13-49 yrs), were below the level of concern with MOEs of 159-180.

Aggregate short- and intermediate-term risks for females (13-49 yrs) were not quantitatively estimated due primarily to ethofumesate residential postapplication risks to turf. Dietary risks (food and drinking water) for this sensitive subpopulation were well below the Agency’s level of concern. While the high-end residential postapplication scenarios resulted in apparent risks of concern (see Table 3), the Agency believes that these scenarios are very conservative and unlikely to occur for reasons detailed in the residential postapplication exposure and risk section above (section III.A.2.b)).

However, the Agency intends to call in a dermal absorption study to permit more realistic estimation of dermal absorption and to confirm that 100% is in fact an overestimate. For more information on aggregate risks and assumptions, please see Section 7.0 of the human health risk assessment.

#### **4. Occupational Exposure and Risk**

Workers can be exposed by mixing, loading, or applying (handlers) ethofumesate or by entering a previously treated site (postapplication). Worker risk is also measured as a MOE, which determines how close the occupational exposure comes to a NOAEL. For handlers, the Agency initially assesses risk at “baseline” which considers an individual’s normal work clothing (e.g., long sleeve shirt and long pants), no gloves, and no respirator. If there is a concern at this level, the Agency considers the use of protective measures (e.g., personal protective equipment and engineering controls) to lower the risk. Personal protective equipment (PPE) can include an additional layer of clothing, chemical-resistant gloves, and respirator. Common examples of engineering controls include enclosed tractor cabs, closed loading systems, and water-soluble packaging.

The Agency has determined that workers may be exposed to ethofumesate while mixing, loading or applying ethofumesate pesticides. Sixteen occupational handler scenarios were evaluated for short and intermediate term exposure to ethofumesate. All of the handler scenarios had MOEs greater than 100 at either baseline (long pants and shirt, socks and shoes) or with the addition of chemical-resistant gloves. When the handler scenarios were assessed for males or females over 49 years of age (NOAEL of 190 mg/kg/day from a 90-day rat oral study), MOEs ranged from 418 to 9200 with chemical-resistant gloves added. When the female (age 13-49 years) population (NOAEL of 30 mg/kg/day from a 21-day rabbit developmental study) was assessed when adding chemical-resistant gloves, the MOEs ranged from 100 to 1700 except for one scenario of mixing and loading for aerial applications at 3.75 b ai/A to sugar beets which resulted in an MOE of 57. For detailed information on handler aerial application assumptions and risks, please refer to section 9.4 of the human health risk assessment.

Handler risks for grower (on-farm) and custom (commercial) mixing, loading and applying ethofumesate to dry bulk fertilizers were not assessed in the original human health risk assessment. For on-farm handlers, estimated MOEs were greater than 100 for applicators at baseline, but required chemical-resistant gloves to reach MOEs of 100 for mixer/loaders. For commercial handlers, estimated MOEs were greater than 100 for applicators at baseline, and required engineering controls (closed mixing/loading) to reach MOEs of 100 for mixer/loaders. For dry bulk fertilizer assumptions, refer to the memorandum entitled “Handler Risks to Dry Bulk Fertilizers on Sugar Beets.”

The Agency has determined that workers may be exposed to ethofumesate upon entering areas which have been previously treated with ethofumesate to work in these areas (e.g., scouting, weeding, irrigating). When risks for males or females over 49 years of age were assessed (NOAEL of 190 mg/kg/day) for food and feed crops (sugar beets, carrots, etc), no concerns for re-entry workers were identified for low exposure activities at the current reentry interval (REI) of 12 hrs. However, for exposures associated with medium and high activities (transplanting, harvesting and thinning), a reentry interval (REI) of 3 days after treatment would be needed to reach an MOE prediction of 100 at the high use rate. When the developmental endpoint (NOAEL of 30 mg/kg/day) was used, again, no concerns for re-entry workers (females 13-49 years) were identified for low exposure activities at

the current REI of 12 hrs, but for medium and high exposure activities, 10-22 days were required to achieve the target MOE of 100. The conservative assumptions used in the risk assessment significantly affected length of these re-entry intervals. Conservative, screening level procedures were followed. The assumptions included: 100% dermal absorption, a default dislodgeable foliar dissipation rate, and an endpoint used for females (13-49 yrs) derived from a developmental study with a large difference between the LOAEL and NOAEL. Further, since ethofumesate use in agricultural food crops (sugar beets, carrots, garden beets, etc.) is primarily pre-plant and pre-emergence, medium and high exposure activities are not likely to occur. See the postapplication risk mitigation section for more description and characterization (section IV.d.1.c.2).

Table 4 illustrates the reentry risks to workers from turf. For turf, estimated risks for males and females > 49 years of age (using the NOAEL of 190 mg/kg/day) engaged in all activities (maintenance and harvesting), resulted in MOEs of  $\geq 100$  after 0 days reentry. For females (aged 13-49 years old), the estimated MOEs for workers performing turf postapplication activities did not reach 100 until 9 days for maintenance activities and 16 days for harvesting sod using the highest application rate. Conservative assumptions were used, such as using a 100% dermal absorption assumption and default assumptions for dissipation of turf transferable residues. Risk mitigation measures for turf are a reentry interval of 9 days for maintenance activities and a pre-harvest interval of 16 days. The Agency intends to call-in a confirmatory dermal absorption (penetration) study to provide a more realistic estimate of the dermal absorption and which, in turn, may alter these risk mitigation requirements.

For detailed information and assumptions on postapplication, please see Section 9.5 of the human health risk assessment

Table 4. Days After Treatment Target MOE Achieved (Target MOE = 100)						
Crop/Use Pattern	Application Rate (lb ai/acre)	Postapplication Activity	Transfer Coefficient (cm <sup>2</sup> /hr) <sup>a</sup>		Days After Treatment Target MOE Achieved	
					NOAEL = 30 mg/kg/day <sup>b</sup>	NOAEL = 190 mg/kg/day <sup>c</sup>
Golf Course Turf	3	Maintenance	ARTF	3,400	9	0
Sod Farms	3	Harvesting		6,800	16	0
Golf Course Turf	1.5	Maintenance	ARTF	3,400	3	0
Sod Farms	1.5	Harvesting		6,800	9	0

<sup>a</sup> Transfer coefficients are derived from ARTF data.

<sup>b</sup> MOE = NOAEL (30 mg/kg/day; based on an oral developmental study) / dermal dose.

<sup>c</sup> MOE = NOAEL (190 mg/kg/day; based on an oral 90-day toxicity study) / dermal dose.

## **5. Occupational Incidents Reports**

Very few ethofumesate incidents have been reported to EPA's Incident Data System, Poison Control Center data, and the California Pesticide Illness Surveillance Program. The symptoms, if present, were minor (irritation, cramps, nausea, dizziness) and did not fit any identifiable patterns.

### **B. Environmental Risk Assessment**

The Agency has conducted an environmental assessment for ethofumesate for the purposes of making a reregistration decision. The Agency evaluated environmental fate and wildlife and aquatic organism toxicity studies submitted for ethofumesate and determined that the data are adequate to support a reregistration decision. More in depth details of the toxicity to aquatic and terrestrial organisms and fate and persistence studies used to develop the risk assessments are provided in the environmental risk assessment available in the electronic docket. A summary of the environmental risk assessment findings and conclusions is provided in the following subsections below.

#### **1. Environmental Fate and Transport Properties**

The major route of dissipation for ethofumesate in surface soil appears to be photodegradation (photolysis half lives were 28 to 31 hours in water and 165 hours in soil). However, ethofumesate below the soil surface appears more stable. It may dissipate by microbial metabolism with aerobic metabolism half lives between 83 and 253 days. Laboratory data indicate that ethofumesate is stable to hydrolysis and anaerobic soil metabolism.

Furthermore, laboratory mobility data indicate that ethofumesate is very mobile in sand with a  $K_d$  of 0.73 and moderately mobile in most other soils with  $K_d$ s ranging from 2.35 to 6.16. Available data indicate that degradate mobility is similar to that of parent ethofumesate. Supplemental terrestrial field dissipation data indicate half lives of approximately 100 days with no detection of ethofumesate below 12 inches.

#### **2. Ecological Risk Assessment**

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

### **3. Risk to Aquatic Animals:**

Ethofumesate is considered to be “slightly toxic” to freshwater fish on an acute basis with LC50's ranging from 17 to 22 ppm. When maximum application rates were assessed, there were no exceedances of the LOC's for non-listed species. RQ's for risks to freshwater fish range up to 0.08.

Based on toxicity values and predicted environmental concentrations, there are no acute or chronic risks of concern (including endangered species risks) for estuarine invertebrates or estuarine/marine fish. There are also no chronic risk concerns for freshwater fish.

For a detailed discussion of risks to aquatic animals including a discussion of toxicity data and aquatic exposure modeling, please see Section VI: Aquatic Exposure and Risk Assessment of the Environmental Fate and Effects risk assessment.

### **4. Risk to Terrestrial Animals**

For birds and mammals, ecotoxicity testing indicates that ethofumesate technical and emulsifiable formulations are “slightly toxic” to “practically non-toxic” for acute toxicity.

For birds, no mortality or sublethal effects were observed in the ethofumesate avian reproduction studies. For mammals, no chronic effects were observed in the rat 3-generation reproduction study. Only at the highest doses were reduced food consumption, dyspnea and weakness observed.

Based on predicted EECs from maximum application rates and available toxicity data, there are no exceedances of any level of concern for terrestrial animals (including direct effects for endangered species).

Available acute data from a honey-bee study indicate that ethofumesate is "practically non-toxic" to honeybees with an 48-hour contact LD50 of >50 ug ai/bee. The Agency does not routinely conduct risk assessments for non-target insects, but these data indicate that there will be no risk concerns from use of ethofumesate.

For a detailed discussion of risks to terrestrial animals including a discussion of toxicity data and pesticide residues on terrestrial food items and terrestrial exposure modeling, please see Section VII: “Terrestrial Exposure and Risk Assessment” of the Environmental Fate and Effects risk assessment.

### **5. Risk to Aquatic Plants**

Review of the non-vascular plant study did not identify any risks of concern for the use of ethofumesate. Based on the recently submitted aquatic vascular plant study, no acute LOC exceedances were seen based on maximum application rates of ethofumesate.

## **6. Risk to Terrestrial Plants**

For seedling emergence, wheat was the most sensitive monocot with an EC25 (the concentration that affects 25% of test organisms) of 0.13 lbs ai/acre. The most sensitive dicot was lettuce with an EC25 of 0.14 lbs ai/acre and tomato with a NOAEC (No Observable Adverse Effects Concentration) of 0.006 lbs ai/acre.

In general, toxicity tests demonstrate that ethofumesate may impact both seedling emergence and vegetative vigor of vascular terrestrial plants. Because ethofumesate is mobile, there is potential for runoff to adversely affect off target plants. Although aerial applications are at lower application rate levels, there is also potential for spray drift impacts as well.

Based on predicted EECs using label maximum application rates and available toxicity data, there are exceedances of the LOC for acute terrestrial non-endangered and endangered species plants for both monocots and dicots.

## **7. Endangered Species**

The screening level risk assessment for endangered species indicates that ethofumesate has the potential for causing direct acute risk to endangered freshwater fish and terrestrial plants from uses on sugar beets, vegetables and turf if exposure should actually occur at modeled levels. A preliminary spatial analysis of the co-occurrence of endangered plants and ethofumesate use suggests that in general the major areas of potential risk to endangered plants are limited to the western United States. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Ethofumesate was found to have no direct acute or chronic effects to estuarine/marine invertebrates, estuarine/marine fish, mammals, birds and aquatic plants and no chronic effects to freshwater fish.

## **8. Ecological Incidents**

According to the EFED Terrestrial Incidence Database there were three reported incidences of plant damage from the use of ethofumesate. The reported incidences involved applications to sugar beets, but did not specify whether damage was to target or non-target crops. The first occurred in Richland county, Montana in June 2002 and involved 600 acres of sugar beets that were damaged from broadcast application of liquid ethofumesate. In the second, again in Richland county, Montana, 500 acres of 1000 acres of sugar beets were damaged from broadcast application of liquid ethofumesate. No residue analysis was performed in either case. The third incident involved ethofumesate use in Malheur county, Oregon where over 60 acres of 68 acres were damaged. The type of application was unknown and no residue analysis was performed.

## **IV. Risk Management, Reregistration, and Tolerance Reassessment Decision**

### **A. Determination of Reregistration Eligibility**

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

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risks associated with the use of pesticide products containing the active ingredient ethofumesate. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient ethofumesate, the Agency has sufficient information on the human health and ecological effects of ethofumesate to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that ethofumesate containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of ethofumesate that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of ethofumesate, and lists the submitted studies that the Agency found acceptable.

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

### **B. Public Comments and Responses**

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for ethofumesate. During the public comment period on the risk assessments, which closed on May 31, 2005, the Agency received comments from three commentors, Bayer CropSciences, University of Hawaii and a concerned citizen. Bayer's and the concerned citizen's comments pertained to risk assessment methods and toxicological endpoints, and the University of Hawaii comment was in support of benefits of use of ethofumesate for use on cool season turf grasses in Hawaii. These comments in their entirety are available in the public docket

(OPP-2004-0346) at <http://www.epa.gov/edockets>. A detailed Response to Comments has been prepared by EPA and is available in the public docket (OPP-2004-0346).

## **C. Regulatory Position**

### **1. Food Quality Protection Act Findings and “Risk Cup” Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to ethofumesate is within its own “risk cup.” An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for ethofumesate meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, drinking water, and residential uses. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for ethofumesate because acceptable developmental and reproduction studies have been submitted and reviewed, and there is a low concern and no residual uncertainties for pre- and postnatal toxicity

### **2. Endocrine Disruptor Effects**

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The available data on ethofumesate indicated that there was no toxicologically significant evidence of endocrine disruption effects. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, ethofumesate may be subject to additional screening and/or testing.

### **3. Cumulative Risks**

Risks summarized in this document are those that result only from the use of ethofumesate. The Food Quality Protection Act (FQPA) requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a



common mechanism of toxicity.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for ethofumesate.

#### 4. Tolerance Reassessment Summary

A tolerance summary for ethofumesate is presented in Table 5. A full description of the tolerance reassessment can be found in the Residue Chemistry Chapter for ethofumesate dated September 9, 2004. In this assessment, tolerances for residues are currently expressed in terms of the combined residues of the herbicide ethofumesate (2-ethoxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate) and its metabolites 2-hydroxy-2,3-dihydro-3,3-dimethyl-5-benzofuranyl methanesulfonate (NC 8493) and 2,3-dihydro-3,3-dimethyl-2-oxo-5-benzofuranyl methanesulfonate (NC 9607), both calculated as parent compound.

Table 5. Tolerance Reassessment Summary for Ethofumesate

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Tolerances Listed Under 40 CFR §180.345(a)(1)			
Beet, sugar, roots	0.1	0.3	Residue data indicate that the tolerances should be increased.
Beet, sugar, tops	1	4	
Grass, straw	1	TBD <sup>a</sup>	
Cattle, fat	0.05	TBD <sup>a</sup>	With respect to residues in tissues, the existing cattle feeding study needs to be upgraded as residues of a major animal metabolite (NC 20645) were not determined. A new cattle feeding study is required as confirmatory data..
Cattle, meat			
Cattle, meat byproducts			
Goat, fat	0.05	TBD <sup>a</sup>	
Goat, meat			
Goat, meat byproducts			
Hog, fat	0.05	Revoke	There are no active regulated swine feed items associated ethofumesate uses; therefore, tolerances for hog commodities should be revoked.
Hog, meat			
Hog, meat byproducts			

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment
Horse, fat	0.05	TBD <sup>a</sup>	See note above under cattle.
Horse, meat			
Horse, meat byproducts			
Sheep, fat	0.05	TBD <sup>a</sup>	See note above under cattle
Sheep, meat			See note above under cattle
Sheep, meat byproducts			See note above under cattle
Tolerances to be Proposed under 40 CFR §180.345(a)(1)			
Beet, garden, roots	None	0.5	
Beet, garden, tops	None	5.0	
Beet, sugar, refined sugar	None	0.2	
Tolerances to be Proposed under 40 CFR §180.345(a)(2)			
Sugar beet molasses	0.5	0.5	Based on HAFT residues of 0.25 ppm and the 1.9x processing factor, maximum expected residues are 0.48
Tolerances to be Proposed under 40 CFR §180.345(c)			
Carrot, root	None	7.0	Residue data support a regional registration restricted to WA State

<sup>a</sup> TBD = To be determined. Although additional data are required to confirm the existing tolerances in or on the following commodities, the Agency has no dietary or drinking water concerns associated with these tolerances and considers them reassessed: grass straw, cattle, goat, horse and sheep commodities.

#### **D. Regulatory Rationale**

The Agency has determined that ethofumesate is eligible for reregistration provided that additional data that the Agency intends to require confirm this decision, the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of ethofumesate. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. Due to risk exceedences for scenarios such as mixing/loading liquids for aerial applications, ethofumesate labels must be amended to prohibit aerial applications at the highest application rate of 3.75 lb ai/acre. Additionally, engineering controls are being required for custom (commercial) mixing of ethofumesate onto dry bulk fertilizer. Although there are risk exceedences for residential dermal exposure to turf, the Agency believes that these apparent exceedences are driven by very conservative risk assumptions such as 100% dermal absorption of ethofumesate. The Agency intends to issue a data call in to require the registrant to submit a dermal absorption (or penetration) study to confirm that this assumption is conservative. There are also

calculated reentry intervals which are quite lengthy for high exposure postapplication activities for the agricultural uses of ethofumesate. The Agency believes that there are no high exposure activities for ethofumesate which is primarily applied pre-emergence. Therefore, these longer restricted re-entry intervals are not necessary for agricultural uses of ethofumesate. For use on turf, reentry intervals of 9 days are required for maintenance activities and a pre-harvest interval of 16 days is required for sod harvesting.

## **1. Human Health Risk Management**

### **a. Aggregate Risk Summary**

As discussed in Chapter 3, aggregate risk refers to the combined risk from food, drinking water, and residential exposures. In addition, aggregate risk can result from one-time (acute), short-term and/or chronic exposures. Below is a discussion of the aggregate risk for each duration of exposure and EPA's decision and rationale for addressing any risks of concern.

#### **1) Acute Aggregate Risk**

An analysis was performed for food and drinking water exposure for females 13-49 years of age since this is the only population subgroup for which a relevant toxicological endpoint has been identified. The acute dietary (food and drinking water) for females 13-49 years of age occupies 4% of the aPAD at the 95<sup>th</sup> percentile. The contribution of food and food forms to this estimate, at the 95<sup>th</sup> percentile, is 2.1%. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD), the dose at which an individual could be exposed on any given day with no adverse health effects, does not exceed the Agency's level of concern. Therefore, EPA has no acute food and drinking water aggregate concerns.

#### **2) Short and Intermediate-term Aggregate Risk**

Aggregate assessments of food, drinking water, and residential exposure were considered only for the short- and intermediate-term exposure scenarios because use patterns do not suggest a long-term residential exposure to ethofumesate. For all population subgroups assessed, except females 13-49 years of age, the aggregate MOEs (food + drinking water + residential) ranged from 159 to 180, which are all higher than the target MOE of 100.

Dietary risks (food and drinking water) for females 13-49 years of age were also well below the Agency's level of concern. While the high-end exposure residential postapplication scenarios resulted in apparent risks of concern (see Table 3) for females 13-49 years of age, the Agency believes that these scenarios are very conservative and unlikely to occur for reasons detailed in the residential

postapplication exposure and risk section (section III.A.2.b). Thus, the Agency concludes that aggregate short-term/intermediate risks to females 13-49 years of age do not present a risk concern.

### **3) Long-term Aggregate Risk**

Chronic exposure resulting from food and drinking water was estimated to be <1% of the cPAD for all subpopulations including females 13 to 49 years of age; this value is below the Agency's level of concern. Long term residential exposures are not expected from ethofumesate use; therefore, there were no chronic aggregate concerns.

#### **b. Aggregate Risk Mitigation**

The Agency does not consider additional mitigation necessary at this time.

#### **c. Occupational Risk Mitigation**

##### **1) Handler Risk Mitigation**

Handlers may be exposed to ethofumesate while mixing, loading or applying ethofumesate pesticides. For evaluations of short and intermediate term exposure to ethofumesate, most of the handler scenarios had MOEs greater than 100 with long pants and long-sleeved shirt, socks and shoes and chemical resistant gloves, which is consistent with the current ethofumesate labels. Therefore, the Agency will require that chemical resistant gloves be maintained as a PPE requirement for all handlers.

Two scenarios require mitigation:

One scenario of mixing and loading for aerial applications at 3.75 lb ai/A to sugar beets resulted in an MOE of 57 which is of potential concern. During the phase 3 public comment period, the registrant commented that the 3.75 lb ai/A rate for sugar beets was for pre-emergence use and required a large volume of water for complete coverage. It is not practical to make this pre-emergence application with aerial equipment. Therefore the label will be clarified to prohibit aerial applications at the rate of 3.75 lb ai/A .

The second scenario of mixing ethofumesate with fertilizer for custom applicators (commercial) requires engineering controls to achieve MOEs  $\geq 100$ . While grower applications (on-farm) require only the addition of chemical resistant gloves to achieve MOEs  $\geq 100$ , custom applicators can mix larger amounts and therefore, need additional protection of closed systems to achieve MOEs  $\geq 100$ . Engineering controls will be required on ethofumesate labels which allow application to fertilizers.

##### **2) Post-application Risk Mitigation**

Workers may be exposed to ethofumesate upon entering areas which have been previously treated with ethofumesate to perform specific work activities in these areas (e.g., scouting, weeding,

irrigating). There are no risk concerns for re-entry workers performing low exposure activities. There were apparent risk concerns when considering medium and high exposure activities such as transplanting, harvesting and thinning for the existing food and feed crops (sugar beets, carrots, etc.). However, these high exposures are not likely to occur following use of a pre-plant, pre-emergence herbicide. Also, the conservative assumptions used in the risk assessment significantly affected exposure predictions for medium and high exposure activities. Conservative, screening level procedures were followed, including assumption of 100% dermal absorption. No mitigation is necessary to protect re-entry workers for food and feed crops. The dermal absorption study which the Agency intends to require to refine the residential risks will be used to confirm this risk management decision.

Most of the ethofumesate labels do not specify a re-entry interval. For agricultural non-turf uses, a 12-hour re-entry interval will be added to all labels for products for use within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS), based on the acute toxicity of the active ingredient

The required dermal absorption study will also allow refinement of predicted re-entry risks for turf. However, in the interim, risk mitigation measures for golf course and sod farm turf include a reentry interval of 9 days for maintenance activities and a pre-harvest interval of 16 days. An acceptable dermal absorption study may enable EPA to alter these label requirement measures.

## **2. Environmental Risk Mitigation**

No mitigation for environmental risks is being required for reregistration of ethofumesate. The screening level ecological risk assessment resulted in slight endangered species risks for freshwater fish when ethofumesate was assessed with maximum application rates.

The main risks from ethofumesate are for terrestrial plants. There are advantages to ethofumesate use and, as an herbicide, plant risks are expected. Spray drift was a large contributor to potential exposures of ethofumesate to aquatic resources, terrestrial animals and plants. Reducing spray drift will lower, but not eliminate, risks to non-target plants. However, the label clarification to prohibit aerial applications at the 3.75 lb ai/A rate will reduce assessed risks to non-target organisms.

### **a. Endangered Species Considerations**

#### **Endangered Species Assessment**

The Agency's screening level ecological assessment for ethofumesate resulted in a determination that use of ethofumesate will have no direct acute or chronic effects on threatened and endangered avian, mammalian, aquatic invertebrate, estuarine fish species. Additionally, a determination of no direct chronic effects can be made for threatened and endangered freshwater fish. The screening level risk assessment for endangered species indicates that ethofumesate RQs exceed the endangered species LOCs for the following combinations of analyzed uses and species:

- **freshwater fish** (direct acute effects) based on predicted EECs for runoff from terrestrial use of ethofumesate on sugar beets, turf, and vegetables
- **terrestrial plants** (direct effects) based on predicted EEC for the terrestrial use of ethofumesate on sugar beets, turf, and vegetables for both monocots and dicots.

Refinement and comparative analysis suggest that risks to endangered freshwater fish can be expected to be mitigated through either spray drift controls or rate reduction, while potential direct risks to terrestrial plants could be mitigated through rate reductions. However, the refinement and comparative analysis also indicates that the effect of mitigation on effects to non-target terrestrial plants through spray drift controls is not likely to be effective at completely eliminating the potential risk. Indirect effects to listed species dependant upon plants which may be affected from the use of ethofumesate, will need to be further assessed when the Agency conducts a species specific analysis.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in limitations on the use of ethofumesate, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of ethofumesate “may affect” listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to ethofumesate at levels of concern. EPA is not requiring specific ethofumesate label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

## **b. Spray Drift Management**

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

Prohibiting aerial applications at the highest rate for sugar beets will result in lower exposures from drift. From its assessment of ethofumesate, as summarized in this document, the Agency concludes that no additional drift mitigation measures are needed for ethofumesate. In the future, ethofumesate product labels may need to be revised to include additional or different drift label statements.

## **V. What Registrants Need to Do**

The Agency has determined that ethofumesate is eligible for reregistration provided that additional data are submitted to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data that the Agency intends to require for ethofumesate.

### **A. Manufacturing Use Products**

#### **1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of ethofumesate for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed in Table 6 below are necessary to confirm the reregistration eligibility decision documented in this RED.

<b>Table 6. Data Requirements for the Reregistration Eligibility Decision on Ethofumesate</b>		
<b>Guideline Study Name</b>	<b>New OPPTS Guideline No.</b>	<b>Old Guideline No.</b>
28-day Inhalation Toxicity	840.3465	82-4
Dermal Penetration Study	870.76	85-3
Aerobic Aquatic Metabolism	835.43	162-4
Accumulation - aquatic, non-target (Reserved)	850.195	165-5
Ground Water - small prospective (Reserved)	835.195	835.71
Residue Analytical Method (Animal Commodities)	860.134	171-4c 171-4d
Multiresidue Method (Recovery data for the ethofumesate metabolites)	860.136	171-4m
Storage Stability Data (Animal Commodities)	860.138	171-4e
Magnitude of the Residue (Meat, Milk, Poultry, Eggs)	860.148	171-4j
Crop Field Trials (Grass, straw)	860.15	171-4k
Field Accumulation in Rotational Crops	860.19	165-2

## **2. Labeling for Manufacturing-Use Products**

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. For agricultural non-turf uses a 12-hour re-entry interval will be added to all labels for products for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS) based on the acute toxicity of the active ingredient. For turf labels a reentry interval of 9 days for maintenance activities and a pre-harvest interval of 16 days will be required. An acceptable dermal absorption study may enable EPA to refine the postapplication risk estimates for turf and could potentially result in altering the existing risk mitigation label requirement measures proposed in this RED.

### **B. End-Use Products**

#### **1. Additional Product-Specific Data Requirements**

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



## **2. Labeling for End-Use Products**

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in the Risk Mitigation Summary section. Table 7 describes how language on the labels should be amended.

## **VI. Conclusions**

The Agency is issuing this Reregistration Eligibility Decision (RED) document for ethofumesate, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing ethofumesate. The Agency has determined that all currently registered uses of ethofumesate are eligible for reregistration provided all required mitigation is put on the label and all required studies are submitted.

The risk assessments for ethofumesate are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making.

## Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 7: Summary of Labeling Changes for Ethofumesate		
Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	“Only for formulation into herbicides” [for use fill blank only with those uses that are being supported by MP registrant].”	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p> <p>“This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	“This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment washwaters.”	Precautionary Statements

End Use Products Intended for Occupational Use

<p>Front Panel Statement for Granular and Liquid</p>	<p>“For sale and use by professional applicators only. Not for sale or use by homeowners/consumers.”</p>	<p>Insert in a prominent position associated with the brand name on the front panel of the pesticide label.</p>
<p>PPE Requirements Established by the RED<sup>1</sup> for Liquid and Granular Formulations</p>	<p>“Personal Protective Equipment (PPE)”                  “Some materials that are chemical-resistant to this product are” (<i>registrant inserts correct chemical-resistant material</i>). “If you want more options, follow the instructions for category” [<i>registrant inserts A,B,C,D,E,F,G,or H</i>]                  “on an EPA chemical-resistance category selection chart.”                   “All mixers, loaders, applications and other handlers must wear”                  Long sleeved shirt, long pants, shoes and socks, and chemical resistant gloves (except flaggers, or applicators in cockpits, and enclosed cabs)                   “See engineering controls for additional requirements.”</p>	<p>Immediately following/below                  Precautionary Statements: Hazards to Humans and Domestic Animals</p>

<p>Engineering Controls: On-Site Closed Mixing and Loading System for Liquid Formulations</p>	<p>On-Site Closed Mixing and Loading System Engineering Controls for Liquid Formulations (Dermal Protection Only):</p> <p>“Mixers and loaders must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4)] for dermal protection, and must:</p> <ul style="list-style-type: none"> <li>-- wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders (this must consist of long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron, or be listed here),</li> <li>-- wear protective eyewear, if the system operates under pressure, and</li> <li>-- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear, and (insert the appropriate type of respirator, if there are inhalation concerns).”</li> </ul>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>Engineering Controls: Enclosed Cabs for Aerial Applicators</p>	<p>“Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</p>	<p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>

<p>User Safety Recommendations</p>	<p>“User Safety Recommendations</p> <p>Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.</p> <p>Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.</p> <p>Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>
<p>Environmental Hazards</p>	<p>This pesticide may be toxic to fish. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Do not contaminate water when disposing of equipment wash waters or rinsate.</p>	<p>Precautionary Statements immediately following the User Safety Recommendations</p>
<p>Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)</p>	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours for all crops, except turf grown for sod. The REI for turf is 9 days. The REI for each crop is listed in the directions for use associated with each crop.”</p>	<p>Directions for Use, Under Agricultural Use Requirements Box</p>
<p>Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS</p>	<p>For minimum early entry PPE use the following:</p> <p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> <li>* coveralls,</li> <li>* shoes plus socks</li> <li>* chemical-resistant gloves made of any waterproof material”</li> </ul>	<p>Direction for Use Agricultural Use Requirements box</p>

WPS Double Notification Statement	“Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area.”	Direction for Use Agricultural Use Requirements box
Entry Restrictions for products	<p><b><i>Entry Restriction for non-WPS uses applied as a spray:</i></b></p> <p>“Do not enter or allow others to enter until sprays have dried.”</p> <p>Professional pesticide applicators applying to residential turf, including home lawns, parks, and recreation areas must inform their customers that all persons and pets must be kept off the treated turf until sprays have dried.</p> <p><b><i>Entry Restriction for non-WPS uses applied dry:</i></b></p> <p>“Do not enter or allow others to enter the treated area (except those involved in the watering) until the recommended watering-in is complete and the surface is dry.”</p> <p>“Professional pesticide applicators applying to residential turf, including home lawns, parks, and recreation areas must inform their customers that all persons (except those involved in the watering) and pests must be kept off the treated turf until the recommended watering-in is complete and the surface is dry.”</p>	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Direction for Use directly above the Agricultural Use Box.

<p>Other Application Restrictions for labels with directions for use on sugar beets.</p> <p>NOTE: The labels also must list the maximum application rates in pounds or gallons of formulation</p>	<p>Sugar Beets: “Do not apply more than 1.5 lb ai/acre with aircraft.”</p>	<p>Directions for Use</p>
<p>Other Application Restrictions for labels with directions for use on sod farm turf</p> <p>NOTE: The labels also must list the maximum application rates in pounds or gallons of formulation</p>	<p>Sod Farm Turf: “Do not harvest treated sod for 16 days following application.”</p>	<p>Directions for Use</p>
<p>Spray drift language for products applied as spray</p>	<p>“SPRAY DRIFT MANAGEMENT”</p> <p>This chemical can contaminate surface water through spray drift. A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product</p> <p><b>Wind Speed</b> “ Do not apply at wind speeds greater than 15 mph.”</p> <p><b>Temperature Inversions</b> “Do not make applications into areas of temperature inversion or stable atmospheric conditions.”</p>	<p>Directions for Use</p>

<sup>1</sup> PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

## Appendix A: Use Patterns Eligible for Reregistration

Site	Formulations	Maximum Single Application Rate (lb ai/acre)	Maximum Seasonal Rate (lb ai/acre)	Preharvest Interval (Days)	Reentry Interval (Days)	Use Limitations
<b>Garden Beets</b>	Flowable Concentrate, and Emulsifiable Concentrate	1.9 preemergent	2.6	NS	NS	
		0.33 postemergent				
<b>Carrots</b>	Flowable Concentrate, and Emulsifiable Concentrate	2.0 preemergent/postemergent	4.0	NS	NS	
<b>Ornamental Lawn and Turf - Professional Use Only</b> (Golf course use, residential lawns, and sod farms)	Flowable Concentrate Emulsifiable Concentrate, and Granular	1.5 preemergent /early postemergent	1.5	16 prohibition for harvesting of sod	9	See label changes summary table in ethofumesate RED.
	Emulsifiable Concentrate	3.0	3.0	16 prohibition for harvesting of sod	9	Bermudagrass suppression on St. Augustine sod farms
<b>Sugar Beets</b>	Flowable Concentrate, and Emulsifiable Concentrate	1.5 postemergent	3.75	NS	NS	See label changes summary table in ethofumesate RED.
		3.75 preemergent and preplant				



## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT		USE PATTERN	CITATION(S)	
<b><u>PRODUCT CHEMISTRY</u></b>				
New Guideline Number	Old Guideline Number			
830.1550	61-1	Product Identity and Composition	ALL	41997202, 41752101, 42956601, 42956602, 45884801
830.1600	61-2	Description of materials used to produce the product	ALL	41752101
830.1620	61-2A	Begin. Mat. & Mnfg. Process	ALL	41752101
830.1670	61-2B	Discussion of Impurities	ALL	41997202, 41752101, 42956602, 45884801
830.1700	62-1	Preliminary Analysis	ALL	41997202, 42956602, 45884801
830.1750	62-2	Certification of limits	ALL	41997202, 42956602, 49884801
830.1800	62-3	Analytical Method	ALL	41997202, 42956602, 45884801
830.6302	63-2	Color	ALL	41997203
830.6303	63-3	Physical State	ALL	41997203
830.6304	63-4	Odor	ALL	41997203
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	ALL	41997203, 43066801
830.7000	63-12	pH	ALL	41752102
830.7050	None	UV/Visible Absorption	ALL	Data Gap

## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT			USE PATTERN	CITATION(S)
830.7200	63-5	Melting Point	ALL	41752102
830.7220	63-6	Boiling Point	ALL	N/A <sup>a</sup>
830.7300	63-7	Density	ALL	41752102
830.7370	63-10	Dissociation Constants in Water	ALL	N/A <sup>b</sup> , 41752102
830.7550	63-11	Octanol/Water Partition Coefficient	ALL	41752102
830.7840	63-8	Solubility	ALL	41752102
830.7950	63-9	Vapor Pressure	ALL	41752102
<b>ECOLOGICAL EFFECTS</b>				
850.2100	71-1	Avian Acute Oral LD <sub>50</sub>	ALL	00115064
850.2200	71-2	Avian Dietary Toxicity LC <sub>50</sub>	ABCDEJK	ACC127694, ACC225319
850.2300	71-4	Avian Reproduction	ABCDEJK	45818111, 45855503
850.1075	72-1	Freshwater Fish LC <sub>50</sub>	ABCDEJK	41970701, ACC232429, 40098001, 42015501, 46546301
850.1010	72-2	Freshwater Invertebrate Acute LC <sub>50</sub>	ALL	ACC232429, ACC231232
850.1075	72-3A	Estuarine/Marine Fish LC <sub>50</sub>	A-K	42409301
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk EC <sub>50</sub>	A-K	42388101
850.1035 850.1045	72-3C	Estuarine/Marine Toxicity - Shrimp EC <sub>50</sub>	A-K	42364502

## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT			USE PATTERN	CITATION(S)
850.14	72-4A	Fish- Early Life Stage - Daphnid	A-K	42008901
850.1300 850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A-K	42871901
850.1500	72-5	Freshwater Full Life Cycle Fish	A-K	Data Gap
850.4100	122-1A	Seed germ/seedling emergence	A-K	Data Gap
850.4150	122-1B	Vegetative vigor	A-K	Data Gap
850.4400	122-2	Aquatic Plant Growth	A-K	46450701
850.4225	123-1A	Seed germ/seedling emergence	A-K	45874702
850.4250	123-1B	Vegetative vigor	A-K	45874701
850.4400	123-2B	Aquatic Plant Growth, Tier 2	A-K	41687601
850.3020	141-1	Honey Bee Acute Contact	A-K	41970703
<b><u>TOXICOLOGY</u></b>				
870.1100	81-1	Acute Oral Toxicity-Rat	ALL	41214215, 00030418
870.1200	81-2	Acute Dermal Toxicity-Rabbit	ALL	00030419
870.1300	81-3	Acute Inhalation Toxicity-Rat	ALL	41554101
870.2400	81-4	Primary Eye Irritation-Rabbit	ALL	41949204, 00030421
870.2500	81-5	Primary Skin Irritation	ALL	41949205, 00030421
870.2600	81-6	Dermal Sensitization	ALL	41404601
870.3100	82-1A	90-Day Feeding - Rodent	ALL	44156201, 44093601

## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT			USE PATTERN	CITATION(S)
870.3150	82-1B	90-Day Feeding - Non-rodent	ALL	00062822
870.3200	82-2	21-Day Dermal - Rabbit/Rat	ALL	42689902, 41997204
870.3465	82-4	90-Day Inhalation-Rat	ALL	Data Gap
870.3700A	83-3A	Developmental Toxicity- Rat	ALL	42067701, 42689901
870.3700B	83-3B	Developmental Toxicity- Rabbit	ALL	00156606, 40263701, 41652501
870.3800	83-4	2-Generation Reproduction - Rat	ALL	00062823
870.4100A	83-1A	Chronic Feeding Toxicity - Rodent	ALL	44093602
870.4100B	83-1B	Chronic Feeding Toxicity - Non-Rodent	ALL	00062822
870.4200	83-2A	Carcinogenicity Rat	ALL	44093603, 44093604
870.4200	83-2B	Carcinogenicity - Mouse	ALL	44156202
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity- Rat	ALL	44093601, 44093602, 44093603, 44093604, 00041853
870.5100	84-2	Gene Mutation (bacterial reverse gene mutation)	ALL	43529501
870.5300	84-2	Gene Mutation (mammalian forward gene mutation in vitro)	ALL	41710501
870.5375	84-2B	Structural Chromosomal Aberration	ALL	41214203
870.5395	84-2B	Mammalian bone marrow micronucleus assay	ALL	41214217

## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT			USE PATTERN	CITATION(S)
870.5550	84-2	Bacterial DNA Damage or Repair	ALL	41214204
870.7485	85-1	General Metabolism	ALL	42689903, 42364503
<b><u>ENVIRONMENTAL FATE</u></b>				
835.1240	163-1	Leaching/Adsorption/Desorption	A-K	41212212, 42438001
835.2120	161-1	Hydrolysis	A-K	00115080
835.2240	161-2	Photodegradation - Water	A-G	42200901, 42364501, 46157901
835.2410	161-3	Photodegradation - Soil	ABC	41214205
835.4100	162-1	Aerobic Soil Metabolism	A-K	42413001
835.4200	162-2	Anaerobic Soil Metabolism	ABC	42413002
835.4300	162-4	Aerobic Aquatic Metabolism	DEFGJ	Data Gap <sup>d</sup>
835.6100	164-1	Terrestrial/Aquatic Field Dissipation	ABCDEFI	41997205 <sup>e</sup>
835.1730	166-1	Ground Water- small prospective	A-K	Reserved
840.1100	201-1	Droplet Size Spectrum	A-K	N/A <sup>f</sup>
840.1200	202-1	Drift Field Evaluation	A-K	N/A <sup>f</sup>
860.1950	165-4	Bioaccumulation in fish	A-G	41970704
850.1950	165-5	Accumulation-aquatic nontarget	A-K	Reserved
<b><u>RESIDUE CHEMISTRY</u></b>				
860.1100	171-2	Chemical Identity	ALL	41752101

## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT			USE PATTERN	CITATION(S)
860.1300	171-4A	Nature of Residue - Plants	ABDHKL	42495901,42495902
860.1300	171-4B	Nature of Residue - Livestock	ABDHK	42364504,42364505
860.1340	171-4C	Residue Analytical Method - Plants	ABDEHKL	00036363, 41214206, 4581101, 45818103, 45818104, 45874703
860.1340	171-4D	Residue Analytical Method-Animals	ABDEHL	41214209, 45818102, 45874703
860.1360	171-4M	Multiresidue Method	ALL	41997206
860.1380	171-4E	Storage Stability Data-Plants	ABDE	00039810, 00115057, 45818105, 45818106, 45818108, 45818109, 45818110
860.1380	171-4F	Storage Stability Data- Animals	ABDE	Data Gap
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg	ABDHL	Data Gap <sup>g</sup> , 41214208, 43458701
860.1500	171-4K	Crop Field Trials (Beet, garden, root)	ABDHK	45892001
860.1500	171-4K	Crop Field Trials (Beet, sugar, root)	ABDHK	00036365, 00036366, 00037839, 00041855, 00041856, 00048415, 41214228, 41214241, 41214242, 43697201
860.1500	171-4K	Crop Field Trials (Grass, Forage, Fodder, and Hay)	ABDHK	41214214, 41214218, 41214219, 41214220, 41214221, 41214222, 41214223, 41214224, 43298103
860.1520	171-4L	Processed Food/Feed (Beet, sugar, molasses)	ABDHL	45855501

## Appendix B: Data Supporting Guideline Requirements for the Reregistration of Ethofumesate

REQUIREMENT			USE PATTERN	CITATION(S)
860.1850	165-1	Confined Accumulation in Rotational Crops	ABCD	42817201
860.1900	165-2	Field Accumulation in Rotational Crops	ABCD	4398104, 45855502

N/A not applicable.

a Data are not required because the TGAI is a solid at room temperature.

b Data are not required because of the low solubility of the PAI in water.

c No data requirements are specified.

d An aerobic aquatic study was classified as supplemental. Additional data is needed to upgrade this study to acceptable.

e A terrestrial field dissipation study was classified as supplemental. Additional data is needed to upgrade this study to acceptable.

f Satisfied through the Spray-Drift Task Force data.

g A new feeding study is required unless the registrant can upgrade the current cattle feeding study.

## Appendix C. Citations Considered to be Part of the Database Supporting the Reregistration Eligibility Decision (Bibliography)

### GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.



- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
  
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

## BIBLIOGRAPHY

MRID	CITATION
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## **Appendix D.      Generic Data Call-In**

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

## **Appendix E. Product Specific Data Call-In**

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.



**Appendix F. List of Registrants Sent This Data Call-In**

Bayer Cropscience Company

Fissions Inc.

United Phosphorus, Inc.

The Andersons Lawn Fertilizer Division, Inc.

The Scotts Company

## **Appendix G. EPA'S Batching of Ethofumesate Products for Meeting Acute Toxicity Data Requirements for Reregistration**

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

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

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

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

Seventeen products were found which contain Ethofumesate as the active ingredient. These products have been placed into 3 batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

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

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

Batch 1	EPA Reg. No.	Percent Active Ingredient
	264-611	97.7
	70506-105	98.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	264-613	42.0
	264-615	42.0
	432-938	42.0
	70506-106	42.0
	70506-107	42.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	264-612	19.0
	432-941	19.0

No Batch	EPA Reg. No.	Percent Active Ingredient
	264-631	Ethofumesate: 6.0 Desmedipham: 6.0 Phenmedipham: 6.0
	264-632	Ethofumesate: 7.0 Desmedipham: 7.0 Phenmedipham: 7.0

	264-815	Ethofumesate: 15.9 Desmedipham: 10.2 Phenmedipham: 13.1
	264-835	Ethofumesate: 12.2 Desmedipham: 7.8 Phenmedipham: 10.1
	264-854	Ethofumesate: 15.9 Desmedipham: 10.2 Phenmedipham: 13.1
	9198-206	2.1
	45639-160	Ethofumesate: 6.0 Desmedipham: 6.0 Phenmedipham: 6.0
	70506-90	Ethofumesate: 7.0 Desmedipham: 7.0 Phenmedipham: 7.0

## Appendix H. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of March 30, 2005. Sixty days later the first public comment period closed. EPA has considered and responded to the public comments, and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

[www.epa.gov/pesticides/](http://www.epa.gov/pesticides/)

These documents include:

### **HED Documents:**

1. Memorandum:HED Revised Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision Document (RED)–Phase 4. Robert Travaglini, Chemist (OPP/HED). DP Barcode: DP304056. August 10, 2005.
2. ETHOFUMESATE: HED Revised Human Health Risk Assessment For Phase 4; Response to Bayer CropScience Phase 3 Comments. Nancy McCarroll  
DP Barcode DP304056. August 10, 2005.

### **EFED Documents:**

1. Memorandum: Revised Environmental Fate and Effects Division Preliminary Risk Assessment for the Ethofumesate Reregistration Eligibility Decision Document. Amer Al-Mudallal and Lewis Brown (OPP/EFED). DP Barcode D296942. August 20, 2005.
2. Revised Environmental Fate and Effects Division Preliminary Risk Assessment for the Ethofumesate Reregistration Eligibility Decision Document. Amer Al-Mudallal and Lewis Brown (OPP/EFED). D296942. August 20, 2005.

### **SRRD Documents:**

1. Memorandum: Handler Risks to Dry Bulk Fertilizers on Sugar Beets. Nathan Mottl and Laura Parsons (OPP/SRRD). September 27, 2005.

## Appendix I. List of Available Related Documents and Electronically Available Forms

**Pesticide Registration Forms are available at the following EPA internet site:**

<http://www.epa.gov/opprd001/forms/>

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

### Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at [williams.nicole@epa.gov](mailto:williams.nicole@epa.gov).

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

8570-1	Application for Pesticide Registration/Amendment	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>

8570-2 7	Formulator's Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>
8570-2 8	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>
8570-3 0	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>
8570-3 2	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>
8570-3 4	Certification with Respect to Citations of Data (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-3 5	Data Matrix (PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a>
8570-3 6	Summary of the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>
8570-3 7	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a>

### **Pesticide Registration Kit**

[www.epa.gov/pesticides/registrationkit/](http://www.epa.gov/pesticides/registrationkit/)

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
  - a. 83-3 Label Improvement Program--Storage and Disposal Statements
  - b. 84-1 Clarification of Label Improvement Program
  - c. 86-5 Standard Format for Data Submitted under FIFRA
  - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
  - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
  - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
  - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
  - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at [http://www.epa.gov/opppmsd1/PR\\_Notices](http://www.epa.gov/opppmsd1/PR_Notices)

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula
  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
  
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
  - a. Registration Division Personnel Contact List
  - a. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - b. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
  - g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

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

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: [ace.orst.edu/info/nptn](http://ace.orst.edu/info/nptn).

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or



petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- 1.Date of receipt;
- 2.EPA identifying number; and
- 3.Product Manager assignment.

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

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