Ethion RED

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Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decision for ethion. The registrants of ethion requested voluntary cancellation of their registrations for technical products with risk mitigation measures to be effective in the interim. The EPA has accepted this proposal. Two ethion tolerances will be revoked at this time, because there are no currently registered uses for the associated crops. The remaining 15 tolerances will be revoked after the cancellation of ethion registrations becomes effective.

The revised risk assessments are based on review of the required target database supporting the use patterns of currently registered products and new information received during the reregistration process. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on ethion. After considering the revised risks, as well as comments and mitigation suggestions from stakeholders, EPA developed its risk management decision for uses of ethion that pose risks of concern. This decision is discussed fully in this document.

Ethion is an organophosphate insecticide and acaricide used on citrus and cattle, first registered in the late 1950's. Domestic use estimates range from approximately 860,000 lbs ai (Florida citrus only) in 1999 to a weighted average for the years 1987-1999 of approximately 1 million lbs ai total.

Overall Risk Summary

EPA's human health risk assessment for ethion indicates some risk concerns. Food risk, both acute and chronic, is not of concern. Drinking water risk estimates based on screening models and monitoring data, exceed levels typically of concern in some cases, but the Agency believes actual

concentrations of ethion in drinking water are much lower. Confirmatory data on the effect of water treatment would have been required had the registrants not requested the voluntary cancellation of their ethion registrations. There are concerns for workers who mix, load, and apply ethion to citrus. Risks to applicators of ethion cattle eartags could not be quantified, but the Agency believes it is prudent to reduce exposures. Risks to some terrestrial and aquatic species are of concern.

To mitigate risks of concern posed by the uses of ethion during the phase-out period, EPA considered mitigation proposals submitted by the stakeholders and decided on a number of label amendments to address the occupational concerns. Results of the risk assessments, and label amendments necessary to mitigate the risks, are presented in this RED.

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water are not of sufficient concern to warrant mitigation for dietary exposures to ethion. The Agency expects that risk estimates for drinking water, while exceeding levels of concern in some cases, are high-end estimates and would likely have been reduced based on data from water treatment studies. As indicated above, these studies will not be required because ethion registrations are being phased-out.Occupational Risk

Occupational exposures to ethion are of concern to the Agency, and it has been determined that a number of mitigation measures are necessary. For the use of ethion on citrus, mixer/loader and applicator risk scenarios are of concern; i.e., Margins of Exposure are less than 100 for both dermal and inhalation exposures. During the phase-out period, these risks will be mitigated with the following label restrictions for the use of ethion on citrus: restricted use classification; only airblast applications will be allowed, with the exception of spot treatments for snow scale; use of closed systems for mixing and loading and enclosed cabs for applicators in airblast applications; spot treatment for snow scale in limited volumes and with additional personal protective equipment. Risks associated with reentry into areas treated with ethion will be mitigated by increasing the restricted entry interval (REI) for high exposure activities (i.e., harvest) to five days from two days for all activities (an exception to the REI for low exposure activities will remain at two days). For the use of ethion-impregnated cattle eartags, risks will be mitigated with label language requiring the use of gloves during application, in addition to baseline personal protective equipment.

Ecological Risk

The ecological risk assessment indicates that some risks are of concern. The Agency has concluded that measures already in place to reduce non-target exposures to ethion, in combination with the restricted use classification, are adequate to address these risk concerns during the phase-out period.

The Agency is issuing this Reregistration Eligibility Document (RED) for ethion, as announced in a Notice of Availability published in the Federal Register. This RED document includes guidance and time frames for complying with label changes for products containing ethion.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to identify the need for additional data on health and environmental effects, and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Ethion belongs to a group of pesticides called organophosphates, which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents the Agency's revised human health and ecological risk assessments; its progress toward tolerance reassessment; and the reregistration eligibility decision for ethion.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments

- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

In addition to the policy issues that resulted from the TRAC process, the Agency issued, on Sept. 29, 2000, a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's baseline approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides. Generally, basic protective measures such as closed mixing/loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals, will be required for most uses where current risk assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this RED are consistent with the Worker Pesticide Registration Notice.

This document consists of six sections. This Section (Section I) contains the regulatory framework for reregistration/tolerance reassessment and descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II profiles the use and usage of the chemical. Section III provides an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes based on the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page http://www.epa.gov/pesticides/op, and in the Public Docket.

II. Chemical Overview

A. Regulatory History

Ethion was first registered in the United States in the 1950's. In 1998, in response to risk concerns, risk mitigation was implemented through reductions in the maximum application rate and number of applications on citrus, prohibition of aerial applications, restrictions on direction of airblast applications, and cancellation of non-commercial uses of ethion.

B. Chemical Identification

- Common Name: Ethion
- Chemical Name: O,O,O',O'-tetraethyl S,S'-methylene bis(phosphorodithioate)
- Chemical Family: Organophosphate
- CAS Registry Number: 563-12-2
- PP Chemical Code: 058401
- Empirical Formula: $C_9H_{22}O_4P_2S_4$
- Vapor Pressure: 1.16 x 10-7 to 5.13 x 10-6 mmHg.
- Metabolites: Ethion monoxon, ethion dioxon
- Basic Manufacturers: Cheminova AGRO A/S, FMC

C. Use Profile

The following information is based on the currently registered uses of ethion.

Type of Pesticide: Non-systemic insecticide/acaricide

Use Sites: Terrestrial food and feed crops: Citrus fruits in Florida and Texas, including grapefruit, lemon, lime, orange, tangelo, temples and tangerines. There is also a single product registered as an eartag for use on beef and lactating dairy cattle. No "public health" uses.

Target Pests: Leaf-feeding insects, mites, scales, horn flies, gulf coast ticks, ear ticks, face flies, lice, stable flies, house flies.

Formulation Types: Emulsifiable concentrates (9.0, 46.5, 47.1, and 81.9%); impregnated material (36.0%)

Method of Application: Ground foliar applications (dilute high volume spray, concentrated low volume spray); cattle eartag

Equipment: (Citrus) high volume ground airblast sprayer; high pressure handwand sprayer; low pressure handwand sprayer

Rate: (Citrus) maximum of 2.5 lbs ai/A per application, with a maximum of two applications per year (maximum 5.0 lbs ai/A/yr)

Spray Interval: 90 days

Use Classification: The 81.9% EC formulation is restricted use; all other ethion end-use products are general use products.

D. Estimated Usage of Ethion

This section summarizes the best estimates available for the pesticide uses of ethion. These estimates are derived from a variety of published and proprietary sources available to the Agency, as well as information supplied by the registrants. Data reflect annual fluctuations in use patterns as well as the variability in data from various information sources. Between 800,000 and 1 million lbs ai of ethion are used on citrus annually. No data were available for the use of ethion in cattle eartags, although usage is likely to be quite small.

Table 1: Estimated Usage of Ethion on Citrus (sources: EPA, USDA, and National Center for Food and Agricultural Policy)

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		LB AI Applied (000)		Average Application Rate3		
		Wtd Avg1	Est Max2	Wtd Avg	Est Max	Wtd Avg	Est Max	lb ai/ acre/yr	#appl/ yr	lb ai/ A/appl
Grapefruit	194	76	111	39.0%	57.0%	250	404	3.3	1.3	2.5
Lemons	63	0	0	0	0	0	1	NA	1.0	NA
Oranges	867	208	300	24.0%	34.6%	640	923	3.1	1.3	2.3
Temples	7	3	6	41.6%	83.1%	11	22	3.8	1.3	2.8
Limes	6	6	6	94.0%	100.0%	18	31	3.1	3.0	1.0
Tangelos	12	5	9	39.6%	59.5%	18	27	3.8	1.4	2.6
Tangerines	26	6	12	23.0%	46.0%	19	38	3.2	1.2	2.7
Total	-	-	-	-	-	956	1446	-	-	-

1 Wtd Avg = Weighted average is based on data for 1987-1996; the most recent years and more reliable data weighted more heavily; values are rounded to the nearest 1000 acres treated
2 Est Max = Estimated maximum
3 Average application rates are calculated from weighted averages.

By contrast, the registrant reports much lower usage in Florida (which should account for 97-98% of use on citrus) in recent years:

1997 396,000 to greater than 400,000 lbs ai
1998 194,000 lbs ai
1999 50,295 lbs ai

Furthermore, EPA sources show much greater usage in 1998 and 1999 (961,000 and 860,000 lbs ai), closer to data from EPA sources.

Ethion usage can vary greatly from year to year based on weather conditions, pest pressures, and overall crop values. The year 1999 was a very dry year; the drought reduced yields, and treatments with ethion and other crop inputs became less economical. A registrant has indicated that the introduction of avermectin decreased usage of ethion beginning about five years ago, but reported resistance problems with avermectin appear to have boosted ethion usage for the last several years (although that effect was offset by the dry weather conditions in 1999).

III. Summary of Ethion Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide ethion, as presented in the documents, "Human Health Risk Assessment-Ethion," dated July 14, 1999, "Transmittal of EFED List A: Summary Report for Ethion," dated September 9, 1994, and subsequent addenda to the health risk document. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and in better understanding the conclusions reached in the assessments.

The risk assessments for ethion were presented at a July 14, 1999 briefing with stakeholders in Florida, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management decision for ethion.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessment for ethion in August 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are discussed below.

A major revision to the dietary risk assessment involves the use of animal data to derive toxicological endpoints. Past assessments had used data from studies with human test subjects to derive endpoints. For the revised assessment, the Agency has selected doses and endpoints to calculate dietary and non-dietary risk based solely on animal studies. The use of animal data to derive endpoints for ethion has resulted in an acute endpoint value which is ten-fold lower than that which would have resulted from the use of the human data (0.0005 mg/kg/day versus 0.005 mg/kg/day for dietary routes). The revised assessment, used an interspecies extrapolation factor informed by the similarities between endpoint values from the human and animal studies-3X rather than the usual 10X. The assessment on which the risk management decisions in this document is based relies on the endpoint values from the animal study, and an interspecies extrapolation factor of 10X. No further assessment of ethion will be conducted in light of the voluntary cancellation.

Another revision to the preliminary risk assessment is the recategorization of subpopulations for estimating dietary risk. Due to low sample numbers, the subpopulations for nursing and non-nursing infants have been combined and replaced with an "all infants" categorization with greater statistical relevance.

The human health risk assessment was revised to include drinking water and aggregate risk assessments. These assessments, required by FQPA, were not part of the preliminary assessment.

The revised risk assessment is based largely upon current label requirements which include a number of risk mitigation measures that had been implemented since the original assessment was completed. These measures include a reduced application rate from 3.0 lb ai/acre to 2.5 lb ai/acre, a reduced number of total applications per year from 3 to 2, elimination of aerial applications, restriction to spraying ethion in a direction away from bodies of water, and the cancellation of all residential uses.

To clarify a change in terminology which does not represent a substantive revision, the July 14, 1999 Human Health Risk Assessment describes dietary risk in terms of the RfD, or reference dose. An RfD adjusted with the appropriate FQPA safety factor is termed a PAD, or population-adjusted dose. This is the terminology which appears in this RED. In the case of ethion, the Agency determined that no additional FQPA safety factor was needed to account for uncertainties in the database or the special sensitivity of children. Had the interspecies extrapolation factor not changed in this revision (as described above), the acute PAD would be numerically identical to the acute RfD. As it is, the difference between the acute RfD cited in the previous assessment and the acute PAD cited in this document is a result of the change in the interspecies extrapolation factor only, not the FQPA safety factor.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all the submitted toxicity studies and determined that the toxicity database is complete and supports a reregistration eligibility determination for all currently registered uses of ethion. A brief overview of the endpoints is outlined in Table 2 below. Further details can be found in the July 14, 1999 human health risk assessment and subsequent addenda.

Table 2. Toxicological Endpoints for Human Dietary Risk Assessment of Ethion

Assessment	NOAEL	Endpoint	Study	PAD
acute dietary	0.05 mg/kg/day	plasma ChEI at0.5 mg/kg/day (LOAEL)	MRID 41188401; chronic toxicity in dogs, observed at Week 3*	0.0005 mg/kg
chronic dietary	0.05 mg/kg/day	plasma, rbc, brain ChEI at0.5 mg/kg/day (LOAEL)	MRID 41188401; chronic toxicity in dogs	0.0005 mg/kg

* The NOAEL is based on plasma cholinesterase inhibition at 0.5 mg/kg/day (LOAEL) observed in a chronic toxicity study in dogs. The plasma cholinesterase inhibition observed during Week 3 of the chronic study was utilized as the endpoint for the acute dietary risk assessment because it occurred at the earliest point in time for which data were available.

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X. The toxicity database includes an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits. These studies show no increased sensitivity to fetuses as compared to maternal animals following acute in utero exposure in the developmental rat and rabbit studies and no increased sensitivity to pups as compared to adults in a multi-generation reproduction study in rats. There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Sufficient actual data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children. Therefore, the 10X factor as required by FQPA was reduced to 1X.

c. Population Adjusted Dose

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose, either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of ethion, the FQPA safety factor is 1; therefore, the acute or chronic RfD is equal to the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

d. Exposure Assumptions

For the dietary (food) risk assessment, dietary exposure was estimated using PDP data for oranges, which were translated to all citrus (grapefruit, tangelos, tangerines, lemons, limes and kumquats); PDP data for orange juice, which were translated to all citrus juices; negligible residues for milk (i.e., no ethion was present); acute anticipated residues for meat; and food consumption data from a 1977-1979 USDA food consumption survey. Percent crop treated data were incorporated into the assessment. Exposure to the only metabolite of toxicological concern (ethion monoxon) was not accounted for in the assessment; the Agency has limited toxicity data on the metabolite and it occurs in treated commodities at much lower levels than the parent material.

A registrant conducted a chronic dietary risk analysis for ethion using the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-91. The chronic dietary exposure estimates resulting from this analysis are in good agreement with EPA's assessment.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose (PAD) does not exceed the Agency's risk concerns. As can be seen in Table 3 below, the ethion acute dietary risk from food is below the Agency's level of concern; that is, less than 100% of the acute PAD is utilized. For example, for the most highly exposed subgroup, children (1-6 years), the % acute PAD value is 43% at the 99.9th percentile of exposure.

Table 3. Acute Dietary Exposure and Risk Estimates

Population	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure mg/kg/d	% of Acute PAD	Exposure mg/kg/d	% of Acute PAD	Exposure mg/kg/d	
US Population	0.000034	6.8	0.000066	13	0.000133	27
All Infants	0.000026	5.2	0.000075	15	0.000147	29
Children (1-6 years old)	0.000069	14	0.000120	24	0.000213	43
Children (7-12 years old)	0.000050	10	0.000087	17	0.000155	32
Females (13-50 years old)	0.000027	5.4	0.000045	9.0	0.000083	17

As can be seen in Table 4 below, the chronic dietary risk from food alone is well below the Agency's level of concern. For the most highly exposed subgroup, children (1-6 years), the % chronic PAD value is 16%.

Table 4. Chronic Dietary Risk Estimates for Ethion

Subgroup	**Exposure (mg/kg/day)**	**% of Chronic PAD**
U.S. population	0.000044	9
Children (1-6 years)	0.000081	16

These analyses could be refined with data on ethion monoxon (the only metabolite of toxicological concern) and monitoring data for commodities other than oranges.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling typically provides a high-end estimate of risk.

The PRZM-EXAMS model was used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. These are considered to be screening models. There are also some monitoring data available for both surface and groundwater.

Groundwater monitoring data and modeling results suggest that the potential for contamination from ethion in groundwater is extremely low. Monitoring data come from the Agency's Pesticides in Ground Water Database (9/92) and the Office of Water's STORET system. Monitoring data indicate no detections in wells even in Florida, where the greatest use occurs.

In contrast, ethion's fate characteristics and monitoring indicate that surface water contamination is possible and does occur. The drinking water assessment for ethion, therefore, is based on surface water sources.

The only environmental degradate of human toxicological concern is ethion monoxon. The environmental fate characteristics of the monoxon are unknown at this time. Currently, there is some uncertainty concerning whether or not this degradate would be found in drinking water.

a. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of drinking water pesticide residues in the diet, EPA first looks at how much of the overall allowable risk is contributed by food (and if appropriate, residential uses), and then determines a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitoring levels exceed this level. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern for dietary risk.

Details of the Agency's drinking water analysis, which used screening models, are found in the HED Human Health Risk Assessment (July 14, 1999) and the addendum dated May 17, 2000.

For acute risk, the potential drinking water exposure for all populations derived from either ground or surface water is of some concern. The DWLOC for the most highly exposed subpopulation, all infants (<1 year old), is 3.4 ppb. The maximum modeled concentration of ethion in surface water is 25 ppb. Even though the DWLOC is exceeded, the Agency has determined that this acute drinking water risk estimate is not of sufficient concern to warrant risk mitigation. The reasons for this determination are explained below.

Monitoring of surface water concentrations in an ethion high usage area and time found concentrations of around 1.0 ppb (the circumstances are described further in the discussion of drinking water chronic risk which follows). This value is much lower than the value derived from surface water monitoring. Because the study from which this value was obtained was not designed to account for daily

fluctuations in water concentrations of ethion, the 1.0 ppb value cannot be used in determining acute risk. Nevertheless, it indicates that the 25 ppb value is a high-end estimate.

In addition, although the maximum modeled surface water concentration exceeds the DWLOCs, ethion has a relatively high soil/water partitioning coefficient which suggests that it will be removed to some extent in the large majority of drinking water treatment facilities through primary settling and flocculation/coagulation. Based on the observed (monitored) concentration used for the chronic assessment, which is considered a high-end assessment, the Agency believes that drinking water from the tap would likely have concentrations of ethion which are actually considerably less than the estimates used for this assessment. A confirmatory study would have been required had the registrants not requested the voluntary cancellation of their products.

For chronic risk, potential exposure to drinking water derived from either surface water or groundwater is not of concern for all populations. The DWLOC for the most highly exposed subpopulation, children (1-6 years old), is 4 ppb; the DWLOC for the U.S. population is 16 ppb. Model estimates of the average concentration of ethion in surface water (6.6 ppb) exceed the former. However, based on a review of surface water monitoring data, the Agency has concluded that the surface water concentration which should be used for estimating chronic exposure is 1.0 ppb. This value is a high-end concentration taken from samples collected at peak ethion usage times, in the county with the greatest citrus production in Florida, in a watershed where grapefruit production is concentrated. Although this value informs our interpretation of the acute drinking water risk assessment (as described above), it is not appropriate to use it in estimating acute drinking water risk because the study from which it was derived does not adequately address daily fluctuations in ethion concentrations. Based on conclusions from the Florida monitoring study, the chronic drinking water risk from ethion is not of concern.

3. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of ethion include: individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators, and workers who enter treated areas to harvest or perform maintenance tasks. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern.

a. Toxicity

The toxicity of ethion is a key component in assessing occupational risk. The risk calculations cited in this document are based on the most current toxicity information available for ethion, including a 21-

day dermal toxicity study in rabbits. The toxicological endpoints used in the occupational risk assessment for ethion are:

- Short and intermediate-term dermal endpoint: brain cholinesterase inhibition observed at the LOAEL of 1.0 mg/kg/day in a 21-day dermal toxicity study in rabbits (MRID 00155499). The NOAEL in this study is 0.8 mg/kg/day. A dermal absorption factor was not required.
- Short and intermediate term inhalation: plasma cholinesterase inhibition observed at the LOAEL of 0.5 mg/kg/day in the chronic dog feeding study (MRID No. 41188401) . The NOAEL in this study is 0.05 mg/kg/day. An absorption factor of 100 percent was assumed for route to route extrapolation (dietary to inhalation) in the absence of empirical data.

In addition, the Agency cites the following acute toxicity information:

Table 5. Acute Toxicity Profile for Ethion (relevant to worker exposures)

Study	Result	Toxicity category	MRID#
Acute dermal LD50 (rat)	838 mg/kg	II	00157590
Acute inhalation LC50 (rat)	2.31 mg/L (M)0.45 mg/L (F)	II	00163159
Primary eye irritation (rabbit)	slight redness	IV	00157590
Primary dermal irritation (rabbit)	slight erythema	IV	00157590
Dermal sensitization(guinea pig)	non-sensitizer	NA	00141205

b. Exposure

Chemical-specific exposure data were not available for ethion, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). Standard assumptions such as average body weight, work day, and daily areas treated were used to calculate risk estimates. Some PHED data are of better quality than others, but all are the best data currently available to the Agency. The quality of the data used for each scenario is discussed in the Human Health Assessment document for ethion, which is available in the public docket.

Anticipated use patterns, application methods, and application rate were derived from current ethion product labeling and discussions with ethion stakeholders. The maximum application rate for airblast applications specified on labels of ethion products used on citrus is 2.5 lbs. active ingredient per acre; the rate for the spot treatment of snow scale is 0.05 lb. active ingredient per gallon. The Agency typically uses acres treated per day values that are thought to represent 8 solid hours of application work for most types of application equipment.

Occupational handler exposure assessments are conducted by the Agency for different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). If the associated MOEs are less than 100 at one tier, the Agency will assess increasing levels of risk mitigation (personal protective equipment and engineering controls) until adequate MOEs are obtained.

The current labels for ethion require handlers to wear coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear with socks; protective eyewear and chemical-resistant apron when mixing/loading, dust/mist filtering respirator (outdoor exposure), and respirator with approved pesticide cannister (indoor exposure). This level of protection did not result in adequate MOEs; the additional levels of protection which were used as the basis for estimates of exposure from ethion on citrus are:

- Maximum Personal Protective Equipment(PPE): coveralls over long sleeved shirt, long pants, chemical-resistant gloves, and a half-face dust/mist respirator.
- Engineering controls: enclosed cab tractor and closed mixing/loading system (with a single layer of clothing, and gloves for mixer/loaders and airblast applicators). Engineering controls typically are not applicable to handheld application methods.

The risk estimates for handlers of ethion used on citrus are for short-term and intermediate-term exposures. The Agency does not have reliable data for estimating exposure from the cattle eartag use of ethion, for either exposure related to current labeling or additional protective measures. The Agency evaluated measures which it believes are prudent to reduce exposure from the eartag use.

Exposure to workers through entry into citrus groves treated with ethion were also considered.

c. Occupational Handler Risk Summary

Risks were assessed for mixer/loaders supporting airblast and high pressure handwand applications of ethion on citrus, applicators using airblast and high pressure handwand equipment for ethion on citrus, and mixer/loader/applicators using backpack sprayers and low pressure handwand equipment for ethion on citrus. These scenarios are:

- Mixing/loading (M/L) liquids for airblast sprayer application (2.5 lb ai/A, 17 acres)
- M/L liquids for high pressure handwand application (0.05 lb ai/gal, 1000 gallons)
- Applying sprays using an airblast sprayer (2.5 lb ai/A, 17 acres)
- Applying sprays using a high pressure handwand (0.05 lb ai/gal, 1000 gallons)
- Mixing/loading/applying (M/L/A) w/a backpack sprayer (0.05 lb ai/gal., 40 gallons)

- M/L/A sprays using a low pressure handwand, (0.05 lb ai/gal., 40 gallons)

In addition, the Agency was asked to consider a spot treatment application for snow scale on the trunk and limbs of citrus trees which is part of an IPM program to control the pest. The spot treatment of affected trees has a lesser impact on predators of the snow scale than a whole-grove airblast treatment. The spot treatment uses a high-pressure hand gun attached to a truck- or trailer-mounted tank; the application rate is no more than 5 gallons per tree at 0.01 lb ai/gal with no more than 250 gallons applied by an applicator per day.

1) Occupational Handler Risk

All these scenarios, evaluated based on current label requirements, pose risks of concern. These risks, based on combined dermal and inhalation exposures, are summarized in Table 6. The effects of additional controls on risk are also summarized. Risks of concern, with MOEs less than 100, are associated with hand-held equipment (high and low pressure handwands and backpack sprayers) even when wearing added personal protective equipment, and for applicators operating airblast sprayers from enclosed cab tractors. The added protective measures in these cases represent the feasible maximum personal protective equipment and engineering controls.

Table 6: Handler Exposure and Margins of Exposure for Short- and Intermediate-Term Exposures to Ethion
Scenario Maximum PPE Engineering Controls

Scenarios	Maximum PPE					Engineering Controls				
	Daily Dermal Dose (mg/kg/day)	Dermal MOE	Daily Inhalation Dose (mg/kg/day)	Inhal-ation MOE	Total MOE	Daily Dermal Dose (mg/kg/day)	Dermal MOE	Daily Inhalation Dose (mg/kg/day)	Inhalation MOE	Total MOE
Mixer/Loader Risk										
Airblast Application	0.010	80	1.5 E-4	330	64	5.5 E-3 (with gloves)	145	4.9 E-5	1020	130
High Pressure Handwand Application	0.012	67	1.7 E-4	290	54	0.006	130	6.0 E-5	830	110
Applicator Risk										
Airblast Sprayer	0.13	6	5.4 E-4	93	5.6	0.012 (with gloves)	67	2.7 E-4	190	50
High Pressure Handwan	0.26	3.1	0.011	4.5	1.8	None	None	None	None	None

d										
Mixer/Loader/Applicator Risk										
Backpack Sprayer	0.046	18	1.7 E-4	290	17	None	None	None	None	None
Low Pressure Handwand	0.011	73	1.7 E-4	290	58	None	None	None	None	None

Dermal MOE = Dermal NOAEL (0.8 mg/kg/day)/Daily Dermal Dose
Inhalation MOE = Oral NOAEL (0.05 mg/kg/day) / Daily Inhalation Dose
Total MOE = 1/[1/Dermal MOE + 1/Inhalation MOE]
Maximum PPE: coveralls, long pants, long sleeve shirt, chemical-resistant gloves, and half face dust/mist respirator (w/open mixing and open cab).
Engineering controls: for M/L, closed mixing/loading; for applicators, enclosed cab (both w/single layer clothing; gloves only where noted, no respirator).
None = Engineering Controls are not feasible.

The MOE for mixer/loader/applicators in the snow scale spot treatment in the low volume scenario described above, wearing cotton coveralls over long-sleeved shirt and long pants, shoes, socks, chemical- resistant gloves, a dust/mist respirator, chemical-resistant apron for mixing and loading, and chemical-resistant headgear for overhead exposures, is 73.

2) Post-Application Occupational Risk

A post-application occupational risk assessment for ethion was conducted for exposures in citrus orchards. The assessment utilizes dislodgeable foliar residue (DFR) data for ethion on citrus. Although the Agency considers these data to be the best available DFR data, the subject study was deemed unacceptable by the Agency. It was conducted at a higher application rate than the 2.5 lb. ai/A maximum. Exposure estimates have been adjusted accordingly. The MOEs in Table 7 reflect that adjustment. The risk estimates in Table 7 also utilize new transfer coefficient data.

Table 7. Summary of Margins of Exposure for Restricted-Entry Intervals for Citrus

Time after Treatment	MOE Calculations	
	Ethion Only	Total: Ethion + Oxon*
12 hours	11	10
1 day	16	14
2 days	22	18
3 days	31	26
4 days	44	35

5 days	63	49
6 days	88	67
7 days	109	80
8 days	162	117
9 days	224	159

*Oxon represents the total, monoxon plus dioxon.

The current REI for foliar treatments with ethion is two days. As indicated in Table 7, the MOEs for reentry do not rise above 100 until the ninth day following application. MOEs less than 100 represent risks of concern.

4. Aggregate Risk Characterization

An aggregate risk assessment typically looks at the combined risk from dietary exposure (food and drinking water routes) and residential exposure. Since ethion has no uses in which residential exposure or other non-occupational exposure is likely, the aggregate risk assessment for ethion is comprised of food and drinking water dietary risks only. The aggregate exposure risk assessments appropriate for ethion are acute (1-day) and chronic (lifetime) exposure.

The acute aggregate risk estimates for ethion are not of sufficient concern to warrant risk mitigation. The acute dietary risk for food only for the most highly exposed subpopulation is estimated at 43% of the acute PAD. Groundwater monitoring data and modeling results suggest that the potential for groundwater contamination from ethion is extremely low. Modeling estimated environmental concentrations (EECs) of ethion in groundwater of 0.05 ppb. This estimate is well below the drinking water level of comparisons (DWLOCs) for the US population of 13 ppb and the most highly exposed subpopulation (all infants) of 3.4 ppb.

Surface water modeling yields a maximum EEC for ethion in surface water of 25 ppb. This estimate exceeds the DWLOC for the US population of 16 ppb and the most highly exposed subpopulation (all infants) of 3.4 ppb, but is considered a high-end estimate. The relatively high soil/water partitioning coefficient of ethion suggests that concentrations will be reduced in most surface water source drinking water through typical methods employed in water treatment facilities. Concentrations of ethion in drinking water which reaches the consumer tap are likely to be considerably less than the estimates derived from surface water modeling. The Agency would have required data on the effect of typical water treatment methodologies on concentrations of ethion in order to confirm this conclusion, but will not since ethion will be phased-out in the near future.

The chronic aggregate risk estimates are not of concern. The chronic dietary risk for food only for the most highly exposed subpopulation is estimated at 16% of the PAD. The chronic DWLOC for the US

population is 16 ppb and for the most highly exposed subpopulation (children 1-6) is 4 ppb. The groundwater EEC is 0.05 ppb, and the Agency has reviewed extensive surface water monitoring data to conclude that the surface water concentration which should be used for estimating chronic exposure is 1.0 ppb. This estimate is less than the chronic DWLOC for the most highly exposed subgroup, therefore, the Agency has concluded that chronic aggregate risk from ethion is not of concern.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated July 14, 1999, available in the public docket.

1. Environmental Fate and Transport

Ethion is moderately persistent in the environment. The primary routes of dissipation appear to be chemical hydrolysis under alkaline conditions and microbial degradation. Ethion degrades to carbon dioxide, ethion monoxon, ethion dioxon, and several polar degradates including diethyl thiophosphate (ESOP), diethyl dithiophosphoric acid (ESSP), and formaldehyde and/or thioformaldehyde. Under anaerobic soil conditions, O,O-diethyl-S-(methylthio)methyl-phosphorodithioate was also identified. The polar degradates and CO2 were the predominant products in laboratory tests. After aging in soil for 30 days, ethion residues were not mobile. The mobility of unaged ethion is not conclusively known at this time. Based on the laboratory and field data submitted thus far, including monitoring data compiled in EPA's Pesticides In Ground Water Database, it is not expected that ethion will pose a threat to groundwater, though it may accumulate in soil if multiple applications are made during a growing season. The mobility of its toxicologically significant degradate, ethion monoxon, is unknown. Volatilization from soil is not an important route of dissipation.

Although it is not likely that ethion will contaminate surface water by way of dissolved runoff, movement into surface water may occur through erosion and/or spray drift. Microbial degradation of ethion in soil is slow. In two studies in Florida orange groves with sandy soils, ethion dissipated with half-lives of 67 to 68 days from the upper 6 inches at the drip line of trees, and 74 to 83 days from the upper six inches from the rows between the trees treated with ethion. The degradate ethion monoxide was also detected.

2. Risk to Birds and Mammals

Ethion ranges from highly toxic to practically nontoxic to birds on an acute oral basis. Ethion is practically nontoxic to tested avian species on a subacute dietary basis. Avian reproductive effects in the mallard duck may occur when residues levels are greater than 75 ppm. Ethion is highly toxic to small mammals and bees on an acute basis. Ethion residues are expected to occur on a large number of potential food sources including seeds, fruits, and insects. Because numerous species inhabit areas

where ethion is used and birds often nest in trees or near the areas where ethion is applied, exposure through dietary ingestion or direct dermal application is a distinct likelihood.

Acute risk quotients for terrestrial species at the maximum allowable application rate range from 0.012 to 0.41 and do not exceed high acute risk levels of concern, although restricted use and endangered species levels of concern are exceeded. Chronic risk quotients range from 0.8 to 27.6, in some cases exceeding chronic levels of concern.

3. Risk to Aquatic Species

Ethion displays very high toxicity to most aquatic organisms tested. Even at the less than maximum application rate of 1.0 lbs. ai/A, acute risk quotients exceed levels of concern for aquatic invertebrates (with risk quotients ranging from 108 to 655) and some fish species (risk quotients ranging from 0.12 to 0.74). Chronic risk quotients exceed levels of concern for fish (risk quotients ranging from 321 to 1921). There are no chronic data for invertebrates.

IV. Reregistration Eligibility and Risk Management Decisions

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 products containing the active ingredient are eligible for reregistration. The Agency identified and required the submission of the generic (i.e., active ingredient-specific) data needed to support the reregistration of products containing ethion.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticides containing the active ingredient ethion, as well as an ethion-specific dietary risk assessment that has not considered the cumulative effects of organophosphates as a class. The Appendix to this document identifies the generic data requirements that the Agency reviewed and lists the submitted studies that the Agency found acceptable.

As a result of its assessment of the risks associated with ethion alone, EPA has determined that registrations of ethion, unless amended as set forth in this document, present risks inconsistent with FIFRA. The registrants have proposed the voluntary cancellation of ethion registrations as well as phase-out dates, with risk mitigation measures to be effective in the interim before cancellation. The sale and distribution of ethion products will cease on December 31, 2003 by the registrants, and these products may not be legally used after December 31, 2004.

B. Summary of Phase 5 Comments and Responses

When making its reregistration decision, the Agency took into account all comments received during Phase 5 of the OP Pilot Process. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Comment: The Agency has improperly removed the tenfold FQPA safety factor for ethion. In the absence of developmental neurotoxicity testing, children cannot be shown to have no special sensitivity to ethion. Risks associated with the contamination of residences adjacent to treated areas and limited monitoring data have not been factored into the safety factor decision-making.

Response: Because ethion is being phased-out, exposures to children and to the general population will drop off markedly in the next several years. The best data available to the Agency show no differential pre- and post-natal effects for developmental exposure to ethion, although the Agency would have required data specifically on developmental neurotoxicity for use in refining risk estimates if ethion were not being phased-out. Residential use of ethion has been prohibited since 1998.

Comment: Exposures to ethion cannot be considered to pose a reasonable certainty of no harm until the cumulative assessment of the organophosphates is considered.

Response: The Agency has completed its regulatory decision for ethion. Because all ethion registrations are being canceled, the Agency believes that no additional risk mitigation or risk assessment is necessary.

Comment: EPA has no basis for using the results of human testing in the ethion risk assessment.

Response: The ethion risk assessment was revised without using human data. Because of the voluntary cancellation, no further revisions will be made.

Comment: Ethion has been used for many years with few cases of worker exposure.

Response: The Agency has evidence of a number of worker incidents associated with ethion exposure, which it considers to lend support to the calculated risks. In general, the Agency believes that such incidents are under reported and cannot be used to quantify risk.

Comment: The greater risk estimate for applicators relative to mixer/loaders is counterintuitive.

Response: The risk estimates in Table 6 are estimates for increased levels of protection over the baseline. Estimates for baseline PPE (that which is required by current labels) show that dermal risks for mixer/loaders are greater than for applicators while inhalation risks are greater for applicators. Risks are greater overall for applicators with maximum PPE, suggesting that maximum PPE is affording more protection to mixer/loaders than applicators.

Comment: Ethion is relatively inexpensive to apply and affords good control of many pest species.

Response: The Agency agrees that ethion can be a valuable tool in pest management, and has considered the benefits of its use in making risk management decisions.

Comment: Because ethion is a general use pesticide, it is available to small growers who would not be able to purchase enclosed cabs with filters that remove pesticide residues from the air.

Response: The Agency does not believe an open cab tractor is adequately protective for any user, and so has specified a general type of enclosed cab which does reduce potential exposure. An extended timeline for implementing the enclosed cabs is intended to help growers anticipate the need for these cabs and to more readily acquire them. Additionally, between 50 and 70% of Florida citrus growers are reported to already own enclosed cab tractors, and the Agency believes that renting this equipment or paying for custom application with enclosed cabs is relatively inexpensive.

Comment: An REI of nine or five days would limit routine agricultural operations.

Response: The Agency considered the economic impacts of the REI, as well as preliminary indications that post-application exposures may actually be lower than the exposures on which the quantitative assessment was based, to determine appropriate REIs for citrus. In addition, the Agency has determined that a shorter REI is appropriate for activities which would be expected to result in less exposure than hand-harvesting of citrus fruits.

Comment: Restrictions on ethion will increase costs for growers, reduce volume applied, and cause the registrants to reconsider their support of the registrations.

Response: The Agency considered available information on the benefits of ethion in making its risk management decision. However, the considerable worker risk associated with this chemical necessitated use of the maximum protection available, i.e., engineering controls. The Agency is allowing time prior to the implementation of risk mitigation to provide a transition period. In addition, the length of the phase-out reflects the benefits of the chemical's use.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this organophosphate. EPA has determined that risk from exposure to ethion is within its own "risk cup." In other words, if ethion did not share a common mechanism of toxicity with other chemicals, EPA

would be able to conclude today that the tolerances for ethion, with some adjustments, meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to ethion "fit" within the individual risk cup.

b. Tolerance Summary

In the individual assessment, tolerances for residues of ethion (40 CFR §180.173) are presently expressed in terms of ethion and its oxygen analog.

At the time when individual organophosphates are being assessed for reregistration eligibility, the Agency will commence proceedings to revoke and lower existing tolerances, and correct commodity definitions. At this time, for ethion, the tolerances listed in 40 CFR § 180.173 for ethion in dried tea and raisins will be revoked. Ethion is not currently registered for use on tea or grapes and the registrant does not intend to support these uses.

Tolerances on all other commodities will be revoked in accordance with the phase-out schedule for ethion registrations. The Agency is proposing at this time that these tolerances will be revoked consistent with the anticipated final use date of December 31, 2004 and a reasonable period for the passage of commodities with legal ethion residues through the channels of trade.

The status of tolerances for ethion is detailed in Table 8 below.

Table 8. Tolerance Summary for Ethion

Commmodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Timing of Revocation Action
Tolerances listed under 40 CFR § 180.173			
Cattle, fat	2.5	0.2	defer1
Cattle, meat (fat basis)	2.5	0.2	defer
Cattle, mbyp	1.0	0.2	defer
Citrus, fruits	2.0	5.0	defer
Citrus, pulp, dehydrated	10	25	defer
Dried tea	10	Revoke	following this RED
Goats, mbyp	0.2	0.2	defer

Hogs, fat	0.2	0.2	defer
Hogs, meat	0.2	0.2	defer
Hogs, mybp	0.2	0.2	defer
Horses, fat	0.2	0.2	defer
Horses, meat	0.2	0.2	defer
Horses, mbyp	0.2	0.2	defer
Milk fat	0.5	0.5	defer
Raisins	4	Revoke	following this RED
Sheep, meat	0.2	0..2	defer
Sheep, mybp	0.2	0.2	defer
Tolerances to be Proposed under 40 CFR § 180.173			
Citrus, oil	N/A	55	defer

1 proposed revocation will be consistent with last date of legal use

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 such endocrine effects as the Administrator may designate." Following the 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 the Program include evaluations of potential effects in wildlife. For pesticide chemicals, 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).

If ethion registrations are still active when the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, ethion may be subjected to additional screening and/or testing to characterize effects related to endocrine disruption.

3. Label Modifications and Terms and Conditions of Registration

The registrants holding technical registrations for ethion have agreed to amend labels to reduce risks to workers and nontarget organisms in the interim prior to cancellation.

These amendments will result in labeling changes effective for the 2002 use season; the labeling will also inform users of the phase-out schedule. The legal sale and distribution of ethion by the registrants will cease by December 31, 2003. The last legal use date of ethion will be determined after publication of a notice of voluntary cancellation as required by sec. 6(f) of FIFRA. Barring substantive comment that date is likely to be December 31, 2004. The regulatory rationale for each of the mitigation measures outlined below is discussed in the section immediately following.

a. Citrus Use

For use on citrus, the registrants have agreed that:

- All ethion products will be classified as Restricted Use Pesticides, based on worker risk and risks to wildlife.
- Only airblast applications will be allowed, except for spot treatment of snow scale, and in both cases, only truck- or trailer-mounted sprayers will be allowed. This restriction will eliminate applications with high and low pressure handwands and backpack sprayers.
- Product labels will be amended to specify that 1) the spot treatments be made with a high-pressure hand-gun attached to a truck- or trailer-mounted tank; 2) applicators making the spot treatments wear cotton coveralls over long-sleeved shirt and long pants, shoes, socks, chemical-resistant gloves, chemical-resistant headgear for overhead exposures, and a dust/mist filtering respirator; 3) applicators use no more than 2.5 lbs ai/day, diluting to 250 gallons for a final concentration of 0.01 lb ai/gal.
- Airblast applications will be made using enclosed cabs. The type of enclosed cab required will be what is required by the WPS and will be articulated on the product label as "as a cab with a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside of the cab" and which provides "protection equivalent to a dust/mist filtering respirator." Alternatively, an enclosed cab affording dermal protection will be allowed in conjunction with the use of a personal dust/mist filtering respirator.
- Closed systems will be used for mixing/loading operations which support airblast applications. The registrants have agreed that production of product for use in 2002 and beyond will be in appropriate containers.
- For reentry into citrus groves which have been treated with ethion the REI will be five days, with an exception for low exposure activities (i.e., irrigation tasks and scouting) after two days.

b. Cattle Eartag Use

For cattle eartags, the registrants have agreed that:

- Persons applying cattle eartags containing ethion will wear chemical-resistant gloves, in addition to baseline personal protective equipment.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of ethion. Where labeling revisions are imposed, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Mitigation

a. Dietary Risk Mitigation

Acute dietary risks are not of sufficient concern to warrant risk mitigation in this area. Data would have been required to assess the ability of water treatment plants to remove ethion from surface water-sourced drinking water. These data will not be required due to the phase-out. Chronic dietary risks are not of concern, so no risk mitigation is required in this area.

b. Occupational Risk Mitigation

Occupational risks associated with ethion are significant. The registrants have agreed that all ethion end-use products will be designated as Restricted Use Pesticides.

The risks associated with mixing, loading, and applying ethion in low and high pressure handwand and backpack sprayer equipment are of concern even when handlers wear the maximum practical personal protective equipment. Engineering controls are not feasible for the handwand and backpack sprayer equipment. The registrants have agreed to remove the use of ethion in low pressure handwands, high pressure handwands, and backpack sprayers from product labels. All products labeled for use on citrus will bear language indicating that the product may only be applied using an airblast sprayer and, for spot treatment of snow scale only, a high-pressure hand-gun attached to a truck- or trailer-mounted tank.

The risks associated with mixing/loading and application of ethion by airblast sprayers are of concern, although these concerns are mitigated to some degree by the use of closed mixing/loading systems and enclosed cab tractors. The registrants have agreed to amend labels to indicate that product to be used in an airblast sprayer, beginning in 2002, may only be mixed and loaded in a closed mixing/loading system. The registrants have agreed that product to be used in 2002 and beyond will be marketed in containers which are compatible with closed mixing/loading systems as described in this document.

The registrants have also agreed to amend labels to indicate that product applied with an airblast sprayer, beginning in 2002, may only be applied from within an enclosed cab. This enclosed cab is defined as a cab having a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside of the cab and is equivalent in protection to a dust/mist filtering respirator. Alternatively, applicators may use an enclosed cab which provides dermal protection in conjunction with a personal dust/mist filtering respirator.

The risks associated with the cattle eartag product have not been quantified, but the registrants have agreed that it is prudent to require handlers to wear chemical-resistant gloves and baseline personal protective equipment during handling.

Risk estimates for workers reentering treated areas for up to eight days after treatment with ethion have MOEs less than 100. The Agency has considered the potential economic impacts associated with the inability of growers to fill packing house orders if workers are not able to enter the fields to harvest fruit for longer intervals after ethion is applied. Because citrus fruit of some varieties becomes ready for harvest continuously over an extended period of time, during which ethion is typically applied, a long REI would prevent some harvest of fruit contracted for delivery to packing houses. The Agency considered the potential impact of such failures to deliver to packing houses at the designated times and the prospective cancellation of ethion registrations in establishing an REI less than that required to raise calculated MOEs over 100. The Agency also has identified low exposure activities (irrigation activities and scouting) for which a shorter exception to the reentry interval is thought to be appropriate. The registrants have agreed to amend product labels to reflect an REI of five days, with an exception for low exposure activities after two days.

c. Residential Risk Mitigation

There are no residential uses for ethion, so no risk mitigation is required in this area.

2. Environmental Risk Mitigation

Risk estimates for some wildlife species are of concern for several citrus scenarios. The Agency has determined that, while it is not possible to quantify the associated risk reduction, risk mitigation implemented previously in the reregistration process (and reflected on labels of ethion products for use on citrus) adequately addresses risk concerns at this time, when viewed in conjunction with the new Restricted Use classification. These measures include, for use on citrus, a reduction of the maximum application rate to 2.5 lb ai/A, reduction of the number of total applications per year to 2, elimination of aerial applications, requirement for spraying ethion in a direction away from adjacent bodies of water, and the cancellation of all residential uses.

E. Other Labeling Requirements

The Agency has identified other use and safety information to be placed on the labeling of all end-use products containing ethion. For the specific labeling statements, refer to Section V of this document

1. Endangered Species Statement

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 will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as it develops, the final program will call for any necessary label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program will be described in a future Federal Register notice. At this time, the Agency is not requiring label modifications for ethion specific to the protection of endangered species. Any requirements for product use modifications in the future will occur under the Endangered Species Protection Program.

A 1989 opinion on ethion from the US Fish and Wildlife Service found the potential for jeopardy to a number of invertebrate, amphibian and fish species. The Service provided "reasonable and prudent alternatives" to reduce exposure of these jeopardized species to ethion. Effects to endangered birds and mammals were not assessed in this opinion. The Agency subsequently concluded that it is unlikely that endangered birds and mammals are exposed from the use of ethion on citrus. Although some endangered species are found in the Florida counties where citrus is grown, their habitat and food preferences would likely preclude their use of citrus groves as habitat or feeding areas.

The registrants of ethion have agreed to the future cancellation of their registrations, and during the phase-out period risks are be mitigated by new measures and measures which have been in place for several years. These measures include the Restricted Use classification, elimination of aerial application, reduction of the application rate to 2.5 lb ai/A/application with no more than two applications per year, directional spraying of citrus with airblast sprayers away from surface water.

Although many additional species, especially aquatic species, have been federally listed as endangered/threatened since the biological opinion of 1989 was written, the Agency believes that the continued use of ethion with the agreed-upon risk reduction measures, particularly the elimination of aerial applications, the reduction in application rate, and directional application--coupled with the phase-out of ethion use anticipated by December 31, 2004--will not affect any additional species not covered by the 1989 biological opinion.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling as specified in section V of this document . The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. Since ethion is no longer applied aerially, labels will be amended to include the following spray drift related language.

"Do not apply this product in a way that will cantact workers or other persons, either directly or through drift. Only protected handlers may be in treated area during application.

"Do not allow spray to drift from the application site and contact people, structures people occupy at any time, non-target property on which those structures are located, animals, non-target crops, parks and recreation areas, aquatic and wetland areas, forests, pastures, and rangelands.

"For airblast applications, apply only when wind speed is 10 mph or less at the application site, as measured by an anemometer outside of the orchard on the upwind side.

"The applicator must use all other measures necessary to control drift in addition to the drift control measures listed above."

V. What Registrants Need to Do

In order to maintain registration during the phase-off period, registrants need to implement the risk mitigation measures outlined in Section IV. Additionally:

For each product containing ethion, registrants need to submit the following items within two months of the date of this document:

(1) an application for registration amendment (EPA Form 8570-1, filled in, with a description on the application, such as, "Responding to Reregistration Eligibility Decision" document);

(2) five copies of the draft label incorporating all label amendments outlined in Table 9 of this document;

(3) two copies of the Confidential Statement of Formula (CSF)

These materials should be addressed to:

By US mail:

Document Processing Desk (Ethion/RD)
Marilyn Mautz
US EPA (7505C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:

Document Processing Desk (Ethion/RD)
Marilyn Mautz
Office of Pesticide Programs (7505C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

The draft labeling, once approved by the Agency, will appear on labels of end-use product which will be used beginning January 1, 2002, as agreed by the Agency and the registrants.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of ethion for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

Guideline 835.1230 Sediment and soil adsorption/desorption of ethion and ethion monoxon
Guideline 835.6100 Terrestrial field dissipation
Guideline 850.1010 Freshwater invertebrate acute toxicity (Daphnia)
Guideline 850.1300 Freshwater invertebrate life-cycle (Daphnia)

Guideline 850.1500 Fish life-cycle
Guideline 850.2300 Avian reproduction (bobwhite)
Special study Effectiveness of water treatment methods in removing ethion from drinking water

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999, 64 FR 42945-42947;
August 18, 1999, 64 FR 44922-44923). DCI requirements included acute, subchronic, and

developmental neurotoxicity studies; the due date is September 2001. Acute and chronic neurotoxicity studies have been submitted and found acceptable. Because ethion registrations are being voluntarily canceled, EPA is not requiring the data listed above at this time

2. Labeling for Manufacturing-Use Products

Manufacturing use product (MUP) labeling will be revised as agreed by the Agency and the registrants and will comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the language contained in Table 9 at the end of this section.

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. Because ethion registrations will be canceled in the near future, EPA will not require such data.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to implement these changes is detailed in Table 9 at the end of this section.

C. Existing Stocks

Registrants and persons other than the registrant remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute. As agreed by the Agency and the registrants, the sale and distribution of ethion by the registrants will cease on December 31, 2003; barring any substantive comment, the last use date for ethion products is anticipated to be December 31, 2004.

D. Labeling Changes Summary Table

Table 9. Summary of Labeling Changes for Ethion		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
Statement describing allowed uses.	"Only for formulation into an insecticide/acaricide for the following uses: air blast treatment on citrus, spot treatment for snow scale control on citrus, and as a cattle eartag."	Directions for Use
Environmental Hazards	"This chemical is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries,	Directions for Use

Statements Required by the RED and Agency Label Policies	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."	
General Sale and Distribution Restrictions	"The sale and distribution of this product is prohibited after [October 1, 2003]. The use of this product is prohibited after [December 31, 2003]."	Directions for Use
All End-Use Products		
General Application Restrictions	"The sale and distribution of this product by the registrants is prohibited after [December 31, 2003]. The sale and distribution of this product by anyone other than the registrants is prohibited after [October 1, 2004]. The use of this product is prohibited after [December 31, 2004]."	Place in the Directions for Use directly above the Agricultural use Box
End-Use Products for Use on Citrus		
Restricted Use Pesticide Requirement	"Restricted Use Pesticide" This product is a Restricted Use Pesticide due to worker and ecological risk. "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators certification."	Top of first page of label
All End-Use Products		
ProductsPPE Requirements Established by the RED	"Personal Protective Equipment (PPE)" Some materials that are chemical-resistant to this product are (registrant inserts correct chemical-resistant material). If you want more options, follow the instructions for category (registrant inserts A,B,C,D,E,F,G,or H) on an EPA chemical-resistance category selection chart."Mixers, loaders, applicators and other handlers supporting airblast applications must wear: • Long-sleeved shirt & long pants • Shoes plus socks • Chemical-resistant gloves and chemical-resistant	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	apron for mixers and loaders and persons exposed to concentrate. "See Engineering Controls for additional requirements. "Mixers, loaders, and applicators supporting high-pressure hand-gun applications from truck- or trailer-mounted tanks must wear: • Coveralls over long-sleeved shirt & long pants • Chemical-resistant footwear plus socks • Chemical-resistant gloves • Chemical-resistant apron for mixers and loaders and persons exposed to concentrate • A NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any R, P, or HE filter." • Chemical-resistant headgear"	
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following the PPE requirements)
Engineering Controls	"Engineering Controls" • Mixers and loaders must: -- use a closed mixing/loading system with a dry disconnect system designed by the manufacturer to enclose the liquid pesticide to prevent it from contacting handlers or other people AND the system must be functioning properly and must be used and maintained in accordance with the manufacturer's written operating instructions. "Mixers and loaders must also: • wear the personal protective equipment required for mixers/loaders in the PPE section of this labeling,	Precautionary Statements: Hazards to Humans and Domestic Animals (immediately following PPE and User Safety Requirements.)

- wear protective eyewear if the system operates under pressure,
  and
- have immediately available for use in case of an accident
  - a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or
  - a NIOSH -approved respirator with any R, P or HE filter, and
  - coveralls and chemical-resistant footwear."

"Applicators using airblast equipment must use an enclosed cab, defined as a cab with a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside of the cab. The enclosed cab must meet the requirements in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for inhalation protection providing at least as much respiratory protection as the type of dust/mist filtering respirator specified in the PPE section of this labeling.

"Alternatively, applicators using airblast equipment may use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators using this type of cab must wear the type of dust/mist filtering respirator specified in the PPE section of this labeling.

"All such applicators, regardless of which type of enclosed cab they are using, must also:

- wear the personal protective equipment required in the PPE section of this labeling for applicators using airblast equipment
- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure, and a respirator of the type specified in the PPE section of this labeling
- e off any PPE that was worn in the treated area before reentering the cab, and tak
- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."

User Safety Recommendations	"User Safety Recommendations "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls(Must be placed in a box.)
Environmental Hazards	"Environmental Hazards "This chemical is toxic to wildlife. Spray last three rows windward of surface water, using nozzles on grove side only, with spray directed away from surface water. Avoid spray going over tops of trees by adjusting or turning off top nozzles. Shut off nozzles on the side away from the grove when spraying the outside row. Shut off nozzles when turning at ends of rows and passing gaps in rows. Do not contaminate water when cleaning equipment or disposing of equipment washwaters."	Precautionary Statements immediately following User Safety Recommendations
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of five days. Exception: In addition to early-entry exceptions allowed by the WPS, you may enter and or allow workers/handlers to enter treated areas to perform irrigation and/or scouting tasks 3 days after application, as long as at least long pants, long-sleeved shirt, shoes, and socks are worn. Notify workers of the exception (including when entry is permitted for each of the tasks named in the exception) by warning them orally OR by posting warning signs at the entrances to treated areas."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment	"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:-- Coveralls over short-sleeved shirt and short pants-- Chemical-resistant gloves made of waterproof material-- Chemical-resistant footwear plus socks- Chemical-resistant headgear for overhead exposures."	Directions for Use, Agricultural Use Requirements Box
Double	"Notify workers of the application by warning them orally and	

Notification Statement	by posting warning signs at entrances to treated areas."	
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."Do not allow spray to drift from the application site and contact people, structures people occupy at any time, non-target property on which those structures are located, animals, non-target crops, parks and recreation areas, aquatic and wetland areas, forests, pastures, and rangelands."For airblast applications, apply only when wind speed is 10 mph or less at the application site, as measured by an anemometer outside of the orchard on the upwind side."The applicator must use all other measures necessary to control drift in addition to the drift control measures listed above."	Place in the Directions for Use directly above the Agricultural Use Box
Site Specific Application Restrictions	"This product may only be applied to citrus."Note to registrant: All other sites must be removed from all product labels."This product may only be applied to citrus via airblast sprayer or, for spot treatment of snow scale on citrus, via high-pressure hand-gun attached to a truck- or trailer-mounted tank. All other application methods are prohibited."Note to registrants: The label must reflect the application rate restrictions noted below:The maximum use rate for citrus via airblast is 2.5 lbs. ai/A per application. The maximum number of applications for citrus via airblast is two per year.Applicators of spot treatments for snow scale must use no more than 2.5 lbs ai/day, diluting to 250 gallons for a final concentration of 0.01 lb ai/gal. Applications for snow scale must not exceed more than 250 gal of material diluted in this way each day. The application rate is 3-5 gallons per tree to the trunk and limbs on trees where snow scale is present.	Direction for Use under General Precautions and Restrictions and/or Application Instructions
Cattle Eartag Products		
Site Specific Application Restrictions	"This product may only be used as a cattle eartag."	Direction for Use under General Precautions and Restrictions and/or Application Instructions
PPE required for products used as "eartags" on cattle	"Applicators of cattle eartags impregnated with ethion must wear:-- Long-sleeved shirt and long pants-- Socks and shoes-- Chemical-resistant gloves, such as (registrant inserts correct glove types)"	Precautionary Statements under Hazards to Humans and Domestic Animals

VI. Related Documents and How to Access Them

This Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, 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 August 13, 1998. Sixty days later the first public comment period closed. EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on July 14, 1999.

All documents may be viewed in the OPP docket room, in hard copy form, or downloaded or viewed via the Internet at the following site: http://www.epa.gov/pesticides/op.