US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Coumaphos

When EPA concluded the organophosphate (OP) cumulative risk assessment in July 2006, all tolerance reassessment and reregistration eligibility decisions for individual OP pesticides were considered complete. OP Interim Reregistration Eligibility Decisions (IREDs), therefore, are considered completed REDs. OP tolerance reassessment decisions (TREDs) also are considered completed.

Combined PDF document consists of the following:

- Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006)

- Coumaphos TRED

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

DATE: July 31, 2006

SUBJECT: Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides

FROM: Debra Edwards, Director
Special Review and Reregistration Division
Office of Pesticide Programs

TO: Jim Jones, Director
Office of Pesticide Programs

As you know, EPA has completed its assessment of the cumulative risks from the organophosphate (OP) class of pesticides as required by the Food Quality Protection Act of 1996. In addition, the individual OPs have also been subject to review through the individual-chemical review process. The Agency's review of individual OPs has resulted in the issuance of Interim Reregistration Eligibility Decisions (IREDs) for 22 OPs, interim Tolerance Reassessment and Risk Management Decisions (TREDs) for 8 OPs, and a Reregistration Eligibility Decision (RED) for one OP, malathion.[1] These 31 OPs are listed in Appendix A.

EPA has concluded, after completing its assessment of the cumulative risks associated with exposures to all of the OPs, that:

(1) the pesticides covered by the IREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) are indeed eligible for reregistration; and

[1] Malathion is included in the OP cumulative assessment. However, the Agency has issued a RED for malathion, rather than an IRED, because the decision was signed on the same day as the completion of the OP cumulative assessment.

(2) the pesticide tolerances covered by the IREDs and TREDs that were pending the results of the OP cumulative assessment (listed in Attachment A) meet the safety standard under Section 408(b)(2) of the FFDCA.

Thus, with regard to the OPs, EPA has fulfilled its obligations as to FFDCA tolerance reassessment and FIFRA reregistration, other than product-specific reregistration.

The Special Review and Reregistration Division will be issuing data call-in notices for confirmatory data on two OPs, methidathion and phorate, for the reasons described in detail in the OP cumulative assessment. The specific studies that will be required are:

- 28-day repeated-dose toxicity study with methidathion oxon; and
- Drinking water monitoring study for phorate, phorate sulfoxide, and phorate sulfone in both source water (at the intake) and treated water for five community water systems in Palm Beach County, Florida and two near Lake Okechobee, Florida.

The cumulative risk assessment and supporting documents are available on the Agency's website at www.epa.gov/pesticides/cumulative and in the docket (EPA-HQ-OPP-2006-0618).

Attachment A:

Organophosphates included in the OP Cumulative Assessment

Chemical	Decision Document	Status
Acephate	IRED	IRED completed 9/2001
Azinphos-methyl (AZM)	IRED	IRED completed 10/2001
Bensulide	IRED	IRED completed 9/2000
Cadusafos	TRED	TRED completed 9/2000
Chlorethoxyphos	TRED	TRED completed 9/2000
Chlorpyrifos	IRED	IRED completed 9/2001
Coumaphos	TRED	TRED completed 2/2000
DDVP (Dichlorvos)	IRED	IRED completed 6/2006
Diazinon	IRED	IRED completed 7/2002
Dicrotophos	IRED	IRED completed 4/2002
Dimethoate	IRED	IRED completed 6/2006
Disulfoton	IRED	IRED completed 3/2002
Ethoprop	IRED	IRED completed 9/2001 IRED addendum completed 2/2006
Fenitrothion	TRED	TRED completed 10/2000
Malathion	RED	RED completed 8/2006
Methamidophos	IRED	IRED completed 4/2002
Methidathion	IRED	IRED completed 4/2002
Methyl Parathion	IRED	IRED completed 5/2003
Naled	IRED	IRED completed 1/2002
Oxydemeton-methyl	IRED	IRED completed 8/2002
Phorate	IRED	IRED completed 3/2001
Phosalone	TRED	TRED completed 1/2001
Phosmet	IRED	IRED completed 10/2001
Phostebupirim	TRED	TRED completed 12/2000
Pirimiphos-methyl	IRED	IRED completed 6/2001
Profenofos	IRED	IRED completed 9/2000
Propetamphos	IRED	IRED completed 12/2000
Terbufos	IRED	IRED completed 9/2001
Tetrachlorvinphos	TRED	TRED completed 12/2002
Tribufos	IRED	IRED completed 12/2000
Trichlorfon	TRED	TRED completed 9/2001

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-R-00-010
September 2000

Reregistration Eligibility Decision Addendum and FQPA Tolerance Reassessment Progress Report

Coumaphos

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency has completed its review of the available data and public comments related to the revised human health risk assessment for the organophosphate (OP) pesticide coumaphos. Due to the relatively low volume use of coumaphos compared to other organophosphates, the Agency determined that a technical briefing was not necessary for this chemical. During Phase 5 of the OP pilot public participation process, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessment. This public participation and comment period commenced on April 26, 2000, and closed on June 26, 2000. The attached document entitled, "Reregistration Eligibility Decision Addendum and FQPA Tolerance Reassessment Progress Report for Coumaphos," which was approved on September 27, 2000, summarizes the Agency's assessment of the dietary and occupational risks from coumaphos. Based on its review and public comments, EPA has identified risk mitigation measures believed necessary to address the human health risks associated with the current use of coumaphos. These risk mitigation measures can be found in the attached document.

The major means by which the Agency reassesses tolerances is through its reregistration process. Each pesticide registered prior to 1984 is subject to a comprehensive evaluation of its effects on human health and the environment. Such an evaluation includes a determination of whether the tolerances are safe. Since coumaphos was first registered in 1958, it is subject to reregistration. The Agency issued a Reregistration Eligibility Decision (RED) document for coumaphos in 1996, prior to the passage of the Food Quality Protection Act of 1996 (FQPA). However, coumaphos tolerances are subject to reassessment in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by FQPA. This Act requires EPA to re-evaluate existing tolerances to ensure that children and other sensitive populations are protected from pesticide risk. The tolerance reassessment decision for coumaphos will be finalized once the cumulative assessment for all of the organophosphate pesticides is complete.

The Coumaphos RED of 1996 established that the U.S. Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) uses of coumaphos were eligible for reregistration, primarily due to the important use of this insecticide in the USDA-APHIS Cattle Fever Tick Eradication Program and the Program's significant benefit to the U.S. economy. In addition, the USDA-APHIS has an established cholinesterase monitoring program, in which staff are tested periodically and prevented from handling coumaphos if cholinesterase levels reach a level of concern.

In the 1996 RED, the Agency deferred making a regulatory decision on all uses of coumaphos other than USDA-APHIS uses, contingent on the submission and review of coumaphos-specific handler exposure studies. However, more recently, based on the small volume, declining trend in the use of coumaphos as livestock and swine bedding treatments, and other information, the Agency determined that the chemical-specific handler exposure studies previously required in the Data Call-In issued along with the 1996 RED were no longer needed.

The attached document, in addition to reassessing coumaphos tolerances, follows-up on the 1996 RED by issuing the reregistration eligibility decision for the non-USDA uses of coumaphos. In order to make this decision, the Agency reviewed and considered surrogate handler exposure data submitted by the registrant and conducted an occupational risk assessment incorporating surrogate exposure data available. The Agency has not conducted a new risk assessment for the effects of coumaphos on non-target species (e.g., fish, birds, mammals), because we have no reason to believe our conclusions would change since the 1996 RED.

A Notice of Availability for this Reregistration Eligibility Decision Addendum and FQPA Tolerance Reassessment Progress Report for coumaphos is being published in the "Federal Register." To obtain a copy of this document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED Addendum and all supporting documents are available on the Internet. See "http://www.epa.gov/pesticides/op."

The RED Addendum is based on the updated technical information found in the coumaphos public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessment, it also includes the Agency's revised risk assessment for coumaphos (revised as of January 13, 2000)**,** a document summarizing the Agency's Response to Comments, and recent revisions/addenda to the dietary (food), drinking water and occupational risk assessments. The Response to Comments document addresses corrections to the preliminary risk assessment submitted by the chemical registrant, as well as responds to comments submitted by the general public and stakeholders during the comment period on the risk assessment. The docket also includes comments on the revised risk assessment, and risk mitigation proposals submitted during Phase 5. A proposal was submitted for coumaphos by the technical registrant, Bayer Corporation. Comments and suggestions on risk mitigation were also submitted by Bayer Corporation.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for the organophosphate pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA)**,** the Agency is undertaking a special effort to maintain open public dockets on the organophosphate pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The reregistration and tolerance reassessment reviews for the organophosphate pesticides are following this new process.

Please note that the coumaphos risk assessment and the attached RED Addendum concern only this particular organophosphate. This document presents the Agency's reregistration decision, except for the decision on tolerance reassessment. Because the FQPA directs the Agency to consider available information on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with cholinesterase enzyme, the Agency will evaluate the cumulative risk posed by the entire organophosphate class of chemicals after completing the risk assessments for the individual organophosphates. The Agency is working towards completion of a methodology to assess cumulative risk and the individual risk assessments for each organophosphate are likely to be necessary elements of any cumulative assessment. The Agency has decided to move forward with individual assessments and to identify mitigation measures necessary to address the human health risk estimates associated with the current uses of coumaphos. The Agency will issue the final tolerance reassessment decision for coumaphos once the cumulative assessment for all of the organophophates is complete.

In this RED Addendum, the Agency has determined that coumaphos will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of coumaphos may pose unreasonable adverse effects to human health, and that such effects can be mitigated with the risk mitigation measures identified in this RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section IV of this RED describes labeling amendments for the technical, manufacturing-use and end-use products necessary to implement these mitigation measures. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by coumaphos. Where the Agency has identified any unreasonable adverse effect to human health, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the proposed label changes, please contact the Chemical Review Manager, Monica Alvarez, at (703) 308-8026. For questions about product reregistration, please contact Moanna Appleyard at (703) 308-8175.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision Addendum and FQPA Tolerance Reassessment Progress Report
for
Coumaphos

Case No. 0018

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COUMAPHOS TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
ARI	Aggregate Risk Index
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e., drinking water) lifetime exposure at which adverse, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography

GLOSSARY OF TERMS AND ABBREVIATIONS

GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
L	Liter
LC_{50}	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_{50}	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.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
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
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product

GLOSSARY OF TERMS AND ABBREVIATIONS

TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
Fg/g	Micrograms Per Gram
Fg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Coumaphos is an organophosphate insecticide/acaricide used on livestock and swine bedding, first registered in 1958 for the control of flies, mites, and ticks. Most recently, the Agency granted emergency FIFRA exemptions to several States for the use of coumaphos in honey bee hives to control varroa mites and small hive beetles. The Agency also established time-limited tolerances for coumaphos residues in honey and beeswax associated with these emergency exemptions. Coumaphos is a small volume use active ingredient, and its use has declined by nearly 50% since 1990.

In the Coumaphos Reregistration Eligibility Decision (RED) document of August 1, 1996, the Agency determined that only U.S. Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) uses of coumaphos were eligible for reregistration, primarily due to the important use of this insecticide in the USDA-APHIS Cattle Fever Tick Eradication Program and the Program's significant benefit to the U.S. economy. In addition, the USDA-APHIS has an established cholinesterase monitoring program, in which staff are tested periodically and prevented from handling coumaphos if cholinesterase levels reach a level of concern. In 1996, prior to the passage of the Food Quality Protection Act of 1996 (FQPA), the Agency deferred a regulatory decision on all uses of coumaphos other than the USDA-APHIS dip vat use, contingent on the submission and review of coumaphos-specific handler exposure studies. Non-USDA uses are spray and back rubber/oiler uses of the liquid formulations and shaker can, mechanical duster and dust bag uses of the dust formulations.

This document follows up on the Coumaphos RED issued in 1996. It establishes the Agency's reregistration eligibility and risk management decision for coumaphos uses other than USDA-APHIS uses, for which no reregistration eligibility decision was made in the 1996 Coumaphos RED and provides information on the reassessment of coumaphos tolerances in accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by FQPA. This Act requires EPA to re-evaluate existing tolerances to ensure that children and other sensitive populations are protected from pesticide risk. progress of the FQPA tolerance reassessment for coumaphos.

In order to make the reregistration eligibility decision, the Agency reviewed and considered surrogate handler exposure data submitted by the registrant and conducted an occupational risk assessment incorporating surrogate exposure data available. The Agency has not conducted a new risk assessment for the effects of coumaphos on non-target species (e.g., fish, birds, mammals), because we have no reason to believe our conclusions would change since that time. Because EPA issued the Coumaphos RED in 1996, before the passage of FQPA; for simplicity, we will refer to this document as a RED Addendum.

EPA has completed its review of public comments on the revised coumaphos dietary and occupational risk assessments and is issuing its risk management decisions for this chemical. The decisions outlined in this document do not include the final tolerance reassessment decision for coumaphos; however, some tolerance actions will be undertaken prior to the completion of the final

tolerance reassessment. Six tolerances should be proposed for revocation because the technical registrant, Bayer Corporation, no longer supports the use of coumaphos on sheep and goats and has requested voluntary cancellation of these uses. The final tolerance reassessment decision for this chemical will be issued once the cumulative assessment for all of the organophosphates is complete. The Agency may need to pursue further risk management measures for coumaphos once the cumulative assessment is finalized.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation decision on coumaphos. After considering revised risks, risk mitigation measures proposed by Bayer Corporation, and comments from other interested parties, including USDA-APHIS, EPA developed its risk management decision for uses of coumaphos that pose risks of concern. This decision is discussed fully in this document.

Overall Risk Summary

EPA's human health risk assessment for coumaphos indicates some risk concerns. Food risks, both acute and chronic, do not exceed the Agency's level of concern. Similarly, acute and chronic exposures to coumaphos in drinking water, based on surface and groundwater screening modeling, are not of concern. There are, however, risk concerns for workers who mix, load, and apply coumaphos to livestock and swine bedding.

To mitigate risks of concern posed by the uses of coumaphos, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments from other interested parties, and has decided on a number of label amendments to address worker risk concerns. Results of the risk assessments and necessary label amendments to mitigate those risks are presented in this document.

Dietary Risk

Acute and chronic dietary risk assessments for food and drinking water indicate risks do not exceed the Agency's level of concern; therefore, no mitigation is warranted at this time for any acute or chronic dietary exposure to coumaphos.

Occupational Risk

Occupational exposure to coumaphos is of concern, and the Agency identified a number of mitigation measures that need to be implemented at this time. Several applicator risk scenarios currently exceed the Agency's level of concern [i.e., Margins of Exposure (MOEs) are less than 100 or Aggregate Risk Indexes (ARIs) are less than 1] at baseline. EPA believes these risks can be mitigated to an acceptable level with the following label changes: restriction of one formulation to only USDA-

APHIS use, deletion of a method of application, limitation on the number of animals and area of animal bedding to be treated, and addition of personal protective equipment. Therefore, with the addition of the label restrictions and amendments detailed in this document, the Agency has determined that, until the outcome of the cumulative risk assessment for all of the organophosphates has been decided, all currently registered uses of coumaphos may continue, except for the uses on sheep and goats for which the technical registrant has requested voluntary cancellation. In addition, the Agency has determined that the non-USDA uses of coumaphos, for which no reregistration decision was made in the 1996 RED document, are eligible for reregistration when the label changes outlined in Section IV of this document are implemented by the registrant.

The Agency is issuing this RED Addendum for coumaphos, as announced in a Notice of Availability published in the "Federal Register." This document includes guidance and time frames for complying with any necessary label changes for products containing coumaphos. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for coumaphos have already been subject to numerous public comment periods, and a further comment period for coumaphos was deemed unnecessary. Therefore, there is no comment period for this document. With regard to complying with the risk reduction measures outlined in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Neither the tolerance reassessment nor the reregistration eligibility decision for coumaphos can be considered final, however, until the cumulative risk assessment for all organophosphate pesticides is complete. The cumulative assessment may result in further risk mitigation measures for coumaphos.

I. INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether 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 of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. 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. Coumaphos 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.

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), which was 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 September 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, and the Agency expects other types of chemicals will be handled similarly. Generally, basic protective measures such as closed mixing and 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 document are consistent with the Worker Pesticide Registration Notice.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment as well as 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 provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health risk assessment resulting from public comments and other information. Section IV presents the Agency's reregistration eligibility and risk management decision. Section V summarizes labeling changes necessary based on the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list the use patterns, data supporting guideline requirements and technical supporting documents, and provide the bibliography, among other information. 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

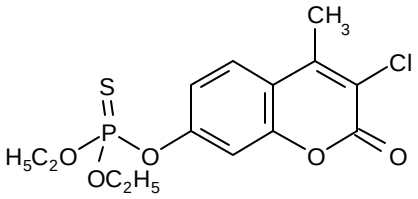
A. Regulatory History

Coumaphos technical was first registered in the United States in 1958 for use as an insecticide. The first end-use product, a dust formulation, was registered the following year for the control of insects on cattle. Coumaphos is currently registered for the control of insects, mites, and ticks on livestock and swine bedding. Since 1999, the Agency has exempted several State agencies from the provisions of FIFRA due to emergency conditions that required the use of coumaphos in bee hives to control varroa mites and small hive beetles. The Agency also established time-limited tolerances for combined residues of coumaphos and its oxygen analog, coumaphoxon, in honey and beeswax associated with these emergency exemptions.

The Coumaphos RED, along with a DCI requiring coumaphos-specific worker exposure and environmental fate studies, was issued in August 1996, prior to the passage of FQPA. In the 1996 RED, the Agency declared the USDA-APHIS dip vat use of coumaphos eligible for reregistration and deferred making a regulatory determination on the non-USDA uses, pending submission of the worker exposure data. This RED Addendum reflects a reassessment of all data submitted in response to the 1996 DCI and other available data, provides an update on FQPA tolerance reassessment progress and announces the reregistration eligibility and risk management decision for the non-USDA uses of coumaphos.

B. Chemical Identification

Coumaphos:



- **Common Name:** Coumaphos
- **Chemical Name:** 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate
- **Chemical family:** Organophosphate
- **Case number:** 0018

- **CAS registry number:** 56-72-4
- **OPP chemical code:** 036501
- **Empirical formula:** $C_{14}H_{16}ClO_5PS$
- **Molecular weight:** 362.8
- **Vapor Pressure:** 1×10^{-7} mm Hg
- **Trade and other names:** Asuntol, Bay 21/199, Baymix, Co-Ral, ENT-17957, Muscatox, Resitox
- **Basic manufacturer:** Bayer Corporation (technical registrant)

Technical coumaphos is a tan solid with a purity of 96% and a melting point of 90-95EC. At 20EC, coumaphos is soluble in acetone (23.82 g/100 ml) and diethyl phthalate (21.50 g/100 ml); much less soluble in denatured alcohol and xylene (0.9 g/100 ml in each); only slightly soluble in octanol (0.13 g/100 ml), hexane (0.07 g/100 ml), and mineral spirits (0.09g/100 ml); and insoluble in water (0.002 g/100 ml). Coumaphos is stable under normal conditions, but hydrolyzes slowly under alkaline conditions.

C. Use Profile

The following information is based on the currently registered uses of coumaphos:

Type of Pesticide: Insecticide/Acaricide

Summary of Use Sites:

All registered uses are classified as indoor food uses.

Food: Coumaphos is used as a direct animal treatment on beef and dairy cattle, horses, goats, sheep and swine. Predominant use is on beef cattle.

Residential: None

Public Health: None

Other Nonfood: Swine bedding

Target Pests: Flies (face fly, horn fly), ticks, lice, mites (scabies mite) and screw worms.

Formulation Types Registered: Technical Grade Active Ingredient (96% pure), manufacturing product (25% ai dust), end-use products (1% ai dust, 11.6% ai and 6.15% ai emulsifiable concentrates, and 42% ai flowable concentrate).

Method and Rates of Application:

Equipment - Dip vats, low and high-pressure hand wands, back rubber/oiler, mechanical dusters, dust bags and shaker cans.

Method and Rate - Applied directly to livestock. Depending on animals treated and formulation type, the maximum label application rates range from 0.005 to 0.025 lbs ai/gallon for spray or dip, 0.076 lbs ai/gallon of oil for back rubbers, 0.000625 to 0.013 lbs ai/animal for dust, and 0.042 lbs ai/1,000 sq. ft. of swine bedding.

Timing - Used primarily during early spring to late summer or during the fly season. Multiple applications to livestock and livestock areas are allowed.

Use Classification: Two liquid products, the 11.6% emulsifiable concentrate and the 42% flowable are classified as Restricted Use Pesticides (RUPs); all other products have general classification.

D. Estimated Usage of Pesticide

This section summarizes the best estimates available for many of the pesticide uses of coumaphos, based on pesticide usage information for 1990-1999 available to the Agency. A full listing of all uses of coumaphos, with the corresponding use and usage data for each site (cattle or other livestock), has been completed and is included in the "Quantitative Usage Analysis for Coumaphos," dated August 15, 2000, which is available in the Public Docket. The data, reported on an aggregate and site basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Approximately 71,000 lbs a.i. of coumaphos is used annually in the United States, according to Agency estimates.

Table 1. Coumaphos Estimated Usage for Representative Sites

Site	Lbs. Active Ingredient Applied (Likely Average[1])	Percent Livestock Treated (Likely Average)
Cattle	59,000	5.1%
Other Livestock	12,000	1.3%

[1] Likely averages are the EPA's estimates of what the average uses are likely to be.
Sources: U.S. Census of Agriculture; State Usage Surveys from TX, KS, NY, WY, and NV; State use recommendations; USDA, NASS, 2000 and EPA data. Refer to the "Quantitative Usage Analysis for Coumaphos," dated August 15, 2000, prepared by OPP Biological and Economic Analysis Division.

III. SUMMARY OF COUMAPHOS RISK ASSESSMENT

The following is a summary of EPA's revised human health risk findings and conclusions for the organophosphate pesticide coumaphos, as fully presented in the document, "Revised Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996," dated January 13, 2000 and more recent revisions to the dietary (food), drinking water and occupational risk assessments. The purpose of this summary is to assist the reader by identifying the key features and findings of this risk assessment, and to better understand the conclusions reached in the assessment.

The risk assessments presented here form the basis of the Agency's risk management decision for coumaphos only; the Agency must complete a cumulative assessment of the risks of all the organophosphate pesticides before any final decisions can be made.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for coumaphos on September 2, 1999 (Phase 3 of the TRAC process). In response to public comments and a dietary risk assessment submitted by the technical registrant during Phase 3, the risk assessments were updated and refined. Major revisions to the human health risk assessment are listed below:

- Development of refined Tier 3 acute and chronic dietary risk assessments;
- Incorporation of refined percent livestock treated information for beef cattle, dairy cattle and swine commodities and monitoring data for the U.S. Department of Agriculture (USDA) Pesticide Data Program (PDP) for milk;
- Deletion of spray foam (canceled effective July 29, 1999) and wettable powder formulations (canceled effective January 31, 2000) from the occupational exposure and risk assessment.

In addition to the changes made during Phase 4, the Agency recently revised the dietary (food) risk assessment to correct an error in the residue files and revised the drinking water assessment to include less conservative K_{oc} and water solubility assumptions for the oxygen analog, coumaphoxon. The Agency also developed an addendum to the revised occupational risk assessment, which provides occupational risk estimates for different handler exposure scenarios considering current labeled personal protective equipment. These documents are available in the OPP Public Docket for coumaphos.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is essentially complete, and that it supports a reregistration eligibility determination for all currently registered uses. Further details on the toxicity of coumaphos can be found in the January 13, 2000 human health risk assessment. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

b. FQPA Safety Factor

The FQPA Safety Factor was reduced to 1X. The toxicity database includes an acceptable two-generation reproduction study in rats, acceptable prenatal developmental toxicity studies in rats and rabbits, and acceptable acute and subchronic neurotoxicity studies in rats. 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/postnatal studies. Adequate 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 required by FQPA was reduced to 1X.

c. Population Adjusted Dose (PAD)

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 coumaphos, the FQPA safety factor is 1; therefore, the acute or chronic RfD is the same as the acute or chronic PAD, respectively. A risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concern.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Dietary Risk Assessment of Coumaphos

Assessment	Dose	Endpoint	Study	UF	FQPA Safety Factor	PAD
Acute Dietary	2.0 mg/kg/day (LOAEL)	Plasma ChE inhibition in females and RBC ChE inhibition in both male and female rats	Acute Oral Neurotoxicity in Rats (MRID 44544801)	300[a]	1X	0.007 mg/kg/day
Chronic Dietary	0.025 mg/kg/day (NOAEL)	Plasma and RBC ChE inhibition in both male and female dogs seen at the LOAEL of 0.77 mg/kg/day	Chronic Toxicity in Dog (MRID 43055301)	100	1X	0.0003 mg/kg/day

[a] Uncertainty factor is 300 due to an additional 3X for the lack of a NOAEL.

d. Exposure Assumptions

Revised acute and chronic dietary risk analyses for coumaphos were conducted with the Dietary Exposure Evaluation Model (DEEM™). DEEM incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-92. The dietary exposure assessments presented in the "Revised Acute and Chronic Dietary Exposure and Risk Analyses for Coumaphos" and in the "Revised Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996" (both dated January 13, 2000) have been revised using the correct residue values for pork commodities. For more details on this revision, please refer to the memorandum entitled: "Addendum to the Acute Dietary Exposure Analysis for Coumaphos."

The Tier 3 acute dietary analysis used monitoring data for milk and percent livestock treated for beef, milk, and pork commodities.

e. Food Risk Characterization

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose does not exceed the Agency's risk concerns. The coumaphos acute dietary risk from food is well below the Agency's level of concern; that is, less than 100% of the acute PAD is utilized. For example, for the most exposed subgroups, infants (<1 year) and children (1-6 years), the percent acute PAD values are 21% and 15%, respectively, at the 99.9th percentile of exposure.

The chronic dietary risk from food alone is well below the Agency's level of concern. For the most exposed subgroups, children (1-6 years) and children (7-12 years) the percent chronic PAD values are 13% and 9%, respectively.

The revised Tier 3 acute and chronic dietary analyses are highly refined. Additional refinements can be made using processing data from cooking and processing studies. These refinements will be considered when the cumulative assessment for all of the organophosphates is conducted.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water 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 is considered to be an unrefined assessment and provides a high-end estimate of risk. In the case of coumaphos, no monitoring data for either ground or surface water were available; therefore, modeling was used to estimate drinking water risks from these sources.

The GENEEC and SCI-GROW screening models were used to estimate surface water and groundwater concentrations of coumaphos and its oxygen analog, coumaphoxon. This degradate is considered in the drinking water assessment, because it is part of the tolerance expression.

The environmental fate database for coumaphos indicates that it is persistent ($t_{1/2}$ >1 year) and relatively immobile (Kd=61 to 298 ml/g; K_{oc}=3,994 to 11,422) in soil. Since the Agency does not have environmental fate data for coumaphoxon, it originally used the most conservative assumptions for its persistence ($t_{1/2}$ >1 year) and mobility (K_{oc}=0.1) for drinking water assessment purposes. However, on June 6, 2000, the Agency revised the drinking water assessment for coumaphos using a computer estimation program (EPI version 3.04), and estimated less conservative K_{oc} value (92.3) and water solubility value (31.61 at 25EC) for coumaphoxon. Therefore, the estimated environmental concentrations for total coumaphos (coumaphos and coumaphoxon) presented below reflect the revised concentrations. Please refer to the document: "Revised Tier 1 Drinking Water Assessment for Coumaphos," dated June 6, 2000 for more details.

For other model input parameters used in the drinking water assessment, the Agency used the guidance it generated on proposed USDA land farming methods. The recommended application rate for coumaphos spent solution from dip vat operations on non-agricultural land is 10,000 liters (L) of coumaphos spent solution containing 10 ppb spread over a one-acre field. A conversion efficiency of coumaphos to coumaphoxon of 10.2% was derived from available (supplemental) data on photodegradation in water. This conversion efficiency was used to estimate a coumaphoxon application rate of 0.02 lbs ai/A.

The Agency believes the revised environmental concentrations (EECs) are still conservative estimates because most of the coumaphos spent solution resulting from the dip use on livestock is collected and transported to concrete-lined evaporation pits, thereby negating any potential for groundwater contamination.

a. Surface Water

Tier I GENEEC screening model, representing a worst-case runoff scenario for pesticides in surface water, was used to estimate the upper-bound concentrations in surface water. Total coumaphos (coumaphos + coumaphoxon) acute and chronic estimated environmental concentrations in drinking water derived from surface water sources are not likely to exceed 1.86 ppb and 0.41 ppb, respectively.

b. Ground Water

A Tier I screening model, SCI-GROW, was used to estimate total coumaphos concentrations in ground water. This is an empirical model based on field data from prospective ground water studies. Estimated environmental concentration of total coumaphos, representing acute and chronic exposures to ground water, is 0.17 ppb.

c. Drinking Water Levels of Comparison (DWLOCs)

To determine the maximum allowable contribution of water-containing pesticide residues permitted 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 Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The results of the Agency's drinking water analysis are summarized herein. Details of this analysis, which used screening models, are found in the "Revised Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996," dated January 13, 2000. As mentioned above, the June 16, 1999 drinking water assessment for coumaphos was revised on June 6, 2000. The revised coumaphos EECs are presented below in Tables 3 and 4. The reader is referred to the "Revised Tier 1 Drinking Water Assessment for Coumaphos," dated June 6, 2000, for more details.

For acute risk, potential exposure to drinking water derived from either ground or surface water is not of concern for any population sub-group. The table below presents the calculations from the acute drinking water assessment.

Table 3. Summary of DWLOC Calculations for Acute Risk

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water EEC (ppb) (SCI-GROW)	Surface Water EEC (ppb) (GENEEC)	DWLOC (ppb)
U.S. Population	0.007	0.000525	0.006475	0.17	1.9	227
Females (13-50 years)	0.007	0.000247	0.006669	0.17	1.9	200
Infants (<1 year)	0.007	0.001492	0.005508	0.17	1.9	55

For chronic risk, potential exposure to drinking water derived from ground water is not of concern. Average (chronic) EECs in ground water do not exceed OPP's levels of comparison or DWLOCs for any population sub-group.

Table 4. Summary of DWLOC Calculations for Chronic Risk

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water EEC (ppb)	Surface Water EEC (ppb) (GENEEC)	DWLOC (ppb)
U.S. Population	0.0003	0.000013	0.000287	0.17	0.41[a]	10
Children (1-6 years)	0.0003	0.000033	0.000267	0.17	0.41	2.7
Females (13-50 years)	0.0003	0.000009	0.000291	0.17	0.41	8.7

[a] The GENEEC model estimated 56-day (average) concentration is divided by a factor of 3 prior to comparison with the $DWLOC_{chronic}$. In this case, (1.2 ppb)/3 = 0.41 ppb.

3. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water routes) and residential exposure to homeowners who handle pesticides or children who incidentally become exposed to these chemicals (e.g., hand-to-mouth exposure, turfgrass ingestion) in residential areas. Since coumaphos has no residential uses, acute and chronic aggregate risks include exposures from food and drinking water only. Acute exposure refers to the exposure for one day and chronic refers to that of a lifetime. Generally, all risks from these exposures must have MOEs of greater than 100 to be not of concern to the Agency. Results of the aggregate risk assessment are summarized herein, and are discussed extensively in the "Revised Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996," dated January 13, 2000.

Acute and chronic aggregate risks are not of concern for the Agency. When residues of coumaphos in drinking water are considered with exposures from food uses, the resulting acute and chronic aggregate human health risks are within acceptable levels.

4. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Residents or homeowners can be exposed to a pesticide through mixing, loading, or applying a pesticide, or through entering or performing other activities on treated areas. Since the only registered uses of coumaphos are on livestock and swine bedding, occupational handlers of coumaphos are limited to individual farmers and USDA-APHIS workers who mix, load, and/or apply the pesticide. Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational or residential exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 do not exceed the Agency's risk concern. In the case of coumaphos, the inhalation target MOE is 300, due to the uncertainty associated with the use of a LOAEL, and the dermal target MOE is 100.

a. Toxicity

The toxicity of coumaphos is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for coumaphos, including 21-day dermal and 5-day dermal toxicity studies. The toxicological endpoints, and other factors used in the occupational risk assessment for coumaphos are listed below.

Table 5a. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Risk Assessment for Coumaphos

Assessment	Dose	Endpoint	Study	Absorption factor
Short-term dermal	NOAEL = 5.0 mg/kg/day	Brain ChE inhibition in female rats	5-day dermal toxicity study in rats (MRID 44749401)	N/A
Intermediate- term dermal	NOAEL = 0.5 mg/kg/day	RBC ChE inhibition in rats	21-day dermal toxicity study in rats (42084901)	N/A
Short-term inhalation	LOAEL= 2.0 mg/kg/day	Plasma ChE inhibition in female rats and RBC ChE inhibition in male and female rats	Acute oral neurotoxicity study in rats (MRID 44544801)	100 percent absorption assumed
Intermediate -term inhalation	LOAEL= 0.2 mg/kg/day	RBC ChE inhibition in rats	13-week dietary study in rats (MRID 00126527)	100 percent absorption assumed

Coumaphos technical is highly acutely toxic via the oral (toxicity category I) and inhalation routes of exposure (toxicity category II). It is moderately toxic via the dermal route of exposure (toxicity category III) and is not a dermal sensitizer or irritant. Coumaphos is classified as a Group E chemical, indicating that it is "Not Likely" to be carcinogenic in humans via relevant routes of exposure.

Table 5b. Acute Toxicity Profile for Occupational Exposure for Coumaphos

Route of Exposure	Category Basis	Toxicity Category
Oral	LD_{50} > 240 mg/kg - male rat; LD_{50} = 17 mg/kg - female rat (MRID 00110597)	I
Dermal	LD_{50} > 2400 mg/kg - male and female rats (MRID 00110598)	III
Inhalation	1 hour inhalation LC_{50} = 1.081 mg/L -male rat; 1 hour inhalation LC_{50} = 0.341 mg/L female rat (MRID 00110601)	II
Eye Irritation	Mild irritant, resolved by day 7 (MRID 00110599)	III
Dermal Irritation	Not irritating (MRID 00110600)	IV
Dermal Sensitizer	Not a sensitizer (MRID 00110602)	N/A

b. Exposure

Coumaphos-specific handler exposure data were not available, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED) for most of the identified occupational exposure scenarios. Since PHED does not contain data to assess exposures resulting from loading and applying dust formulations, for informational purposes, the Agency used the published study: "Application Exposure to the Home Gardener" (1985) to estimate dermal exposure associated with dust application to livestock. However, the Agency believes the exposures derived from this study are an under estimate. This is because the exposures from applying a dust formulation to low garden vegetables will be very different from applying to livestock which are taller, mobile, and more active.

The Occupational and Residential Exposure Task Force (ORETF) study submitted by the technical registrant presents inhalation and dermal exposures estimates from applying dusts to garden vegetables and could not be used to assess exposure to handlers likely to occur from the use of coumaphos on livestock. Our concerns for the dermal exposure estimates derived from this study were the same as our concerns were for the 1985 data. For the inhalation exposure, EPA believes the exposures from applying dusts to relatively tall, moving livestock are likely to be significantly higher than those resulting from the application of dusts to low-growing plants since it is likely that more dust will reach the applicator's breathing zone during application to livestock. Therefore, the Agency had no data to estimate inhalation exposure from loading and/or applying dust formulations.

Standard assumptions including average body weight, work day, daily animals or area treated, and volume of pesticide were used to calculate risk estimates. The quality of the data and exposure

factors represent the best sources of data currently available to the Agency for completing these kinds of assessments. These exposure factors are all standard values that have been used by the Agency over several years, and the PHED unit exposure values are the best available estimates of exposure. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the revised "Occupational Exposure and Risk Assessment Updating the Coumaphos RED Published August, 1996," dated December 28, 1999, which is available in the public docket.

Anticipated use patterns and application methods, range of application rates, and daily amount treated were derived from current labeling. Application rates specified on coumaphos labels range from 0.005 to 0.025 pounds of active ingredient per gallon for sprays and dips, 0.076 lbs ai/gallon of oil for back rubbers, 0.000625 to 0.013 lbs ai/animal for dust, and 0.042 lbs ai/1,000 sq. ft. of swine bedding. The Agency typically uses number of animals or area treated per day that are thought to represent 8 solid hours of application work for specific types of application equipment.

Occupational handler exposure assessments are conducted by the Agency using 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). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than 100), increasing levels of risk mitigation, such as personal protective equipment (PPE) and engineering controls (EC). Some of the current labels of coumaphos products require handlers to wear long pants, long-sleeved shirt, and chemical-resistant gloves. The levels of protection that formed the basis for calculations of exposure from coumaphos activities include:

- Baseline: Long-sleeved shirt and long pants, shoes and socks.
- Label: Long-sleeved shirt and long pants, chemical-resistant footwear plus socks and chemical-resistant gloves. (Note: labels of coumaphos liquid products currently registered require this PPE)
- Additional PPE: Baseline + coveralls, chemical-resistant gloves, chemical-resistant apron and a respirator.
- Engineering controls: A closed mixing/loading system, for example, a farm closed mechanical transfer system for liquids or a packaged based system. Some engineering controls are not applicable for certain scenarios (e.g., for handheld application methods there are no known devices that can be used to routinely lower the exposures).

All the occupational exposure scenarios identified are of short-term duration (i.e., less than seven days), except for mixing and loading coumaphos for cattle dip vats, which is considered a short-term and an intermediate-term (i.e., duration is seven days to several months) occupational exposure scenario. Most of the non-dip vat uses of coumaphos are performed by farmers on their own animals

when arthropod pests become a problem. Mixing and loading liquids for dip vat operations carried out by USDA-APHIS are not considered chronic exposures. Chronic exposures are exposures of more than 180 days per year. USDA-APHIS employees who conduct dip vat operations are expected to be exposed on a daily basis of no more than 60 days.

c. Occupational Handler Risk Summary

In the revised assessment, EPA assessed handler risk using different toxicological endpoints and uncertainty factors for dermal and inhalation exposures. For coumaphos, the inhalation target MOE for the short-term and intermediate-term exposures is 300 and the dermal target MOE for short-term and intermediate-term exposures is 100. These risks were then combined into an Aggregate Risk Index (ARI). This method is used when the uncertainty factors associated with dermal and inhalation doses of concern are different and the endpoints are the same, i.e., cholinesterase inhibition. ARIs show how close the total exposure was to the dose at which no adverse effect was observed (NOAEL), except where no inhalation data were available. In these latter cases, only dermal MOEs were calculated. Additionally, the risk associated with certain handler exposure tasks were combined to represent one exposure scenario (e.g., a farmer mixing, loading and applying a spray solution to his own livestock). All the occupational exposure scenario descriptions, assumptions and estimated risks presented herein are included in Tables 3-9 of the revised "Occupational Exposure and Risk Assessment Updating the Coumaphos RED Published August 1996," dated December 28, 1999. Refer to these tables for more information on the assessment.

The following tables summarize the risk concerns after the occupational risk assessment was revised to include the most current data and assumptions for occupational handlers. The tables presented in this summary document outline the occupational handler risks at baseline, current PPE, and provide the risk estimates for each of these scenarios separately with additional PPE and, in some cases, with engineering controls to show the level of risk mitigation that could be achieved. Note that ARIs < 1 (for combined exposure), MOEs < 100 (for dermal exposure) and MOEs < 300 (for inhalation exposure) represent risks of concern for the Agency. More details on the description of each occupational exposure scenario, data sources and data quality may be found in Tables 3-9 of the revised "Occupational Exposure and Risk Assessment Updating the Coumaphos RED Published August 1996," dated December 28, 1999.

1) Occupational Handler Risk

The Agency identified eleven major occupational handler scenarios associated with the use of coumaphos and assessed risks for eight short-term and two intermediate-term exposure scenarios. However, the Agency did not develop an informational risk assessment for loading dusts into dust bags due to the lack of surrogate exposure data. The ten scenarios assessed represent twenty-three combinations of different application methods, formulations, use rates, number of animals/area treated for the short-term and intermediate-term exposures assessed. Seven of the nine short-term exposure

scenarios and two intermediate-term exposure scenarios pose risk concerns at baseline. ARIs presented in the tables below represent combined dermal and inhalation MOEs, except for those exposure scenarios related to the handling of the dust formulation for which no inhalation data were available. Dermal MOEs corresponding to the handling of dusts are presented in this document for informational purposes only, because exposure data used to calculate these MOEs were derived from a vegetable garden exposure scenario, which the Agency believes underestimates exposures to handlers from dust application to livestock. The exposure scenarios of concern at baseline are listed below and in Tables 6a and 6b; the number preceding each of them corresponds to the scenario number given in the occupational risk assessment document.

The short-term exposure scenarios of concern at baseline are:

(1a) Mixing/loading (M/L) liquids for high pressure handwand (at the application rate for cattle/horse, handling a volume of 100 gallons/day). ARI for this exposure scenario is 0.57; the risk is driven by dermal exposure.

(1b) M/L liquids for hydraulic type dip vats (1,800 gal/day). ARI for this exposure scenario is 0.027; the risk is driven by dermal exposure.

(1c) M/L liquids for swim dip vats (4,000 gal/day). ARI for this exposure scenario is 0.012; dermal exposure drives the risk.

(3) Applying liquids for high pressure hand wand (at the application rate for cattle/horse, handling a volume of 100 gal/day). ARI for this exposure scenario is 0.70; risk is driven by dermal exposure.

(4) Applying dusts with a shaker can (at the application rate for cattle/horse, treating 50 animals/day; at the application rate for swine, treating 50 animals/ day; and at the application rate for swine bedding, treating 1000 sq. ft./day). Dermal MOEs for these exposure scenarios are 27, 55, and 41, respectively. Although the dermal MOEs were estimated based upon exposures from the application of dusts to garden vegetables, and are likely an underestimate, the Agency believes they provide a reasonable frame of reference to qualitatively assess risks to applicators from applying dusts to livestock and swine bedding. No inhalation data were available to assess risks associated with the application of dusts to livestock.

(5) Mixing/loading/applying (M/L/A) liquids with a low pressure hand wand (at the application rate for cattle/horse, handling 40 gal/day; and at the application rate for swine, handling 40 gal/day). ARIs are 0.042 and 0.17, respectively; risks are driven by the dermal route of exposure.

(6) Loading/applying dust with a mechanical duster (at the application rate for cattle/horse, treating 50 animals/day; at the application rate for swine, treating 50 animals/day; and at the application rate for swine bedding, treating 1000 sq. ft./day). Qualitative dermal MOEs for these exposure scenarios are 27, 55, and 41, respectively. No inhalation data were available to assess risks associated with the application of dusts to livestock.

It should be noted that individual farmers who treat only their own cattle are more likely to have short-term exposures (i.e., exposures of seven days or less) than other handlers, such as USDA-APHIS staff, who operate the dip vats and could be exposed to coumaphos multiple times over the course of one week or several months.

The intermediate-term exposure scenarios of concern <u>at baseline</u> are:

(1b) M/L liquids for hydraulic type dip vats (450 gal/day), ARI=0.011;

(1c) M/L liquids for swim dip vats (1000 gal/day), ARI=0.0048.

The risks calculated from these two exposure scenarios are driven by the dermal route of exposure.

Table 6a. Coumaphos Short-Term Dermal and Inhalation Occupational Handler Risks Exceeding Levels of Concern at Baseline

				Short-term ARIs								
Scenario	Daily animals/ area treated or amount used	Animal	Rate	Baseline[1]			Current Label PPE[2]			Additional PPE[3]		
				Dermal MOE	Inhalation MOE	ARI	Dermal MOE	Inhalation MOE	ARI	Dermal MOE	Inhalation MOE	ARI
(1a) M/L liquids for high pressure handwand	100 gal/day	cattle/ horse	21 lbs ai/1000 gal	60	56,000	0.57	7,200	56,000	52	9,800	280,000	87
(1b) M/L liquids for hydraulic type dip vats	1800 gal/day	cattle	25 lbs ai/1000 gal	3	2,600	0.027	--	--	--	460	13,000	4
(1c) M/L liquids for swim dip vats	4000 gal/day	cattle	25 lbs ai/1000 gal	1	1,200	0.012	--	--	--	210	5,800	1.9
(3) Applying liquids for high pressure hand wand	100 gal/day	cattle/ horse	21 lbs ai/1000 gal	93	840	0.70	260	840	1.4	460	4,200	3.5
(4) Applying dusts with a shaker can[4]	50 animals/ day	cattle/ horse	0.0013 lbs ai/animal	27	no data	--	--	--	--	48	no data	--
	50 animals/ day	swine	0.000625 lbs ai/animal	55	no data	--	--	--	--	100	no data	–
	1000 sq. ft./day	swine bedding	0.042 lbs ai/1000 sq. ft.	41	no data	--	--	--	--	74	no data	–

				Short-term ARIs								
Scenario	Daily animals/ area treated or amount used	Animal	Rate	Baseline[1]			Current Label PPE[2]			Additional PPE[3]		
				Dermal MOE	Inhalation MOE	ARI	Dermal MOE	Inhalation MOE	ARI	Dermal MOE	Inhalation MOE	ARI
(5) M/L/A liquids with a low pressure hand wand	40 gal/day	cattle/ horse	21 lbs ai/1000 gal	4	5,600	0.042	970	5,600	6.3	1,100	28,000	10
	40 gal/day	swine	5 lbs ai/1000 gal	18	23,000	0.17	4,000	23,000	27	4,700	120,000	42
(6) L/A dust with a mechanical duster[4]	50 animals/ day	cattle/ horse	0.0013 lbs ai/animal	27	no data	--	--	--	--	48	no data	--
	50 animals/ day	swine	0.000625 lbs ai/animal	55	no data	--	--	--	--	100	no data	--
	1000 sq. ft./day	swine bedding	0.042 lbs ai/1000 sq. ft.	41	no data	--	--	--	--	74	no data	--

[1] Long pants, long sleeved shirt, no gloves, open mixing/loading, no respirator

[2] Long-sleeved shirt and long pants, chemical-resistant footwear plus socks and chemical-resistant gloves. (Note: this PPE is in some of the currently registered coumaphos product labels)

[3] Double-layer of clothing, coveralls, chemical-resistant apron and chemical-resistant gloves, dust/mist respirator

[4] Dermal MOEs corresponding to the handling of dusts are presented in this document for informational purposes only. Exposure data used to calculate these MOEs were derived from a vegetable garden exposure scenario, which the Agency believes underestimates exposures to handlers from dust application to livestock.

Table 6b. Coumaphos Intermediate-Term Dermal and Inhalation Occupational Handler Risks Exceeding Levels of Concern at Baseline

				Intermediate-term ARIs								
Scenario	Daily animals /area treated or amount used	Animal	Rate	Baseline[1]			Additional PPE[2]			Engineering Controls [3]		
				Dermal MOE	Inhalation MOE	ARI	Dermal MOE	Inhalation MOE	ARI	Dermal MOE	Inhalation MOE	ARI
(1b) M/L liquids for hydraulic type dip vats	450 gal/day	cattle	25 lbs ai/1000 gal	1	1,000	0.011	180	5,200	1.7	--	--	--
(1c) M/L liquids for swim dip vats	1000 gal/day	cattle	25 lbs ai/1000 gal	0.48	470	0.0048	82	2,300	0.74	160	6,700	1.5

[1] Long pants, long sleeved shirt, no gloves, open mixing/loading, no respirator
[2] Double-layer of clothing, coveralls, chemical-resistant apron and chemical-resistant gloves, dust/mist respirator
[3] Closed mixing/loading, single layer of clothing, chemical resistant gloves.

2) Post-Application Occupational Risk

The Agency determined that there is likely to be minimal exposure to people contacting treated animals after application is complete and believes exposure is relatively lower than that to handlers. Therefore, post-application exposure was not assessed. In addition, current labeling does not permit contact with treated livestock immediately after application.

B. Environmental Risk Assessment

This RED Addendum does not include an environmental risk assessment for coumaphos. The Agency did not conduct a new environmental risk assessment for the effects of coumaphos on non-target species (e.g., fish, birds, mammals), because we have no reason to believe our conclusions would change since the 1996 RED.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether 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 to support reregistration of products containing coumaphos as an active ingredient.

In the Coumaphos Reregistration Eligibility Decision (RED) of 1996, the Agency established that USDA-APHIS uses of coumaphos were eligible for reregistration because the use of this insecticide is very important to the USDA-APHIS Cattle Fever Tick Eradication Program and the U.S. economy. USDA estimated the economic significance of the use of coumaphos to be between $1-5 billion dollars per year. With this program, USDA-APHIS has helped in preventing the re-establishment of the cattle fever tick and its associated disease, piroplasmosis (babesiosis), into the United States.

EPA also considered the cholinesterase monitoring program currently run by USDA-APHIS in making the USDA-APHIS uses eligible for reregistration. As part of this program, all APHIS employees exposed to any carbamate or organophosphate pesticide as a result of handling the pesticide in concentrated or diluted form, reentering a treated field, or being exposed to drift are required to be monitored for cholinesterase levels before assuming their duties to establish baseline, and every 60 days thereafter. If cholinesterase levels in blood serum indicate a significant drop (50 percent or more from the highest baseline result, regardless of whether it is within the normal range, males: 10.1-22.1 U/ml and females: 8.3-20U/ml) or an abnormal result (less than 8.0 U/ml), APHIS will relieve the employee

from work involving contact with the pesticide, retest the employee in 30 days and prevent the employee from returning to work until another sample shows normal cholinesterase levels.

In the 1996 RED, the Agency deferred making a reregistration eligibility decision for coumaphos uses other than those to control cattle fever tick by USDA-APHIS until chemical-specific handler studies were submitted and reviewed. These handler studies were required from the registrant in a generic Data Call-In (DCI) issued as part of the 1996 RED. However, more recently, based on the small volume and declining trend in the use of coumaphos as livestock and swine bedding animal treatments, the Agency determined the chemical-specific handler exposure studies were not needed.

The Agency has completed its assessment of the occupational risk associated with the use of pesticides containing the active ingredient coumaphos, as well as a coumaphos-specific dietary risk assessment. However, the Agency has not yet considered the cumulative effects of organophosphates as a class. Based on a review of surrogate handler exposure data submitted by the technical registrant, dietary and handler exposure data available to the Agency and public comments on the Agency's assessments for the active ingredient coumaphos, EPA has sufficient information on the human health effects of coumaphos to make a determination of reregistration eligibility for the non-USDA uses and to make some decisions as part of the tolerance reassessment process under FQPA. Although the Agency has not yet completed its cumulative risk assessment for the organophosphates, the Agency is issuing this assessment now in order to identify risk reduction measures that are necessary to allow the continued use of coumaphos. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of coumaphos, and lists the submitted studies that the Agency found acceptable.

As a result of its assessment of the remaining risks of coumaphos alone, EPA has determined that certain uses of coumaphos, unless amended as set forth in this document, present risks inconsistent with FIFRA. Accordingly, EPA may commence a full risk/benefit analysis, the outcome of which may indicate that cancellation proceedings are warranted, unless registrants agree to label changes implementing the risk reduction measures discussed in this reregistration eligibility decision. At the time that a cumulative assessment is conducted, the Agency will address any outstanding risk concerns. However, the Agency may take further actions or require additional studies, if warranted, to finalize the reregistration eligibility decision for coumaphos after assessing the cumulative risk of the organophosphate class. Such an incremental approach to the reregistration process is consistent with the Agency's goal of improving the transparency of the reregistration and tolerance reassessment processes. By evaluating each organophosphate in turn and identifying appropriate risk reduction measures, the Agency is addressing the risks from the organophosphates in as timely a manner as possible.

Since the Agency has not yet completed the cumulative risk assessment for the organophosphates, this reregistration eligibility decision does not fully satisfy the reassessment of the existing coumaphos food residue tolerances as called for by the Food Quality Protection Act (FQPA).

When the Agency has completed the cumulative assessment, coumaphos tolerances will be reassessed in that light. At that time, the Agency will reassess coumaphos along with the other organophosphate pesticides to complete the FQPA requirements and make a final reregistration determination. By publishing this reregistration eligibility decision and requiring risk mitigation now for the individual chemical coumaphos, the Agency is not deferring or postponing FQPA requirements; rather, EPA is taking steps to assure that uses which exceed FIFRA's unreasonable risk standard do not remain on the label indefinitely, pending completion of assessment required under the FQPA. This decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide or any other in the future.

If the Agency determines, before finalization of this document, that any of the determinations described herein are no longer appropriate, the Agency will pursue appropriate action, including but not limited to, reconsideration of any portion of this document.

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. Comments on risk mitigation were only submitted by the technical registrant, Bayer Corporation. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Comment. Bayer commented that submitted worker exposure studies and an upcoming environmental fate study address each of the Agency's identified risk concerns. To address risk concerns associated with the application of liquid and dust formulations, the registrant has submitted surrogate exposure data from the Outdoor Residential Exposure Task Force (ORETF), which Bayer believes yield adequate margins of safety. In addition, Bayer has deleted the use of the mechanical duster from all its dust end-use products. Regarding the drinking water dietary risk concern presented in the Agency's "Revised Dietary and Occupational Risk Assessment Update for the Coumaphos RED Published August, 1996," Bayer has conducted and will be submitting an absorption/desorption study on coumaphoxon that the registrant believes will allow the Agency to refine the conservative assumption for the K_{oc} of coumaphoxon and that this value, in turn, would yield ground water EECs well below the Agency DWLOCs.

Response. The ORETF study estimated exposure from applying dusts to a garden. The Agency believes inhalation exposures from applying dust to livestock are likely to be significantly higher than those resulting from applying dusts to low-growing garden plants. Livestock are tall and move while dust application is taking place, therefore, livestock are closer to the applicator's breathing zone than garden plants. Although the Agency has no exposure study with which to estimate the inhalation exposure likely from applying dust to livestock and swine bedding with a shaker can or loading dust into dust bags, EPA believes that adding a dust/mist respirator is a prudent risk reduction measure.

Regarding the dietary (drinking water) risk concern, the Agency has revised the drinking water assessment (please refer to the "Revised Tier 1 Drinking Water Assessment for Coumaphos," dated June 6, 2000) to reflect more realistic environmental fate parameters, and estimated coumaphos concentrations in ground water do not exceed the chronic DWLOCs. Therefore, the Agency has no chronic aggregate (food and water) risk concerns at this time. As an additional safety measure, the Agency and the registrant have agreed that coumaphos solution from dip vat use be disposed of in concrete-lined pits. The Agency also encourages Bayer to submit the final study report for the absorption/desorption study on coumaphoxon.

Comment. Bayer commented that, even though it believes adequate margins of safety exist with the ORETF worker exposure studies, it is willing to implement several risk mitigation measures, such as limiting the dip vat use of coumaphos to only USDA and maintaining the current label limit of 100 gallons per day for the treatment of livestock with hand held sprayers at the maximum application rate.

Response. The Agency has reviewed risk mitigation measures proposed by Bayer and determined that these measures would adequately address the Agency's occupational risk concerns associated with the use of coumaphos in dip vat operations and with the application of liquid formulations as spray using hand held sprayers. However, additional measures are necessary to mitigate the remaining occupational risk concerns. These measures are outlined in the "Label Modifications" section of this document.

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. The assessment was for this individual organophosphate, and does not attempt to fully reassess these tolerances as required under FQPA. FQPA requires the Agency to evaluate food tolerances on the basis of cumulative risk from substances sharing a common mechanism of toxicity, such as the toxicity expressed by the organophosphates through a common biochemical interaction with the cholinesterase enzyme. The Agency will evaluate the cumulative risk posed by the entire class of organophosphates once the methodology is developed and the policy concerning cumulative assessments is resolved.

EPA has determined that risk from exposure to coumaphos is within its own "risk cup." In other words, if coumaphos did not share a common mechanism of toxicity with other chemicals, EPA would be able to conclude today that the tolerances for coumaphos 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 within acceptable levels; that is, combined risks from all exposures to coumaphos "fit" within the individual risk cup. Therefore, the coumaphos tolerances remain in effect until a full reassessment of the cumulative risk from all organophosphates is completed, except for those tolerances no longer supported, which will be revoked.

b. Tolerance Summary

In the individual assessment, tolerances for residues of coumaphos in/on meat, fat, and meat byproducts [40 CFR §180.189] are presently expressed in terms of combined residues of parent coumaphos and its oxygen analog, coumaphoxon. The Agency has determined that no changes to the milk, cattle, horse and hog tolerances are presently required. Six coumaphos tolerances for residues in meat, fat, and meat byproducts of goats and sheep should be proposed for revocation, since the technical registrant no longer supports these uses and has requested voluntary cancellation of these uses from all its registered product labels.

Table 7. Tolerance Summary for Coumaphos

Commodity	Current Tolerance, ppm	Interim Tolerance Decision[1], ppm	Comment
Tolerances Listed Under 40 CFR §180.189			
Cattle, fat	1	1	
Cattle, MBYP	1	1	
Cattle, meat	1	1	
Goats, fat	1	1	To be revoked
Goats, MBYP	1	1	To be revoked
Goats, meat	1	1	To be revoked
Hogs, fat	1	1	
Hogs, MBYP	1	1	
Hogs, meat	1	1	
Horses, fat	1	1	
Horses, MBYP	1	1	
Horses, meat	1	1	
Milk, fat	0.5	0.5	
Sheep, fat	1	1	To be revoked
Sheep, MBYP	1	1	To be revoked
Sheep, meat	1	1	To be revoked

[1]Tolerances may only be reassessed upon completion of the cumulative risk assessment of all organophosphates, as required by FQPA. The tolerances provided in this table are for this single chemical and are supported by all of the submitted residue data.

The Agency will commence proceedings to revoke six tolerances for sheep and goat (fat, MBYP, and meat tolerances for each) as soon as the registrant's request has gone through the voluntary cancellation process, including the publication of notice in the "Federal Register," as established by FIFRA.

On August 16, 2000, the Agency established two time-limited tolerances for combined residues of coumaphos and its oxygen analog, coumaphoxon, in or on honey (0.1 ppm) and beeswax (100 ppm), in response to the emergency exemptions granted under section 18 of FIFRA, authorizing the use of the pesticide in beehives. These tolerances will expire on December 31, 2002 (65 FR 49927).

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 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).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, coumaphos may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of coumaphos. 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

1) Acute Dietary (Food)

Acute dietary risk from food is well below the Agency's level of concern. A Tier 3 acute dietary exposure assessment was performed using DEEM™, and analysis yielded a percent acute PAD value of 21% for the most highly exposed population subgroup, infants < 1 year, at the 99.9th percentile. Therefore, no risk mitigation measures are necessary at this time to address acute dietary risk from food.

2) Chronic Dietary (Food)

Chronic dietary risk from food is also well below the Agency's level of concern. A Tier 3 chronic dietary exposure assessment was performed using DEEM™ and analysis yielded a percent acute PAD value of 13% for the most highly exposed population subgroup, children 1-6 years. Therefore, no risk mitigation measures are necessary at this time to address chronic dietary risk from food.

3) Drinking Water

Acute exposure to drinking water from surface or ground water sources is not of concern; estimated coumaphos concentrations in surface and ground water do not exceed the acute DWLOCs. No mitigation is necessary at this time to reduce risks resulting from acute drinking water exposure.

Chronic exposure to drinking water from surface water sources is not of concern. In the revised risk assessment for coumaphos released on April 26, 2000, the Agency identified a potential chronic risk concern from exposures to drinking water derived from groundwater sources. However, the Agency revised the drinking water assessment to reflect more realistic environmental fate parameters, and current estimated environmental concentrations of coumaphos in ground water do not exceed the chronic DWLOCs for any population sub-group. The revised document: "Revised Tier 1 Drinking Water Assessment for Coumaphos," dated June 6, 2000, is available in the OPP Public Docket for coumaphos.

To further reduce the possibility of groundwater contamination resulting from the disposal of bioremediated coumaphos spent solution from dip vat operations, the technical registrant agreed to incorporate the following risk mitigation measure, in addition to existing label requirements:

- Restrict the disposal of bioremediated coumaphos spent solution from dip vat operations to shallow, concrete-lined evaporation ponds.

b. Occupational Risk Mitigation

To address risk from dermal and inhalation exposures for the handler scenarios presented in Section III of this document and shown in Tables 6a and 6b of that section, the risk mitigation measures presented below, in addition to existing label requirements and label modifications established in the Coumaphos RED of 1996, need to be incorporated into labels.

For the liquid products:

- Restrict the use of the 42% flowable product to USDA-APHIS staff enrolled in the USDA-APHIS cholinesterase monitoring program; and

- Maintain the current use restriction on the liquid formulations, limiting the number of animals an individual may treat with hand held sprayers to100 head per day at the maximum application rate, and move this restriction to a more prominent place on the labels.

At baseline, risks to handlers from mixing/loading and applying liquids for high-pressure hand wand at the application rate for cattle/horse (ARI=0.057) and at the application rate for swine (ARI=0.24) exceed the Agency's level of concern at a higher use rate of 1,000 gallons per day. The Agency estimates that one gallon of dilute is used per animal. Therefore, the current label restriction on all liquid products limiting the number of animals an individual can treat with hand held sprayers to 100 head per day at the maximum application rate needs to be maintained (200 head per day if they are treated at ½ maximum label rate, etc.").

The use restriction of 100 head per day at the maximum application rate and at currently required level of personal protection yields occupational risk estimates that are not of concern to the Agency. ARIs for exposure from mixing/loading of liquids for high-pressure hand wand (scenario 1a) and for exposure from applying liquids with high-pressure hand wand (scenario 3) are 52 and 1.4, respectively. Current liquid product labels require that handlers use chemical-resistant gloves, which is a protective equipment not considered at baseline.

For the dust products:

- Prohibit the use of mechanical dusters as a method of application for coumaphos technical, all dust manufacturing-use products and all dust end-use products;

- Require the use of a dust/mist respirator and a chemical-resistant apron on all dust product labels; and

- Limit the number of animals an individual may treat with dust products by use of a shaker can to 25 head per day and the swine bedding area treated to 1,000 sq. ft. per day.

The Agency had no handler exposure data to assess dermal and inhalation risks associated with the application of coumaphos dusts to livestock and swine bedding. However, dermal risk to applicators based on surrogate exposure studies provided a frame of reference. In the absence of data, as a prudent safety precaution, EPA has determined that a dust/mist respirator and a chemical-resistant apron are necessary to mitigate occupational risks from the use of coumaphos dust products.

E. Label Modifications

The Agency has determined that the coumaphos registration should be amended to mitigate risks to handlers from use of coumaphos on livestock and swine bedding. The Agency believes the measures presented above, in addition to existing label requirements, will reduce worker risks of concern to acceptable levels and that unreasonable adverse effects are unlikely to result from such uses or practices. In addition, the technical registrant agreed to implement additional risk mitigation measures to prevent potential groundwater contamination resulting from the disposal of coumaphos waste solution on non-agricultural land.

The technical registrant does not support the use of coumaphos on sheep and goats and has indicated its intention to request voluntary cancellation of these two uses from all coumaphos manufacturing-use and end-use products; therefore, the following measure needs to be incorporated into labels:

- Restrict the formulation of coumaphos products for use on beef cattle, dairy cattle, horses, swine and swine bedding uses only.

Provided the risk mitigation measures are incorporated in their entirety into labels for coumaphos-containing products, the Agency finds that all currently registered uses of coumaphos are eligible for reregistration, pending a cumulative assessment of the organophosphate pesticides.

F. Other Labeling Modifications

In order to be eligible for reregistration, other use and safety information need to be placed on the labeling of all end-use products containing coumaphos. For the specific labeling statements, refer to Table 8 in Section V of this document.

1. Endangered Species Statement

The Agency has developed a program ("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 provides information to users to help them protect these species on a voluntary basis. As currently planned, the final program will call for label modifications referring to 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. The Agency is not imposing label modifications at this time through the RED. Rather, any requirements for product use modification will occur in the future under the Endangered Species Protection Program.

V. WHAT REGISTRANTS NEED TO DO

A. Manufacturing-Use Products

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV, by submitting label amendments and meeting the data requirements described in this section.

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of coumaphos for the above eligible uses has been reviewed and determined to be essentially complete. The following data gap remains:

- Developmental Neurotoxicity Study, Guideline No. 870.6300

A Data Call-In Notice (DCI) sent on September 10, 1999 to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18, 1999 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. The technical registrant of coumaphos requested a generic data waiver to the developmental neurotoxicity study, and the Agency denied such request in a letter dated March 10, 2000. Currently, the registrant intends to support the registration of coumaphos and has committed to submit the required developmental neurotoxicity study. As stated in the Agency's March 10 letter to Bayer Corporation, the DCI issued in September 1999 supercedes previous chemical-specific determinations that may have been rendered by the Agency. The Agency acknowledges that the revised risk assessments and supporting documents for coumaphos contain outdated statements that a developmental neurotoxicity study in rats is not required. These statements are not correct. The toxicology data base for coumaphos has not been completely fulfilled, and the developmental neurotoxicity study is still required.

2. Labeling for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use product (MPs) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. In addition, labeling changes are necessary to implement measures outlined in Section IV above.

The Agency is reviewing revised labeling submitted by the registrants in response to the label changes outlined in the 1996 Coumaphos RED to determine which additional modifications are needed to reflect the reregistration conditions specified in this RED Addendum. The Agency will contact the registrants if label changes, other than the ones already implemented, are necessary. Therefore, registrants do not need to submit applications for amended registrations or draft labels at this time. The Special Review and Reregistration Division contact for product reregistration is Moana Appleyard. Her phone number is (703) 305-5428.

B. End-Use Products

1. Additional Generic 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. This RED Addendum does not contain a product-specific data call-in, since it was issued in the 1996 Coumaphos RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to implement these changes is specified in Table 8 at the end of this section. The Agency is reviewing revised labeling submitted by the registrants in response to the label changes outlined in the 1996 Coumaphos RED to determine which additional modifications are needed to reflect the reregistration conditions specified in this RED Addendum. The Agency will contact the registrants if label changes, other than the ones already implemented, are necessary. Therefore, registrants do not need to submit applications for amended registrations or draft labels at this time. The Special Review and Reregistration Division contact for product reregistration is Moana Appleyard. Her phone number is (703) 305-5428.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Reregistration Eligibility Decision Addendum document. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this document. However, existing stocks time frames will be established case-by-case,

depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; "Federal Register", Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrant may distribute and sell coumaphos products bearing old labels/labeling for 12 months from the date of issuance of this RED Addendum. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this document. 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.

D. Labeling Changes Summary Table

Table 8 contains labeling changes previously identified in the 1996 Coumaphos RED and additional changes established in this RED Addendum for coumaphos. Labeling changes from both REDs should be incorporated in their entirety into labels for coumaphos-containing products, in order for currently registered uses of coumaphos to be eligible for reregistration. The PPE that would be established on the basis of acute toxicity category of the end-use product must be compared to the active-ingredient-based personal protective equipment specified in Table 8. The more protective PPE should be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Table 8: Summary of Labeling Changes for Coumaphos

Description	Amended Labeling Language	Placement on Label
Manufacturing-Use Products		
Formulation Restriction	"Only for formulation into an insecticide for the following use(s): beef cattle, dairy cattle, horses, swine and swine bedding."	Directions for Use
	"This product may not be used to formulate products for use in mechanical dusters."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to birds, 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."	Precautionary Statements
End-Use Products Intended for Occupational Use (Non-WPS)		
Restricted Use Pesticide Statements for the 42% Flowable and 11.6% EC Products (EPA Reg. Nos. 11556-98 and 11556-23)	"RESTRICTED USE PESTICIDE: Due to Acute Oral Hazard- 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 Applicator's Certification"	Top of Front Panel
Use Restriction Statement for the 42% Flowable Product (EPA Reg. No. 11556-98)	"Use restricted to employees of the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) who are enrolled in the USDA-APHIS cholinesterase monitoring program."	Front panel, immediately following the Restricted Use Pesticide statement

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
Handler PPE Requirements for the 42% Flowable Product (EPA Reg. No. 11556-98)	"Some materials that are chemical-resistant to this products 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, and others exposed to the concentrate (such as during a spill or equipment breakdown) and all other handlers participating in dip-vat applications must wear: *long-sleeve shirt and long pants, *chemical-resistant gloves, *chemical-resistant footwear plus socks, *chemical-resistant apron, and *face shield or goggles. All other handlers, including spray applicators, must wear: *long-sleeve shirt and long pants, *chemical-resistant gloves, and *chemical-resistant footwear plus socks."	Precautionary Statement Directly below the Hazards to Humans and Domestic Animals

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
Handler PPE Requirements for the 11.6% and 6.15% Emulsifiable Concentrate Products (EPA Reg. Nos. 11556-23 and 11556-115)	"Some materials that are chemical-resistant to this products 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, and others exposed to the concentrate (such as during a spill or equipment breakdown) must wear: *long-sleeve shirt and long pants, *chemical-resistant gloves, *chemical-resistant footwear plus socks, *chemical-resistant apron, and *face shield or goggles. Applicators and all other handlers exposed to the dilute must wear: *long-sleeve shirt and long pants, *chemical-resistant gloves, and *chemical-resistant footwear plus socks."	Precautionary Statement Directly below the Hazards to Humans and Domestic Animals

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
Handler PPE Requirements for all Bulk Dust Products	"Some materials that are chemical-resistant to this products 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." "Loaders, applicators and other handlers must wear: *long sleeve shirt and long pants, *chemical-resistant gloves, *shoes plus socks, *chemical-resistant apron, *a NIOSH-approved dust/mist respirator, with MSHA/NIOSH approval number prefix TC21C or a NIOSH-approved respirator with any N* R, P, or HE filter."	Precautionary Statements Directly below the Hazards to Humans and Domestic Animals
Handler PPE Requirements for all Ready-to-Use Dust Products	"Some materials that are chemical-resistant to this products 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." "Applicators and other handlers must wear: *long sleeve shirt and long pants, *chemical-resistant gloves, *shoes plus socks, *chemical-resistant apron, *a NIOSH-approved dust/mist respirator, with MSHA/NIOSH approval number prefix TC21C or a NIOSH-approved respirator with any N* R, P, or HE filter."	Precautionary Statements Directly below the Hazards to Humans and Domestic Animals

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from the other laundry."	Precautionary Statements Directly below the PPE
Engineering Controls or Improved Packaging for all Liquid Products	EPA requires that all liquid concentrate formulations be contained in "no-glug" containers, water-soluble gel packs, or other equivalent methods approved by the Agency.	Not for placement on label
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 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 Directly below the User Safety Requirements (must be placed in a box)
Environmental Hazards	"This pesticide is toxic to mammals, birds, fish and aquatic invertebrates. Coumaphos washed off of wading treated livestock may be hazardous to aquatic organisms. Do not contaminate water when disposing of equipment washwater or rinsate."	Precautionary Statements under Environmental Hazards

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
Disposal Restriction Statement for the 42% Flowable Product (EPA Reg. No. 11556-98)	"Cattle Dip Solution Disposal: The Agency requires that spent dip-vat solution be bioremediated, and recommends the bioremediation method developed by the USDA. The treated solution must be transferred to shallow, concrete-lined evaporation ponds for further degradation. The evaporation ponds must be constructed to prevent overflow or flooding during wet seasons and must be lined with reinforced concrete. Dried sludge generated in the evaporation ponds must not be applied to agricultural land and should be disposed according to solid waste disposal regulations established by your Local and/or State Environmental Control Agency. Questions concerning the disposal of the spent solution should be directed to the waste representative at the nearest EPA Regional Office."	Directions for Use under Storage and Disposal
Re-entry Restriction for Liquid Products	"Entry Restrictions: Do not contact or allow others to contact treated animals until their coats are dry."	Directions for Use under General Precautions and Restrictions
Re-Entry Restriction for Dust Products	"Entry Restrictions: Do not enter treated areas or allow contact with treated animals until dusts have settled."	Directions for Use under General Precautions and Restrictions

Table 8: Summary of Labeling Changes for Coumaphos		
Description	**Amended Labeling Language**	**Placement on Label**
Application Restriction for all Liquid Products	"Do not spray in a confined, non-ventilated area."	Directions for Use under Application Restrictions
Application Restriction for all Liquid and Dust Products	"Do not treat areas such as drinking cups, mangers, or troughs where livestock feed. Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment."	Directions for Use under Application Restrictions
Application Restriction for all Products	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may in the area during application."	Directions for Use under Application Restrictions
Application Restriction for Products Applied by Hand Held Sprayer	"Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum label rate, 200 if they are treated at ½ maximum label rate, etc."	Directions for Use under Application Restrictions
Application Restriction for all Dust Products	"Individuals must limit the number of animals they can treat per day with shaker can to no more than 25 and the area of swine bedding they can treat per day to 1,000 sq. ft."	Directions for Use under Application Restrictions
Application Restriction for all Dust Products	"The use of mechanical dusters is prohibited."	Directions for Use under Application Restrictions
Application Restrictions	Move the Application Restrictions section to the beginning of the Directions for Use section	Beginning of Directions for Use
Use Deletion for all Dust Products	The use of mechanical dusters are no longer supported by the technical registrant and will be deleted from all dust products.	Not for placement on label

* If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.
Instructions in the Labeling Required section appearing in quotations represent the exact language that must appear on the label.
Instructions in the Labeling Required section not in quotes represents actions that the registrant must take to amend their labels or product registrations.

VI. RELATED DOCUMENTS AND HOW TO ACCESS THEM

This Reregistration Eligibility Decision Addendum 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 September 2, 1999. Sixty days later the first public comment period closed. The 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 April 26, 2000.

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: "http://www.epa.gov/pesticides/op/."

VII. APPENDICES

Appendix A. TABLE OF USE PATTERNS ELIGIBLE FOR REREGISTRATION

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/gal)	Max.# Apps	Restrictions/Comments
Food Uses				
Beef and Non-Lactating Dairy Cattle				
Dip vat treatment	4.2 lb/gal Flowable	0.025 lb/gal	2/year	Use of this formulation is restricted to USDA-APHIS staff enrolled in the USDA-APHIS Cholinesterase Monitoring Program. Animals should not be dipped more than twice per year unless additional treatments are required by APHIS Veterinary Services Regulations/Memoranda for Animals included in the Federal Eradication Programs.
Spray treatment	4.2 lb/gal Flowable	0.021 lb/gal	6/year	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Spray treatment	1.0 lb/gal EC	0.029 lb/gal	Not specified	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Spray treatment	0.5 lb/gal EC	0.02 lb/gal	6/year	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Backrubber treatment	1.0 lb/gal EC	0.076 lb/gal fuel oil	Not specified	
Backrubber treatment	0.5 lb/gal EC	0.038 lb/gal fuel oil	Not specified	
Dust bag treatment	1% ai bulk dust	N/A	Not specified	

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/gal)	Max.# Apps	Restrictions/Comments
Shaker can treatment	1% ai bulk dust	0.0013 lb ai/animal	12/year	Individuals must limit the number of animals they may treat with shaker can to no more than 25 head per day.
Shaker can treatment	1% ai shaker can	0.0013 lb ai/animal	12/year	Individuals must limit the number of animals they may treat with shaker can to no more than 25 head per day.
Lactating Dairy Cattle				
Spray treatment	1.0 lb/gal EC	0.0024lb/gal	Not specified	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Spray treatment	0.5 lb/gal EC	0.01 lb/gal	6/year	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Dust bag treatment	1% ai bulk dust	N/A	Not specified	

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/gal)	Max.# Apps	Restrictions/Comments
Horses				
Spray treatment	4.2 lb/gal Flowable	0.021 lb/gal	6/year	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Spray treatment	1.0 lb/gal EC	0.029 lb/gal	Not specified	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Spray treatment	0.5 lb/gal EC	0.02 lb/gal	6/year	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.

Site Application Type	Formulation % AI	Max. Single Application Rate (lb ai/gal)	Max.# Apps	Restrictions/Comments
Swine				
Spray treatment	1.0 lb/gal EC	0.005 lb/gal	Not specified	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Spray treatment	0.5 lb/gal EC	0.005 lb/gal	6/year	Individuals must limit the number of animals they treat per day with hand held sprayers to no more than 100, if the animals are treated at the maximum application label rate, 200 if they are treated at ½ maximum label rate, etc.
Shaker can treatment	1% ai bulk dust	0.000625 lb ai/animal	6/year	Individuals must limit the number of animals they may treat with shaker can to no more than 25 head per day.
Bedding treatment	1% ai bulk dust	0.042 lb ai/1000 sq. ft.	6/year	Individuals must limit the number of animals they can treat per day with shaker can to no more than 1,000 sq. ft per day.
Shakercan treatment	1% ai shaker can	0.000625 lb ai/animal	6/year	Individuals must limit the number of animals they may treat with shaker can to no more than 25 head per day.

Appendix B. DATA SUPPORTING GUIDELINE REQUIREMENTS FOR THE REREGISTRATION OF COUMAPHOS

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #0018 (coumaphos) covered by this RED Addendum. It contains generic data requirements that apply to coumaphos in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

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

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

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

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**			
830.1600	**61-2A**	**Start. Mat. & Mnfg. Process**	**All**	**41117401, 41117403, 41778502, 42378501**
830.1670	**61-2B**	**Formation of Impurities**	**All**	**41117401, 41117403, 41778502, 42378501**
830.1700	**62-1**	**Preliminary Analysis**	**All**	**42258601, 42675001, 42675003**
830.7370	**63-10**	**Dissociation Constant**	**All**	**Waived**
830.7550	**63-11**	**Octanol/Water Partition Coefficient**	**All**	**41778501**
830.6313	**63-13**	**Stability**	**All**	**41778502**
ECOLOGICAL EFFECTS				
850.2500	**71-5B**	**Actual Field Study**	**N/A**	**Waived, 42512603, 42512604**
None	**72-4A**	**Fish-Early Life Stage**	**A**	**43066301**
None	**72-4B**	**Estuarine/Marine Invertebrate Life Cycle**	**A**	**43116601**
TOXICOLOGY				
870.3200	**82-2**	**21-Day Dermal - Rabbit/Rat**	**L**	**42084901, 42666401, 44749401**
None	**82-5(b)**	**90-Day Neurotox-Mammal**	**All**	**44775901**

REQUIREMENT			USE PATTERN	CITATION(S)
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	L	43055301
870.3800	83-4	2-Generation Reproduction - Rat	L	43061701
870.5375	84-2B	Structural Chromosomal Aberration	L	41847501, 42254501
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A	00263038
835.2240	161-2	Photodegradation - Water	A	42764101, 43022101, 43103901
835.2410	161-3	Photodegradation - Soil	N/A	42920301, 43167401
835.4400	162-3	Anaerobic Aquatic Metabolism	A	Waived
835.1240	163-1	Leaching/Adsorption/Desorption	A	42084901, 42097401
None	166-3	Ground Water-Irrigation Retrospe	N/A	N/A
RESIDUE CHEMISTRY				
860.1300	171-4B	Nature of Residue - Livestock	A	42097402, 42323402
860.1340	171-4D	Residue Analytical Method - Animals	A	42097403, 42323401, 43123401
860.1380	171-4E	Storage Stability	A	43569801, 43569802, 43569803, 43569804, 43569805, 43569806, 43569807, 43569808, 43569809, 43569810

REQUIREMENT			USE PATTERN	CITATION(S)
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg	N/A	N/A
OTHER				
None	231	Estimation of Dermal Exposure	A	Waived
None	232	Estimation of Inhalation Exposure	A	Waived
None	70-1-SS	Aquatic Monitoring		42512601, 42512602
None	81-8-SS	Acute Neurotox	All	44544801
870-6200	81-8	Neurotox Scrn Batt-Acu	A	44544801
870-6200	82-7	Neurotox Scrn Batt-Sub	A	44775901
870-6300	None	Developmental Neurotox	A	Data Gap

Appendix C. LIST OF AVAILABLE RELATED DOCUMENTS

These documents are available from the Public Docket Office or at the following web site: www.epa.gov/pesticides/op/coumaphos.htm

5) Hazard Assessment of the Organophosphates
6) FQPA Safety Factor Recommendations for the Organophosphates
7) Frequently Asked Questions
8) *Federal Register* Notice Vol. 65, Number 81, Pages 24468-24469 (Comment period ending June 26, 2000)
9) *Federal Register* Notice Vol. 64, Number 170, Pages 48164-48165 (Comment period ending November 1, 1999)
10) Transmittal Letter to Bayer Corporation Regarding the Preliminary Risk Assessment
11) Preliminary Dietary and Occupational Risk Assessment
12) Revised Dietary and Occupational Risk Assessment
13) Preliminary Acute and Chronic Dietary Exposure and Risk Analyses
14) Addendum to the Acute and Chronic Dietary Exposure and Risk Analysis
15) Revised Acute and Chronic Dietary Exposure and Risk Analyses
16) Addendum to the Acute Dietary Exposure Analysis for Coumaphos
17) Preliminary Occupational Exposure and Risk Assessment
18) Revised Occupational Exposure and Risk Assessment
19) Addendum to the Occupational Exposure and Risk Assessment
20) Tier 1 Drinking Water Assessment for Land Farming of Bioremediated Coumaphos from Cattle Dips
21) Revised Tier 1 Drinking Water Assessment for Coumaphos
22) Report of the FQPA Safety Factor Committee
23) Report of the Hazard Identification Assessment Review Committee
24) Percent Dairy Cattle Treated with Coumaphos
25) Quantitative Usage Analysis for Coumaphos
26) Coumaphos Summary
27) Overview of Coumaphos Revised Risk Assessments
28) Registrant's Response to EPA's Letter Transmitting the Preliminary Risk Assessment
29) EPA's Response to the Registrant's Error Comments
30) HED's Response to Public Comments
31) EPA's Response to Public Comments

Appendix D. CITATIONS SUPPORTING THE REREGISTRATION ELIGIBILITY DECISION ADDENDUM AND FQPA TOLERANCE REASSESSMENT PROGRESS REPORT (BIBLIOGRAPHY)

GUIDE TO APPENDIX D

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

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

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

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

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

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

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

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

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

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

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

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

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00110597	Shmidl, J.; Rainey, L.; Kohlenberg, M. (1981) Oral LD50 Evaluation for Coumaphos Compound: Report No. 72212. (Unpublished study received on unknown date under 11556-4; submitted by Bayvet, Shawnee Mission, KS; CDL:248200-B)
00110598	Shmidl, J.; Kohlenberg, M.; Rainey, L. (1981) Dermal LD50 Evaluation for Coumaphos Technical Compound: Report No. 72216. (Unpublished study received on unknown date under 11556-4; submitted by Bayvet, Shawnee Mission, KS; CDL:248200-C)
00110599	Shmidl, J.; Kohlenberg, M.; Rainey, L. (1981) Eye Irritation Evaluation for Coumaphos Technical in Rabbits: Report No. 72213. (Unpublished study received on unknown date under 11556-4; submitted by Bayvet, Shawnee Mission, KS; CDL:248200-D)
00110600	Shmidl, J.; Kohlenberg, M.; Rainey, L. (1981) Primary Dermal Irritancy of Coumaphos Technical to Rabbits: Report No. 72205. (Unpublished study received on unknown date under 11556-4; submitted by Bayvet, Shawnee Mission, KS; CDL:248200-E)
00110601	Sangha, G.; De Jong, M.; Lamb, D.; et al. (1982) Acute Inhalation Toxicity Study with Coumaphos Technical in Rats: Study No. 81-041-14, Report No. 72398. (Unpublished study received on unknown date under 11556-4; submitted by Bayvet, Shawnee Mission, KS; CDL:248200-F)
00110602	Shmidl, J.; Kohlenberg, M.; Hess, L. (1982) Dermal Sensitization Evaluation of Coumaphos Technical in Guinea Pigs: Report No. 72452. (Unpublished study received on unknown date under 11556-4; submitted by Bayvet, Shawnee Mission, KS; CDL:248200-G)
00115167	Kruckenberg, S. (1981) Acute Delayed Neurotoxicity of Coumaphos in Hens--81-Chicken-02: [Submitter] 72206. (Unpublished study received Sep 23, 1982 under 11556-11; prepared by Kansas State Univ., Veterinary Medical Center, Dept. of Pathology, submitted by Bayvet, Shawnee Mission, KS; CDL:248397-A)
00126527	Porter, M.; Jasty, V.; Bare, J.; et al. (1983) Subchronic (13 Week) Oral Toxicity Evaluation of Coumaphos in the Rat: Bayvet Report No. 72586. (Unpublished study received Mar 21, 1983 under 11556-11; prepared in cooperation with Miles Laboratories, submitted by Bayvet, Shawnee Mission, KS; CDL:249746-A)

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MRID	CITATION
00131684	Clemens, G.; Hartnagel, R. (1983) Study of the Toxicity of Coumaphos: III. Teratology (Segment II) Study in the Rat: Report No. 8; 72754. (Unpublished study received Oct 18, 1983 under 11556-11; prepared by Miles Laboratories, Inc., submitted by Bayvet, Shawnee Mission, KS; CDL:251532-E)
00159928	Waggoner, T. (1986) Hydrolysis of ?Carbon 14F Coumaphos in Sterile Buffered Aqueous Solutions: Report No. 73320. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 118 p.
263038	See MRID #159928
41117401	Shoup, R. (1989) Rabon Oral Larvicide Manufacturing Base: Product Identity and Composition. Unpublished study prepared by Fermenta Animal Health Co. 16 p.
41117403	Shoup, R. (1989) 75% Rabon Insecticide Wettable Powder: Product Identity and Composition. Unpublished study prepared by Fermenta Animal Health Co. 16 p.
41778501	Rose, W. (1990) Co-Ral 25% Dust Base (Coumaphos): Lab Project Number: 74114; 74115. Unpublished study prepared by Mobay Corp. 77 p.
41778502	Rose, W. (1990) Product Chemistry of Coumaphos Technical Grade 1: Lab Project Number: 74111; 74113; 72899. Unpublished study prepared by Mobay Corporation. 98 p.
41847501	Putman, D. (1991) Micronucleus Cytogenetic Assay in Mice: Coumaphos Technical: Lab Project Number: T9423/122. Unpublished study prepared by Microbiological Associates, Inc. 36 p.
42084901	Sheets, L.; Phillips, S. (1991) Repeated Dose (21-Day) Dermal Toxicity Study with Technical Grade Coumaphos in Rats: Lab Project Number: 91-122-IE. Unpublished study prepared by Mobay Corp. 253 p.
42097401	Waggoner, T. (1991) Coumaphos: Adsorption/Desorption of Two Degradation Products: Chlorferon and HOL-5461: Lab Project Number: COUM91E: COUM91D. Unpublished study prepared by M. C. Bownam and Associates. 101 p.
42097402	Waggoner, T. (1991) Coumaphos: Nature of the Residue: Lab Project Number: 9014B. Unpublished study prepared by Southwest Bio-Labs, Inc. 138 p.

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Appendix E. LIST OF REGISTRANTS

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