REREGISTRATION ELIGIBILITY DOCUMENT

ALUMINUM TRIS (O-ETHYLPHOSPHONATE)
(REFERRED TO AS FOSETYL-Al)

LIST A

DECEMBER 1990

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
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
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest Dose Tested
K+CWHR	Kernel plus Cob with Husk Removed
LC50	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 or feed, e.g., mg/l or ppm.
LD50	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.
LDT	Lowest Dose Tested
LEL	Lowest Effect Level
MP	Manufacturing Use Product
MPT	Maximum Permissible Intake

GLOSSARY OF TERMS AND ABBREVIATIONS CONT'D

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per Million
RfD	Reference Dose
RS	Registration Standard
TMRC	Theoretical Maximum Residue Contribution

EXECUTIVE SUMMARY

Fosetyl-Al is a fungicide registered in the United States for use on almonds, asparagus, avocados, caneberries, citrus, ginseng, pome fruits, pineapples, stone fruits and ornamental plants, lawns and turf. There are two registered products: 95% technical product and 80% wettable powder. Products which contain fosetyl-al as an active ingredient are eligible for reregistration for the uses mentioned above.

A registration standard entitled, "Guidance for the Reregistration of Pesticide Products containing aliette as the active ingredient" (pb 84-206564), was developed in 1983 in conjunction with the initial reregistration of the chemical. A draft revised registration standard for fosetyl-Al was issued for public comment in December 1986, and issued in final in February 1988. The registration standards summarized the available data supporting the registration of fosetyl-Al and required additional data to assure that the proper use of the pesticide poses no potential adverse effects to human health or the environment.

Recently, the Agency conducted a thorough review of the scientific database and all relevant information supporting the reregistration of fosetyl-Al, including the data submitted in response to the registration standards. The data base consists of toxicology, residue and product chemistry, environmental fate, ecological effects, and non-dietary exposure data (refer to appendix a). No further generic or product-specific data are required. The established tolerances are set at the appropriate levels and no new tolerances are required to cover the existing uses for the registered products.

The data are sufficient to allow the Agency to conduct a reasonable risk assessment for all registered uses of fosetyl-Al. The Agency has determined for all registered uses that fosetyl-Al can be used according to label directions without resulting in unreasonable adverse effects. Based on the data reviewed, the agency has determined that fosetyl-Al poses no unreasonable adverse effect to human health and the environment and declares that products containing fosetyl-Al as an active ingredient are eligible for reregistration and will be reregistered when appropriate labels are submitted.

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.

Section 4 (g) (2) (A) of FIFRA 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 of fosetyl-Al. The document consists of five sections. Section I is this introduction. Section II describes fosetyl-Al, its uses and regulatory history. Section III discusses the human health and environmental effects assessment based on the data available to the Agency. Section IV discusses the reregistration decision for fosetyl-Al and Section V discusses product reregistration. Additional details concerning the Agency's review of available data are available on request.[1]

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[1] EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from the OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA Washington, D.C. 20460.

II. ACTIVE INGREDIENTS COVERED BY THIS REREGISTRATION DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENT

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

Chemical Name: Aluminum tris (O-ethylphosphonate)
(Referred to hereafter as fosetyl-Al)

Common Name: None[2]

CAS Number: 39148-24-8

Office of Pesticide Programs
Chemical Code Number: 123301

Empirical Formula: Al(H6C2O3P)3

Trade Name: Aliette®

Pesticide Chemical Code: 123301

Case Number: 0646

Basic Manufacturer: Rhone-Poulenc

B. USE PROFILE

Type of Pesticide: Systemic fungicide

Pests Controlled: Oomyceteous fungi causing damping-off and rot of roots, stems and fruit.

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[2] For the purposes of this document, the name fosetyl-Al, is used rather than Aluminum tris (O-ethylphosphonate).

Registered Use Sites:

Terrestrial, Food

almonds (non-bearing)
asparagus
avocados (non-bearing)
caneberries
citrus (bearing and non-bearing)
ginseng
pome fruits (non-bearing)
pineapples
stone fruits (non-bearing)

Terrestrial, Non-Food

ornamental herbaceous plants
ornamental lawns and turf

Formulation Types Registered: Technical - 95 percent active ingredient

Formulation - 80 percent wettable powder

Methods of Application: dip treatment; pre-plant soil incorporation; foliar; drench

C. REGULATORY HISTORY

Fosetyl-Al was first registered by the Agency in 1983 for use on pineapples, ornamentals and turf. The uses of fosetyl-Al for foliar application to pineapple and to citrus were added in 1985 and 1986, respectively. A Registration Standard was developed in 1983 in conjunction with the initial registration of the chemical. A draft revised Registration Standard for fosetyl-al was issued for public comment in December 1986. No comments were received on this draft document. This draft document was issued in final in February 1988 and listed the following data as required for reregistration:

171-4	Storage Stability of Residues in Pineapples and Citrus
132-1	Foliar Dissipation
122-2	Aquatic Plant Growth
141-1	Honeybee Acute Contact LD_{50}

Product chemistry and acute toxicity data on the formulated end-use product were also required to be submitted.

Since 1988, six new uses have been registered: avocados, asparagus, pome fruits, stone fruits, almonds and caneberries.

III. AGENCY ASSESSMENT

The Agency has conducted a thorough review of the scientific data base for fosetyl-Al. Based on the evaluation of these data, the Agency has no reason to change the major findings made in the 1988 document "Guidance for the Reregistration of Pesticide Products Containing Fosetyl-Al." These findings are summarized below:

A. Product Chemistry Assessment

Fosetyl-Al is a white odorless powder that melts with decomposition at temperatures greater than 200° celsius. The solubility of fosetyl-al in water at 20° celsius is 120 grams per liter. The chemical is stable under normal storage conditions.

B. Human Health Assessment

1. Toxicology Data Base

All toxicology data requirements are satisfied. No further data were required in the 1988 Guidance Document and no additional data have been submitted. The results of the review of the toxicology data base are presented below:

a. Acute and Subchronic Toxicity

The LD_{50} from the acute oral rat study is 5.4 g/kg and the LD_{50} from an acute dermal rabbit study is >2 g/kg. The LC_{50} for a rat inhalation study is >1.73 mg/1. The acute oral rat and primary dermal irritation studies indicate category IV toxicity. A guinea pig dermal sensitization study shows fosetyl-Al is not a skin sensitizer. The primary eye irritation study in rabbits shows fosetyl-Al to be an eye irritant with Category I toxicity.

A 21-day dermal study in rabbits showed mild to moderate skin irritation and a No Effect Level (NOEL) of 1.50 g/kg/day. A 90-day feeding study in rats showed a NOEL of >5000 ppm; the Lowest Effect Level (LEL) was 25,000 ppm with extramedullary hematopoiesis in the spleen. A 90-day dog feeding study showed a NOEL of 10,000 ppm and a LEL at 50,000 ppm, at which the test animals had a lower serum potassium level than untreated animals.

b. Chronic Toxicity

Fosetyl-Al was fed to dogs for 2 years at doses up to 40,000 ppm. The NOEL was 10,000 ppm, equivalent to 250 mg/kg/day. The LEL was 20,000 ppm based on a slight degenerative effect on the testes. These testicular changes, as well as a few scattered clinical changes, were seen in the high dose dogs.

c. Oncogenicity

Rat

Oncogenic effects were noted in the rat chronic feeding/oncogenicity study. In this study, Charles River CD rats were dosed with fosetyl-Al at levels of 0, 2,000, 8,000, and 40,000/30,000 ppm (0, 100, 400, and 2,000/1,500 mg/kg bwt/day). The 40,000 ppm dose was reduced to 30,000 ppm after 2 weeks following observations of staining of the abdominal fur and red coloration of the urine at 40,000 ppm (2,000 mg/kg bwt/day).

The highest dose level of the chemical tested in the male Charles River CD-1 rats (2,000/1,500 mg/kg bwt/day) in this study appears to be adequate for assessing the carcinogenic potential based on the finding of urinary bladder hyperplasia at this dose. Similarly the dose level appeared to be adequate in the female Charles River CD-1 rats at the high-dose level of 2,000 mg/kg bwt/day during the first 2 weeks of the oncogenicity/chronic feeding study, before the dose level was reduced to 1,500 mg/kg bwt/day.

The study demonstrated a significant increase of urinary bladder tumors (adenomas and carcinomas combined) at the highest dose level tested (2,000/1,500 mg/kg) in male Charles River CD-1 rats. The tumors were mainly seen in surviving males at the time of terminal sacrifice. The original pathological diagnosis of these tumors was independently confirmed by another consulting pathologist, who also reported an elevated incidence of urinary bladder hyperplasia in high-dose male rats. No increase of urinary bladder tumors was observed in female rats.

Based on the diagnosis of the pathologist at the test laboratory where the study was performed, fosetyl-al appeared to produce a statistically significant elevated increase of adrenal pheochromocytomas (adenomas and carcinomas combined) at the middle (400 mg/kg) and high (2,000/1,500 mg/kg) dose levels in the male Charles River CD-1 rats. The elevated pheochromocytoma increase was primarily due to an increase in the adenomas. This diagnosis was not confirmed by two other pathologists who reevaluated the data. The consulting pathologists reread the adrenal gland slides and did not find statistically significant dose-related increases in the incidence of pheochromocytomas for the male rats. The Agency attributes the difference in pathological diagnoses to the fact that a high degree of variability exists in the interpretation of adrenal medullary neoplasia compared to adrenal medullary hyperplasia in identifying pheochromocytomas. None of the three pathologists reported a statistically significant increase in the combined incidence of the three types of adrenal medullary lesions (i.e., adenomas, carcinomas, and hyperplasia).

Based on the available information, the Agency has concluded that fosetyl-Al did not produce a compound-related increase in adrenal pheochromocytomas in the high-dose male rats. No adrenal gland tumors were produced in female rats.

An oncogenicity feeding study with monosodium phosphite, which is a metabolite of fosetyl-Al, was conducted in rats. There was no evidence of oncogenicity in this study.

Mouse

In a chronic oncogenicity study in mice, fosetyl-Al was fed at levels up to 20,000/30,000 ppm. Although this dose was extremely high and may have approached a level that affected nutrition, it produced no oncogenicity or other toxic changes.

Classification of Oncogenic Potential

The Agency has concluded that the available data provide limited evidence of the oncogenicity of fosetyl-Al in male rats and has classified the pesticide as a category C oncogen (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the Federal Register of September 24, 1986 (51 FR 33992). The Agency has determined that a quantitative human risk assessment using a low dose linear extrapolation model is not appropriate for the following reasons:

1. The oncogenic response observed with this chemical was confined solely to the high dose males at one site (urinary bladder) in rats.

2. The tumor response was primarily due to an increase in benign tumors.

3. The tumors were seen only in surviving animals at the time of terminal sacrifice.

4. The oncogenic effects were observed only at unusually high doses which exceed the commonly used limit dose of 1 g/kg/day recommended as an upper-limiting dose for bioassays.

5. The chemical was not oncogenic when administered in the diet to Charles River CD-1 mice at dose levels ranging from 2,500 to 30,000 ppm (357 to 4,286 mg/kg bwt/day).

6. Fosetyl-Al was not mutagenic in eight well conducted genotoxicity assays.

The Agency concludes that data do not demonstrate developmental or reproductive effects of concern.

d. Developmental Toxicity

Rat Teratology

A teratology study in rats showed a developmental NOEL of 1,000 mg/kg. At 4,000 mg/kg there was maternal toxicity, as evidenced by effects on animal weights, maternal deaths, increased resorptions, and delayed fetal ossification.

Rabbit Teratology

A rabbit teratology study showed no toxic effects at oral doses up to 500 mg/kg.

Rat Reproduction

A three generation rat reproduction study had a NOEL of 6,000 ppm. The LEL at 12,000 ppm showed effects on animal weights in some groups and urinary tract changes in some groups.

MUTAGENICITY

Eight mutagenicity tests performed with fosetyl-Al were negative. The tests included two Ames tests with S. typhimurium, two phage induction tests using E. coli, two micronucleus tests in Swiss mice and CD-1 mice, one DNA repair test using E. coli, and one saccharomyces cereviseae assay. Fosetyl-Al is not a mutagen.

e. METABOLISM

Rat metabolism studies showed that most of the radiolabel rapidly appeared in exhaled carbon dioxide. There was also some radio-label excreted in the urine as phosphite, along with a smaller amount as the unchanged parent compound. It appears that fosetyl-Al is essentially completely absorbed after ingestion and extensively hydrolyzed to carbon dioxide which is exhaled. The phosphite is excreted in the urine without further oxidation to phosphate.

2. DIETARY EXPOSURE

All residue chemistry data requirements have been satisfied.

a. Residue Data

Tolerances have been established in 40 CFR 180.415 for residues of fosetyl-Al in or on the following raw agricultural commodities:

Commodity	Tolerance(ppm)
Asparagus	0.1[3]
Caneberries	0.1
Citrus	0.5
Ginseng root, fresh	0.1[2]
Pineapple	0.1
Pineapple Fodder	0.1
Pineapple Forage	0.1

There are no Codex (international) tolerances for fosetyl-Al. The Agency has evaluated the residue data supporting the established tolerances. These data are summarized below:

Metabolism Data

The metabolism of fosetyl-Al is adequately understood. Adequate data on the nature of the residues in both plant and animals, including identification of major metabolites and degradates of fosetyl-Al are available. The major residues were fosetyl-Al, phosphorous acid, and ethanol. The tolerances are established for the parent only, that is, fosetyl-Al.

There is no reasonable expectation of residues occurring in milk and meat of livestock and poultry. A statement on the label prohibits the grazing of livestock in treated citrus groves and feeding forage from treated groves. Accordingly, tolerances in meat, animal by products, and milk are not necessary.

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[3] These tolerances are associated with regional registrations as defined in 40 CFR Section 180.1 (n). Fosetyl-Al is registered for use on asparagus only in California; and on ginseng in Wisconsin only.

Radio labeled studies on the uptake, translocation and metabolism of fosetyl-Al in plants show that the chemical proceeds through hydrolytic cleavage of the ethyl ester, with phosphorous acid and most likely ethanol as the major plant metabolites.

Analytical Methodology

There are two analytical methods acceptable for determining the levels of residues of fosetyl-Al in plants: a gas chromatography method for pineapples with an analytical sensitivity of 0.1 ppm and a phosphorous specific flame photometric gas chromatography method for citrus with an analytical sensitivity of 0.02 ppm.

The only additional residue data required in the 1988 Guidance Document were storage stability of residues in pineapples and citrus. These data are currently under development but are not essential to the reregistration decision on these commodities for the following reasons:

1. No detectable residues of fosetyl-Al have been observed in any of the residue trials performed on pineapples. Some of these trials reflected exaggerated application rates and Pre-Harvest Interval (PHI's) as short as 90 days.

2. Pineapples spiked with fosetyl-Al and stored at -18°C showed a 66 to 90% decrease of residues of this chemical within 1 to 2 months. It is the Agency's judgement that residues of fosetyl-Al would decrease at even faster rates at higher temperatures, especially during a 90 day PHI, thus making the possibility of observing any detectable residues on pineapples extremely remote.

Magnitude of the Residue

There are adequate residue studies to support the existing tolerances.

b. Tolerance Reassessment

The data submitted have been evaluated and adequately support the existing tolerances established on fosetyl-Al as listed in Section 2b of this document. The established tolerances are set at the appropriate levels and no new tolerances are required to cover the existing uses for the registered product.

c. Reference Dose and Dietary Risk Assessment

The following data were considered for establishing the Reference Dose (RfD) for fosetyl-Al:

Study	Species
Chronic Toxicity (2 year)	Dog
Chronic Toxicity/Oncogenicity	Rat
3-Generation Reproduction	Rat
Teratology	Rat
Teratology	Rabbit

Using a 100-fold safety factor to account for inter - and intra-species differences and the NOEL of 250 mg/kg bwt/day determined by the 2-year dog feeding study, the RfD is 3.0 mg/kg bwt/day (rounded to the nearest whole number). The effect observed in the chronic dog study was a slight degeneration of the testes. This study is acceptable along with all of the other studies considered in establishing the RfD. Therefore, the RfD is given a high confidence rating.

The Theoretical Maximum Residue Contribution (TMRC) from the established tolerances is 0.000274 mg/kg/bwt/day and utilizes less than 1.0 percent of the RfD based on the average American dietary intake. The dietary exposure of subgroups (e.g., children and infants) also did not exceed the RfD. Therefore, the dietary risk from fosetyl-Al is very low.

3. Non-Dietary Exposure

Fosetyl-Al is a systemic fungicide registered for use on several raw agricultural commodities and ornamentals. Methods of application include foliar application to pineapples and citrus and thus, fieldworker exposure can be expected. Fosetyl-Al is a severe eye irritant but does not produce dermal irritation. In addition, fosetyl-Al exhibits a low degree of oral, dermal, and inhalation toxicity. Reentry data (foliar dislodgeable residue dissipation) were required by the 1988 Fosetyl-Al Reregistration Guidance Document.

In support of reregistration of fosetyl-al, the registrant submitted a foliar dislodgeable residue dissipation study. The study was reviewed and found to be unacceptable to fulfill the guideline requirement. However, the Agency has reevaluated the reentry data requirements based on the toxicity data for fosetyl-Al. Reentry data are required to determine the correlation between foliar dislodgeable residue levels and dermal exposure to fieldworkers. Since eye irritation is the toxicological end point of concern for fosetyl-Al and dermal exposure is not a concern, reentry data are not required to support the reregistration of fosetyl-Al.

Label requirements for products containing fosetyl-Al are specified in Section IV C and V C.

C. ENVIRONMENTAL ASSESSMENT

All environmental fate and ecological effects data requirements have been satisfied. No further environmental fate data were required in the 1988 Guidance Document. Additional ecological effects data were required in the 1988 Guidance Document.

122-2 Aquatic Plant Growth

141-1 Honey Bee Acute Contact LD_{50}

These studies have been submitted, reviewed, and determined to be acceptable. The results are discussed below.

1. Environmental Fate Assessment

The potential for groundwater and/or surface water contamination by fosetyl-Al and its degradates is expected to be very low, in most cases, due to the rapid degradation of the compound in soil to non-toxic degradates under both aerobic and anaerobic conditions. Data have shown that fosetyl-Al is much more persistent on vegetation than in soil. Therefore, when applied foliarly to vegetation, may be available for wash off followed by dissolved runoff to surface water for a much longer period than might be predicted based upon its rapid degradation in soil. In addition, due to its high aqueous solubility, susceptibility to leaching, and stability to abiotic hydrolysis, fosetyl-Al may possibly leach to ground water (in porous areas with extremely shallow unconfined aquifers or outcroppings) in cases where an unexpected heavy rainfall closely succeeds application.

2. Ecological Effects Assessment

a. Ecological Effects Data

In the 1988 Guidance Document, the ecological effects data base was reviewed and determined to be essentially complete except for two guideline data requirements: honey bee acute contact LD_{50} and aquatic plant growth. These studies which are discussed below, have been submitted, reviewed and determined to be acceptable.

Non-target Insects

An acute contact toxicity test with honey bees was conducted, the LD_{50} for the honey bee is greater than 100 ug/bee, the highest concentration tested for technical fosetyl-Al (95% a.i.). Fosetyl-Al is practically non-toxic to honey bees.

Aquatic Plant Growth

Five aquatic plant growth studies were performed with technical fosetyl-Al (95% a.i.). The EC_{50} values for the following five species were determined to be:

SPECIES	EC_{50} VALUE
NAVICULA PELLICULOSA	8.93 MG/L
LEMNA GIBBA	56.13 MG/L
SKELETONEMA COSTATUM	0.84 MG/L
ANABAENA FLOS-AGUAE	7.24 MG/L
SELENASTRUM CAPRICORNUTUM	4.99 MG/L

b. Ecological Effects Risk Assessment

For the 1988 Guidance Document, all available data were reviewed and no risk to non-target species was identified from the registered uses of fosetyl-Al.

In the intervening time from 1988 to the present, six new uses for fosetyl-Al have been registered: avocados, asparagus, apples and pears, stone fruit, almonds and caneberries. No additional testing is required for the new registered uses. An assessment of the new uses is presented below:

1. A review of the caneberry use indicates no risk to non-target species.

2. Because of similar application rates and similar uses previously approved, the use on asparagus and avocados should not present a risk to non-target species.

3. A risk assessment on stone fruit (apple/pear) and almonds indicate that fosetyl-Al poses no risk to non-endangered species; but a concern is raised for endangered freshwater mussels resulting from a biological opinion about other pesticides used on apples and pears.

The estimated environmental concentration from run off into adjacent ponds is 122 ppb which is larger than 1/20 (95 ppb) of the oyster/embryo larvae EC_{50} of 1900 ppb. Therefore, the endangered species level of concern was exceeded for the apple/pear use.

The above consideration constitutes a "May Effect" finding for the endangered mussel. In accordance with the Memorandum of Understanding with Fish and Wildlife Service (FWS), the Agency has formally consulted the FWS regarding the reregistration of fosetyl-Al on pome fruits, as required by Section 7 of the Endangered Species Act. As part of this consultation, the Agency has provided the FWS with the data and analysis upon which the "May Effect" determination was based.

The FWS will decide whether the use of fosetyl-Al will pose jeopardy to the endangered mussels and, if so, what actions the Agency must take to avoid jeopardy. At this time, the FWS has not made a determination on this issue. If the FWS determines jeopardy, it also will indicate the geographic areas in which any label restrictions will apply. At that time, EPA's Endangered Species Protection Program will implement the appropriate actions needed to protect endangered species.

Except for the endangered mussel concern, the Agency believes that currently registered uses of fosetyl-Al will not adversely affect non-target species. Data required in the 1988 Guidance Document were received and indicated no new potential risk and the ecological effects data base is complete. No changes in labeling will be required with the exception of possible endangered species restrictions.

IV. REREGISTRATION DECISION FOR FOSETYL-Al

A. DETERMINATION OF ELIGIBILITY FOR REREGISTRATION

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 all the generic (i.e., active-ingredient specific) data required to support reregistration of products containing fosetyl-Al as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient and complete to support reregistration of products containing fosetyl-Al and support the existing tolerances established on fosetyl-Al. Appendix A identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of fosetyl-Al, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix A were sufficient to allow the Agency to conduct a reasonable risk assessment for all registered uses of fosetyl-Al and to determine for all such uses that fosetyl-Al can be used without resulting in unreasonable adverse effects on the environment. The Agency therefore finds that all products containing fosetyl-Al as an active ingredient are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

The Agency 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, and the data identified in Appendix A. Although the Agency has found that products containing fosetyl-Al are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support registration of products containing fosetyl-Al, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Additional Generic Data Requirements

The generic data base supporting the reregistration of products containing fosetyl-Al has been reviewed and determined to be complete. No further generic data are required to support reregistration.

C. Labeling Requirements for Manufacturing-Use Products Containing Fosetyl-Al

1. The labels and labeling of all products must comply with EPA's current regulations and requirements as outlined in the Product Reregistration Handbook.

2. Based on the reviews of the generic data, the following additional label statements are required:

   a. All manufacturing-use products must state that they are intended for formulation into end-use products for which the use pattern is supported for reregistration.

   b. In the directions for use, the following statement must appear:

      "Formulators using this product are responsible for obtaining EPA registration of their formulated products."

   c. In the directions for use, the following statement regarding acceptable use patterns must appear:

      "For formulation into end-use fungicide products intended only for (list acceptable sites)."

   d. If detailed instructions for formulating are not provided on the label, the following statement must appear:

      "Refer to attached Technical Bulletin for formulating and other information."

      NOTE: The technical bulletin must be submitted with the product label for Agency review.

   e. "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For

guidance contact your State Water Board or Regional Office of the EPA."

f. "Pesticide Handlers: During mixing, loading, or formulating of this product, wear long pants (or coveralls), long sleeved shirt, shoes, socks, goggles or face shield, and chemical/water resistant gloves."

V. PRODUCT REREGISTRATION

A. Determination of Eligibility

All products currently registered containing the active ingredient fosetyl-Al are eligible for reregistration. The Agency may require submission of additional data before establishing any new uses. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide by use after a determination of eligibility has been made. No such data is needed at this time.

The Agency has previously identified and required the submittal of all product-specific data required to support the reregistration of products containing fosetyl-Al as an active ingredient. The Agency has completed its review of the product-specific data and has determined that the data are sufficient to support the reregistration of the one currently registered product containing fosetyl-Al.

B. Product Specific Data Requirements

There are no additional product-specific data required.

C. Labeling Requirements for End-Use Products Containing Fosetyl-Al

1. The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration Handbook with respect to labels and labeling.

2. Based on the reviews of the generic data the following additional label statements are required.

   a. "Do not apply directly to water, swamps, bogs, marshes, and potholes. Do not

contaminate water when disposing of rinsate or equipment washwaters."

b. "Do not enter into treated areas for 24 hours after application. During early reentry into treated areas to perform hand labor tasks, wear long pants (or coveralls), long-sleeved shirt, shoes, socks; chemical/water resistent gloves; goggles or face shield."

3. End-use products labelled for use on citrus are to bear the following statement:

"Do not graze livestock in treated citrus groves. Do not feed forage from treated groves."

Labels of currently registered products must be amended to include this statement and must be submitted within 8 months of issuance of this document as described in the Product Reregistration Handbook.

GUIDE TO APPENDICES A AND B

Appendix A contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table are generally organized according to 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 out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. 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 crop
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

Any other designations will be defined in a footnote to the table.

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 Appendices for a complete citation of the study.

APPENDIX A

Generic Data Requirements for Reregistration of Fosetyl-Al and Data Citations Supporting Reregistration

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS

SUPPORTING REREGISTRATION

158.120 PRODUCT CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
61-1	Chemical Identity	All	00098326
61-2(a)	Begin. mat. & mnfg. proc	All	00098326
61-2(b)	Discussion of Impurities	All	00098326
62-1	Preliminary Analysis	All	00098326
62-2	Certification of limits	All	00098326
62-3	Analytical Method	All	00098326
63-2	Color	All	00098325
63-3	Physical State	All	00098325
63-4	Odor	All	00098325
63-5	Melting Point	All	00098325
63-7	Density	All	00098326
63-8	Solubility	All	00098325
63-10	Dissociation Constant	All	00098325

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS

SUPPORTING REREGISTRATION

158.120 PRODUCT CHEMISTRY CONTINUED

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
63-11	Oct/Water partition Coef.	All	00098325
63-12	pH	All	00098325
63-13	Storage stability	All	40901602

158.145 ECOLOGICAL EFFECTS

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
71-1(a)	Acute avian oral quail/duck	A,B,C	00098360
71-2(a)	Acute avian diet. quail	A,B,C	00098362
71-2(b)	Acute avian diet. duck	A,B,C	00098363
72-1(a)	Fish toxicity bluegill	A,B,C	00119526
72-1(c)	Fish toxicity rainbow trout	A,B,C	00128944
72-2(a)	Invertebrate toxicity	A,B,C	00128943
72-3(a)	Estu/mari tox. fish	A,B,C	00147360

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS

SUPPORTING REREGISTRATION

158.145 ECOLOGICAL EFFECTS

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
72-3(b)	Estu/mari tox. mollusk	A,B,C	00147359
72-3(c)	Estu/mari tox. shrimp	A,B,C	00098368

158.135 TOXICOLOGY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
81-1	Acute oral tox. rat	A,B,C	00098330
81-2	Acute dermal tox. rabbit/rat	A,B,C	00098331
81-3	Acute inhal. tox rat	A,B,C	00098332
82-1(a)	90-day feeding-rodent	A,B	00098336
82-1(b)	90-day feeding-nonrodent	A,B	00098337
82-2	21-day dermal-rabbit/rat	A,B,C	00098338
83-1(a)	Chronic tox-rodent	A,B	00098339, 00098353 00126757, 00128233

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS

SUPPORTING REREGISTRATION

158.135 TOXICOLOGY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
83-1(b)	Chronic tox - non-rodent	A,B	00098340
83-2(a)	Oncogenicity - rat	A,B	00098339, 00098352
83-2(b)	Oncogenicity-mouse	A,B	00098353
83-3(a)	Teratogenicity - rat	A,B	00098347
83-3(b)	Teratogenicity - rabbit	A,B	00114091
83-4	2-generation repro.-rat	A,B	00098348
84-2(a)	Gene mutation-ames	A,B,C	00098343, 00098345
84-2(b)	Struct. chrom. aberration	A,B,C	00098343
84-4	Other genotoxic effects	A,B,C	00098345
85-1	General metabolism	A,B	00098358

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS SUPPORTING REREGISTRATION

158.150 PLANT PROTECTION

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
122-2	Aquatic plant growth	A,B,C	41128601, 41128602 41128603, 41128604 41128605

158.155 NONTARGET INSECT TESTING - POLLINATORS

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
141-1	Honey bee acute contact	A,B,C	40676301

158.130 ENVIRONMENTAL FATE

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
161-1	Hydrolysis	A,B,C	00098370
161-2	Photodegradation-water	A,B,C	00098371
161-3	Photodegradation-soil	A,B,C	00098371
161-4	Photodegradation-air	A,B,C	00098371
162-1	Aerobic soil metabolism	A,B,C	00106018, 00098372
162-3	Anaerobic aquatic metab.	A,B,C	00147361

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS SUPPORTING REREGISTRATION

158.130 ENVIRONMENTAL FATE

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
163-1	Leach/adsorp/desorption	A,B,C	00098375, 00106019
132-1	Foliar dissipation	A,B,C	41049901

158.125 RESIDUE CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
171-2	Chemical identity	A,B	00098326
171-3	Directions for use	A,B	00139527, 00148619
171-4(a)	Nature of residue - plants	A,B	00103249, 00103250, 00148290
171-4(b)	Nature of residue - livestock	A,B	41133001
171-4(c)	Res. analyt. method - plant	A,B	00148619, 41034500, 00147569
			41034501, 40285601
171-4(k)	Cropfield trials		
	Pineapples	A,B	00139527, 00148619, 00103250
		A,B	00165341
	Citrus	A,B	00148290, 41001701

APPENDIX A

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF

FOSETYL-AL AND DATA CITATIONS

SUPPORTING REREGISTRATION

158.125 RESIDUE CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
171-4(k)	Cropfield trials		
	Asparagus	A,B	40654300, 40654301
	Ginseng	A,B	40285600, 40285601, 40600800
			40600801, 40833100, 40833101
	Caneberries	A,B	40747701

APPENDIX B

Product Specific Data Requirements for Products Containing Fosetyl-Al and Data Citations Supporting Reregistration of Products

APPENDIX B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR PRODUCTS CONTAINING FOSETYL-AL AND DATA CITATIONS SUPPORTING REREGISTRATION OF MANUFACTURING AND END-USE PRODUCTS

DATA FOR MANUFACTURING-USE PRODUCTS

158.120 PRODUCT CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
61-1	Chemical Identity	All	00098325
61-2(a)	Begin. mat. & mnfg. proc	All	00098325
61-2(b)	Discussion of Impurities	All	00098325
62-1	Preliminary Analysis	All	00098325
62-2	Certification of limits	All	00098325
62-3	Analytical Method	All	00098327
63-2	Color	All	00098325
63-3	Physical State	All	00098325
63-4	Odor	All	00098325
63-7	Density	All	00098325
63-12	pH	All	00098325
63-13	Storage stability	All	40901602

APPENDIX B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR

PRODUCTS CONTAINING FOSETYL-AL AND

DATA CITATIONS SUPPORTING REREGISTRATION OF MANUFACTURING

AND END-USE PRODUCTS

DATA FOR MANUFACTURING-USE PRODUCTS (CONTINUED)

158.120 PRODUCT CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
63-14	Oxidizing/Reducing Action	All	00098325
63-15	Flammability	All	00098328
63-16	Explodability	All	00098328
63-17	Storage stability	All	00098325
63-20	Corrosion characteristics	All	00098325

158.135 TOXICOLOGY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
81-1	Acute oral tox. rat	A,B,C	00098330
81-2	Acute dermal tox. rabbit/rat	A,B,C	00098331
81-3	Acute inhal. tox rat	A,B,C	00098332
81-4	Primary eye irration-rabbit	A,B,C	00098333

APPENDIX B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR

PRODUCTS CONTAINING FOSETYL-AL AND

DATA CITATIONS SUPPORTING REREGISTRATION OF MANUFACTURING

AND END-USE PRODUCTS

158.135 TOXICOLOGY (CONTINUED)

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
81-5	Primary dermal irritation	A,B,C	00098334
81-6	Dermal sensitization	A,B,C	00098335

APPENDIX B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR

PRODUCTS CONTAINING FOSETYL-AL AND

DATA CITATIONS SUPPORTING REREGISTRATION OF MANUFACTURING

AND END-USE PRODUCTS

DATA FOR END-USE PRODUCTS

158.120 PRODUCT CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
61-1	Chemical Identity	All	40901601
61-2(a)	Begin. mat. & mnfg. proc	All	40901601
61-2(b)	Discussion of Impurities	All	40901601
62-1	Preliminary Analysis	All	41036301
62-2	Certification of limits	All	41036301
62-3	Analytical Method	All	41036301
63-2	Color	All	00098325
63-3	Physical State	All	00098325
63-4	Odor	All	00098325

APPENDIX B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR

PRODUCTS CONTAINING FOSETYL-AL AND

DATA CITATIONS SUPPORTING REREGISTRATION OF MANUFACTURING

AND END-USE PRODUCTS

DATA FOR END-USE PRODUCTS (CONTINUED)

158.120 PRODUCT CHEMISTRY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
63-7	Density	All	00098325
63-12	pH	All	00098325
63-14	Oxidizing/Reducing Action	All	00098325
63-15	Flammability	All	N/A
63-16	Explodability	All	N/A
63-17	Storage stability	All	40901602
63-20	Corrosion characteristics	All	41286401
63-21	Dielectric breakdown volt	All	N/A

APPENDIX B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR

PRODUCTS CONTAINING FOSETYL-AL AND

DATA CITATIONS SUPPORTING REREGISTRATION OF MANUFACTURING

AND END-USE PRODUCTS

DATA FOR END-USE PRODUCTS (CONTINUED)

158.135 TOXICOLOGY

GUIDELINE	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
81-1	Acute oral tox. rat	A,B,C	00122781
81-2	Acute dermal tox. rabbit/rat	A,B,C	00122782
81-3	Acute inhal. tox rat	A,B,C	00122783
81-4	Primary eye irration-rabbit	A,B,C	40131101, 40625101
81-5	Primary dermal irritation	A,B,C	00122785
81-6	Dermal sensitization	A,B,C	40676401

APPENDIX C

BIBLIOGRAPHY

GUIDE TO APPENDIX C

1. CONTENT 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, will be 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 attempted also 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 at any time 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 identifier 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 standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, 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 author. As a last resort, the Agency has shown the first submitter as author.

b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence 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 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, following the phrase "submitted by." 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," standing 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. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

00098325 Rhone-Poulenc Chemical Company (1981) Product Chemistry: [Fosetyl- al!. Includes method LS 74.783 dated Jul 7, 1980, method dated May 7, 1981 and undated method RE-18-81. (Compilation; unpublished study received Apr 5, 1982 under 359-705; CDL:247159-A)

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00098330 Pasquet, J.; Mazuret, A.; Maratrat, ?; et al. (1977) LS 74-783 (Aluminium Ethyl Phosphite; 32 545 R.P., Aluminium Salt): Acute Toxicity in the Rat and Rabbit: R.P./R.D./C.N.G. No. 19 143-E. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-B)

00098331 Pasquet, J.; Mazuret, A.; Kalifat, R.; et al. (1981) Fosetyl-al (32 545 R.P., Aluminium Salt): Acute Percutaneous Toxicity in the Rabbit: Reference C.R. Vitry/C.N.G. No. 21 162-E. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Industries, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-C)

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00098335 Elliott, P.H.; Seaber, J.A. (1979) Screening Test for Delayed Contact Hypersensitivity with Efosite-al (LS 74-783) in the Albino Guinea Pig: 79443D/RNP/168. (Unpublished study received Apr 5, 1982 under 359-705; prepared by Huntingdon Research Centre, England, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-G)

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

DEC 31 1990

CERTIFIED MAIL

SANDOZ CROP PROTECTION CORP.
1300 EAST TOUHY AVENUE
DES PLAINES, IL 60018

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Registrant:

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient Heliothis zea NPV. The RED is the Environmental Protection Agency's evaluation of the Heliothis zea NPV data base and presents the Agency's conclusions on which uses may be maintained and under what conditions and requirements. Also enclosed is the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

Generic data requirements usually will have been fulfilled prior to making a reregistration eligibility decision. However, there may be some instances where additional generic data of a confirmatory nature are required. If generic data requirements remain to be fulfilled, all registrants will have to complete the appropriate Data Call-In Response Form and Requirements Status and Registrant's Response Form. These forms will also be appendices to the RED.

The RED also identifies any specific labeling requirements such as restricted use classification, groundwater hazard statements, endangered species precautions, etc., necessary for reregistration based on the risks associated with the active ingredient. In addition, in order to be reregistered all product labeling must be in compliance with format and content labeling as described in 40 CFR 156.10 and all labeling changes imposed by Pesticide Regulatory (PR) Notices.

The Pesticide Reregistration Handbook contains detailed instructions for compliance with the RED and should be read thoroughly.

Questions on product specific data requirements and labeling (both End-Use Products and Manufacturing Use Products) should be directed to the Registration Division Product Manager for Heliothis zea NPV. Questions on generic data requirements and labeling should be directed to the Review Manager in the Special Review and Reregistration Division. If you do not know the name of the RD or SRRD contact, please call June Layton at 703-308-8080.

Sincerely yours,

Douglas D. Campt
Director
Office of Pesticide Programs

Enclosures

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

DEC 31 1990

CERTIFIED MAIL

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

RHONE-POULENC AG COMPANY
P.O. BOX 12014
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK
NORTH CAROLINA, 27709

Dear Registrant:

Enclosed is a **Reregistration Eligibility Document (RED)** for the pesticide active ingredient fosetyl-Al. The RED is the Environmental Protection Agency's evaluation of the fosetyl-Al data base and presents the Agency's conclusions on which uses may be maintained and under what conditions and requirements. Also enclosed is the **Pesticide Reregistration Handbook** which provides instructions to registrants on how to respond to any labeling and data requirements specified in the RED and how to reregister products.

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Sincerely yours,

Douglas D. Campt
Director
Office of Pesticide Programs

Enclosures