United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-96-014
August 1996

Reregistration Eligibility Decision (RED)

Coumaphos

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case **coumaphos** which includes the active ingredient, **O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate**. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from receipt of this letter. The second set of required responses are due 8 months from receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in a tolerance is necessary, that tolerance too will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative, Edward Setren at (703) 308-8166. Address any questions on required generic data to the Special Review and Reregistration Division representative, Dennis McNeilly at (703) 308-8066.

Sincerely yours,

Lois A. Rossi, Director
Special Review
and Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five

batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

COUMAPHOS

LIST A

CASE 0018

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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COUMAPHOS REREGISTRATION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

Doug Sutherland	Biological Analysis Branch
John Faulkner	Economics Analysis Branch
Steve Jarboe	Biological Analysis Branch

Environmental Fate and Effects Assessment

Harry Winnik	Ecological Effects Branch
Richard Mahler	Environmental Fate and Groundwater Branch
David Farrar	Science Analysis and Coordination Staff

Health Effects Assessment

John Redden	Risk Characterization & Analysis Branch
William Greear	Toxicology Branch I
Bruce Kitchens	Occupational and Residential Exposure Branch
Christine Olinger	Reregistration Support Chemistry Branch

Registration Support

Linda Arrington	Insecticide-Rodenticide Branch
Mark Perry	Registration Support Branch
Edward Setren	Policy, Planning and Operations Branch

Risk Management Coordination

Dennis McNeilly	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
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, non carcinogenic health effects are not anticipated to occur.
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/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
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.
HDT	Highest Dose Tested
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.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed 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.
µg/g	Micrograms Per Gram
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.
N/A	Not Applicable
NOEC	No effect concentration

GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
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
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
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
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.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) document addresses the reregistration eligibility of the insecticide coumaphos, i.e., O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate.

Coumaphos is applied as a direct animal treatment to control arthropod pests of beef cattle, dairy cattle, goats, horses, sheep, and swine. Coumaphos is also used to treat swine bedding. Coumaphos was previously registered for use on poultry but these uses do not appear on any currently registered product. Most coumaphos use is on beef cattle, with most of the remaining use on dairy cows and swine. There are no registered uses for coumaphos on agricultural crops, ornamentals or in residences.

Coumaphos is available in a variety of formulations for manufacturing use (90% technical, 25% dust base), for spot and wound treatment (1% dust, 5% dust, 3% spray, 3% foam), animal spray and dip vat treatments (25% wettable powder, 11.6% emulsifiable liquid, 42% flowable), back rubbers (5.8% and 11.6% emulsifiable liquids), back dusters (1% dust, 5% dust), bedding treatment (1% dust) and as pour-on treatments (4%). Multiple applications to livestock and/or livestock premises are permitted by current labels.

Technical coumaphos is highly acutely toxic by the oral and inhalation routes of exposure and is moderately acutely toxic dermally. Technical coumaphos can cause mild eye and/or dermal irritation. Coumaphos is not considered to be carcinogenic. Based on animal studies coumaphos does not produce organophosphate-type induced delayed neurotoxicity (OPIDN).

The Agency has determined that coumaphos products, labeled and used as specified in this Reregistration Eligibility Decision, may pose adverse effects to humans, i.e., low MOEs for mixer/loader/applicators. Uncertainties in the existing worker exposure databases do not allow the Agency to determine, with confidence, the appropriate MOEs for these exposure scenarios. Therefore, the Agency defers making a regulatory decision except in those instances where a regular cholinesterase monitoring program is in place. A regulatory decision on the non-USDA uses of coumaphos will be made when chemical-specific worker exposure studies are submitted and reviewed. The U.S. Department of Agriculture (USDA) uses coumaphos along the U.S./Mexico border to control ticks that carry Equine and Bovine piroplasmosis (Texas Cattle Fever). The Agency does believe that available data indicate an exposure problem exists and is requiring improvements to reduce handler exposure during the mixing/loading of coumaphos products registered for dip vat and/or hand held spraying. The improvements consist of water soluble packaging for powders and either gel packs or no-glug containers (or other equivalent system approved by the Agency) for the flowable formulations. The Agency is leaving the determination of the appropriate method to reduce handler exposure for flowables during mixing/loading to the registrant. However, that determination must be supported with appropriate data indicating adequate MOEs are achieved. In the interim, the Agency is imposing a label advisory for individuals to limit the number of animals they treat per day to no more than 100

(assuming animals are treated at the maximum label rate, 200 if they are treated at 1/2 maximum label rate, etc.). It should be noted that the USDA has a program in place to monitor the cholinesterase levels of the workers involved in treating animals with coumaphos to prevent outbreaks of Texas Cattle Fever, which is transmitted by ticks. The Agency is in consultation with the USDA concerning possible strengthening of this existing program. The Agency is requiring the registrant to submit the worker exposure studies on an accelerated schedule, i.e., one year from the issuance of this document. When chemical-specific exposure data required by this RED are received and reviewed, the Agency will be in a position to make a regulatory decision regarding the reregistration eligibility of the non-USDA uses of coumaphos.

The Agency can make a regulatory decision concerning the USDA uses (Texas Cattle Fever) of coumaphos because of the very high economic benefits. It is estimated, by USDA, that the cattle industry would sustain annual losses of $1-5 billion dollars if cattle fever ticks and the associated disease, babesiosis, were to become re-established in the U.S.. Equine babesiosis could result in mortality rates of about 10% or greater in susceptible horses. There are no available estimated economic losses due to the disease if introduced in the horse population in the U.S.. It should be noted that international movement of show and race horses and cattle from the United States would be severely restricted.

Coumaphos is essentially immobile and persistent in soil and therefore there are no immediate concerns for ground water contamination from non-point source application of coumaphos. However, coumaphos is apparently more mobile when poured at high concentrations into disposal pits (ca. 1300 ppm) associated with the animal dip vat use. Coumaphos could pose a threat to ground water quality if spent coumaphos animal vat dip solution were disposed of improperly. The current disposal practice is to dispose of the spent vat solutions by pumping it to shallow, unlined evaporation ponds. When the water evaporates, the dried sludge is removed from the pond and disposed of on land by plowing it under (on non-agricultural land) to encourage further degradation in the soil. The Agency is concerned that evaporation ponds and/or associated liners could leak and is working with the U.S. Department of Agriculture, Agricultural Research Service together with the technical registrant Bayer to develop an improved disposal method. In that on-going research effort, the USDA has conducted pilot scale studies, partially funded by Bayer Animal Health, to evaluate the potential for bioremediation of the coumaphos spent dip vat solutions. Laboratory and preliminary field studies indicate that coumaphos levels can be reliably reduced from 1300 ppm to ca. 10 ppm using relatively simple technology practical for use in remote locations where many of these dip vats are located. The Agency concludes that reducing the coumaphos levels by bioremediation is preferable to lined evaporation ponds alone and will continue to pursue this method of waste disposal with the USDA and the coumaphos technical registrant, Bayer. Disposal of spent vat solution in unlined pits will no longer be allowed.

Technical coumaphos is highly to very highly toxic to birds. Birds may be exposed to coumaphos by feeding in the vicinity of treated cattle, or directly from the hides of treated cattle. However, the limited use pattern, i.e., only used for direct livestock treatment, is expected to

confine problems to areas around feedlots or other areas where treated cattle may congregate. There is only one known avian incident during the thirty years that coumaphos has been registered for use and the source of exposure in that incident is unknown.

Technical coumaphos is moderately toxic to freshwater fish and very highly toxic to aquatic invertebrates. There is a potential exposure to aquatic organisms resulting from washing-off of the material from the backs of newly treated cattle which have entered a stream or pond. A hazard to aquatic invertebrates could also result from improper disposal of spent vat dipping solutions. The hazard to aquatic invertebrates cannot be eliminated, however, it may be mitigated by label warnings.

The USDA Tick Eradication Program restricts cattle access to water for seven days after treatment with coumaphos. It should be noted that USDA use of coumaphos comprises almost one-half of total coumaphos use in the U.S.. For the remainder of uses the Agency will address the risks to aquatic organisms with a label advisory.

Due to the acute toxicity of coumaphos, the lack of chemical specific exposure data for all coumaphos uses, and the low MOEs calculated for mixer/loader/applicator the Agency is now requiring handler exposure data. The Agency has previously required acute and subchronic neurotoxicity testing, that requirement remains unchanged by this RED. While the data base is "substantially complete" for the purposes of making this reregistration decision, the Agency is requiring this data as confirmatory for the USDA uses of coumaphos. The handler exposure studies are required before the Agency can make a regulatory decision regarding reregistration eligibility of all other uses of coumaphos. The Agency is also requiring additional environmental fate data, i.e., an anaerobic aquatic metabolism study which is considered confirmatory for all coumaphos uses.

The Agency is requiring "baseline" personal protective equipment (PPE) for mixer/loader/applicators of coumaphos due to its acute toxicity. PPE requirements vary depending on the particular scenario, e.g., less PPE is required for closed system mixing/loading. Details concerning the PPE requirement for coumaphos can be found in Section V of this RED.

Before reregistering the products containing coumaphos, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and the revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base 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" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of coumaphos. The document consists of six sections. Section I is the introduction. Section II describes coumaphos, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for coumaphos. Section V discusses the reregistration requirements for coumaphos . Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Coumaphos
- **Chemical Name:** O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 56-72-4
- **OPP Chemical Code:** 036501 (OPP - Office of Pesticide Programs)
- **Empirical Formula:** $C_{14}H_{16}ClO_5PS$
- **Trade and Other Names:** Asuntol, Bay 21/199, Baymix, Co-Ral, Coumarin, ENT-17957, Meldane, Muscatox, Negashunt and Resitox
- **Basic Manufacturer:** Bayer Corp.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these use of coumaphos is in Appendix A.

Type of Pesticide: Insecticide/acaricide

Use Sites: Use on beef and dairy cattle; sheep; goats; horses; swine and swine bedding. Predominate use is on beef cattle.

Target Pests: Face fly, horn fly, fly larvae, cattle grubs, ticks (including ear tick), lice, mites, screwworms, sheep ked and fleeceworms

Formulation Types

Registered: Technical Grade Active Ingredient:
Solid 90.0%
Manufacturing Product:
Dust 25.0%
End Use Products:
Dust 1.0 to 5.0%
Emulsifiable Concentrate 5.8 to 11.6%
Flowable Concentrate 42.0%
Liquid-Ready to Use 4.0%
Pressurized Liquid 3.0%
Wettable Powder 25.0%

Method and Rates of Application:

Equipment - Dip vats, low-pressure hand-wand, high-pressure hand-wand, backrubber oiler, handheld/mechanical dusters, dust bags, aerosols, ready-to-use pour-on devices.

Method and Rates - Dusts, sprays, dips, pour-ons, dust bags, and backrubber oils. Maximum use rates are specified in the following table.

Table A. Registered uses and maximum rates of application for coumaphos products.

INDOOR FOOD

Dairy Animals

DAIRY CATTLE (LACTATING OR UNSPECIFIED)

Animal treatment (backrubber), when needed, backrubber
11.6% emulsifiable concentrate; 1.0 lb AI/13 gal oil
5.8% emulsifiable concentrate; 0.5 lb AI/13 gal oil

Animal treatment (dust bag), when needed, dust bag
5.0% dust; dose by product
1.0% dust; 0.005 lb AI/animal

Animal treatment (dust), when needed, duster/hand held duster/mechanical duster/shaker can
1.0% dust; 0.00125 lb AI/animal

Animal treatment (dust), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (ear), when needed, aerosol can
3.% pressurized liquid; 5 sec/ear; dose by product

Animal treatment (ear), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (spray), when needed, sprayer
26.3% wettable powder; 0.25 lb AI/100 gal water
11.6% emulsifiable concentrate; 0.25 lb AI/100 gal water
5.8% emulsifiable concentrate; 0.25 lb AI/100 gal water

Animal treatment (wound), when needed, aerosol can
3.0% pressurized liquid; dose by product

Animal treatment (wound), when needed, squeeze applicator
5.0% dust; dose by product

DAIRY CATTLE (NON-LACTATING)

Animal treatment (spray), when needed, high pressure sprayer
42.0% flowable concentrate; 2.1 lb AI/100 gal water
26.3% wettable powder; 4.0 lb AI/100 gal of water

11.6% emulsifiable concentrate; 3.0 lb AI/100 gal water
5.8% emulsifiable concentrate; 2.0 lb AI/100 gal water

Animal treatment (spray), when needed, sprayer
42.0% flowable concentrate; 2.1 lb AI/100 gal water
26.3% wettable powder; 1.0 lb AI/100 gal water
11.6% emulsifiable concentrate; 1.0 lb AI/100 gal water
5.8% emulsifiable concentrate; 1.0 lb AI/100 gal water

Dip treatment, when needed, Vat
42.0% flowable concentrate; 2.55 lb AI/100 gal water
26.3% wettable powder; 2.5 lb AI/100 gal water

Pour-on, when needed, Not on label
4.0% liquid RTU; 0.0015625 lb AI/100 lb animal weight

DAIRY GOATS (NON-LACTATING)

Animal treatment (spray), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal of water

Animal treatment (wound), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal of water

Dip treatment, when needed, Vat
26.3% wettable powder; 2.0 lb/100 gal of water

Pour-on,when needed,Not on label
4.0% liquid RTU; 0.0015625 lb AI/100 lb animal weight

Meat Animals Other Than Poultry
BEEF (RANGE/FEEDER) CATTLE (MEAT)

Animal treatment (backrubber), when needed, backrubber
11.6% emulsifiable concentrate; 1.0 lb AI/13 gal oil
5.8% emulsifiable concentrate; 0.5 lb AI/13 gal oil

Animal treatment (dust), when needed, dust bag
5.0% dust; dose by product
1.0% dust; 0.005 lb AI/animal

Animal treatment (dust), when needed, duster/hand held duster/mechanical duster/Shaker can
1.0% dust; 0.00125 lb AI/animal

Animal treatment (dust), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (ear), when needed, aerosol can
3.0% pressurized liquid; 5 sec/ear; dose by product

Animal treatment (ear), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (spray), when needed, high pressure sprayer
42.0% flowable concentrate; 2.1 lb AI/100 gal water
26.3% wettable powder; 4.0 lb AI/100 gal water
11.6% emulsifiable concentrate; 3.0 lb AI/100 gal water
5.8% emulsifiable concentrate; 2.0 lb Ai/100 gal water

Animal treatment (spray), when needed, sprayer
42.0% flowable concentrate; 2.1 lb AI/100 gal water
26.3% wettable powder; 1.0 lb AI/100 gal water
11.6% emulsifiable concentrate; 1.0 lb AI/100 gal water
5.8% emulsifiable concentrate; 1.0 lb AI/100gal water

Animal treatment (wound), when needed, aerosol can
3.0% pressurized liquid; dose by product

Animal treatment (wound), when needed, high pressure sprayer
11.6000% emulsifiable concentrate; 2.0 lb/100 gal water

Animal treatment (wound), when needed, squeeze applicator
5.0% dust; dose by product

Dip treatment, when needed, vat
42.0% flowable concentrate; 2.55lb AI/100 gal water
26.3% wettable powder; 2.5 lb AI/100 gal water

Pour-on, when needed, no rate specified
4.0% liquid RTU; 0.0015625 lb AI/100 lb animal weight

GOATS (MEAT); SHEEP (MEAT)

Animal treatment (dust), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (ear), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (spray), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal water

Animal treatment (wound), when needed, aerosol can
3.0% pressurized liquid; dose by product

Animal treatment (wound), when needed, sprayer
26.3% wettable powder; 2 lb AI/100 gal water

Animal treatment (wound), when needed, squeeze applicator
5.0% dust; dose by product

Dip treatment, when needed, vat
26.3% wettable powder; 2.0 lb AI/100 gal water

HOG/PIG/SWINE (MEAT)

Animal bedding/litter treatment, when needed, duster/hand held/mechanical duster/shaker can
1.0% dust; 0.00004125 lb AI/sq.ft

Animal treatment (dust), when needed, duster/hand held duster/mechanical duster/shaker can
1.0% dust; 0.000625 lb AI/animal

Animal treatment (dust), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (ear), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (spray), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal water
11.6% emulsifiable concentrate; 0.5 lb AI/100 gal water
5.8% emulsifiable concentrate; 0.5 lb AI/100 gal water

Animal treatment (wound), when needed, aerosol can
3.0% pressurized liquid; dose by product

Animal treatment (wound), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal water

Animal treatment (wound), when needed, squeeze applicator
5.0% dust; dose by product

SHEEP (MEAT); (see GOATS (MEAT))

INDOOR NON-FOOD
Fur and Wool Bearing Animals
GOATS (ANGORA ANIMAL); SHEEP (WOOL)

Animal treatment (dust), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (ear), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (spray), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal water

Animal treatment (wound), when needed, aerosol can
3.0% pressurized liquid; dose by product

Animal treatment (wound), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal water

Animal treatment (wound), when needed, squeeze applicator
5.0% dust; dose by product

Dip treatment, when needed, vat
26.3% wettable powder; 2.0 lb AI/100 gal water

SHEEP (WOOL), See GOATS (ANGORA ANIMAL)

Specialized Nonfood Animals
HORSES

Animal treatment (dust), when needed, mechanical duster/shaker
1.0% dust; 0.00125 lb AI/animal

Animal treatment (dust), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (ear), when needed, squeeze applicator
5.0% dust; dose by product

Animal treatment (spray), when needed, high pressure sprayer
42.0% flowable concentrate; 2.1 lb AI/100 gal water

Animal treatment (spray), when needed, sprayer
42.0% flowable concentrate; 2.1 lb AI/100 gal water
26.3% wettable powder; 2.0 lb AI/100 gal water
11.6% emulsifiable concentrate; 2.0 lb AI/100 gal water
5.8% emulsifiable concentrate; 2.0 lb AI/100 gal water

Animal treatment (wound), when needed, aerosol can
3.0% pressurized liquid; dose by product

Animal treatment (wound), when needed, sprayer
26.3% wettable powder; 2.0 lb AI/100 gal water
11.6% emulsifiable concentrate; 2.0 lb AI/100 gal water
5.8% emulsifiable concentrate; 2.0 lb AI/100 gal water

Animal treatment (wound), when needed, squeeze applicator
5.0% dust; dose by product

Timing - See above. Used primarily during the early spring to late summer, e.g., the fly season.

Use Practice Limitations: Do not apply to lactating dairy cattle at rates above 1 lb. of CO-RAL 25% Wettable Powder per 100 gallons of water.

Avoid contamination of feed, feed containers and watering troughs.

Do not treat sheep or goats within 3 days of slaughtering.

Do not treat non-lactating dairy cattle at rates above 1 lb. of CO-RAL 25% Wettable Powder per 100 gallons of water within 14 days of freshening. If freshening should occur within 14 days after

treatment at higher intervals, do not use milk as human food for the balance of the 14 day interval.

Do not apply to sick, convalescent or stressed livestock or to animals less than 3 months old except in Federal or State eradication programs (screw worm, scabies, cattle fever ticks) where immediate treatment of all animals in an infested herd is mandatory.

Do not dip animals when they are over-heated.

Do not spray in confined, non-ventilated area.

Do not apply in conjunction with oral drenches or other internal medications such as phenothiazine.

CO-RAL is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment or exposure to cholinesterase inhibiting drugs, pesticides or chemicals.

C. Estimated Usage of Pesticide

Exact amounts of coumaphos used or sold in the U.S. are Confidential Business Information. However, the following table gives a general indication of which coumaphos uses are most prevalent. The predominant uses of coumaphos are on beef cattle and dairy cattle. Use on goats, sheep, hogs and horses is a small component of the overall usage in the U.S.. It should be noted that a significant amount of coumaphos purchased in the U.S., by the USDA for dip vat use, is actually used in Mexico. Cattle are treated on the Mexican side of the border (to prevent outbreak of Texas Cattle Fever) prior to being delivered to feedlots in the U.S.. It should also be noted that while coumaphos is an important animal use insecticide, its use in the U.S. is small when compared to other agricultural insecticides used on crops.

Application Method	**Estimated** % of Usage
Dip vat use	40 - 45%
Dust Bags, backrubbers, pour-on, spray, shaker can, aerosol, etc.	55 - 60%

D. Data Requirements

Data requested in the 1981 Registration Standard and the 1989 Revised Registration Standard for coumaphos included studies on product chemistry, ecological effects, environmental fate, toxicology and residue chemistry. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration. A Data Call-In (DCI) was issued on Nov 11, 1992 requiring additional human neurotoxicity and aquatic toxicity data. The aquatic toxicity studies required were conducted, and the data submitted and reviewed in this reregistration eligibility decision. The registrant (Bayer Corp.) was granted an extension in submitting the neurotoxicity data, due to the large number of active ingredients they are required to test. The acute and chronic neurotoxicity data are due April 30, 1998 and Nov 30, 1998, respectively.

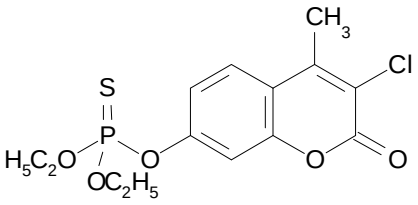
E. Regulatory History

Coumaphos was registered in the United States in 1958 for use as an insecticide. Data Call-In's were issued in 1981, 1989 and 1992 for coumaphos requiring additional data. A Registration Standard for coumaphos was issued in September 1989 (NTIS #PB90-122243) which evaluated the studies submitted as a result of the 1981 DCI. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and other acceptable data, e.g., Pesticide Handlers Exposure Database (PHED).

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Coumaphos [O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate] is an insecticide/acaracide registered for direct application to cattle, goats, horses, sheep, and swine.



Empirical Formula:	$C_{14}H_{16}ClO_5PS$
Molecular Weight:	362.8
CAS Registry No.:	56-72-4

Identification of the active ingredient

Technical coumaphos is a tan powder with a melting point of 90-95 C. At 20 C, 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 (0.09 g/100 ml); and insoluble in water (0.002 g/100 ml). Coumaphos is stable under normal use conditions, but hydrolyzes slowly under alkaline conditions.

Manufacturing-Use Products

Two coumaphos manufacturing-use products (MPs) are registered to Bayer, Inc. (EPA Registration numbers: 11556-11 and 11556-20)

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for coumaphos is adequate to support risk assessment in connection with the reregistration eligibility decision. A six month ocular toxicity study in dogs, required because coumaphos is an organophosphate, is reserved until the Agency develops testing protocols. The acute and subchronic mammalian neurotoxicity studies are needed as confirmatory data.

a. Acute Toxicity

TEST	RESULT	CATEGORY
(81-1) Oral LD50 in rat (MRID 00110597)	>240 mg/kg - males 17 mg/kg - females	I
(81-2) Dermal LD50 in rat (MRID 00110598)	>2400 mg/kg - males and females	III
(81-3) 1 Hour Inhalation LC50 in rat (MRID 00110601)	1.081 mg/L - males 0.341 mg/L - females	II
(81-4) Eye irritation in rabbit (MRID 00110599)	Mild irritant, resolved by day 7	III
(81-5) Dermal irritation in rabbit (MRID 00110600)	Not irritating	IV
(81-6) Dermal sensitization in rabbit (MRID 00110602)	Not a sensitizer	N/A
(81-7) Acute neurotoxicity in hen (MRID 00115167)	Does not produce delayed neurotoxicity	N/A

Acute Neurotoxicity - Mammalian

This study is required and is considered confirmatory data.

b. Subchronic Toxicity

Subchronic Oral Toxicity

Coumaphos was orally administered in a 13-week feeding study to 20 Charles River [Crl: CR (SD)Br] rats/sex/group at dose levels of 0, 2, 5 or 10 ppm (0, 0.2, 0.5 or 1.0 mg/kg/day). Plasma, erythrocyte (RBC) and brain cholinesterase (ChE) levels were determined at 3, 8 and 13 weeks. (MRID 00126527)

Plasma cholinesterase was inhibited throughout the study at all dose levels in males, but was only statistically significant at 10 ppm (16, 15 and 24%, from low- to high-dose) and for females at 10 ppm (not significant, 21%). RBC ChE was significantly inhibited in males (18, 34, 50%, from low- to high-dose) and females (32, 39, 64%, from low- to high-dose) at all dose levels and time points except at 2 ppm where significance occurred only at 13 weeks. Brain ChE was not inhibited at any time. The LEL for cholinesterase inhibition is equal to or less than 2 ppm (0.2

mg/kg/day) based on RBC ChE inhibition. The NOEL for cholinesterase inhibition is less than 2 ppm.

No signs of systemic toxicity were observed at any dose. The systemic LEL and NOEL are greater than 10 ppm (1.0 mg/kg/day).

This study is not completely acceptable (core-supplementary) due to deficiencies in the study. However, a new study is not likely to significantly alter the NOEL or LEL levels, therefore, the Agency will use the results for risk assessment.

Subchronic Dermal Toxicity

In a 21-day dermal study coumaphos (98.5%) was administered to 6 male and 6 female Sprague-Dawley [Sas:CD(SD)BR] rats/group at dose levels of 0, 2, 4, 20 or 100 mg/kg/day. (MRID 42084901)

Relative to the concurrent controls at 2 mg/kg/day (LDT), there was erythrocyte cholinesterase (RBC ChE) inhibition in males (20, 24, 84 and 96% from low- to high-dose) and females (14, 42, 89 and 95% from low- to high-dose) and plasma ChE inhibition in females (38, 38, 65 and 91% from low- to- high-dose). At 20 and 100 mg/kg/day, plasma (males 44, 78% for the 2 highest doses) and brain ChE were decreased in males (22 and 59% for the 2 highest doses) and females (26 and 67% for the 2 highest doses). **The LEL for cholinesterase inhibition was 2 mg/kg/day based on RBC and plasma ChE. The NOEL for cholinesterase inhibition was less than 2 mg/kg/day.**

This 21-day dermal study indicates that significant plasma and brain cholinesterase inhibition occur at approximately the same doses. As noted in the next paragraph clinical signs characteristic of neurotoxicity were also observed at these doses.

Signs of systemic toxicity occurred at 20 mg/kg/day and above and included muscle fasciculation in males (17% and 67% for the 2 highest dose levels) and females (17 and 100% for the 2 highest dose levels) sporadically throughout the study. Tremors occurred in females (17 and 83% at the two highest doses) after the first week and there were anal stains in males. At 100 mg/kg/day, there were increased incidences of hypothermia and activity in females and decreased body weight gains in males and females. The systemic LEL was 20 mg/kg/day based on muscle fasciculation and tremors. The systemic NOEL was 4 mg/kg/day.

This study is not completely acceptable (core-supplementary: a NOEL for ChE was not determined) when considered alone and is not acceptable for regulatory purposes. However, the study is considered to be acceptable when taken together with a second study conducted using lower doses in females (MRID 42666401).

In a 21-day dermal study, technical grade coumaphos (99.1%) was administered to 5 female Sprague-Dawley [Sas:CD(SD)BR] rats per group at dose levels equivalent to 0, 0.1, 0.5, 1.1 or 2.1 mg/kg/day. (MRID 42666401)

At 1.1 mg/kg/day, RBC ChE was inhibited (24 and 28% for the two highest doses). The LEL for cholinesterase inhibition was 1.1 mg/kg/day based on inhibition of RBC ChE in females. The NOEL for cholinesterase inhibition is 0.5 mg/kg/day.

There was no systemic toxicity observed at any dose level. The systemic LEL is greater than 2.1 mg/kg/day. The systemic NOEL is 2.1 mg/kg/day (4 mg/kg/day based on a separate study). This study is considered acceptable when taken together with the study cited above, i.e., MRID 42084901.

When the two studies are considered together, the NOEL and LEL for systemic effects are 4 and 20 mg/kg/day, respectively. The NOEL and LEL for cholinesterase inhibition are 0.5 and 1.1 mg/kg/day, respectively.

c. Chronic toxicity

1) Rat: In a 2-year chronic feeding/carcinogenicity study, technical grade coumaphos (99.2%) was fed to groups of 70 SPF Wistar [Bor:WISW(SPF Cpb)] rats/sex at dose levels of 0, 1, 5 or 25 ppm in the diets (males - 0, 0.05, 0.25 or 1.22 mg/kg/day; females - 0, 0.07, 0.36 or 1.70 mg/kg/day). (MRIDs 40836001, 40955801)

Body weight gain of females in the 25 ppm group was marginally decreased by up to 4% throughout the study, but the effect is considered to be treatment related. The systemic NOEL and LEL are 5 ppm (0.36 mg/kg/day) and 25 ppm (1.70 mg/kg/day) in females, respectively, based on decreased body weight gain.

Plasma cholinesterase (ChE) was decreased in males in the 25 ppm group (up to 43%), and in females in the 5 ppm (up to 27%) and 25 ppm (up to 53%) groups. Erythrocyte ChE was decreased in males in the 25

ppm group (up to 28%), and in females in the 5 ppm (up to 11%) and 25 ppm (up to 34%) groups. The NOEL (ChE) and LEL (ChE) are 5 ppm (0.36 mg/kg/day) and 25 ppm (1.70 mg/kg/day) in females, respectively.

There was no evidence of carcinogenicity at any dose. Dosing was adequate to evaluate carcinogenic potential.

In a second carcinogenicity study, coumaphos TGAI (95%) was administered to groups of 50 F344 rats/sex at dose levels of 10 or 20 ppm in the diet for 103 weeks. The control group contained 25 rats/sex. (MRID 05009938)

Body weights of female rats were slightly lower than the controls at 10 and 20 ppm. Decreases in male body weight was observed at 20 ppm. No other toxic manifestations were apparent. There was no evidence that administration of coumaphos was associated with an increase in tumors. Dosing was considered adequate to evaluate carcinogenic potential.

2) Mouse: In a carcinogenicity study technical grade coumaphos (95%) was administered to groups of 50 $B_6C_3F_1$ mice/sex at dose levels at 10 and 20 ppm in the diet for 103 weeks. The control group contained 25 mice/sex. (MRID 05009938)

No toxic manifestations were apparent. There was no evidence that administration of coumaphos was associated with an increase in tumors. Dosing was considered adequate to evaluate carcinogenic potential based on range-finding data. It was expected that ChE would have been inhibited if the measurement was evaluated.

3) Dog: In a 1-year feeding study male and female Beagle dogs (4 per sex/group) were given technical grade coumaphos (98.0-99.0%) in the diet at concentrations of 1, 30, or 90 ppm (equivalent to 0.025, 0.775, or 2.295 mg/kg/day for males, and 0.024, 0.705, or 2.478 mg/kg/day for females, respectively). Control groups received untreated diet. (MRID 43055301)

When compared to pretreatment levels, plasma cholinesterase (ChE) and erythrocyte cholinesterase (RBC ChE) activity levels were significantly depressed ($p \leq 0.05$) in the 30 and 90 ppm exposure groups. Specifically, plasma ChE levels in the 30 ppm males at 91, 182, 273, and 363 days were 62.5%, 73.6%, 72.1%, and 76.1% less than pretreatment values and in the 30 ppm females were 53.8%, 62.0%, 61.7%, and 72.1%

less than pretreatment levels. In the 90 ppm groups, plasma ChE activity at days 91, 182, 273, and 363 were depressed 70.8%, 73.8%, 80.2% and 77.9% (males) and 74.4%, 76.5%, 73.4%, and 84.4% (females). For RBC ChE activity levels in the 30 ppm group at these time points, the respective values were 41.9%, 37.3%, 42.4%, and 46.6% (males), and 49.3%, 33.9%, 42.1% and 42.9% (females) of respective pretreatment values. RBC ChE activity levels in the 90 ppm group at days 91, 182, 273, and 363, were 76.9%, 66.2%, 75.2%, and 59.7% (males), and 79.2%, 75.1%, 82.1% and 75.6% (females) less than the pretreatment values. Comparison to concurrent controls and evaluation of brain cholinesterase and ocular muscle cholinesterase at the termination of the study corroborated these findings. Although some statistically significant plasma ChE depression was also observed in females in the 1 ppm group, the difference could be attributed to the high degree of individual variability. Based upon significant and biologically relevant depression of RBC ChE and plasma ChE activity levels in dogs, this study provided a NOEL of 0.025 mg/kg/day and a LEL of 0.7 mg/kg/day.

There were no other treatment related systemic changes at any dose level. The systemic NOEL was 2.3 mg/kg/day and the LEL was greater than 2.3 mg/kg/day.

d. Carcinogenicity Classification

Coumaphos was classified by the HED RfD/Peer Review Committee on October 13, 1994 as a "Group E", i.e., evidence of non-carcinogenicity for humans, based on adequate studies in two animal species.

e. Developmental Toxicity

1) Rat: In a developmental toxicity study, coumaphos (TGAI) was administered by gavage to groups of 28 Charles River CDBS rats at dose levels of 0, 1, 5 or 25 mg/kg/day during day 6 to 15 of the gestation period. (MRID 00131684)

Three females in the 25 mg/kg/day group exhibited tremors and 2 of these showed additional signs of mild anticholinesterase-type toxicity. The NOEL and LEL for maternal toxicity were 5 mg/kg/day and 25 mg/kg/day, respectively, based on clinical signs of cholinesterase toxicity. No developmental effects were observed. The NOEL and LEL for developmental toxicity was greater than or equal to 25 mg/kg/day.

2) Rabbit: Technical coumaphos was administered by gavage to groups of 17 American Dutch rabbits at dose levels of 0, 0.25, 2.0 or 18.0 mg/kg/day during days 7-19 of gestation. Maternal toxic signs, including death and abortion, were observed in the 18.0 mg/kg/day group. The NOEL and LEL for maternal toxicity were 2.0 mg/kg/day and 18.0 mg/kg/day, respectively. No developmental effects were observed. The NOEL for developmental toxicity was 18.0 mg/kg/day. The LEL for developmental toxicity was greater than 18.0 mg/kg/day. (MRID 00131683)

f. Reproductive Toxicity

In a two-generation reproduction study Sprague-Dawley rats (30/group) received technical coumaphos (99%) in the diet at dose levels of 0, 1, 5, or 25 ppm. These dose levels correspond to approximately 0, 0.07, 0.30, and 1.79 mg/kg/day for F_O males and 0, 0.08, 0.34, and 2.02 mg/kg/day for F_O females respectively, during premating. (MRID 43061701)

Cholinesterase inhibition, observed at 5 and 25 ppm was manifested as dose-related decreases in erythrocyte (RBC) and plasma cholinesterase (ChE). The RBC ChE was inhibited 31-70%, relative to concurrent controls, at 5 ppm and 53%-95% at 25 ppm. Generally, no differences were noted between Day 47 (or 56) and Day 91 ChE levels. Brain levels were biologically significantly inhibited ($\approx$30%) in F_O and F_1 females. In pups, plasma and RBC ChE levels were inhibited (31%-44%) at 25 ppm on lactation day 21 but not on lactation day 4. Based on these results, the NOEL and LEL for ChE inhibition were 1 and 5 ppm, respectively.

There were no other signs of systemic toxicity. The NOEL and LEL for systemic toxicity was equal to or greater than 25 ppm. Reproductive toxicity was not observed in this study. Consequently, the NOEL for reproductive toxicity was 25 ppm and the LEL for reproductive toxicity was greater than 25 ppm.

g. Mutagenicity

1) Gene Mutation

A Salmonella/microsome study was conducted. Coumaphos was not mutagenic when tested at levels up to 12,500 μg/plate with and without metabolic activation in Salmonella typhimurium strains TA1535, TA1537, TA100, and TA98. (MRID 00131680)

2) Structural Chromosomal Aberration

Coumaphos was tested in a mouse-micronucleus test at levels up to 1920 mg/kg by gavage. Negative results were obtained at 480 mg/kg. Cytotoxicity was observed at dose levels above 480 mg/kg. Mortality was observed at higher dose levels making the results uninterpretable. (MRIDs: 41847501, 42254501)

3) Direct DNA Damage and Repair

A Pol A test on Escherichia coli was conducted. Coumaphos was not mutagenic when tested at levels up to 5000 μg/plate with and without metabolic activation. (MRID 00131681)

h. Metabolism

Radiolabeled coumaphos was administered to rats at dose levels of 1.0 mg/kg intravenously and 1.0 and 15.0 mg/kg, orally. A fourth group received 1.0 mg/kg coumaphos daily for 14 days. (MRID 01155611)

The plasma half life ranged from 2.35 to 3.30 hours at 1.0 mg/kg (including the repeated dose group) and 2.93 to 5.30 hours at 15.0 mg/kg. Urinary excretion was rapid with 63-87% of the administered dose being excreted within 24 hours. 76-96% of the administered dose was excreted within 168 hours. Tissue residues were highest in fat, kidney, liver and muscle. The urine contained 5 to 8 metabolites and the feces contained 5 to 7 metabolites. The major metabolite is chlorferone (the hydroxylated leaving group). Coumaphos represented 0.1% of the urinary metabolites. Coumaphos represented 0.2% of the fecal metabolites when administered intravenously. However, when administered orally coumaphos represented approximately 15 to 55% of the fecal metabolites. The range varied depending on whether coumaphos was administered as a single dose or repeated dose.

i. Endpoints Used for Risk Assessment

Acute Dietary Exposure

The endpoint for acute dietary risk assessment is the RBC ChE inhibition NOEL (0.2 mg/kg/day) from the 13-week rat dietary study (MRID 00126527). The LEL (0.5 mg/kg/day) is based upon RBC ChE inhibition. Although the above endpoint was observed at 21 days (earliest time point measured) there is no reason to believe that the inhibition did

not occur within the first week of exposure. The RBC ChE inhibition observed at 0.2 mg/kg/day is not appropriate for this exposure scenario since it was only statistically significant at 13 weeks not at 3 weeks. Effects (RBC ChE inhibition) were noted at 0.2 mg/kg/day at 13 weeks but not at earlier time intervals. Therefore, the 0.2 mg/kg/day is considered a NOEL for exposures of less than 13 weeks.

Short-term Occupational Exposure (1-7 days)

The endpoint for short-term occupational or residential risk assessment is the RBC ChE NOEL (0.5 mg/kg/day) from the 21-day dermal rat study (MRID 42666401). The LEL (1.1 mg/kg/day) is based upon inhibition of RBC ChE. Although the above studies are 21 days in duration there is no reason to believe that the inhibition would not or did not occur within the first week of exposure.

Intermediate-term Occupational or Residential Exposure (1-Week to Several Months)

The endpoint for intermediate-term occupational or residential risk assessment is the RBC ChE NOEL (0.5 mg/kg/day) from the 21-day dermal rat study (MRID 426664-01). The LEL (1.1 mg/kg/day) is based upon inhibition of RBC ChE.

j. Reference Dose

The RfD/Peer Review Committee recommended, in the October 13, 1994 meeting, to establish the RfD for coumaphos based on the NOEL of 0.025 mg/kg/day observed in the newly submitted 1-year dog chronic toxicity study (MRID 43055301). Plasma and erythrocyte ChE inhibition was observed at the next highest dose level of 0.775 and 0.705 mg/kg/day in males and females, respectively. An uncertainty factor of 100 was applied to account for inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated to be 0.007 mg/kg/day. It should be mentioned that this chemical had been reviewed in 1990 by the FAO/WHO Joint Committee on Pesticide Residue (JMPR). However, an acceptable daily intake (ADI) was not established.

2. Exposure Assessment

a. Dietary Exposure

Plant Metabolism

There are no registered uses for coumaphos on crops. Plant metabolism data are not necessary or required.

Animal Metabolism

The qualitative nature of the residue in ruminants is adequately understood based on an adequate metabolism study reflecting dermal exposure to lactating cattle. The residues of concern are coumaphos and its oxygen analog. The salient features of the dermal treatment study are summarized below.

One cow received [phenyl-^{14}C]coumaphos treatment daily for two consecutive days. The test substance totalling 2.252 g was poured along the center line of the back. Milk was collected twice a day and the cow was sacrificed and tissues collected 24 hours after the second dose. The total radioactive residue (TRR) in milk plateaued at 0.022 ppm after 36 hours; the maximum residues in milk were 0.023 ppm at 48 hours. At the treatment site, TRR were 3.019 ppm in subcutaneous fat and 0.425 ppm in muscle. TRR in other tissues were 0.054 ppm in kidney, 0.03 ppm in liver, 0.003 ppm in muscle, and 0.021-0.043 ppm in fat. Coumaphos was the major residue accounting for 70-96% of the residue in tissues from the treatment site. Neither coumaphos oxygen analog nor the metabolite potasan [O,O-diethyl O-(4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate] was detected. As the registrant has canceled uses on poultry, there is no requirement for poultry metabolism data.

Residue Analytical Methods - Animals

Adequate methodology is available for enforcement of animal commodity tolerances. A fluorophotometric method is published in PAM, Vol. II as Method I. This method does not distinguish between coumaphos and the oxygen analog. An improved method, method 74310, uses GC with NPD (nitrogen-phosphorus detector) detection and distinguishes between coumaphos and its oxygen analog. The detection limits for each analyte are 0.01 ppm in milk and 0.05 ppm in tissues. Method 74310 was successfully validated by an independent laboratory after modifications.

The modified method will be submitted to the Agency and validated at the EPA Beltsville Laboratory.

The FDA PESTDATA database dated 1/94 (PAM Vol. I, Appendix II) indicates that coumaphos and its oxygen analog are completely recovered (>80%) using multiresidue method PAM Vol. I Section 302 (Luke method). Coumaphos is completely recovered using Section 304 (Mills fatty food method), although recovery may vary with choice of Florisil elution system; the oxygen analog is not recovered using Section 304. Neither analyte is recovered by Section 303 (Mills, Onley, Gaither method).

Storage Stability Data - Supporting Residue Studies

Adequate storage stability data are available for meat and milk. Milk samples with residues bearing 0.19 ppm of coumaphos and 0.15 ppm of coumaphos oxon were stored up to 75 weeks with no change in residue levels. Residue levels in cattle tissue from the various types of treatment indicate stability whether the samples were stored frozen for less than 30 days or greater than 30 days. In addition, coumaphos residue levels in muscle from the dermal metabolism study were relatively stable after one year of frozen storage.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Numerous magnitude of residue studies for cattle, goats, hogs, and sheep are available reflecting the current types of registered external uses (dusts, sprays, dips, pour-ons, backrubbers, and bedding treatments). The August 1981 Residue Chemistry Science Chapter of the Registration Standard summarized the studies by use and by livestock, and highlighted maximum application rates and maximum residues found. Application rates reported in the reviewed studies range from being the same as, to being substantially higher than, currently registered maximum rates. Intervals between treatments reflected current uses, with zero to 14 days elapsing between treatments. Residues in cattle from dermal treatments were <0.02 ppm in milk and up to 0.1 ppm in muscle, 0.2 ppm in liver and kidney, and 0.7 ppm in fat. Goat and sheep fat contained up to 1 ppm and 0.2 ppm, respectively. In swine, residues up to 0.58 ppm in fat and 0.64 ppm in meat were found.

b. Occupational and Residential

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete.

Handler (Mixer/Loader/Applicators) Exposures

The Agency believes that there is potential exposure associated with coumaphos use to handlers, including mixers, loaders, and applicators. The Agency is concerned about potential exposures arising from mixing, loading, and application of emulsifiable-concentrate, flowable-concentrate and wettable-powder formulations, but also application by pouring on ready-to-use liquid, and application with backrubbers, foam, pressurized liquid, dust bags, shaker cans, and mechanical dusters. The greatest potential for coumaphos exposure appears to exist in the livestock dip vat use and with handheld sprayers, due to the sheer amount of material handled.

Based on the registered uses of coumaphos there are eight different exposure scenarios: (1) mixing/loading/application of the liquid from a high or low-pressure handwand sprayer, (2) application by foam spray can, (3) mixing/loading/application of dipping solutions, (4) application of ready-to-use, pour-on solutions, (5) application of backrubber formulations, (6) application with dust bags, (7) application of dust with shaker cans, and (8) application with mechanical dusters. The different exposure scenarios are discussed further in the risk assessment section of this RED.

Coumaphos-specific handler exposure data are not available and were not required in the Coumaphos Registration Standard (1989). Additionally, no exposure data currently are available in Pesticide Handler's Exposure Data (PHED) specifically for animal treatments. However, applicable handler exposure data are available in PHED for mixing/loading of liquid and wettable-powder formulations and for application with handheld spray equipment. The Agency believes that given the registered uses of coumaphos these exposure data will provide a reasonable frame of reference to roughly assess the risks to handlers mixing, loading, and applying coumaphos, especially for the spray and dip-vat applications where there is the greatest potential for significant exposure.

No coumaphos-specific or generic (PHED) data are currently available to assess exposures resulting from (1) loading and applying dust formulations, (2) applying ready-to-use livestock pour-on solutions, (3) ready-to-use livestock foam formulations, or (4) livestock backrubbers.

The assessment for handler exposure to coumaphos associated with spray applications incorporates the following assumptions:

- a typical (or average) herd size ranges from 50-100 head;
- a maximum herd size ranges from 500-1000 head of cattle;
- the treatment rate of spray per animal is one gallon.

Therefore, spraying an entire typical herd of 100 animals would require mixing/loading and spraying 100 gallons of dilute coumaphos/water mixture. The maximum spray application rate for coumaphos is 4.0 pounds of active ingredient (a.i.) per 100 gallons of water, while the maximum dilution rate or minimum use rate is 0.5 lbs a.i. per 100 gallons for all coumaphos products labeled for spraying. Thus a mixer/loader preparing to spray a typical herd would handle at least 0.5 pounds of coumaphos per day while mixing/loading, assuming the livestock are treated with the most dilute solution. Likewise at the same use rate, a mixer/loader preparing to spray the maximum herd size would handle 5.0 pounds of coumaphos per day while mixing/loading. These estimates are based on the upper limits of the typical and maximum herd sizes and the most dilute application rate of 0.5 lbs a.i./100 gallons. Calculation of the exposure to applicators using hand-held spray equipment also assumes they are handling 0.5 lb ai/day to 5 lb a.i./day, depending on the size of the herd they are treating.

The assessment for handler exposure to coumaphos associated with dip-vat applications incorporates the following assumptions:

- mixers/loaders handling liquid (emulsifiable concentrate) formulation at a rate of 10 pounds of active ingredient per day for a small dip-vat operation (ca. 450 gallons) and 22 pounds active ingredient per day for a large dip-vat operation (ca. 1000 gallons).
- mixers/loaders handling wettable powder formulation at a rate of 11.25 pounds of active

ingredient per day for a small dip-vat operation and 25 pounds active ingredient per day for a large dip-vat operation.

COUMAPHOS UNIT EXPOSURE ESTIMATES RESULTING FROM OPEN-SYSTEM MIXING/LOADING OF LIQUIDS AND WETTABLE POWDERS FOR LIVESTOCK SPRAYING (µg/lb ai)				
Usage Scenario	Dermal Exposure	Hand Exposure	Total Dermal Exposure	Inhalation Exposure
Livestock Spraying **(liquid formulations)**	22.8	30.6	53.4	0.1333
Livestock Spraying **(wettable powders)**	148.7	12.4	161.1	4.2

The total dose was calculated by multiplying the unit exposure times the maximum application rate times the maximum amount of material handled divided by 70 kg, i.e.:

dose = [dermal & inhalation exposure X amount handled]/body weight.

NOTE: Conversion factors are used as necessary to express in consistent units.

COUMAPHOS UNIT EXPOSURE ESTIMATES RESULTING FROM OPEN-SYSTEM MIXING/LOADING OF LIQUIDS AND WETTABLE POWDERS FOR DIP VAT OPERATIONS (µg/lb ai)				
Usage Scenario	Dermal Exposure	Hand Exposure	Total Dermal Exposure	Inhalation Exposure
Recharge Dip Vat (liquid formulations)	71.0	25.7	96.7	0.1041
Recharge Dip Vat (wettable powder)	148.7	12.4	161.1	4.2

COUMAPHOS UNIT EXPOSURE ESTIMATES RESULTING FROM HANDHELD SPRAYER APPLICATION TO LIVESTOCK (µg/lb ai)				
Application Method	Dermal Exposure	Hand Exposure	Total Exposure	Inhalation Exposure
Handheld Sprayer	823.7	26.9	850.6	6.3

Post-Application Exposures and Assumptions

EPA has determined that there is likely to be some exposure to persons contacting treated animals immediately after application is complete. No exposure data are available to assess the risk from such contact. However, EPA has determined that the amount of exposure is likely to be substantially lower than the exposure mixers and loaders receive in handling coumaphos to prepare spray solutions for a typical (average) herd size. Therefore, no post-application exposure data are required.

3. Risk Assessment

a. Dietary

The reference dose (RfD) for coumaphos is exceeded using the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from published tolerances. However, this exposure estimate and RfD calculation includes exposure to coumaphos residues at the tolerance level in poultry and eggs. There are currently no registered uses of coumaphos on poultry. Additionally, use of coumaphos on poultry is not being supported in reregistration. In order to more accurately define the dietary exposure to coumaphos residues the Agency conducted a second, more refined, analysis using anticipated residues for only those commodities with registered uses, i.e., excluding poultry and eggs.

Chronic Exposure Using Anticipated Residues:

The Anticipated Residue Contribution (ARC) for the overall U.S. population from published uses supported in reregistration are listed below. Anticipated residues are average or the typical amount of residue present and are considered appropriate to use for chronic exposure.

Subgroup	Exposure (mg/kg/day)	%Reference Dose
U.S. population	0.000098	39
Children (1-6 years)	0.000183	73

When only the supported uses are considered the ARCs for the U.S. population and all DRES subgroups are well below the Reference Dose. **When poultry and eggs are not considered in the chronic dietary risk assessment the chronic dietary risk posed from coumaphos is not of**

concern. These uses are not being supported in reregistration. The coumaphos tolerances for poultry and eggs need to be revoked.

Acute Exposure

A detailed dietary acute exposure analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of coumaphos in the commodity supply. Since the toxicological effect to which high end exposure is being compared in this analysis is red blood cell and plasma cholinesterase inhibition, all subgroups are of concern. For substances whose acute NOEL is based on an animal study, the Agency is not generally concerned unless the MOE is below 100.

High end or maximum anticipated residues (ARs), i.e, conservative or very protective of human health, were evaluated. Only uses of coumaphos supported in reregistration were included in the acute analysis, i.e., poultry and eggs were not included in the acute risk assessment. High end ARs, were used to calculate the high-end exposure for all subgroups from meat and milk. The MOEs for each subgroup are listed in the attached table. The high end MOE is for the 100% of the U.S. population. The percentile at which the MOE reaches 100 is listed in parenthesis. For example, consider the U.S. population category. The 100% percentile has an MOE of 63, while an MOE of 100 is reached at the 98% percentile level. Roughly, this means that there is a 2% chance that an individual in this category (U.S. population) will have an MOE less than 100.

DRES Subgroup	High end Exposure (mg/kg/day)	**High end MOE**	Percentile at which MOE is acceptable
U.S. pop.(48 states)	0.0032	**63**	(98th) 100
Infants (< 1 year)	0.006	**33**	(95th) 100
Children(1-6 years)	0.006	**33**	(90th) 100
Females(13+ years)	0.002	**100**	-
Males(13+ years)	0.0024	**83**	(99th) 100

The table of distribution of exposures includes the MOEs for five subgroups. The calculated MOEs are lower than 100 (at the 100th

percentile level) for four of the five subgroups used in the DRES acute program. For the children (1-6 years) subgroup, the MOE does not reach 100 until the 90% percentile.

It should be noted that the dose required to produce RBC/ChE inhibition at three weeks was used to perform the acute dietary (single dose) risk assessment. This approach would overestimate the dose that would be expected to produce ChE inhibition from a single exposure. Actual MOEs are expected to be near 100.

Two additional acute analyses were conducted to further define the exposure and the acute dietary risk from coumaphos. One analysis considers only milk and the other considers only beef products. Although this is not the method of acute risk assessment generally preferred by the Agency, the analysis helps identify higher risk commodities.

Acute Analysis Results for Coumaphos on Milk Only:

Subgroup	High End MOE	Percentile MOE
U.S. Population	100	
Infants <1	50	100 (85%)
Children 1-6	67	100 (99%)
Females 13+	333	
Males 13+	250	

Acute Analysis Results for Coumaphos on Beef Only:

Subgroup	High End MOE	Percentile MOE
U.S. Population	100	
Infants <1	67	100 (98%)
Children 1-6	67	100 (98%)
Females 13+	100	
Males 13+	100	

Although the acute analysis on milk for the infant subgroup does not reach an acceptable MOE until the 85 percentile, it is generally considered that infant formula is a mixed or blended commodity and not taken directly from one dairy cow. Any such mixing or blending would tend to reduce the variability in residue levels in the composite samples which people would consume. This would reduce the likelihood of consuming milk with residue levels at or near the maximum ever observed, i.e., 0.017 ppm. The upper bound residue estimate was estimated to be 0.02 ppm for milk, while the average residue was estimated to be 0.006 ppm in milk. The practical effect of mixing or blending would be to lower the maximum residue observed in the composite sample, making it closer to the average or median estimated value. In addition, neither of these analyses considers the effect of processing (e.g. pasteurization) or cooking which would likely reduce coumaphos levels.

Neither analysis considers the effect of processing and or cooking on residues levels because these data are not available. The original analysis also assumes that both meat and milk are consumed with coumaphos residues present in both commodities at the highest level observed in the feeding studies. Although this is certainly possible, it is highly unlikely and it should be considered as conservative, i.e., very protective of public health.

b. Occupational and Residential

A NOEL of 0.5 mg/kg/day (cholinesterase inhibition) derived from a 21-day dermal rat study was used to estimate MOE's. Because the effects discussed above are from a dermal study, no dermal absorption adjustment is necessary. An average handler body weight of 70 kilograms is used in the risk assessment. Inhalation exposures did not contribute significantly to the total exposure and consequently were not used in the MOE calculations.

Risk is calculated as follows:

$$\text{Dose (mg/kg/day)} = \frac{\text{Exposure (mg/day)}}{\text{Worker Body Weight (70 kg)}}$$

$$\text{MOE} = \frac{\text{NOEL (0.5 mg/kg/day)}}{\text{Dose (mg/kg/day) x Dermal Absorption (100\%)}}$$

Even with the uncertainties in the data (which may either overestimate or understate the risk), the Agency is concerned with the low MOEs for certain handler exposure uses. MOEs of less than 100 trigger a risk concern when the toxicity endpoint is based on animal tests.

The calculated MOE's are presented in the following tables. The calculations indicate that:

- MOEs are less than 100 for handlers mixing and loading (1) wettable powder formulations to prepare spray for the maximum herd size, (2) liquid (emulsifiable concentrate) formulations to prepare dip-vat solutions for small and large dip-vat operations, and (3) wettable powder formulations to prepare dip-vat solutions for small and large dip-vat operations.

- MOEs are less than 100 for handlers applying spray to livestock with handheld equipment for both the typical herd size and the maximum herd size.

- MOEs are greater than 100 for handlers mixing and loading liquid (emulsifiable concentrate) formulations to prepare spray for the typical and maximum herd size.

The various exposure scenarios corresponding to the different registered uses of coumaphos are summarized in the table below along with the corresponding exposure/risk assessment. All Margin of Exposure (MOE) calculations are derived from the 21-day dermal rat NOEL of 0.5 mg/kg/day. The minimum use rate was used (0.5 lbs ai/100 gallons) to calculate MOEs for spray application, MOEs for the maximum application rate (4 lbs ai/100 gallons) are therefore lower by a factor of 8.

COUMAPHOS EXPOSURE ESTIMATES RESULTING FROM OPEN-SYSTEM MIXING/LOADING OF LIQUIDS AND WETTABLE POWDERS FOR LIVESTOCK SPRAYING AND DIP VAT OPERATIONS (mg/kg/day)				
Usage Scenario	Formulation	Dermal Exposure	Inhalation Exposure	MOE
Typical Spraying	Powder	$1.2x10^{-3}$	$3x10^{-5}$	434
Typical Spraying	Liquid	$3.8x10^{-4}$	$9.5x10^{-7}$	1,311
Max Spraying	Powder	$1.2x10^{-2}$	$3x10^{-4}$	43
Max Spraying	Liquid	$3.8x10^{-3}$	$9.5x10^{-6}$	131
Small Dip Vat	Powder	$2.6x10^{-2}$	$6.8x10^{-4}$	19
Small Dip Vat	Liquid	$1.4x10^{-2}$	$1.5x10^{-5}$	36
Large Dip Vat	Powder	$5.7x10^{-2}$	$1.5x10^{-3}$	9
Large Dip Vat	Liquid	$3x10^{-2}$	$3.3x10^{-5}$	16

The total dose (not shown) was calculated by multiplying the unit exposure times the maximum application rate times the maximum amount of material handled divided by 70 kg.

The Margin of Exposure for the vat use was calculated to range from 9 to 36 assuming a 1000 gallon "topping off" or recharging of the dip vats after animals moving through the vats have depleted the liquid level. When the dip vats are filled, up to 4000 gallons of solution are handled. This means that the MOEs associated with filling the vats from empty are smaller by up to a factor of 4 (MOE 2.2 to 9). The Agency understands that totally emptying and refilling a dip vat typically occurs between six to 24 months.

COUMAPHOS EXPOSURE ESTIMATE RESULTING FROM SPRAY APPLICATION OF LIQUIDS TO LIVESTOCK (mg/kg/day)			
Applicator	Dermal	Inhalation	MOE
Typical Spray	$6.1x10^{-3}$	$4.5x10^{-5}$	82
Maximum Spray	$6.1x10^{-2}$	$4.5x10^{-4}$	8.2

The following comments pertain to the registrant's PHED runs:

- The Agency's PHED policy prohibits the analysis of different solid formulations in the same run due to their variable exposure

potential. Granulars, pellets and wettable powder all have different potential unit exposure values. Only different liquid formulations may be analyzed in the same analysis.

- The Agency's PHED runs reflect the closest lbs ai handled that are available in PHED.

- There are no open Mixer/Loader dust formulation data in PHED. Data are needed to support dust formulation uses.

- Wettable powder data were only available at the ABC grade (medium confidence) level.

- The Agency's policy is to view water soluble bags as a closed loading system. Therefore, these data are not included for analysis on wettable powder and dust formulations.

- For the purpose of determining an estimated exposure for the handheld sprayer, studies were combined representing low pressure handwand, high pressure handwand, and handgun sprayer. This exposure value is also based on medium confidence data (ABC grade).

- The PHED data for mixing and loading the liquid formulation were subsetted to more closely reflect the two scenarios of concern. For mixing/loading to support spraying with hand equipment, the data were limited to exposure scenarios where up to and including 5.0 lbs ai were handled per day. For mixing/loading to support dip-vat operations, the data were limited to exposure scenarios where between 10 to 24 lbs ai were handled per day.

- **Each exposure assessment is based on the workers wearing long pants, long sleeved shirts and chemical-resistant gloves.**

Risk From Post-Application Exposures

EPA has determined that the risk from post-application exposure is likely to be substantially lower than the risk mixers and loaders receive in handling coumaphos to prepare spray solutions for typical herd size. The risk assessment indicates that the risk to such mixers and loaders is greater than 100. Based on this rough post-application exposure and risk estimate, EPA has determined that post-application exposures do not appear to pose

an unreasonable risk to persons contacting treated animals, as long as contact is not permitted immediately after application.

Additional Occupational Exposure Studies

Exposure Studies for Handlers (Mixers/Loaders/Applicators)

Requirements for mixer/loader/applicator (handler) exposure studies are addressed in Part V. Exposure studies are required for the following exposure scenarios:

- Mixing/loading/application of dipping solutions for both the liquid and wettable formulations (The Agency will use these data to represent all mixing/loading operations, e.g., backrubber and dust bag setup).

- Application by shaker can, mechanical duster, pour-on and foam spray can.

- Mixing/loading/application of liquid and wettable powder formulations from a high and low-pressure handwand sprayers.

The registrant has proposed conducting exposure studies for only the "worst case" exposure scenarios. The Agency is willing to consider these arguments provided the registrant is willing to agree to accept the resulting MOEs as applying to all uses.

Exposure Studies for Post-Application Workers

Post-application exposure studies are not required.

C. Environmental Assessment

1. Environmental Fate

This section describes the environmental fate characteristics of coumaphos, its persistence in the environment, mobility, major route(s) of degradation, identity of degradates, and the potential of the pesticide to contaminate surface and/or ground water.

In addition to normal environmental fate data requirements, the Agency required studies concerning the environmental fate of coumaphos after dermal treatment of cattle for control of cattle grubs, ticks, flies and lice. These studies characterize coumaphos exposure to nontarget terrestrial and aquatic animals. The studies estimate the amount of coumaphos washed off cattle when they wade into surface waters. These studies evaluate variables such as concentration of active ingredient (coumaphos) in different formulations and various drying intervals following treatment.

a. Environmental Chemistry, Fate and Transport

(1) Hydrolysis

Hydrolysis is not a significant route of dissipation for coumaphos. The single study available does not by itself satisfy the data requirements, however, it does provides supplemental information. That information, along with information from the aerobic soil metabolism and aqueous photolysis studies, is sufficient for a qualitative assessment. Therefore, a replacement study will not be required.

Coumaphos degraded with a half-life of over 30 days in sterile aqueous buffered solution adjusted to pH 5, 7 and 9 and incubated in the dark for 30 days. At 30-Days post-treatment, coumaphos comprised 95.1% of the applied radioactivity recovered from the pH 5 solution, 93.4% of the recovered from the pH 7 solution and 84.2% of the recovered from the pH 9 solution. The half-life for coumaphos at pH 9 is estimated to be ca. 123 days. Three degradates were identified: chlorferon (maximum of 4.3% in all three solutions), the oxygen analog (maximum of 5.0, 1.4 and 0.9%, respectively in the pH 5, 7 and 9 solutions) and 6-hydroxy-3-methylbenzofuran (maximum of 0.7, 2.6 and 11.5%, respectively in the pH 5, 7 and 9 solutions).

The study is not completely acceptable because the actual pH values tested in the study tended to converge towards a pH of 7, so that too narrow a range of actual pH was actually tested (6.1 - 8.4). Data supplied by the registrant from a previous hydrolysis study indicates that coumaphos is most stable at pH 7 and is less stable under acidic and basic conditions. In this study, the tendency of the pH of the solutions towards pH 7 may have increased the observed stability of the compound. (MRID 00150197, 00159928)

(2) Photodegradation in water

Coumaphos photodegrades in water with a half-life of ca. 33 hours when exposed to natural sunlight. The major photodegradate representing 43% of the radioactivity after 83.5 hours of exposure was O,O-diethyl-O-(3-acetoxy) phenylphosphorothioate. Besides the parent compound and the major degradate there were two other major degradates, i.e. each representing more than 10% of the applied radioactivity, after 83.5 hours. Coumaphoxon was identified as the analyte representing 10.2% of applied radioactivity. The other degradate, representing 11.7% was not identified. The second peak eluted early -- nearly with the void volume -- and could have been composed of more than one very polar component. A number of other minor photoproducts were detected which peaked at 10% and declined over the course of the study.

The study is not completely acceptable because a degradate at a concentration of 0.06 ppm (11.7% of the applied TRR, after 83.5 hours) was not identified. To fulfill the data requirement, the registrant must identify this degradate. (MRID 42764101)

(3) Aerobic soil metabolism

Two different studies indicate that aerobic metabolism is not a significant route of dissipation for coumaphos in soil. In one study, coumaphos degraded in a sandy loam soil with a half-life apparently much longer than 1 year when incubated in the dark for a year. One year after treatment coumaphos accounted for 80.4% of the total radioactivity and unextractable radioactivity accounted for 13.4% of the total recovered radioactivity. Four organosoluble compounds were identified: chlorferon (maximum of 6.2% at 6 months), the coumaphos oxygen analog (maximum of 0.1-0.2%),

3-methyl-6-hydroxybenzofuran (maximum of 4.1% at 3 months) and 6-hydroxyl-3-methylbenzofuran (maximum of 0.1% at 9 months). This study is considered supplemental because up to 0.09 mg/l of the organosoluble radioactivity was not identified. To fulfill the data requirement, the registrant must identify the uncharacterized degradates.

In the other available study, coumaphos degraded with a half-life of 318 days. Three degradates were identified: chlorferon (maximum of 13.3% of the recovered), coumaphos oxygen analog (maximum of 1.4% at 60 days) and 3-methyl-6-hydroxybenzofuran (maximum of 3.6% at 180 days). This study was found to be unacceptable because the material balances were variable, and because the study terminated at 180 days, before the pattern of degradation of parent and the formation and decline of degradates were adequately defined. (MRID 00115165, 40518701)

(4) Leaching, Adsorption, and Desorption

The available information from an acceptable study and a supplemental study indicates that aged coumaphos is relatively immobile in soil. Information on the mobility of unaged coumaphos in soil is not available from these studies. However, these data will not be required at this time since laboratory data indicate that coumaphos is stable to hydrolysis and aerobic soil metabolism. Aged column leaching studies also provide data that shows coumaphos does not degrade rapidly. Therefore, no additional information is needed on the mobility of unaged coumaphos at this time.

In an acceptable study, coumaphos aged 30 days was relatively immobile in a column of sandy loam soil leached with 20 inches of water. After leaching, the upper 6 cm of the sandy loam soil column contained 97.93% of the recovered residues, 1.2% occurred at depths 6 to 12 cm, 0.04% occurred at depths 12 to 24 cm, and the leachate contained 0.4%. The radioactivity recovered in the upper 6 cm of the soil was characterized as 95.8% coumaphos, 3.1% chlorferon, and 0.9% unidentified organosoluble residues.

In a second study, which was not completely acceptable, aged coumaphos was found to be relatively immobile on sand, silt loam, and silty clay loam soils. After leaching, the upper 6 cm of

the three columns contained 95 to 97.5% of the radioactivity, while the leachate contained only 1 to 2% of the total radioactivity. The radioactivity in the upper 6 cm was identified to be primarily coumaphos, i.e., 77.5% of the recovered radioactivity in the silt loam soil was coumaphos; 95.25% was coumaphos in the sand soil. The major degradate, chlorferon, was 20.8% of the recovered in the silt loam, 8.0% in the silty clay loam, and 6.7% in the sand soil. The coumaphos oxygen analog was up to 1.4% of the total recovered residue, while unidentified residues ranged from 0.3 to 3.6%. The material balances after leaching ranged from 70 to 89%. For this study to be acceptable the registrant needs to characterize the aged residues before leaching and to provide adequate material balances. (MRID 00163806)

(5) Terrestrial field dissipation

The terrestrial field dissipation studies submitted, although not completely acceptable, indicate that coumaphos is relatively persistent, as was also indicated by the aerobic soil metabolism study.

Coumaphos was applied at 300 mg/l to two field plots. One plot was tilled to a depth of 6 inches after treatment, while the other plot was left undisturbed. The tilled plot study was a supplemental study, i.e., not completely acceptable. This study was not completely acceptable primarily because the soil was not sampled to a sufficient depth to define the extent of leaching. Additionally, the soil was not analyzed for all major coumaphos residues, and data were not provided concerning the stability of parent/degradates during frozen storage. The study does indicate that coumaphos dissipated with a half-life of 185 days in the upper 6 inches of the soil. At depths to 6 inches coumaphos concentration decreased from 294 mg/l at 1 week following treatment, to 80 mg/l at 52 weeks. At depths of 6 to 12 inches (the deepest layer analyzed), coumaphos concentration was 25 mg/l at 32 weeks and 5 mg/l at 52 weeks.

The untilled plot study was also found to be unacceptable. The half-life estimate was 118 days for the upper 6 inches of soil. At depths to 6 inches, estimated coumaphos concentrations were 343 mg/l 1 week following treatment, 549 mg/l at 4 weeks, 254 mg/l at 16 weeks, 375 mg/l at 32 weeks, and 69 mg/l at 52 weeks. At depths of 6 to 12 inches (the deepest layer analyzed),

coumaphos concentration was 83 mg/l at 32 weeks and 49 mg/l at 52 weeks. The study was not acceptable primarily because the data were highly variable, the soil was not sampled at sufficient depth to define the extent of leaching, the soil was not analyzed for all major coumaphos residues, and no data were provided on stability in frozen storage. (MRID 00115166)

(6) Special retrospective field dissipation study

The information provided by a single study indicates that coumaphos will leach to the subsurface (66-72 inches depth) when disposed of in unlined pits. Ground water contamination could result where ground water is close to the surface.

The Agency required that this study be conducted to evaluate retrospectively six major use areas in the continental U.S., including at least one site involving a sandy soil over a shallow water table. The registrant submitted one study performed in Texas at eight locations, which evaluated the depth of leaching in disposal pits and walkways of coumaphos treatment dip vats. (Not a guideline study, No MRID has been assigned)

(7) Bioaccumulation in fish

The information provided by a supplemental study suggests that coumaphos will not be significantly biomagnified in aquatic food chains.

Two studies were reviewed. Only one was found to provide useful information on bioaccumulation. In the study found to be supplemental, total coumaphos accumulated in bluegill sunfish with a maximum bioconcentration factor of 541 in whole fish during 30 days of exposure at 10 µg/l, in a flow-through aquatic system. In both edible and nonedible tissues, 33% of the extractable radioactivity was coumaphos, while 63-68% remained at the origin. In general, accumulated coumaphos residues were depurated rapidly, with 98% elimination after 1 day in untreated water. This study is not acceptable primarily because the analytical methods may not have been adequate to identify the majority of coumaphos residues extracted from fish tissues, the material balance was not complete, and residues in the water were not characterized.

In the unacceptable study high mortality precluded estimation of accumulation and depuration of coumaphos: 42 out of 80 fish died during the 30 days of the study. (Cause of death was not reported but is probably due to coumaphos exposure.) (MRIDs: 00115168, 00115169, 00150619)

b. Environmental Fate Assessment

The various degradation, metabolism, mobility, dissipation and ground water studies discussed above, although found mostly to be supplemental, do nevertheless support a qualitative characterization of the properties of coumaphos in the environment. Based upon a review of studies submitted, coumaphos is persistent in the environment, with the exception that aqueous photolysis is rapid (half-life 33 hours). The half-life is much greater than 30 days for hydrolysis; much greater than a year for aerobic soil metabolism; and ca. 118 to 185 days for field dissipation. Coumaphos also appears to be immobile, with K_d values ranging from 61 to 298 for parent and from 91 to 161 for the degradate chlorferon. Coumaphos accounted for 0.4% of leachate from a sandy loam column and less than 2% of leachate from columns of sand, silt loam, and silty clay loam.

The major degradates identified under aerobic conditions were chlorferon, which reached a maximum of 6.2% of the organosoluble radioactivity recovered at six months, and 6-hydroxyl-3-methylbenzofuran, the oxygen analog, which comprised a maximum of 0.2% of recovered radioactivity at six months. In column leaching studies, chlorferon and 6-hydroxyl-3-methylbenzofuran comprised 3.1% and 0.2%, respectively, in the top six inches of the sandy loam soil column. Similar results were obtained in the three other soil columns (using sand, silt loam, and silty-clay loam.)

In two field dissipation studies, the half-life for coumaphos was estimated at 118 and 185 days. Coumaphos was applied at 300 mg/l with and without incorporation. The soil was not sampled at sufficient depth to define the extent of leaching; however, samples taken 6 to 12 inches deep contained coumaphos at concentrations of 25 to 375 mg/l 32 weeks after treatment and at 5 to 69 mg/l 52 weeks after treatment.

A special retrospective field dissipation study was conducted to characterize the depth of leaching in disposal pits and walkways of coumaphos treatment dip vats. On-site disposal of spent coumaphos in unlined pits was found to result in leaching of coumaphos, chlorferon and

potasan to the subsurface (72 inches in the study), and could result in ground-water contamination in areas of shallow ground water. These compounds may reach ground water, although there was insufficient depth of soil sampling conducted in the study to determine if coumaphos and/or its metabolites could have reached the deep wells that were tested during the study.

Results of the special field dissipation study support the finding that coumaphos is persistent; however coumaphos moved to greater depths than expected based on it's K_d values. The apparently higher mobility in the special dissipation study could have resulted from the high concentration of spent coumaphos in soil evaporation pits. (See also EPA, 1980, 600/2-80-124).

2. Ecological Effects

Coumaphos is highly to very highly acutely toxic to birds if consumed, based on terrestrial vertebrate test data. Available measurements of avian acute oral LD_{50}, for coumaphos TGAI, ranged from 2.4 to 29.8 mg/kg based on bobwhite quail, mallard duck and pheasant. Available measurements of the avian dietary LC_{50}, using TGAI coumaphos as the test material, ranged from 82.1 to 401.9 mg/kg based on tests including: bobwhite quail, mallard duck, ring-necked pheasant and Japanese quail. For terrestrial mammals, a wide range of LD_{50} values have been obtained based on testing using rats that indicate slight to high toxicity on an acute oral basis: LD_{50} values were as low as 17 mg/kg for the TGAI, and as low as 32 mg/kg for an end-use product.

Data for aquatic organisms indicate that coumaphos is moderately to highly toxic to fish on an acute basis: LC_{50} measurements for coumaphos TGAI ranged from 0.34 mg/kg for bluegill sunfish to 5.9 mg/kg for rainbow trout. Coumaphos can be characterized as very highly toxic to aquatic invertebrates on an acute basis: LC_{50} values for coumaphos TGAI ranged from 0.074 μg/l for *Gammarus lacustris* to 0.224 μg/l for *Gammarus fasciatus*.

Chronic toxicity data are available for aquatic animals. Data from a fish early life stage study with coumaphos showed that for Rainbow trout, based on the most sensitive parameters, length and weight, the NOEC, LOEC and MATC are 11.7 μg/l, 24.6 μg/l and 16.9 μg/l, respectively. Data from a *Daphnia magna* life cycle chronic toxicity study with coumaphos showed that based on the most sensitive parameter, survival, the NOEC, LOEC and MATC are 33.7 ng/l, 75.8 ng/l and 50.5 ng/l, respectively. (The concentrations here represent average measured values.)

Data on marine and estuarine animals indicate that coumaphos is highly toxic to marine and estuarine fish. The LC_{50} for sheepshead minnow is 280 μg/l. Coumaphos is also highly toxic to marine and estuarine mollusks on an acute basis. The LC_{50} measurements for marine and estuarine mollusks ranged from 290 μg/l to 880 μg/l based on the oyster *Crassostrea virginica*. Coumaphos is very highly toxic to marine crustaceans on an acute basis. The available LC_{50} measurement was 2.0 μg/l.

Data requirements for non-target insects and plants are **not applicable** for coumaphos, due to the limited use pattern of the chemical.

a. Ecological Effects Data

(1) Terrestrial Data

To evaluate the toxicity of a pesticide to birds, the following tests are required using the TGAI material:

- An avian single-dose oral (LD_{50}) study on one species, preferably mallard or bobwhite quail;
- A subacute dietary (LC_{50}) study using one waterfowl species, preferably the mallard duck;
- A subacute dietary (LC_{50}) study using one upland game species, preferably bobwhite quail or ring-necked pheasant.

Tests on wild mammals may be required, depending on intended use pattern, environmental fate characteristics, or based on the results of lower tier studies such as acute/subacute toxicity tests. These data are not required for coumaphos due to it's limited use pattern.

An acute contact LD_{50} for honey bees is required if the proposed use will result in exposure to honey bees.

(a) Avian Acute Oral Toxicity

The data requirement is fulfilled based on studies available. Ten studies were evaluated, and all were determined to be acceptable for use in this risk assessment. There are sufficient data to characterize coumaphos as **highly to very highly toxic to birds on an acute oral basis**. Available toxicity measurements are summarized in the table below.

Avian Acute Oral Toxicity

Species	Test Material (% AI)	LD_{50} mg/kg
Bobwhite quail	98.25%	2.4
Mallard duck	95%	29.8
Pheasant	95%	7.94

(MRIDs: 112841, 160000)

(b) Avian Subacute Dietary Toxicity

There are sufficient data to characterize coumaphos as **highly toxic to birds on a dietary basis**. Available toxicity data are summarized in the table below.

Avian Subacute Dietary Toxicity

Species	Test Material (% AI)	LC_{50} ppm
Bobwhite quail	98.25%	82.1
	95%	120
Mallard duck	98.25%	401.9
	95%	709
Ring-necked Pheasant	95%	318
Japanese quail	95%	225

(MRIDs: 112842, 022923, 112843)

Until recently the Agency would have required a Level 1 terrestrial field study to evaluate the risk to birds. A pilot field study has actually been conducted. That study was classified as supplemental; however, it is scientifically sound and provides information concerning potential exposure pathways to birds, as described in greater detail later under Acute Avian Risk. (MRID: 42512604)

(c) Avian Reproductive Toxicity

Avian reproduction studies will not be required for coumaphos at this time. Such studies may be required when birds are likely to be exposed to a pesticide repeatedly or continuously. The assessment of acute risk (§A.2.b) indicates that if there were significant exposure to birds, they would be killed before chronic effects can occur.

(2) Aquatic Data

(a) Freshwater Fish Toxicity

To evaluate toxicity to freshwater fish, LC_{50} measurements are required for two species using TGAI. One study should use a coldwater species, preferably rainbow trout, and the other should use a warmwater species, preferably bluegill sunfish.

Nine studies in three documents were evaluated under this topic, and all studies were acceptable for use in a risk assessment. Toxicity measurements are summarized in the following table.

Acute Toxicity to Fish (72-1a,c)		
Species	**Test Material (% AI)**	**LC_{50} (mg/l)**
Bluegill sunfish	99.6%	5.0
	95%	0.34
Rainbow trout	99.6%	5.9
	95%	0.89
Lake trout	95%	0.593
Cutthroat trout	95%	0.862
Largemouth bass	95%	1.1
Walleye	95%	0.780

(MRIDs: 112840, 40098001, 112840)

Coumaphos is **moderately to highly toxic to both warmwater and coldwater fishes**.

A fish early life stage study has been received and reviewed. The following results were obtained.

Fish Early Life Stage Study [72-4(a)]		
Species	**Test Material (% AI)**	**Toxicity (µg/l)**
Rainbow trout	99.2%	NOEC = 11.7 LOEC = 24.6 MATC = 16.9

(MRID: 43066301)

(b) Toxicity to Freshwater Invertebrates

To evaluate toxicity to freshwater aquatic invertebrates, an LC_{50} measurement is required, preferably using first instar *Daphnia magna*, or early-instar amphipods, stone-flies, mayflies, or midges. LC_{50} values are displayed in the table below.

Five studies were evaluated under this topic. These studies were deemed acceptable for use in a risk assessment. There is sufficient information to characterize coumaphos as **very highly toxic to freshwater aquatic invertebrates**. The following toxicity measurements are available.

Acute Toxicity to Aquatic Invertebrates [72-2(a)]		
Species	**Test Material (% AI)**	**LC_{50} (µg/l)**
Gammarus lacustris	95%	0.074
	98.9%	0.224
	97.0%	0.14
Daphnia magna	98.9%	0.192

(MRIDs: 40098001, 41778503, 41778504, 05009242)

An aquatic invertebrate life cycle test was submitted and reviewed. The following results were obtained.

Aquatic Invertebrate Life-Cycle Study [72-4(b)]		
Species	**Test Material (% AI)**	**Toxicity (ng/l)**
Daphnia magna	99.1%	LOEC = 33.7 NOEC = 75.8 MATC = 50.5

(MRID: 43116601)

(c) Acute Toxicity to Estuarine and Marine Animals

Data on acute toxicity to estuarine and marine organisms are required to support the registration of end use products intended for direct application to the estuarine or marine environment or if the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern. Because the current uses of coumaphos do not meet these criteria, no estuarine and marine toxicity studies are required. The following measurements are available, from four studies in one literature source. There is sufficient information to

characterize coumaphos as **highly toxic to marine fish** and **very highly toxic to marine invertebrates**. (MRID 40228401)

Acute Toxicity to Estuarine and Marine Invertebrates (72-3)		
Species	**Test Material (% AI)**	**Toxicity (µg/l)**
Fish [72-3(a)]		
Cyprinodon variegatus	95%	LC_{50} = 280
Mollusk [72-3(b)]		
Crassostrea virginica	95%	EC_{50} = 880
	95%	EC_{50} = 290
Crustacean [72-3(c)]		
Penaeus duorarum	95%	EC_{50} = 2.0

(3) Non-Target Insects Data

Data requirements for non-target insects testing are not applicable for the coumaphos use patterns, and no studies were required or submitted.

(4) Non-Target Plants Data

Data requirements for non-target plant testing are not applicable for the coumaphos use patterns, and no studies were required or submitted.

b. Ecological Effects Risk Assessment

The Agency has evaluated the risks to terrestrial and aquatic non-target organisms resulting from treatment of cattle for control of arthropod pests. Coumaphos is applied to cattle primarily by dip vats, whole body sprays, back rubbers and dust bags.

In order to assess exposure to nontarget organisms, it is necessary to have information on the concentration of active ingredient on the hides of treated cattle, and information on the potential of coumaphos to wash

off into water when cattle wade into bodies of water. The registrant has submitted two studies that address these issues. Those studies have been reviewed and found to be acceptable for use in a risk assessment. Information from those studies is incorporated in risk assessments for both terrestrial and aquatic nontarget organisms. Additional information for exposure assessment was obtained by personal communications from the U.S. Hide, Skin and Leather Association (USHSLA). (MRIDs: 42512601, 42512602).

(1) Risk to Terrestrial Animals

Risk to nontarget terrestrial animals is expected to result primarily from direct treatment of livestock. Use of coumaphos to treat livestock bedding is not expected to result in significant risk to terrestrial wildlife, because that is primarily an indoor use, associated with minimal exposure to terrestrial wildlife.

(a) Avian Acute Risk

Coumaphos is very highly toxic to birds on an acute oral basis, based on LD_{50} estimates as low as 2.4 mg/kg. Birds may be subject to primary exposure (ingestion of hair and skin debris from treated cattle) or secondary exposure (ingestion of birds killed by the pesticide, and contaminated with pesticide.)

Apart from the values of risk quotients (described in detail below), there is evidence that birds are at risk under field conditions, as a result of the cattle treatment use of other organophosphate insecticides. Studies in peer-reviewed scientific literature indicate that treatment of cattle with pesticides (none were coumaphos) has resulted in mortality in a variety of bird species, primarily the black-billed magpie *Pica pica* (Henny et al., 01985; Henny et al., 1987; Felton et al., 1981). That literature also indicates a potential for secondary poisoning of birds.

A pilot field study submitted to the Agency confirms that birds may be exposed to coumaphos by direct contact with treated cattle, exposure to cattle hair, and/or by exposure to contaminated soil and feed in and around treatment areas. Eight cattle in one pen were sprayed with coumaphos (2 lb ai in 50 gal water) until each individual was thoroughly soaked. After treatment, coumaphos residues were detected in soil samples (4.35-635 ppm, *n*=40), cow feces (<0.01-0.53 ppm, *n*=32), cow hair samples (<0.1-1450 ppm,

n=32), and stomach contents (<0.003-0.901 ppm, *n*=17) of cowbirds. Brain cholinesterase activity was inhibited 2-59% in 13 of 19 cowbirds examined. Thirty-four bird species were recorded within 200 m of the treatment site, with six species observed on the ground in the pen. Based on several counts, 290 birds were estimated to frequent the 3.7-hectare pen. The results from treating only 8 cows in one pen are too limited in scope to draw any major conclusions. The study did indicate that a variety of birds are likely to be present at treatment sites and that they may be exposed to coumaphos residues from soil, cattle feces, and cattle hair. That study also includes information regarding bird use of feedlots and pastures, and species likely to be exposed, ranked in order of potential exposure in feedlots. The black-billed magpie, because of its close association with cattle, was listed as the species most likely to be exposed. The pilot field study, and the literature sources cited previously, indicate that many bird species utilize pastures or feedlots. (MRID: 42512604)

The Agency has a report of an incident in which a bald eagle was found dead as a result of coumaphos poisoning. The exact mechanism of exposure is unknown for that incident.

The Agency has determined that the cattle use of coumaphos could pose high risk to birds feeding from the surfaces of treated cattle. That conclusion is based on the following calculations, which appropriately adapt standard risk assessment procedure to this context. As an index of risk, the risk quotient (RQ) is calculated from exposure and toxicity data. The RQ formula compares the quantity of active ingredient on a square foot of cow hide to the LD_{50}, i.e., to the quantity expected to cause 50% mortality when ingested. The RQ is calculated according to the following formula:

$$RQ = \frac{\text{Mass coumaphos a.i. per sq.ft.}}{LD_{50} \times \text{Bird Body Weight}}$$

Appropriate units for the RQ calculation are mass of coumaphos in mg, LD_{50} in mg/kg, and body weight in kg. RQ values 0.5 or larger are taken to indicate high risk, values 0.2 or larger are taken to indicate concerns for restricted use pesticides, and values 0.1 or larger indicate concerns for endangered species. (The values 0.5, 0.2, and 0.1 denote the levels of concern or LOCs.)

RQs (displayed in the table following) were calculated based on the following assumptions. The assumed body weight is 0.1775 kg, which is an average weight for the black-billed magpie. Toxicity measurements are unavailable for that species. Based on available measurements of toxicity to birds, the appropriate LD_{50} value is 2.4 mg/kg. Mass of coumaphos per square foot of cow hide was determined based on information from labels, information from the U.S. Hide, Skin and Leather Association (USHSLA), and the two submitted studies, cited previously. The mass of coumaphos per square foot (displayed with RQ values in the table following) depends on the method of application and on the formulation used. Calculated RQ values substantially exceed high risk levels of concern.

Risk Quotient (RQ) values for birds. The finding of high risk is supported by RQ values that substantially exceed 0.5, which is the high risk level of concern (LOC).

Formulation	Coumaphos mass a.i. per sq.ft. cow hide	Risk Quotient (RQ)
5% Dust	48 mg	113
11.6% Emulsifiable Powder	179.3 mg	429
25% Wettable Powder	249.6 mg	586

Example: For the 5% Dust formulation (row 1),

$$RQ = 112.7 = \frac{48 \text{ mg}}{2.4 \text{ mg/kg} \times 0.1775 \text{ kg}}$$

(b) Avian Chronic Risk

Avian chronic effects have not been characterized. Assessment of chronic effects could be required for registration of new uses, rates or methods of application.

(c) Mammalian Acute Risk

Coumaphos is not expected to pose a risk to non-target endangered or non-endangered mammals because the limited use pattern of coumaphos, i.e., treatment of cattle in confined areas, is not expected to result in significant exposure.

(2) Risk to Aquatic Animals

Coumaphos is toxic to all types of aquatic animals that have been tested. There will be some exposure of aquatic organisms if treated cattle enter bodies of water. Cattle enter bodies of water, particularly in summer, for relief from heat and flies. This risk assessment is based on certain assumptions including the concentration of coumaphos on a cow's skin, fraction of a cow's skin surface that is submerged (25% assumed), and fraction of coumaphos on submerged skin that becomes available for exposure to aquatic organisms. It is also assumed that cattle wade into a body of water with surface area 1 acre and depth 6 feet. Results of the analysis (with assumptions described in detail in a subsequent section) indicate a **high acute risk to aquatic invertebrates**, but do not indicate high chronic or acute risk for endangered or non-endangered fish.

Quantification of washoff. When treated cattle enter water, some fraction of the coumaphos on their skins, here denoted as *washoff*, dissolves in the water. Studies of washoff have been submitted and determined to be acceptable for use in risk assessment.

Washoff appears to depend on the coumaphos formulation and on the time that a cow's skin is permitted to dry before the animal enters water (see table below). In the washoff studies submitted, fresh cow hides were treated with different coumaphos formulations, then dried for 0.5, 3, or 24 hours. Washoff was measured after hides had been soaked in water for 0.5, 1.0, 2.0 or 4.0 hours. For one of the two studies submitted, the coumaphos formulation was Co-Ral® 11.6% emulsifiable liquid; the other study used Co-Ral® 25% wettable powder. The longer the drying time, the lower the washoff. Washoff is also affected by formulation, however, after 24 hrs of drying there was little difference between the different formulations. There was no

statistically significant effect of soaking time. The following table relates washoff to formulation and drying time.

Percent Washoff for Different Formulations of Coumaphos at Different Drying Intervals

Formulation	Drying Times (hrs)		
	0.5	3	24
11.6 % Emulsifiable Liquid	11.6%	4.6%	2.7%
25% Wettable Powder	38%	21%	2.0%

(MRIDs: 42512601, 42512602)

Estimated Environmental Concentrations and Risk Quotients for Aquatic Organisms.

The quantities displayed in the following table have been calculated based on following assumptions:

- **EEC/cow**is the estimated concentration in a body of water (1 acre surface, depth 6 feet) if a single treated cow wades into it.
- **RQ/cow** is the risk quotient for organisms in a body of water, if a single treated cow wades into the body of water.
- **cows/LOC** is the number of treated cattle that will cause the level of concern (LOC) in a body of water to be exceeded, if that number of treated cattle wade into the body of water.

These quantities are calculated as follows:

EEC/cow = surface area of cow in sq. ft.

× µg coumaphos per sq.ft. hide

× fraction of cow surface submerged in a body of water containing nontarget organisms

× fraction washoff (term defined above)

× 2.205×10^{-9} lb/µg

× 61 µg/l concentration in pond per lb loading.

RQ/cow = (EEC/cow) / LC_{50}

cows/LOC = LOC / (RQ/cow) --> express as an integer, round up to the nearest whole number.

(NOTE: cows/LOC is the number of cows needed to exceed the LOC.)

The numerical inputs for these expressions are:

- The surface area of a 1000-2000 lb. cow is about 45 sq.ft., based on communication from Jerry Breiter of the U.S. Hide and Leather Association.
- µg coumaphos per sq.ft. hide 1793×10^2 for the 11.6% emulsifiable liquid formulation; 2496×10^2 for the 25% wettable power formulation (as displayed above for the terrestrial risk assessment).
- A cow will generally enter water up to the hair break line, which is a clearly visible line on the sides of the cow, where the types of hair change visibly. According to the USHSLA, this means that about 25% of the skin surface is submerged.
- Fraction washoff is specific to formulation and drying time as displayed above, e.g., 0.116 for the 11.6% emulsifiable liquid formulation with 0.5 hr. drying.
- LC_{50} = 0.074 µg/l for invertebrates; LC_{50} = 340 µg/l for fish.
- LOC is a critical risk quotient value for determination of concerns: LOC = 0.5 for high risk, 0.1 for restricted use, or 0.05 for endangered species.

Example. The values in row 1 of the table following are calculated as follows.

EEC/cow = $45 \times 179300 \times 0.25 \times 0.116 \times 2.2 \times 61 / 10^9$

= 0.0314 µg/l.

RQ/cow = 0.0314 / 0.074 = 0.424

cows/LOC = 0.424 / 0.5 = 1.2, i.e., 2 cows are just enough.

When these quantities are calculated for fish, the result is that over 100 cows must wade into a 1 acre body of water in order for the LOC to be exceeded for endangered species; over 1000 cows must enter in order for the acute high risk LOC to be exceeded. This suggests that the

coumaphos cattle use does not pose a threat to endangered or non-endangered fish species on an acute basis.

Coumaphos does not pose a risk to fish on a chronic basis. The chronic LOC is EEC/MATC equal to 1 or larger for endangered or non-endangered species. The fish chronic MATC is 16.9 µg/l based on a measurement with rainbow trout. For that concentration to be achieved, over 100 cows would have to wade into the 1 acre body of water. Additionally, the short half-life of coumaphos in water (33 hours, photolytic) indicate that chronic exposure will not be a problem.

For aquatic invertebrates, the calculations are displayed in full below, and indicate that a small number (1 to 6) of treated cattle wading into a body of water would cause the high risk LOC (acute) to be exceeded. Also, coumaphos is sufficiently toxic on an chronic basis that a single treated cow wading into the body of water could cause high risk to invertebrates on a chronic basis.

LOC determination for Aquatic Invertebrates (Acute risk)
(based on LC_{50} = 0.074 µg/l)

Formulation	Drying Time (hours)	EEC/cow (µg/l)	RQ/cow	cows/LOC[a]
11.6% Emulsifiable Liquid	0.5	0.031	0.42	(HR)[b] 2 (RU)[c] 1 (ES)[d] 1
	3.0	0.012	0.17	(HR) 3 (RU) 1 (ES) 1
	24.0	0.0073	0.099	(HR) 6 (RU) 2 (ES) 1
25% Wettable Powder	0.5	0.14	1.9	(HR) 1 (RU) 1 (ES) 1
	3.0	0.076	1.0	(HR) 1 (RU) 1 (ES) 1
	24.0	0.0073	0.098	(HR) 6 (RU) 2 (ES) 1

[a]Number of wading cattle necessary to exceed the LOC
[b]cows/LOC for high risk LOC
[c]cows/LOC for restricted use LOC
[d]cows/LOC for endangered species LOC

(3) Risk to Plants

A characterization of risk to plants (terrestrial, aquatic, or semi-aquatic) is not required for coumaphos due to its limited use pattern.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of generic (i.e. active ingredient specific) data to support reregistration of products containing coumaphos as an active ingredient. Handler exposure data (mixer/loader/applicators) were not required by either the 1981 or 1989 Registration Standards. The Agency stated in the 1989 Registration Standard-Second Round Review that: "... the need for this data would be reassessed upon receipt and review of the required toxicology data." The Agency has completed its review of the toxicological database, and has determined that handler/occupational exposure data are required. The Agency has made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. In addition, the Agency made extensive use of the Pesticide Handlers Exposure Database (PHED) for occupational exposure estimates, i.e., mixer/loader/applicators. Use and economic benefit information for coumaphos provided by the registrant, State Agricultural Program Reports and from the USDA were also considered, especially economic benefit estimates for USDA's quarantine use of coumaphos. The Agency also considered the fact that the Department of Agriculture, Animal & Plant Health Inspection Service has an on-going program to monitor cholinesterase levels in handlers involved in treating animals with 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.

1. Eligibility Decision

The Agency has determined that coumaphos products, labeled and used as specified in this Reregistration Eligibility Decision, may pose adverse effects to humans, aquatic invertebrates and birds. The Agency has concerns with low MOEs for mixer/loader/applicators, with the proper disposal of the spent cattle dip vat solutions, and with the acute toxicity of coumaphos to aquatic invertebrates and birds.

The Agency defers making a regulatory decision on non-USDA uses of coumaphos until chemical-specific handler exposure studies are submitted (see Section V). The Agency can make a regulatory decision concerning the USDA

uses of coumaphos because of the very significant economic benefits, the lack of an acceptable alternative, and the fact that USDA has a program in place to monitor the cholinesterase levels of the handlers involved. In the USDA Import program livestock are treated with coumaphos to control ticks and prevent outbreaks of Texas Cattle Fever (also known as Southern Fever). Coumaphos is also used in a quarantine mode. Together these uses account for almost half of coumaphos usage in the U.S. Despite uncertainties in the existing handler exposure databases, the Agency finds that MOEs for large dip vat and hand-held sprayer treatment of large herds are very low. Therefore, the Agency is requiring closed systems for the mixing/loading of coumaphos products used in dip vats and/or hand-held sprayers, i.e., water-soluble bags for the WP formulation. The registrant must determine an appropriate system to reduce handler exposure during mixing/loading for the flowable and emulsifiable concentrate formulations. The appropriate system to reduce handler exposure during mixing/loading may be gel packs, "no glug" containers or any other equivalent system approved by the Agency. Appropriate systems to reduce handler exposure must be addressed in the eight-month required response. The registrant must propose a system and submit handler exposure studies to document handler exposure and confirm that improved packaging/closed system now results in acceptable MOEs (specified in Part V). When the chemical-specific exposure data required by this RED are received and reviewed, the Agency will make a regulatory decision regarding the reregistration eligibility of the non-USDA uses of coumaphos. The Agency may reassess the USDA uses of coumaphos if the exposure data required as part of this RED (considered confirmatory when closed systems are introduced) indicates a high risk to handlers.

2. Eligible and Ineligible Uses

The technical registrant (Bayer) has stated, over a year ago, that they will voluntarily cancel the pour-on use of coumaphos. They also state that mechanical dusting of animals is no longer a common practice and that they are willing to propose label restrictions to prohibit such use. However, until these actions are actually accomplished, data will be required to support these uses.

The Agency does not have chemical-specific data for coumaphos and preliminary calculations using surrogate data (PHED) indicate a potential for handler exposure and/or risk from coumaphos as it is currently registered. The Margin of Exposure (MOE) for the dip vat use was calculated to range from 9 to 36 for "topping off" or refilling the dip vats which is required after animals moving through the vats have depleted the liquid level. MOEs for refilling empty dip vats (up to 4000 gallons) would be smaller by a factor of four (MOE of 2.5 to 9). These MOEs are considered to be of concern by the Agency, and normally the Agency would consider these uses ineligible for reregistration due to the potential

risk for mixer/loader/applicators. However, the risks must be considered in context with the benefits. In addition, the Agency is requiring closed systems and/or improved packaging to reduce exposure during mixing/loading of all coumaphos end use products registered for use in either dip vats or hand-held sprayers. The closed system for the WP formulation(s) should be water soluble bags. The registrant must determine appropriate systems for the flowable and emulsifiable concentrate formulations. It could be gel packs, "no glug" containers or any other equivalent system approved by the Agency. In either case, data must be submitted that supports the system chosen.

USDA/APHIS is a major consumer of coumaphos, using almost half of the total amount sold in the U.S.. Coumaphos is used in dip vats along the Texas/Mexico border in a program to eliminate Texas Cattle Fever, carried by certain species of ticks. USDA has estimated the economic importance of this use to be between $1-5 billion dollars. The Agency has decided based on the economic importance of coumaphos to the Texas Cattle Fever eradication program, that all USDA fever tick uses are considered eligible for reregistration provided the required exposure studies are submitted and closed systems discussed above are introduced.

The USDA routinely monitors the cholinesterase activity of its employees actively involved in the fever tick program (Boophilus spp., Dermacentor nitems, and exotic ticks). The Agency is in consultation with USDA/APHIS concerning this program and may request additional safeguards, however, existence of the program provides a "safety net" that enables the Agency to make a regulatory decision for these uses. Therefore, all USDA uses of coumaphos to treat for Texas Cattle Fever are considered eligible for reregistration. The Agency is aware that there are at least twelve other non-USDA dip vats (located in CO and TX), however, when there are quarantine or tick problems the USDA/APHIS operates the dip vats for the duration of the quarantine treatment(s). Therefore, the cholinesterase levels of the handlers (mixer/loaders/applicators) involved in treating the cattle would be monitored by the USDA. The Agency is requiring in this RED handler exposure data as outlined in Part V. If these data, even with closed systems, indicate low MOEs (i.e., < 100) then the Agency may take further regulatory action.

The Agency has conducted exposure assessments for the various uses, i.e., different methods of application. The Agency has calculated handler exposure and risk estimates based on a handler handling "typical" and "maximum" amounts of coumaphos of 0.5 lb ai and 5.0 lb ai/day, respectively, for spray operations. This corresponds to treating 100 and 1,000 cattle with coumaphos per day based on a use rate of 0.5 lbs ai/100 gallons the minimum use rate. MOEs for these exposure scenarios were 82 and 8.2, respectively. However, uncertainties in the

existing handler exposure databases (PHED) do not allow the Agency to determine, with confidence, the exact MOEs for these exposure scenarios. Therefore, the Agency has determined that a decision concerning the reregistration of non-USDA uses of coumaphos cannot be made until handler/occupational exposure data are received and reviewed.

The Agency does believes the data indicate a sufficient risk concern to require closed systems and improved packaging now, rather than delay a decision for several years until exposure data are conducted, submitted and reviewed. The registrant's own calculations report MOEs of 28 for a "topping off" of a large dip vat and 122 for "maximum spraying". These MOEs differ from Agency calculated MOEs because of different assumptions. However, if these numbers are corrected to reflect real maximum use rate not minimum rates as reflected in the registrant's submission, i.e., 4000 gallon dip vats (not 1000 gallons) and maximum spray use rate of 4.0 lbs/100 gallons (not 0.5 lbs ai/100 gallons) then the MOEs are 7.0 and 15.2, respectively. Again the registrant's MOEs are slightly higher from those calculated by the Agency due to less conservative, i.e., less protective of human health assumptions (see the Occupational Risk Assessment Section for details).

SUMMARY OF THE AGENCY'S REREGISTRATION DECISION

Animal	Reregistration Decision	ChE Monitoring Program	Handler Data Gaps
Beef Cattle			
USDA	Yes	Yes	Yes
Non-USDA	No	No	Yes
Dairy cows			
USDA	Yes	Yes	Yes
Non-USDA	No	No	Yes
Sheep			
USDA	Yes	Yes	Yes
Non-USDA	No	No	Yes
Hogs			
USDA	Yes	Yes	Yes
Non-USDA	No	No	Yes
Horses			
USDA	Yes	Yes	Yes
Non-USDA	No	No	Yes
Goats			
USDA	Yes	Yes	Yes
Non-USDA	No	No	Yes

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for coumaphos. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

Coumaphos is an important tool for the control of Texas Cattle Fever in the USDA's Tick Eradication Program. It is estimated, by USDA, that the cattle industry would sustain annual losses of $1-5 billion dollars if cattle fever ticks and the associated disease, babesiosis, were to become re-established in the U.S.. Equine babesiosis could result in mortality rates of about 10% or greater in susceptible horses. There are no available data to estimate economic losses due to the disease if introduced in the horse population in the U.S.. It should be noted that the international movement of show and race horses and cattle from the United States would be severely restricted. It should also be noted that the total use volume of coumaphos is relatively low (when compared to insecticides with agricultural uses on crops) and the USDA has a program in place to monitor worker's cholinesterase levels. The Agency is declaring all USDA uses of coumaphos to control Texas Cattle Fever eligible for reregistration provided the required exposure data outlined in this RED are submitted and closed systems/improved packaging to reduce exposure during mixing/loading of dip vat and hand-held sprayer solutions. The Agency must defer a decision on the remaining uses of coumaphos until the handler exposure data required in this RED are submitted and reviewed.

1. Tolerance Reassessment

The tolerances listed under 40 CFR §180.189 are for the combined residues of coumaphos and its oxygen analog. A summary of coumaphos tolerance reassessments is presented in the Table below.

Sufficient data are available to ascertain the adequacy of established tolerances listed in 40 CFR §180.189 for meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep, and milk.

The established tolerances for meat, fat, and meat byproducts of poultry, and eggs should be revoked, as the uses of coumaphos on poultry have been voluntarily canceled.

Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/Correct Commodity Definition
Cattle meat	1	1	Cattle, meat
Cattle fat	1	1	Cattle, fat
Cattle meat byproducts	1	1	Cattle, meat byproducts
Eggs	0.1	Revoke: Use on poultry was voluntarily cancelled, tolerance is no longer necessary	Use withdrawn
Goats meat	1	1	Goats, meat
Goats fat	1	1	Goats, fat
Goats meat byproducts	1	1	Goats, meat byproducts
Hogs meat	1	1	Hogs, meat
Hogs fat	1	1	Hogs, fat
Hogs meat byproducts	1	1	Hogs, meat byproducts
Horses meat	1	1	Horses, meat
Horses fat	1	1	Horses, fat
Horses meat byproducts	1	1	Horses, meat byproducts
Milk fat, reflecting negligible residues in milk	0.5	0.02	Milk (Tolerance expression should be revised to reflect levels in milk not milk fat)
Poultry meat	1	See eggs above	Use withdrawn
Poultry fat	1	See eggs above	Use withdrawn
Poultry meat byproducts	1	See eggs above	Use withdrawn
Sheep meat	1	1	Sheep, meat
Sheep fat	1	1	Sheep, fat
Sheep meat byproducts	1	1	Sheep, meat byproducts

CODEX HARMONIZATION

The FAO/WHO Joint Committee on Pesticide Residue (JMPR) has recommended Guideline Levels (GL; Step 4) for residues of coumaphos and its oxygen analog in animal commodities. The U.S. tolerances are expressed in terms of the same residues. GLs and corresponding U.S. tolerances are summarized in the Table below. Meat tolerances and GL levels are the same only for cattle and poultry meat (1 ppm). The GLs for goat, swine, and sheep meat (0.5 ppm) are lower than the corresponding U.S. tolerances (1 ppm). The U.S. tolerance for milk fat will be modified to harmonize with the CODEX GL for milk. The GL for

eggs (0.05 ppm) is lower than the U.S. tolerance of 0.1 ppm; however, this is not of concern because the U.S. tolerances for poultry meat and eggs should be revoked as there are no registered uses of coumaphos on poultry. The available residue data do not support lowering the U.S. tolerance for coumaphos residues in goat and pig meat to 0.5 ppm.

JMPR GLs and Applicable U.S. Tolerances.

Commodity	GL (mg/kg) [1]	U.S. Tolerance Reassessment (ppm)	Recommendation/ Comments
Cattle meat	1 (fat)	1	GL and U.S tolerance are compatible
Eggs	0.05	0.1	U.S. tolerance to be revoked
Goat meat	0.5 (fat)	1	
Milks	0.02	0.02 in milk	Codex GL and U.S. tolerance are compatible
Pig meat	0.5	1	
Poultry meat	1	1	U.S. tolerance to be revoked
Sheep meat	0.5	1	

1. GLs are established for the sum of coumaphos and its oxygen analogue (fat-soluble).

2. Summary of Risk Management Decisions

a. Human Health

(1) Dietary

Acute Dietary

The acute dietary analysis for the infant subgroup (<1) reaches an MOE of 100 at the 90 percentile. However, the dose required to produce RBC inhibition at 3 weeks was used to perform the acute dietary (single dose) risk assessment. This is the most appropriate data available to the Agency for risk assessment, however, this approach in all likelihood overestimates the dose that would be expected to produce ChE inhibition from a single exposure. Actual MOEs are expected to be at or near 100 from dietary exposure. Additional, toxicological data to further refine the acute dietary risk assessment will not be required for the reasons specified below.

Infant formula is a mixed or blended commodity and not normally taken directly from one dairy cow. Any such mixing or

blending would tend to reduce the variability in residue levels in the composite samples which children would consume. This would in effect reduce the likelihood of consuming milk with residue levels at or near the tolerance. The practical effect of mixing or blending would be to lower the residues observed in composite samples, making residue levels closer to the average or median estimated value.

In addition, Agency analysis cannot consider the effect of processing (e.g. pasteurization) or cooking which would likely reduce coumaphos levels because these data are not available. The Agency analysis also assumes that both meat and milk are consumed with coumaphos residues present in both commodities at the highest level observed in the feeding studies. Although this is possible, it is highly unlikely and should be considered as conservative, i.e., protective of public health.

(2) Handler (Mixer/Loader/Applicator)

Acute (Short-Term) and Intermediate

The Agency does not have chemical-specific data for coumaphos and preliminary calculations using surrogate data (PHED) indicate a potential for unacceptable handler exposure and/or risk from coumaphos as it is currently registered.

For dip-vat treatments, however, the USDA routinely monitors the cholinesterase activity of its employees actively involved in the fever-tick quarantine program (Boophilus spp., Dermacentor nitems, and exotic ticks). Therefore, all USDA uses of coumaphos in dip-vats (and spray treatment) to treat for Texas Cattle Fever (Southern Fever) are considered eligible for reregistration. The Agency is aware that there are other non-USDA dip-vats located in Colorado and Texas, however, when there are quarantine or tick problems the USDA/APHIS operates those dip-vats for the duration of the quarantine treatment(s). In those instances, the cholinesterase levels of the handlers (mixers/ loaders/applicators) involved in treating the cattle would be monitored by the USDA.

For spray applications to livestock, the Agency has conducted rough risk assessments for the various exposure scenarios registered for use. The Agency has roughly calculated

handler exposure and risk estimates based on a handler handling 0.5 lb ai (minimum use rate sufficient to treat 100 cattle) and 5.0 lb ai/day respectively for spray operations. This corresponds to treating 100 and 1,000 cattle with coumaphos per day. MOEs for these exposure scenarios were calculated to be 82 and 8.2, respectively. However, uncertainties in the existing handler exposure databases (PHED) do not allow the Agency to determine, with confidence, the exact MOEs for the various exposure scenarios. Therefore the Agency is requiring exposure data as outlined in Part V of this RED. In the interim, the Agency is imposing a label advisory for individuals to limit the number of animals they treat per day to no more than 100 (assuming animals are treated at the maximum dose, 200 if treated at 1/2 max. dose etc.). The Agency is also requiring closed systems/improved packaging (water soluble bags for powders; and, gel pack or "no glug" containers or equivalent system approved by the Agency for flowables) to minimize exposure during mixing/loading of coumaphos products for use in dip vats or application by hand-held sprayers as discussed above.

The Agency has determined that a decision concerning the reregistration of non-USDA uses of coumaphos cannot be made until occupational handler exposure data are received and reviewed. The handler exposure studies should be conducted using the closed systems required as part of this RED.

Post-Application

The Agency believes that there is minimal potential exposure to persons entering treated sites after application is complete because most coumaphos is applied directly to animals. However, contact with treated livestock shortly after treatment could result in coumaphos exposure. USDA workers are involved in a monitoring program and are withdrawn from treatment programs if ChE is significantly depressed. A decision concerning the reregistration of non-USDA uses of coumaphos cannot be made until occupational handler exposure data, which include evaluation of post-application exposure, are received and reviewed.

b. Environmental

(1) Avian

Technical coumaphos is highly to very highly toxic to birds. Birds may be exposed to coumaphos by feeding in the vicinity of treated cattle, or directly from the hides of treated cattle. However, the limited use pattern, i.e., only used for direct livestock treatment, is expected to confine problems to areas around feedlots or other areas where treated cattle may congregate. There is only one known avian incident during the thirty years that coumaphos has been registered for use and the source of exposure in that incident is unknown. Coumaphos is not expected to cause chronic effects because any exposure large enough to cause a chronic effect would likely be a lethal dose.

(2) Mammals

Coumaphos is not expected to pose a direct risk to non-target endangered or non-endangered mammals. There is no evidence that the use of coumaphos on livestock will result in direct exposure to non-target mammals.

(3) Insects

Coumaphos' use pattern is not expected to pose a direct risk to beneficial insects. There is no evidence that the use of coumaphos on livestock will result in significant exposure to beneficial insects.

(4) Freshwater fish

Fish could be exposed to coumaphos if treated livestock enter bodies of water shortly after treatment. The Agency has calculated that over 100 cows must wade into a 1 acre body of water in order for the most sensitive Level of Concern (i.e., endangered species) for fish to be exceeded. This indicates that coumaphos does not pose a threat to endangered or non-endangered fish species on an acute basis. Coumaphos does not pose a risk to fish on a chronic basis.

(5) Aquatic invertebrates

Coumaphos has the potential for causing adverse effects in aquatic invertebrates due to its high acute toxicity. Coumaphos is also sufficiently toxic on a chronic basis to cause a high risk to invertebrates. Aquatic organisms could be exposed to coumaphos if treated cattle enter bodies of water. Cattle enter bodies of water, particularly in the summer, for relief from heat and insects. The Agency does not expect sensitive, relatively undisturbed aquatic ecosystems to be closely associated with feedlots. The Agency previously required studies to quantify the extent of washoff of coumaphos from cattle hides after treatment with coumaphos. The studies indicate that between 2.0 - 38% of the applied coumaphos could be washed off the cattle hide depending upon formulation and drying time or interval. The available data indicate that after 24 hours the amount of coumaphos washed off would be a very small percentage, i.e., 2 - 3%. The Agency believes that the acute and chronic risks to aquatic organisms can be addressed with a label advisory.

(NOTE: USDA policy, detailed in Veterinary Services Memorandum 556.1, is to restrict cattle from entering streams or ponds for at least 7 days after treatment. This use constitutes almost half of the total U.S. coumaphos usage.)

(6) Estuarine & marine organisms

Data on acute toxicity to estuarine and marine organisms are required to support the registration of end use products intended for direct application to the estuarine or marine environment of if the product is expected to enter this environment in significant concentrations because of its use pattern or mobility. The registered uses of coumaphos do not meet these criteria. Literature data available indicate that coumaphos is highly toxic to marine fish and invertebrates, however, coumaphos exposure to these species is not likely due to its use pattern.

(7) Nontarget plants (Terrestrial, Semi-Aquatic & Aquatic)

Coumaphos is a livestock insecticide/acaricide and is not used on agricultural crops or ornamental plants. Exposure to

nontarget plants is assessed to be minimal. Plant testing was not required for this insecticide.

(8) Endangered species

Endangered species LOCs have been exceeded for aquatic invertebrates and birds. When the Endangered Species Protection Program becomes final, limitations in the use of coumaphos may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific.

(9) Surface & ground water

Coumaphos is used as an acaricide for control of the southern tick (Boophilus microplus) and the cattle tick (Boophilus annulatus) by the Animal and Plant Inspection Service (APHIS), in its Tick Eradication Program. Several hundred thousand head of cattle are dipped every year in one of the ca. 45 USDA vats along the U.S.-Mexican border. The vats contain approximately 15,000 liters of coumaphos solution with the active ingredient concentration of 0.15-0.31%. Vats are emptied, cleaned, and recharged every six to 12 months, depending on usage, generating approximately one million liters of coumaphos waste per year. Typically the vats are recharged when the sediment level reaches 10% of the total volume.

Coumaphos is essentially immobile and persistent is soil, but is apparently more mobile when applied at the high concentrations that occur is disposal pits. The Agency believes that threats to ground water can be mitigated without excessive difficulty or expense using the techniques discussed below.

Since 1986 the Agricultural Research Service of the USDA has been conducting research (e.g. see, Journal of Agricultural & Food Chemistry, July/August 1988, 831-834) concerning the degradation of coumaphos in cattle-dipping vats. Dip vat solutions of coumaphos can be inactivated through the metabolic action of bacteria that are naturally present in some dip vats. The USDA/ARS has been experimenting with microbial degradation of the spent vat solutions and has now successfully demonstrated a detoxification procedure. This procedure has been tested in laboratory scale equipment and most recently in the field in a full scale (4,000 gallon tank) pilot test conducted in Texas. Two spent

vat solutions were bioremediated to ca. 10 ppm. To date field testing of this bioremediation method indicates that coumaphos levels in the spent vat solutions are reduced from ca. 1200-1300 ppm to 10 ppm in approximately two weeks. The spent solution would then be put into lined evaporation pits. Currently the untreated 1200-1300 ppm spent solution is deposited in unlined evaporation pits. It may be possible, depending on local regulations, to eliminate the need for the evaporation ponds altogether and simply spray the treated or bioremediated waste vat solution directly onto the ground in order for further in-situ bioremediation to occur. This decision should be made by the individual states involved who are most familiar with the soil types and ground water situation in their area. In any case the Agency endorses this method of treatment. The Agency has concerns about leakage of spent dip vat solution from lined evaporation ponds. Reducing the absolute amount of active ingredient in the spent vat solution deposited in the evaporation ponds greatly mitigates the Agency's concern with leakage. This procedure appears to be relatively inexpensive and initial communication with USDA/APHIS, the dip vat operators, indicates that this treatment of vat solutions is being pursued.

The Agency considers the aerobic biodegradation of the spent dip vat solution in this manner critical in preventing the downward and or lateral movement of coumaphos and ultimately in preventing the contamination of groundwater. Although this will result in increased cost, the use of bioremediation is certainly much less expensive than any "clean-up" of groundwater that may be necessary if even one evaporation pond were to leak. Because this is new a procedure and will require capital upgrades (bioremediation tank and/or lined pits) the Agency will phase this disposal method revision in over a two year period. The Agency also understands that technical assistance, e.g., answering questions concerning construction of bioremediation tanks, will initially be provided by USDA/ARS. The USDA/ARS **will not** operate bioremediation sites to treat non-USDA spent dip vat solutions.

The Agency is requiring labeling that requires the use of this bioremediation procedure and/or the use of lined pits. If lined pits are used without first bioremediating the spent vat solutions, then protocols must be submitted to monitor the lined pits for leakage. The Agency is allowing local and/or State Environmental Control Agencies the option to permit use of lined evaporation ponds. The

Agency believes that the lined evaporation pond method of disposal is much less desirable than bioremediation and that it should be permitted only in those instances when use of the bioremediation method is not feasible. Exact label language required is found in Part V.

3. Restricted Use Classification

Coumaphos 11.6% EC and 42% flowable concentrate formulations must bear the following restricted-use statement:

"RESTRICTED USE CLASSIFICATION
Due to acute oral hazards
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."

NOTE: Closed system that precludes oral exposure (poisoning) may obviate the need for restricted use classification.

4. Reference Dose Exceedance

When only the supported uses are considered the ARCs for the U.S. population and all DRES subgroups are well below the Reference Dose.

5. Endangered Species Statement

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will address the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirement for the product use modifications will occur in the future under the Endangered Species Protection Program.

6. Labeling Rationale

Occupational and Residential Labeling Rationale/Risk Mitigation

The Worker Protection Standard (WPS)

At this time, there are no registered uses of coumaphos within the scope of the WPS. WPS does not include uses on livestock or other animals, or use in or around animal premises.

Personal Protective Equipment/Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, EPA may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body

protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for coumaphos. The MOEs for dermal exposure were a serious concern for mixers, loaders, and applicators. EPA is requiring active-ingredient-based protections for handlers of coumaphos in these exposure situations.

Based on the unacceptable MOE calculated for the handwand spray applications, the minimum (baseline) PPE for all coumaphos end-use products is: long-sleeved shirt, long pants, chemical-resistant gloves, chemical-resistant footwear and socks for all handlers. In addition, mixer/loaders supporting spray applications and handlers (mixers, loaders, and applicators) participating in dip-vat applications must wear a chemical-resistant apron and face shield or goggles.

Homeowner-Use Products

Currently there are no coumaphos products intended primarily for homeowner use.

Post-Application/Entry Restrictions

Occupational-Use Products

Since EPA has some concerns about post-application exposures to persons contacting treated animals immediately after liquid applications of coumaphos, it is establishing restrictions on contact with treated livestock on all end-use products containing directions for use as a livestock spray or dip. For specific requirements, refer to Section V of this document.

Homeowner-Use Products

Currently there are no coumaphos products intended primarily for homeowner use.

Other Labeling Requirements

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

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

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 substantially complete with the exception of occupational (mixer/loader/applicator) exposure data. The following data are required before the Agency can make a regulatory decision regarding reregistration eligibility:

Handler exposure

Guideline 231: Estimation of Dermal Exposure at Outdoor Sites

- Mixing/loading/application of dipping solutions for both the liquid and wettable formulations. These studies must include the impact of the closed systems/improved packaging on mixing/loading exposure, e.g., water soluble bags for the WP formulation.

- Mixing/loading operations for backrubber and dust bag setups.

- Mixing/loading/application of liquid and wettable powder formulations using high and low-pressure handwand sprayers. These studies must include the impact of the closed systems/improved packaging on mixing/loading exposure, e.g., water soluble bags for the WP formulation.

- Application of ready-to-use, pour-on solutions.

- Application with shaker cans, foam spray can, and application with mechanical dusters.

Guideline 232: Estimation of Inhalation Exposure at Outdoor Sites

- Mixing/loading/application of dipping solutions for both the liquid and wettable formulations. These studies must include the impact of the closed systems/improved packaging on mixing/loading exposure, e.g., water soluble bags for the WP formulation.

- Mixing/loading operations for backrubber and dust bag setups.

- Mixing/loading/application of liquid and wettable powder formulations using high and low-pressure handwand sprayers. These studies must include the impact of the closed systems/improved packaging on mixing/ loading exposure, e.g., water soluble bags for the WP formulation.

- Application of ready-to-use, pour-on solutions.

- Application with shaker cans, foam spray can, and application with mechanical dusters.

The following data are considered confirmatory:

<u>Environmental Fate</u>

Guideline 162-3 Anaerobic Aquatic Metabolism

This information is needed to ascertain the effects of anaerobicity, a condition which can have an effect

on many oxidation-reduction systems, and consequently may indirectly affect the metabolism and fate of coumaphos.

NOTE: Acute and subchronic neurotoxicity testing of coumaphos required in the 1992 DCI is still required. The registrant requested and was granted a time extension, due to the large number of active ingredients they must test. Due dates for these studies are unchanged by this RED: 4/30/98 for the acute study and 11/30/98 for the subchronic study. In addition, the registrant must upgrade the aqueous photolysis study by explaining why an unknown, possibly a degradate, was detected at a concentration of 0.06 ppm (11.6%) and eluted at a retention time of 4 minutes in the HPLC chromatogram was present in the original study (MRID 42764101) but was not present in the replacement study.

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into a insecticide for the following use(s): beef cattle, dairy cattle, sheep, goats, horses, swine and swine bedding."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, use group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s)."

(b) "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 the support of such (use)s."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix D, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Restricted Use Classification

The 1989 Registration Standard classified coumaphos 11.6% EC and 42% flowable concentrate end-use products as restricted use due to high acute oral toxicity.

NOTE: Closed system(s) that precludes oral exposure (poisoning) may obviate the need for restricted use classification.

b. Worker Protection

PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain coumaphos, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain coumaphos must compare the handler personal protective equipment/engineering control requirements set forth in this section to the PPE requirements on their current labeling and retain the more protective. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

Minimum (Baseline) PPE/Engineering Control Requirements

EPA is establishing active-ingredient-based minimum (baseline) engineering control requirements for liquid-concentrate and wettable-powder formulations. EPA is also establishing active-ingredient-based minimum (baseline) personal protective equipment requirements for all handlers.

Ready-To-Use Products: EPA is establishing minimum (baseline) PPE for all ready-to-use formulations of coumaphos as follows:

Applicators and other handlers must wear:
-- long-sleeve shirt and long pants,
-- chemical-resistant gloves*, and
-- shoes plus socks.

Wettable Powder Products: EPA is requiring that wettable powder formulation be contained in water-soluble packets. In addition, EPA is establishing minimum (baseline) PPE for wettable powder formulations as follows:

"Handlers exposed to the concentrate, such as during a spill, or equipment break-down, and all 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 must wear:
-- long-sleeve shirt and long pants,
-- chemical-resistant gloves*, and
-- chemical-resistant footwear plus socks."

"Water-soluble packets when used correctly qualify as a closed loading system. Handlers handling this product while it is enclosed in intact water-soluble packets are permitted to wear long-sleeved shirt, long pants, chemical-resistant gloves*, shoes plus socks, and a chemical-resistant apron. However, such handlers must be provided a face shield or goggles

and have such PPE immediately available for use in a emergency, such as a spill or equipment break-down."

Emulsifiable Concentrate and Flowable Concentrate Products: EPA is requiring that all liquid concentrate formulations be contained in "no-glug" containers, water-soluble gel-packs, or other equivalent methods approved by the Agency. In addition, EPA is establishing minimum (baseline) PPE requirements for all liquid-concentrate formulations as follows:

"Mixers, loaders, and others exposed to the concentrate (such as during a spill or equipment break-down) and all 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 must wear:
-- long-sleeve shirt and long pants,
-- chemical-resistant gloves*, and
-- chemical-resistant footwear plus socks."

* For the glove statement, use the statement established for coumaphos through the instructions in Supplement Three of PR Notice 93-7.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Entry Restrictions

For **sole-active-ingredient** end-use products that contain coumaphos the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain coumaphos the entry restriction set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained.

Products Intended Primarily for Occupational Use

"Do not contact treated animals until their coats are dry."

Entry restrictions do not apply to coumaphos treatment of swine bedding.

Placement in labeling:

Place the entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements be located on all end-use products containing coumaphos that are intended primarily for occupational use:

Application Restrictions:

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

The following restriction must appear on products labeled for hand held sprayer application:

"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 1/2 maximum label rate, etc."

User Safety Requirements:

1. Registrant, place the following statement on end-use product labeling if coveralls are required for pesticide handlers:

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

2. Registrant, always place the following statement on the end-use product labeling:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

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."

Environmental Hazard Statements

All labels must have standard language, including:

"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."

Premise Precautions

All products labeled for use in livestock premise or areas must include the following:

"Do not spray in a confined, non-ventilated area."

"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."

ANIMAL DIPPING-VAT DISPOSAL

DISPOSAL OF SPENT VAT SOLUTION

"Cattle Dip Vat Solution Disposal: Contact your Local and/or State Environmental Control Agency for specific recommendations or details for the geographical area where the dip vat is located. The Agency recommends that spent dip-vat solution be bioremediated in accordance with a method developed by the USDA. The treated solution can then be transferred to lined, shallow evaporation ponds or incorporated into the soil to encourage further degradation. If an evaporation pond is used it should be constructed to prevent overflow or flooding during wet seasons and should be lined with compacted clay, reinforced concrete or flexible membrane liner. Questions concerning the disposal of the spent solution should be directed to the waste representative at the nearest EPA Regional Office. Details are available concerning the bioremediation procedure and ultimate disposition of the remediated solution. Do not apply dried sludge or the bioremediated/treated solution to land used for raising crops for human consumption."

OTHER LABEL RESTRICTIONS

Other current label restrictions, e.g., restrictions against treating lactating cows, or other limitations/precautions on existing labels are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. 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 registrants may distribute and sell coumaphos products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES													
BEEF/RANGE/FEEDER CATTLE (MEAT)				Use Group: INDOOR FOOD									
Animal treatment (back rubber)., When needed., Not on label.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, S09(0)
	EC	NA	UC	*	NS	NS	NS	NS	NS	NS			C04, C93, F05
Animal treatment (dust)., When needed., Dust bag.	D	NA	.005 lb animal	*	NS	NS	NS	.03 lb	14	NS			C04, G64, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	1	NS			C04, G64, S06
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	1	NS			C04, G64, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	1	NS			C04, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	1	NS			G64, S06
Animal treatment (dust)., When needed., Duster.	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Hand held duster.	D	NA	.001 lb animal	*	NS	26/1 yr	NS	NS	14	NS			C04, G64, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Hand held sprayer.	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Mechanical duster.	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Not on label.	D	NA	.001 lb animal	*	NS	26/1 yr	NS	NS	14	NS			C04, G64, S09(0)
	D	NA	.001 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, G64, S09(0)

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps @ Max. /crop cycle	Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
BEEF/RANGE/FEEDER CATTLE (MEAT) (con't)			Use Group: INDOOR FOOD (con't)										
Animal treatment (dust)., When needed., Shaker can.	D	NA	.001 lb animal	*	NS	NS	NS	NS	10	NS			C04, S09(0)
	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (ear)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(0)
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (spray)., When needed., High pressure sprayer.	EC	NA	UC	*	2	NS	NS	NS	NS	NS			C04, S06
	EC	NA	UC	*	NS	NS	NS	NS	14	NS			C04, S06
	FlC	NA	UC	*	NS	NS	NS	NS	14	NS			S09(0)
	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04, S09(0)
Animal treatment (spray)., When needed., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, S06
	FlC	NA	UC	*	NS	NS	NS	NS	14	NS			S09(0)
	WP	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, S09(0)
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(0)
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (wound)., When needed., High pressure sprayer.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, S06
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment., When needed., Duster.	D	NA	UC	*	NS	NS	NS	NS	1	NS			C04, G64, S06

APPENDIX A) CASE 0018, [Coumaphos] Chemical 036501 [Coumaphos]

SITE Application Type, Application Timing, Application Equipment | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. Max. Dose | # Apps @ Max. /crop cycle | Rate /year | Max. Dose [(AI unless noted otherwise)/A] /crop cycle | /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Disallowed | Use Limitations Codes
FOOD/FEED USES (con't)

BEEF/RANGE/FEEDER CATTLE (MEAT) (con't)				Use Group: INDOOR FOOD (con't)								
Animal treatment., When needed., Hand held duster.	D	NA		UC	*	NS	NS	NS	NS	1	NS	C04, G64, S06
Animal treatment., When needed., Mechanical duster.	D	NA		UC	*	NS	NS	NS	NS	1	NS	C04, G64, S06
Dip treatment., When needed., Vat.	FlC	NA		UC	*	NS	NS	NS	NS	10	NS	S09(0)
	WP	NA		UC	*	NS	NS	NS	NS	10	NS	C04, S09(0)
Pour-on., When needed., Not on label.	RTU	NA	.001563 lb	100 lb animal	*	NS	NS	NS	NS	14	NS	S06
	RTU	NA	.001419 lb	100 lb animal	*	NS	NS	NS	NS	NS	NS	C04, S06
Spray., When needed., Hand held sprayer.	EC	NA		UC	*	NS	NS	NS	NS	NS	NS	C04, C93, F05
DAIRY CATTLE (LACTATING OR UNSPECIFIED)				Use Group: INDOOR FOOD								
Animal treatment (back rubber)., When needed., Not on label.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS	C04, C93, F05
	EC	NA		UC	*	NS	NS	NS	NS	AN	NS	C04, F06(0)
Animal treatment (dust)., When needed., Dust bag.	D	NA	.005 lb	animal	*	NS	NS	NS	.03 lb	14	NS	C04, F06(0), G64
	D	NA	6.250E-04 lb	animal	*	NS	NS	NS	NS	1	NS	C04, F04, G64
	D	NA	6.250E-04 lb	animal	*	NS	NS	NS	NS	1	NS	C04, F06(0), G64
	D	NA	6.250E-04 lb	animal	*	NS	NS	NS	NS	1	NS	F04, G64
	D	NA		UC	*	NS	NS	NS	NS	NS	NS	C04, F06(0)
Animal treatment (dust)., When needed., Duster.	D	NA	.001 lb	animal	*	NS	NS	NS	NS	14	NS	C04, F06(0), G64

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
DAIRY CATTLE (LACTATING OR UNSPECIFIED) (con't)			Use Group: INDOOR FOOD (con't)										
Animal treatment (dust)., When needed., Hand held duster.	D	NA	.001 lb animal	*	NS	26/1 yr	NS	NS	14	NS			C04, F06(0), G64
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, F04, G64
	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, F06(0), G64
Animal treatment (dust)., When needed., Mechanical duster.	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, F06(0), G64
Animal treatment (dust)., When needed., Not on label.	D	NA	.001 lb animal	*	NS	26/1 yr	NS	NS	14	NS			C04, F06(0), G64
	D	NA	.001 lb animal	*	NS	NS	NS	NS	10	NS			C04, F06(0), G64
	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, F06(0), G64
Animal treatment (dust)., When needed., Shaker can.	D	NA	.001 lb animal	*	NS	NS	NS	NS	10	NS			C04, F06(0)
	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, F06(0), G64
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F04, G64
Animal treatment (ear)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F04, G64
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F06(0), G64
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F04, G64
Animal treatment (spray)., When needed., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F06(0)
	WP	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F06(0)
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F04, G64
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, F06(0), G64

APPENDIX A) CASE 0018, [Coumaphos] Chemical 036501 [Coumaphos]

SITE Application Type, Application Timing, Application Equipment | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. | Max. # Apps @ Max. Rate Max. /crop cycle | /year | Max. Dose [(AI unless noted otherwise)/A] /crop cycle | /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Disallowed | Use Limitations Codes
FOOD/FEED USES (con't)

DAIRY CATTLE (NON-LACTATING)				Use Group: INDOOR FOOD								
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA		UC	*	NS	NS	NS	NS	AN	NS	C04, F04, G64
Animal treatment., When needed., Duster.	D	NA		UC	*	NS	NS	NS	NS	1	NS	C04, F04, G64
Animal treatment., When needed., Hand held duster.	D	NA		UC	*	NS	NS	NS	NS	1	NS	C04, F04, G64
Animal treatment., When needed., Mechanical duster.	D	NA		UC	*	NS	NS	NS	NS	1	NS	C04, F04, G64
Spray., When needed., Hand held sprayer.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS	C04, C93, F05
Animal treatment (spray)., When needed., High pressure sprayer.	EC	NA		UC	*	NS	NS	NS	NS	14	NS	C04, F01(14)
	FlC	NA		UC	*	NS	NS	NS	NS	14	NS	F04
	WP	NA		UC	*	NS	NS	NS	NS	14	NS	C04, F01(14)
Animal treatment (spray)., When needed., Sprayer.	EC	NA		UC	*	NS	NS	NS	NS	AN	NS	C04, F01(14)
	FlC	NA		UC	*	NS	NS	NS	NS	14	NS	F04
	WP	NA		UC	*	NS	NS	NS	NS	AN	NS	C04, F01(14)
Dip treatment., When needed., Vat.	FlC	NA		UC	*	NS	NS	NS	NS	10	NS	F04
	WP	NA		UC	*	NS	NS	NS	NS	10	NS	C04, F01(14)
Pour-on., When needed., Not on label.	RTU	NA	.001563 lb	100 lb animal	*	NS	NS	NS	NS	14	NS	F01(14), F05
	RTU	NA	.001419 lb	100 lb animal	*	NS	NS	NS	NS	NS	NS	C04, F01(14), F05

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
DAIRY GOATS (NON-LACTATING)			Use Group: INDOOR FOOD										
Animal treatment (spray)., When needed., Sprayer.	WP	NA		UC	*	NS	NS	NS	NS	14	NS		C04, F01(14), F05
Animal treatment (wound)., When needed., Sprayer.	WP	NA		UC	*	NS	NS	NS	NS	14	NS		C04, F01(14), F05
Dip treatment., When needed., Vat.	WP	NA		UC	*	NS	NS	NS	NS	10	NS		C04, F01(14), F05
GOATS (MEAT)			Use Group: INDOOR FOOD										
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA		UC	*	NS	NS	NS	NS	AN	NS		C04, G64, S09(3)
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA		UC	*	NS	NS	NS	NS	AN	NS		C04, G64, S09(3)
Animal treatment (spray)., When needed., Sprayer.	WP	NA		UC	*	NS	NS	NS	NS	14	NS		C04, S09(3)
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	AN	NS		C04, G64, S09(3)
Animal treatment (wound)., When needed., Sprayer.	WP	NA		UC	*	NS	NS	NS	NS	14	NS		C04, S09(3)
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA		UC	*	NS	NS	NS	NS	AN	NS		C04, G64, S09(3)
Dip treatment., When needed., Vat.	WP	NA		UC	*	NS	NS	NS	NS	10	NS		C04, S09(3)
GOATS (WOOL/ANGORA ANIMAL)			Use Group: INDOOR FOOD										
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA		UC	*	NS	NS	NS	NS	NS	NS		C04, G64, S09(3)
HOG/PIG/SWINE (MEAT)			Use Group: INDOOR FOOD										
Animal bedding/litter treatment., When needed., Duster.	D	NA	4.125E-05 lb sq.ft		*	NS	NS	NS	NS	10	NS		C04, G64, S09(0)

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
HOG/PIG/SWINE (MEAT) (con't)			Use Group: INDOOR FOOD (con't)										
Animal bedding/litter treatment., When needed., Hand held duster.	D	NA	4.125E-05 lb sq.ft	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
Animal bedding/litter treatment., When needed., Mechanical duster.	D	NA	4.125E-05 lb sq.ft	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	4.125E-05 lb sq.ft	*	NS	NS	NS	NS	10	NS			C04, S09(0)
Animal bedding/litter treatment., When needed., Not on label.	D	NA	4.125E-05 lb sq.ft	*	NS	36/1 yr	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	4.125E-05 lb sq.ft	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
Animal bedding/litter treatment., When needed., Shaker can.	D	NA	4.125E-05 lb sq.ft	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	4.125E-05 lb sq.ft	*	NS	NS	NS	NS	10	NS			C04, S09(0)
Animal treatment (dust)., When needed., Duster.	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Hand held duster.	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
Animal treatment (dust)., When needed., Mechanical duster.	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, S09(0)
Animal treatment (dust)., When needed., Not on label.	D	NA	6.250E-04 lb animal	*	NS	36/1 yr	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps @ Max. /crop cycle	Rate /year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	Max. Dose [(AI unless noted otherwise)/A] /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
FOOD/FEED USES (con't)													
HOG/PIG/SWINE (MEAT) (con't)			Use Group: INDOOR FOOD (con't)										
Animal treatment (dust)., When needed., Shaker can.	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, G64, S09(0)
	D	NA	6.250E-04 lb animal	*	NS	NS	NS	NS	10	NS			C04, S09(0)
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (spray)., When needed., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, S06
	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04, S06
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(0)
	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Animal treatment (wound)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04, S06
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(03)
Spray., When needed., Hand held sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS			C04, C93, F05
SHEEP (MEAT)			Use Group: INDOOR FOOD										
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(3)
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64, S09(3)
Animal treatment (spray)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04, S09(3)

APPENDIX A) CASE 0018, [Coumaphos] Chemical 036501 [Coumaphos]

SITE Application Type, Application Timing, Application Equipment | Form(s) | Min. Appl. Rate (AI unless noted otherwise) | Max. Appl. Rate (AI unless noted otherwise) | Soil Tex. Max. Dose | # Apps @ Max. /crop cycle | Rate /year | Max. Dose [(AI unless noted otherwise)/A] /crop cycle | Max. Dose [(AI unless noted otherwise)/A] /year | Min. Interv (days) | Restr. Entry Interv [day(s)] | Geographic Limitations Allowed | Geographic Limitations Disallowed | Use Limitations Codes
FOOD/FEED USES (con't)

SHEEP (MEAT) (con't)			Use Group: INDOOR FOOD (con't)									
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS		C04, G64, S09(3)
Animal treatment (wound)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS		C04, S09(3)
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS		C04, G64, S09(3)
Dip treatment., When needed., Vat.	WP	NA	UC	*	NS	NS	NS	NS	10	NS		C04, S09(3)
NON-FOOD/NON-FEED												
GOATS (WOOL/ANGORA ANIMAL)			Use Group: INDOOR NON-FOOD									
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS		C04, G64
Animal treatment (spray)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS		C04
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS		C04, G64
Animal treatment (wound)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS		C04
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS		C04, G64
Dip treatment., When needed., Vat.	WP	NA	UC	*	NS	NS	NS	NS	10	NS		C04
Ear treatment. Use code ATN., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS		C04, G64

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	# Apps @ Max. Rate /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
NON-FOOD/NON-FEED (con't)													
HORSES (SHOW/RACE/SPECIAL/PONIES)				Use Group: INDOOR NON-FOOD									
Animal treatment (dust)., When needed., Mechanical duster.	D	NA	.001 lb animal	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (dust)., When needed., Not on label.	D	NA	.001 lb animal	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (dust)., When needed., Shaker can.	D	NA	.001 lb animal	*	NS	NS	NS	NS	14	NS			C04, G64
	D	NA	.001 lb animal	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (spray)., When needed., High pressure sprayer.	FlC	NA	UC	*	NS	NS	NS	NS	14	NS			
Animal treatment (spray)., When needed., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04
	FlC	NA	UC	*	NS	NS	NS	NS	14	NS			
	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (wound)., When needed., Sprayer.	EC	NA	UC	*	NS	NS	NS	NS	AN	NS			C04
	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Dip treatment., When needed., Vat.	FlC	NA	UC	*	NS	NS	NS	NS	10	NS			
Spray., When needed., Hand held sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS			C04, C93, F05

SITE Application Type, Application Timing, Application Equipment	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex.	Max. # Apps @ Max. Rate Max. /crop cycle	/year	Max. Dose [(AI unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
NON-FOOD/NON-FEED (con't)													
SHEEP (con't)			Use Group: INDOOR NON-FOOD (con't)										
Animal treatment (dust)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (ear)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (spray)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04
Animal treatment (wound)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Animal treatment (wound)., When needed., Sprayer.	WP	NA	UC	*	NS	NS	NS	NS	14	NS			C04
Animal treatment (wound)., When needed., Squeeze applicator.	D	NA	UC	*	NS	NS	NS	NS	AN	NS			C04, G64
Dip treatment., When needed., Vat.	WP	NA	UC	*	NS	NS	NS	NS	10	NS			C04

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise)	Minimum dose for a single application to a single site. System calculated. Microbial claims only.
Max. Appl. Rate (AI unless noted otherwise)	Maximum dose for a single application to a single site. System calculated.
Soil Tex. Max. Dose	Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate	Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"
Max. Dose [(AI unless noted otherwise)/A]	Maximum dose applied to a site over a single crop cycle or year. System calculated.
Min. Interv (days)	Minimum Interval between Applications (days)
Restr. Entry Interv (days)	Restricted Entry Interval (days)
PRD Report Date	LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

*	Non-specific
C	Coarse
M	Medium
F	Fine
O	Others

FORMULATION CODES

D	DUST
EC	EMULSIFIABLE CONCENTRATE
FlC	FLOWABLE CONCENTRATE
PRL	PRESSURIZED LIQUID
RTU	LIQUID-READY TO USE
WP	WETTABLE POWDER

ABBREVIATIONS

AN	As Needed
NA	Not Applicable
NS	Not Specified (on label)
UC	Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC	Dosage Can Not be Calculated
No Calc	No Calculation can be made
W	PPM calculated by weight
V	PPM Calculated by volume
U	Unknown whether PPM is given by weight or by volume
cwt	Hundred Weight
nnE-xx	nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

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USE LIMITATIONS CODES
C04 : Proper ventilation required.
C93 : Do not apply directly to water.
F01 : __ day(s) prefreshening interval.
F04 : Prefreshening and/or premilking interval not located on label.
F05 : Do not apply to lactating animals.
F06 : __ day(s) premilking interval.
G64 : Avoid contamination of feed, feed containers and watering troughs.
S06 : Preslaughter interval not located on the label.
S09 : __ day(s) preslaughter interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case coumaphos covered by this Reregistration Eligibility Decision Document. 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 format:

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 Guidelines, 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 lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	CSFs dated 6/22/93
61-2A	**Start. Mat. & Mnfg. Process**	All	00110596, 41778501, 42378501, 42557001
61-2B	**Formation of Impurities**	All	00110596, 41778501, 42378501
62-1	**Preliminary Analysis**	All	00110596, 42258601, 42675001, 42675003
62-2	**Certification of limits**	All	CSFs dated 10/20/93
62-3	**Analytical Method**	All	00110596, 41778501, 42258602, 42258603, 42378502, 42675002, 43115802
63-2	**Color**	All	00110596
63-3	**Physical State**	All	00021999, 00110596
63-4	**Odor**	All	00110596
63-5	**Melting Point**	All	00021999, 00110596
63-6	**Boiling Point**	All	00021981
63-7	**Density**	All	00110596
63-8	**Solubility**	All	00110596, 41778502
63-9	**Vapor Pressure**	All	00005193
63-10	**Dissociation Constant**	All	Waived
63-11	**Octanol/Water Partition**	All	41778502
63-12	**pH**	All	00110596

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	All	00021981, 00141225, 41778502, 42378503, 43115801
63-14	**Oxidizing/Reducing Action**	All	Waived
63-15	**Flammability**	All	N/A
63-16	**Explodability**	All	ltr. dtd. 10/28/93
63-17	**Storage stability**	All	42378503
63-18	**Viscosity**	All	N/A
63-19	**Miscibility**	All	N/A
63-20	**Corrosion characteristics**	All	Data gap
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck TGAI**	A	00112841, 00160000
71-1B	**Acute Avian Oral - Quail/Duck TEP**	A	N/A
71-2A	**Avian Dietary - Quail**	A	00112842, 00022923
71-2B	**Avian Dietary - Duck**	A	00112843, 00022923
71-3	**Wild Mammal Toxicity**	N/A	N/A
71-4A	**Avian Reproduction - Quail**	A	Waived
71-4B	**Avian Reproduction - Duck**	A	Waived
71-5A	**Simulated Field Study**	N/A	N/A
71-5B	**Actual Field Study**	N/A	N/A
72-1A	**Fish Toxicity Bluegill - TGAI**	A	00112840, 40098001

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
72-1B	**Fish Toxicity Bluegill - TEP**	A	N/A
72-1C	**Fish Toxicity Rainbow Trout**	A	00112840, 40098001
72-1D	**Fish Toxicity Rainbow Trout- TEP**	N/A	N/A
72-2A	**Invertebrate Toxicity**	A	40098001, 41778503, 41778504, 05009242
72-2B	**Invertebrate Toxicity - TEP**	N/A	N/A
72-3A	**Estuarine/Marine Toxicity - Fish**	A	40228401
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A	40228401
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A	40228401
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	N/A	N/A
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	N/A	N/A
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	N/A	N/A
72-4A	**Early Life Stage Fish**	A	43066301
72-4B	**Life Cycle Invertebrate**	A	43116601
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	All	**00110597, 00110603, 00112832, 00110609, 00112827, 00112821, 00026376, 00026377, 00026379, 00026371**

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	All	**00110598, 00110604, 00112833, 00112816, 00112827, 00112822, 00026375, 00026378, 00026372**
81-3	**Acute Inhalation Toxicity - Rat**	All	**00110601, 00110607, 00112836, 00112820, 00112830, 00112825, 00026374**
81-4	**Primary Eye Irritation - Rabbit**	All	**00110599, 00110605, 00112834, 00112818, 00112828, 00112824, 00026370**
81-5	**Primary Dermal Irritation - Rabbit**	All	**00110600, 00110605, 00112835, 00112817, 00112829, 00112823, 00026373**
81-6	**Dermal Sensitization - Guinea Pig**	All	**00110602, 00110608, 00112837, 00112819, 00112831, 00112826, 00082524**
81-7	**Acute Delayed Neurotoxicity - Hen**	All	**00115167**
81-8-SS	**Acute Neurotoxicity - mammal**	All	**00126527**
82-1A	**90-Day Feeding - Rodent**	L	**00126527**
82-1B	**90-Day Feeding - Non-rodent**	L	**N/A**
82-2	**21-Day Dermal - Rabbit/Rat**	L	**00117106, 42084901, 42666401**
82-3	**90-Day Dermal - Rodent**	N/A	**N/A**
82-4	**90-Day Inhalation - Rat**	N/A	**N/A**
82-5A	**90-Day Neurotoxicity - Hen**	N/A	**N/A**
82-5B	**90-Day Neurotoxicity - Mammal**	All	**Data gap**
83-1A	**Chronic Feeding Toxicity - Rodent**	All	**40836001, 40955801**
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	L	**43055301**
83-2A	**Oncogenicity - Rat**	L	**40836001, 40955801**

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
83-2B	**Oncogenicity - Mouse**	L	**05009938**
83-3A	**Developmental Toxicity - Rat**	L	**00131684**
83-3B	**Developmental Toxicity - Rabbit**	L	**00131683**
83-4	**2-Generation Reproduction - Rat**	L	**43061701**
84-2A	**Gene Mutation (Ames Test)**	L	**00131680**
84-2B	**Structural Chromosomal Aberration**	L	**41847501, 42254501**
84-4	**Other Genotoxic Effects**	L	**00131681**
85-1	**General Metabolism**	L	**00138596**
85-2	**Dermal Penetration**	N/A	**N/A**
86-1	**Domestic Animal Safety**	K	**00138251**
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
231	**Estimation of Dermal Exposure at Outdoor Sites**	A	**Data gap**
232	**Estimation of Inhalation Exposure at Outdoor Sites**	A	**Data gap**
233	**Estimation of Dermal Exposure at Indoor Sites**	L	**Data gap**
234	**Estimation of Inhalation Exposure at Indoor Sites**	L	**Data gap**
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A	Data gap partially satisfied by: 00150197, 00159928

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
161-2	**Photodegradation - Water**	A	Data gap partially satisfied by: 42764101, 43103901, 430022101
161-3	**Photodegradation - Soil**	N/A	N/A
161-4	**Photodegradation - Air**	N/A	N/A
162-1	**Aerobic Soil Metabolism**	A	Data gap partially satisfied by: 0115165, 40518701
162-2	**Anaerobic Soil Metabolism**	A	WAIVED FOR 162-3 STUDY
162-3	**Anaerobic Aquatic Metabolism**	A	Data gap
162-4	**Aerobic Aquatic Metabolism**	N/A	N/A
163-1	**Leaching/Adsorption/Desorption**	A	Data gap partially satisfied by: 00163806, 42084092, 42097401
163-2	**Volatility - Lab**	N/A	N/A
163-3	**Volatility - Field**	N/A	N/A
164-1	**Terrestrial Field Dissipation**	A	Data gap partially satisfied by: 00115166
164-2	**Aquatic Field Dissipation**	N/A	N/A
164-5	**Long Term Soil Dissipation**	N/A	N/A
165-4	**Bioaccumulation in Fish**	A	N/A, however data are available in: 00115168, 00115169, 00150619
165-5	**Bioaccumulation - Aquatic NonTarget**	N/A	N/A
166-1	**Ground Water - Small Prospective**	N/A	N/A
166-2	**Ground Water - Small Retrospective**	A	Data gap partially satisfied by: No MRID: JHJ;05/03/93

Data Supporting Guideline Requirements for the Reregistration of Coumaphos

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4A	**Nature of Residue - Plants**	N/A	N/A
171-4B	**Nature of Residue - Livestock**	A	00005392, 00005402, 05004087, 05004483, 05012748, 42097402, 42323402
171-4C	**Residue Analytical Method - Plants**	N/A	N/A
171-4D	**Residue Analytical Method - Animal**	A	00005195, 00005289, 00005342, 00005438, 42097403, 42323401, 43123401
171-4E	**Storage Stability**	A	00005341, 00073248, 43569801, 43569802, 43569803, 43569804, 43569805, 43569806, 43569807, 43569808, 43569809, 43569810, 43569811, 43569812
171-4F	**Magnitude of Residues - Potable H2O**	N/A	N/A
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A	00005042, 00005047, 00005048, 00005051, 00005056, 00005074, 00005080, 00005081, 00005235, 00005293, 00005295, 00005330, 00005331, 00005333, 00005339, 00005399, 00005400, 00005479, 00005489, 00005493, 00005510, 00005822, 00005830, 00021731, 00021732, 00060807

GUIDE TO APPENDIX C

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

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

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

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

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

    b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID **CITATION**

00005042 Chemagro Corporation (1971) Chemagro Corporation Residue Experiment Nos. AH 70G-810, AH 71G-818: Report No. 30331. (Unpublished study received Oct 29, 1971 under 11556-4; submitted by Bayvet, Shawnee Mission, Kans.; CDL:010122-F)

00005047 Chemagro Corporation (1967) Chemagro Corporation Residue Experiment No. KC-201-66D: Report No. 20652. (Unpublished study received Dec 15, 1967 under 11556-19; submitted by Bayvet, Shawnee Mission, Kans.; CDL:014008-D)

00005048 Chemagro Corporation (1967) Chemagro Corporation Residue Experiment No. KC-300-66H: Report No. 20964. (Unpublished study received Dec 15, 1967 under 11556-19; submitted by Bayvet, Shawnee Mission, Kans.; CDL:014008-E)

00005051 Chemagro Corporation (1968) Chemagro Corporation Residue Experiment No. ?: Report No. 23942. (Unpublished study received Jul 23, 1970 under 11556-16; submitted by Bayvet, Shawnee Mission, Kans.; CDL:007188-A)

00005056 Chemagro Corporation (1963) Chemagro Corporation Residue Experiment No. KC-215-63D: Report No. 12541. (Unpublished study including letter dated Jan 22, 1964 from G.G. Stetson to G.M. Downard, received Jan 28, 1964 under 11556-21; submitted by Bayvet, Shawnee Mission, Kans.; CDL:025715-A)

00005074 Anderson, C.A. (1959) Co-Ral Residues in Goat Tissues: Report No. 4008. (Unpublished study received Sep 11, 1959 under 1155621; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:011001-A)

00005080 Chemagro Corporation (1969) Synopsis of Analytical and Residue Information for Spray Application of Co-Ral to Dairy Cattle. Summary of studies 006078-B through 006078-G. (Unpublished study received Feb 20, 1970 under 11556-21; submitted by Bayvet, Shawnee Mission, Kans.; CDL:006078-A)

00005081 Chemagro Corporation (1969) Chemagro Corporation Residue Experiment No. KC-201-68D: Report No. 24216. (Unpublished study received Feb 20, 1970 under 11556-21; submitted by Bayvet, Shawnee Mission, Kans.; CDL:006078-G)

00005193 Chemagro Corporation (1957) Co-Ral (Formerly Bayer 21/199) for Experimental Use Only. (Unpublished study received Jul 1, 1957 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124847-A)

00005195 Anderson, C.A. (1958) A Photofluorometric Method for the Determination of Co-Ral (Bayer 21/199) Residues in Animal Tissues: Report No. 2216. Method dated Aug 13, 1958. (Unpublished study received Feb 27, 1976 under 11556-EX-3; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL: 224167-E)

BIBLIOGRAPHY

MRID **CITATION**

00005235 Chemagro Corporation (1964) Chemagro Corporation Residue Experiment No. KC-214-63D: Report No. 12786. (Unpublished study received Jun 8, 1964 under 11556-25; submitted by Bayvet, Shawnee Mission, Kans.; CDL:102326-B)

00005289 Adams, J. (1964) A Quantitative Method for the Determination of Residues of Co-Ral (0-(3-Chloro-4-methyl umbelliferone) 0,0 Diethyl phosphorothioate) and Chlorferron (3-Chloro-4-methyl-7hydroxycoumarin) in Animal Tissues and Milk: Report No. 13656. Method dated May 6, 1964. (Unpublished study received Aug 18, 1966 under 7F0612; submitted by Chemagro Corp., Kansas City, Mo.; CDL:090796-K)

00005293 Chemagro Corporation (1966) Chemagro Corporation Residue Experiment No. KC-3400-66D: Report No. 17971. (Unpublished study received Aug 18, 1966 under 7F0612; CDL:090796-Q)

00005295 Chemagro Corporation (1966) Chemagro Corporation Residue Experiment No. KC-3401-66H: Report No. 18522. (Unpublished study received Aug 18, 1966 under 7F0612; CDL:090796-S)

00005330 Chemagro Corporation (1963) Chemagro Corporation Residue Experiment No. KC-201-63D: Report No. 10923. (Unpublished study received on unknown date under PP0306; CDL:090321-D)

00005331 Chemagro Corporation (1961?) Synopsis of Analytical and Residue Information on Co-Ral: (Milk). Summary of studies 090321-F through 090321-H. (Unpublished study received Sep 4, 1961 under PP0306; CDL:090321-E)

00005333 Chemagro Corporation (1960) Residue Report: Report No. 5515. (Unpublished study including report nos. 5533 and 5534, received Sep 4, 1961 under PP0306; CDL:090321-H)

00005338 Chemagro Corporation (1966) Synopsis of Analytical and Residue Information for Dust Application to Cattle. Summary of studies 092586-B, 092586-D through 092586-E and 092586-G. (Unpublished study including supplement, received Mar 18, 1968 under 1F0306; CDL:092586-A)

00005339 Chemagro Corporation (1967) Chemagro Corporation Residue Experiment No. KC-201-67D: Report No. 20599. (Unpublished study including report nos. 20651, 20663 and 20677, received Mar 18, 1968 under 1F0306; CDL:092586-B)

00005341 Chemagro Corporation (1963) The Effect of Storage on CoRal Residues in Milk: Report No. 11212. (Unpublished study received on unknown date under 1F0306; CDL:092586-F)

BIBLIOGRAPHY

MRID **CITATION**

00005342 Adams, J.M. (1963) A Quantitative Method for the Determination of Residues of Co-Ral (O-(3-Chloro-4-methyl umbelliferone) O,O Diethyl phosphorothioate) and Chlorferron (3-Chloro-4-methyl-7 hydroxycoumarin) in Animal Tissues and Milk: Report No. 7165. Rev. (pp. 1-6 only; unpublished study received on unknown date under 1F0306; submitted by Chemagro Corp., Kansas City, Mo.; CDL:092586-G)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-96).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You are Receiving this Notice
Section II - Data Required by this Notice
Section III - Compliance with Requirements of this Notice
Section IV - Consequences of Failure to Comply with this Notice
Section V - Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI - Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share, Data Compensation Forms, and Confidential Statement of Formula

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions

of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Reqistrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Reqistrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first

page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to

generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full
description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other

registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are

necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been
submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on
the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see

Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you

believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form.

   ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

   iii. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such

existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

COUMAPHOS DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing coumaphos.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 0018. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this coumaphos Product Specific Data Call-In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for coumaphos are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on coumaphos are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible coumaphos products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Edward Setren at (703) 308-8166.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Edward Setren
Chemical Review Manager, Team 81
Product Reregistration Branch
Special Review and Reregistration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Coumaphos**

COUMAPHOS DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing coumaphos.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of coumaphos. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) a list of registrants receiving this DCI (Attachment 5), and (5) the Cost Share and Data Compensation Forms in replying to this coumaphos Generic Data Call In (Attachment 6). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for coumaphos are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional product chemistry data on coumaphos are needed. These data are needed to fully complete the reregistration of all eligible coumaphos products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dennis McNeilly at (703) 308-8066.

All responses to this Notice for the generic data requirements should be submitted to:

Dennis McNeilly, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: **Coumaphos**

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

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 crop
J Forestry
K Residential
L Indoor food
M Indoor non-food
N Indoor medical
O Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient

TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also

submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

EPA'S BATCHING OF COUMAPHOS PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data,

he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Twenty-five products were found which contain coumaphos as the active ingredient. The products have been placed into three batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 lists the products which have been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% coumaphos	Formulation Type
1	407-386	1.0	Solid
	606-105	1.0	Solid
	960-169	1.0	Solid
	960-184	1.0	Solid
	2393-378	1.0	Solid
	2393-385	1.0	Solid
	11556-4	1.0	Solid
	11556-14	1.0	Solid
	28293-122	1.0	Solid
	34704-267	1.0	Solid
	34704-306	1.0	Solid
	47000-47	1.0	Solid
	67517-21	1.0	Solid
	67517-22	1.0	Solid
2	11556-20	25.0	Solid
	11556-21	25.0	Solid
3	11556-23	11.6	Liquid
	34704-635	11.6	Liquid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. Registrants of these products are responsible for meeting the acute toxicity data requirements separately for each product.

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
11556-11	90.0	Solid
11556-25	4.0	Liquid
11556-40	3.0	Spray
11556-98	42.0	Liquid
11556-115	5.8	Liquid
28293-88	3.0	Spray
28293-91	5.0	Solid

LIST OF REGISTRANTS SENT THIS DATA CALL-IN (REMOVE THIS PAGE)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			

18. Signature of Approving Official	19. Title	20. Phone No. *(Include Area Code)*	21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

EPA	United States Environmental Protection Agency Washington, DC 20460 **CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA**	Form Approved OMB No. 2070-0106 2070-0057 Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX E - LIST OF RELATED DOCUMENTS

The following is a list of available documents for coumaphos that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Edward Setren at (703)-308-8166.

1. PR Notice 86-5.

2. PR Notice 91-2 (pertains to the Label Ingredient Statement).

3. A full copy of this RED document.

4. A copy of the fact sheet for coumaphos.

The following documents are part of the Administrative Record for coumaphos and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria