United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-024
September 1995

Reregistration Eligibility Decision (RED)

Asulam

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 **asulam** which includes the active ingredients **methyl sulfanilylcarbamate and the sodium salt of methyl sulfanilylcarbamate**. 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 the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

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, Jeffrey Billingslea at (703) 308-8004. Address any questions on required generic data to the Special Review and Reregistration Division representative, Karen Jones at (703) 308-8047.

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

ASULAM

LIST A

CASE 0265

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

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ASULAM REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

James Saulmon	Biological Analysis Branch
Harry Gaede	Economic Analysis Branch
Gabe Patrick	Label Use Information System Staff

Environmental Fate and Effects Division

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Harry Craven	Ecological Effects Branch
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Health Effects Division

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Steve Funk	Chemistry Branch II - Reregistration Support
Jeffrey Evans	Occupational and Residential Exposure Branch
Elizabeth Doyle	Dietary Risk and Evaluation Section

Registration Division

Eugene Wilson	Fungicide-Herbicide Branch
Ian Blackwell	Registration Support Branch

Special Review and Reregistration Division

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Linda Propst	Reregistration Branch
Carol Stangel	Policy, Planning and Operations Branch

Office of Compliance

Rick Colbert	Agriculture and Ecosystems Division

Office of General Counsel

Jon Fleuchaus	Pesticides and Toxic Substances Division

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
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
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
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.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Reregistration Decision

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide asulam (methyl sulfanilylcarbamate) and sodium salt of asulam (sodium salt of methyl sulfanilylcarbamate). The risk assessments and data requirements in this document that refer to asulam also include the sodium salt of asulam.

Based on the reviews of the generic data for the active ingredients asulam and its sodium salt, the Agency has reviewed information on the health effects of asulam and its sodium salt and on its potential for causing adverse effects in fish and wildlife and the environment. Based on this information, the Agency concludes that products containing asulam for the registered uses on Christmas tree plantations, ornamentals, turf, and non-cropland will not cause unreasonable risk to humans or the environment, and are eligible for reregistration. However, at this time, the Agency is unable to make a reregistration eligibility decision for the use of asulam on **sugarcane.**

Residue data submitted for reregistration showed that sugarcane concentrates in the processed feed commodity, blackstrap molasses. Under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Agency may be barred from establishing a feed additive regulation (tolerance) for blackstrap molasses because asulam may be found to be an animal carcinogen within the meaning of the Delaney clause. The Agency has committed to revoking the underlying raw agricultural commodity tolerance where food/feed additive tolerances have been established or need to be established but cannot because of Delaney. As part of a settlement agreement in a recent lawsuit, the Agency agreed to complete these revocations by the year 2000. During the 5 years before final revocation, the Agency believes it is important to amend the existing raw agricultural commodity tolerance on sugarcane to reflect new residue data. The Agency will also establish new meat, milk, and meat by-product tolerances. Current residue data suggest the existing tolerance should be raised to 15 ppm from 0.1 ppm. However, the registrant is submitting further additional data reflecting longer PHI's and more accurate timing of applications which will likely result in a tolerance level lower than the 15 ppm. After reviewing these data, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk, and meat by-product tolerances. These actions will prevent possible overtolerance situations and should reduce any public confusion regarding dietary risks associated with a crop or commodity seizure.

In addition, the Agency will also review blackstrap molasses as part of its new policy regarding implementation of Delaney that was recently published in the Federal Register as a response to the National Food Processors Association petition (June 14, 1995; 60 FR 31300). The Agency will determine if blackstrap molasses is "ready-to-eat" as an animal feed. If dilution with other feed items is necessary before animal consumption, and subsequent

dilution lowers the level of asulam in the diluted feed mixture to the level of the raw agricultural commodity tolerance, then a processed feed tolerance will not be necessary. Then the new sugarcane tolerance and new meat, milk and meat by-product tolerances will not be revoked.

Asulam exceeds the levels of concern (LOCs) for endangered and non-endangered terrestrial and semi-aquatic plants for all uses. For non-cropland uses, asulam exceeds LOCs for endangered and non-endangered aquatic plants. In addition, asulam exceeds the level of concern for ground water and the Agency also has some moderate concerns regarding surface water. The Agency is requiring additional environmental fate and ecological effects data to confirm the environmental and ecological risk assessment for all uses of asulam.

Several risk mitigation measures are being required for asulam. These measures include the following:

- prohibiting the aerial uses of asulam for non-cropland and Christmas trees use sites
- clarifying the non-cropland use to limit 1 gallon/A rate, 1 application/season
- clarifying the Christmas tree uses to limit 1 application/season
- clarifying the turf use to limit use to state sod farms only and 1 application/season

These risk mitigation measures would reduce the amount of asulam entering the environment. Based on asulam's potential to contaminate surface water and to leach to ground water, the Agency is requiring a ground water label advisory and a surface water advisory for all asulam product registrations. Also, long term monitoring is necessary in and near areas where asulam is used. In addition, the registrant is required to clarify the environmental fate assessment methodology and the uncertainty associated with the extraction technique and recovery of asulam from the laboratory versus the field studies.

Background Information

Asulam (methyl sulfanilylcarbamate) is a selective postemergent systemic carbamate herbicide registered for the control of a variety of annual grasses and broadleaf weeds on sugarcane, Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass) and non-cropland uses (boundary fences, fencerows, hedgerows, lumberyards, storage areas and industrial plant sites, and warehouse lots). Sugarcane is the major use site for asulam. The registered modes of application are aerial or ground spray, broadcast, band, and spot treatment. The only end-use formulation of asulam is the sodium salt of asulam (sodium salt of methyl sulfanilylcarbamate) which is formulated as soluble concentrate/liquid (36.2% a.i.) There are currently 3 end-use products and 1 technical product registered for asulam.

Asulam was initially registered as a pesticide in 1975. Technical asulam is currently being produced in England by Rhone-Poulenc Inc. A Registration Standard for Asulam was

issued in December 1987 (NTIS# PB88-168588). The Registration Standard summarized available data supporting the registrations of products containing asulam. The Registration Standard also required the submission of product chemistry, residue chemistry, toxicology, ecological effects and environmental fate studies.

In 1989, Rhone-Poulenc voluntarily deleted the ditchbank use of asulam; therefore, data for the ditchbank use required in the 1987 Registration Standard to support an aquatic nonfood industrial use pattern are no longer required. In 1991, a Data Call-In (DCI) was issued for asulam requiring the submission of neurotoxicity, plant protection, animal feeding, dermal mixer/loader exposure and inhalation mixer/loader exposure studies. This RED reflects a reassessment of all data that were submitted in response to the Registration Standard and the subsequent DCI.

Supporting Rationales for Reregistration Decision

• Health Effects

Asulam is classified as Category IV for acute oral toxicity, acute inhalation toxicity and primary dermal irritation; Category III for acute dermal toxicity and primary eye irritation. Asulam is also a nonsensitizer. The Agency classified asulam as a Group C, possible human carcinogen, based on thyroid and adrenal tumors in the rat study. The Agency has decided not to quantify the carcinogenic risk by low dose linear extrapolation.

The Reference Dose (RfD) is 0.36 mg/kg/day based on a chronic dietary feeding study in rats. The No Observed Effect Level (NOEL) in this study was 36 mg/kg/day, based on thyroid follicular hyperplasia at 180 and 953 mg/kg/day. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability. The chronic dietary exposure to the general population is expected to be 3.85% of the RfD. Of the standard subgroups analyzed by the Dietary Risk Evaluation System (DRES), the exposures for the two highest exposed subgroups, children (1-6 years old) and non-nursing infants (<1 year old), are 3.48×10^{-2} and 2.64×10^{-2} mg/kg body weight/day, respectively. These exposure values represent 9.7% and 7.3% of the RfD, respectively. Therefore, the Agency does not have concern for chronic dietary exposure to asulam since the RfD is not exceeded for either the general population or any subgroup.

The Agency does not have concerns for developmental or reproductive toxicity associated with oral exposure to asulam. There is no acute dietary toxicological endpoint of concern (the NOEL in the developmental toxicity study in rats is 1000 mg/kg/day). There is no toxicological endpoint of concern for short term or intermediate term occupational or residential exposure (the NOEL in the 21-day dermal toxicity is 1000 mg/kg/day). Therefore, neither an acute dietary risk assessment nor a short term or intermediate worker exposure or risk assessment was performed.

The Health Effects Division (HED) Metabolism Committee determined that although the metabolites hydroquinone/quinone are of toxicological concern, these compounds are naturally occurring plant constituents and the levels of hydroquinone/quinone present in the treated sugarcane, cane sugar, and molasses may not represent a significantly different risk than naturally occurring levels of hydroquinone/quinone. The residues for regulation and risk assessment are the parent compound, asulam, and all metabolites containing the sulfanilamide moiety.

The qualitative nature of asulam residue in plants, ruminants, and poultry is adequately understood. The Agency is requiring a new plant metabolism study on sugarcane to confirm the levels of hydroquinone and quinone contributed to the existing background levels resulting from the use of asulam.

Previously submitted crop field trial data indicate that residues in excess of tolerances (15 ppm) occur in/on sugarcane following treatment at the maximum registered rates. The registrant has committed to supporting a lower tolerance for sugarcane based upon lower application rates and longer PHI's which would change the tolerance to a level lower than 15 ppm but greater than 0.1 ppm. Residue data submitted for reregistration showed that sugarcane concentrates in the processed feed commodity, blackstrap molasses. A feed additive regulation for residues of asulam in blackstrap molasses is needed. However, under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), the Agency may be barred from establishing a feed additive regulation (tolerance) for blackstrap molasses because asulam may be found to be an animal carcinogen within the meaning of the Delaney clause. The Agency has committed to revoking the underlying raw agricultural commodity tolerance where food/feed additive tolerances have been established or need to be established but cannot because of Delaney. The Agency also is establishing new meat, milk, and meat by-product tolerances.

A confined rotational crop study utilizing radiolabeled asulam is required (GLN 165-1). The study is essential to determine the nature of the residue in secondary crops and to determine total residue levels at various plantback intervals. The presence/absence of quinone and hydroquinone in the radiolabeled residue must be established.

- **Occupational and Residential Exposure**

There is the potential for handler (mixer/loader/applicator, etc.) exposure and post-application exposure for the usual use-patterns associated with asulam; however, there are no toxicological endpoints of concern for the short to intermediate term occupational exposure. There are no residential uses for asulam; therefore, no exposure or risk is expected from asulam to homeowners.

The Agency is requiring a restricted entry interval (REI) of 12 hours for uses within the scope of the WPS. This 12 hour REI is the minimum acceptable REI for asulam. There

are no special toxicological concerns about asulam that warrant the establishment of active-ingredient-based minimum personal protective equipment (PPE) requirements.

● Environmental Fate

The environmental fate assessment is considered preliminary because of contradictory data. Although there is a lack of acceptable terrestrial field dissipation data, the Agency has concerns about the integrity of data for key laboratory studies. Based on supplemental data, it appears that asulam is highly mobile and has a strong potential to leach into ground water or move offsite into surface water. Also, based on available data (including those from unreliable studies), asulam has the following characteristics: 1) highly to very highly soluble, 2) stable in water without light, 3) unstable in water and on soil under light; however, small amounts of asulam were detected in surface water, 4) relatively unstable in soil under aerobic conditions, 5) very stable in soil and sediment under anaerobic conditions, 6) very mobile in soil, 7) not volatile, and 8) does not accumulate in fish.

The Agency is requiring additional storage stability data (aerobic soil metabolism and anaerobic soil/aquatic metabolism) to validate the results of the laboratory studies and to assess the need for the field dissipation study. In addition, a groundwater label advisory and a surfacewater label advisory are required. Due to concerns about the off-target damage by the aerial application of asulam, spray drift data (droplet size spectrum and drift field evaluation) and a label advisory are also required.

● Ecological Effects

Technical asulam is practically nontoxic to freshwater fish and slightly toxic to freshwater invertebrates. Also, asulam is practically nontoxic to estuarine/marine species, honeybees, and small mammals. Chronic effects to avian species and aquatic invertebrate cannot be fully assessed due to lack of adequate data. However, based on the overall low risk asulam poses to aquatic and avian species, the Agency does not expect that asulam will pose a high chronic risk to aquatic invertebrates or avian species. The Agency is requiring a confirmatory aquatic invertebrate life cycle study. The Agency is not requiring avian reproduction studies due to the extremely short photolytic half-life (approximately 2 hours) and in acute studies, the practically non-toxic nature of asulam to birds and mammals.

Levels of concern from all uses of asulam have been exceeded for endangered and non-endangered terrestrial and semi-aquatic plants. For non-cropland uses, asulam exceeds levels of concern for endangered and non-endangered aquatic plants. Risk to nontarget plants cannot be assessed due to the lack of adequate data. High risk to nontarget plants is likely, based on the herbicidal properties of asulam. The Agency is requiring additional phytotoxicity data to complete the nontarget plants risk assessment for asulam.

In summary, based on the information currently available to the Agency, all uses of asulam are eligible for reregistration, with the exception of **sugarcane**. Furthermore, the Agency is requiring that additional confirmatory data be submitted to fulfill the generic data requirements for reregistration of asulam.

Acute Aquatic Invertebrate Toxicity - *Daphnia magna*
Aerobic Soil Metabolism
Anaerobic Soil and Aquatic Metabolism
Droplet Size Spectrum
Drift Field Evaluation

Directions for Use - Label amendment (lower application rate and/or longer PHI)
Plant Metabolism Study
Magnitude of Residue - Sugarcane
Confined Rotational Crop

After reviewing additional field trial data for sugarcane, the Agency will establish a new sugarcane tolerance and require the registrant to petition for the new meat, milk, and meat by-product tolerances.

Certain data are not part of the reregistration target database for asulam, but are also required:

Seedling emergence - soybeans and radish
Vegetative vigor - cucumber and onion

Before reregistering the products containing asulam, 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 for all products containing asulam. The product specific data include product chemistry for each registration and acute toxicity testing. After reviewing all these data and any revised labels and finding them acceptable in accordance with section 3(c)(5) of FIFRA, the Agency will reregister a product. However, those products which bear uses of this or any other active ingredients which have not been determined to be eligible for reregistration will be reregistered only when such uses and 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 asulam. The document consists of six sections. Section I is the introduction. Section II describes asulam, 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 asulam. Section V discusses the reregistration requirements for asulam. 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 ingredients are covered by this Reregistration Eligibility Decision:

- **Common Name:** Asulam
- **Chemical Name:** Methyl sulfanilylcarbamate
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 3337-71-1
- **OPP Chemical Code:** 106901
- **Empirical Formula:** $C_8H_{10}N_2O_4S$
- **Trade and Other Names:** Asulox®
- **Basic Manufacturer:** Rhone Poulenc

- **Common Name:** Sodium salt of asulam
- **Chemical Name:** Sodium salt of methyl sulfanilylcarbamate
- **Chemical Family:** Carbamate
- **CAS Registry Number:** 2302-17-2
- **OPP Chemical Code:** 106902
- **Empirical Formula:** $C_8H_9N_2NaO_4S$
- **Trade and Other Names:** Asulox®
- **Basic Manufacturer:** Rhone Poulenc

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. Technical asulam is a formulating use only product. A detailed table of these uses of asulam and its sodium salt is in Appendix A.

For **asulam and its sodium salt**:

Type of Pesticide: Herbicide

Use Sites: Terrestrial Food + Feed Crop
Sugarcane

Terrestrial NonFood Crop
Christmas tree plantations; industrial areas (outdoor); nonagricultural uncultivated areas/soils; rights-of-

way/fencerows/ hedgrerows; ornamental and/or shade trees; ornamental lawns and turf; ornamental woody shrubs and vines

Target Pests: fern: western brackenfern; broadleaves: marestail, horseweed; grasses: alexandergrass, barnyardgrass, broadleaf panicum, bullgrass, crabgrass, foxtail, goosegrass, itchgrass, johnsongrass, paragrass, sandbur

Formulation Types Registered:
Single active ingredient (asulam)
86.4% a.i. technical (manufacturing-use product)

Single active ingredient (sodium salt of asulam)
36.2% soluble concentrate/liquid

Method and Rates of Application:

Sodium salt of asulam (Soluble concentrate/liquid)

Apply to sugarcane as broadcast, band, or spot treatment with ground equipment or broadcast by air at 3.34 lb active ingredient (AI)/A. Apply to Christmas trees as a delayed dormant spray with air or ground equipment at 3.34 lb (AI)/A. Apply to ornamental and/or shade trees or ornamental woody shrubs and vines as a postemergence ground broadcast at 3.34 lb (AI)/A. Apply to ornamental lawns and turf as a postemergence spray with ground equipment at 2.088 lb (AI)/A. Or, apply to industrial areas (outdoor), nonagricultural rights-of-way/fencerows, or nonagricultural uncultivated areas when needed as spray with ground equipment at 3.34 lb (AI)/A or as spot treatment at 6.68 lb (AI)/A.

Use Practice Limitations:

Asulam
Do not discharge into lakes, streams, ponds, or public waters unless in accordance with an NPDES permit.

Sodium salt of asulam (Soluble concentrate/liquid)
Do not apply through any type of irrigation system. Do not feed treated foliage to livestock or graze treated areas. Do not treat within 90 days of harvest.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of asulam. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

The table below summarizes the pesticide's use.

Estimates of Typical Annual Usage of Asulam As of 5/95

State	Crop	Acres Treated	Percent Crop Treated	Lbs A.I. Applied	Rate (lbs ai per year per acre)
Florida	Sod	14,986	30	29,971	2.00
Florida	Sugarcane	265,800	60	576,786	2.17
Louisiana	Sugarcane	52,500	14	113,925	2.17
Texas	Sugarcane	3,930	10	5,895	1.50
Total		337,216	---	726,577	---

Source: EPA information and National Ctr. Data

D. Data Requirements

Data required in the 1987 Registration Standard for Asulam include studies on product chemistry, residue chemistry, toxicology, ecological effects and environmental fate. 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.

E. Regulatory History

Asulam was first registered under the Federal Insecticide, Fungicide and Rodenticide Act on October 24, l975. The technical product contained 96.0% asulam, methyl sulfanilyl carbamate. The product label was revised to reflect only 86.4% asulam on July 14, l982 which resulted from extracting almost 10% of the water in the technical product. This technical product is presently registered and used for formulation of two end-use products: Asulox Herbicide (EPA Registration No. 264-447) and Asulam Liquid Herbicide (EPA Registration No. 64764-3), both products bear ingredient claims that are identical, and reflect 36.2% sodium salt of asulam.

The Agency issued a Registration Standard under the title of "EPA Guidance for the Reregistration of Pesticide Products Containing Asulam as the Active Ingredient" dated December, l987. In that document the Agency listed the required data for continuing the registration of registered pesticide products that contained or were derived from asulam. The time lines for submitting the required data to continue the registration of these products were stated in that document. Both product specific and product generic data were identified if required and the date lines for submitting the data were listed.

In the Asulam Registration Standard (RS) labeling amendments for bringing all asulam products into compliance with existing labeling policy of the Agency at the time of issuance of the RS were required.

On February 17, l988, the Agency's Health Effects Division Carcinogenicity Peer Review Committee (HED-CPRC) classified asulam as a Group C, possible human carcinogen based on adequate studies in two animal species. A second mouse study was submitted in l993. In October 1994, the Committee again reviewed the data, including this mouse study and concluded that the new study would not impact on the classification of asulam as a "Group C", possible human carcinogen.

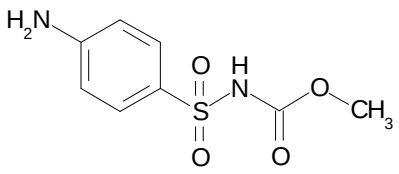
The end uses of asulam products are for postemergence grass control in sugarcane, Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass) and noncropland uses (boundary fences, fencerows, hedgerows, lumberyards, storage areas and industrial plant sites, and warehouse lots).

III. SCIENCE ASSESSMENT

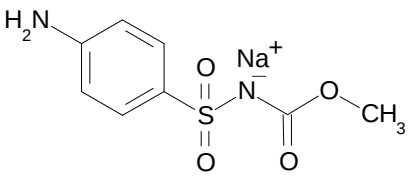
A. Physical Chemistry Assessment

Description of Chemical

Asulam (methyl sulfanilylcarbamate) is a herbicide used for weed control on sugarcane, Christmas tree plantations, ornamentals, turf, and noncropland uses. Asulam is formulated into and applied as the asulam sodium salt.



Asulam



Asulam, sodium salt

Empirical Formula:	$C_8H_{10}N_2O_4S$ (asulam) $C_8H_9N_2NaO_4S$ (asulam sodium salt)
Molecular Weight:	230.2 (asulam) 252.2 (asulam sodium salt)
CAS Registry No.:	3337-71-1 (asulam) 2302-17-2 (asulam sodium salt)
PC Code:	106901 (asulam) 106902 (asulam sodium salt)

Identification of Active Ingredient

Asulam is a colorless, crystalline solid with a melting point of 143-145°C. Asulam sodium salt is a buff-colored powder with a melting point of 212-215°C. Asulam is soluble at approximately 0.5% in water, and moderately soluble in chlorinated hydrocarbons, petroleum oils, and hydroxylic solvents. Asulam sodium salt is soluble at >100 g/100 mL in water at pHs 5, 6.5, and 9.

Physical Chemistry Assessment

The Asulam Guidance Document dated December 1987 required that all new generic and product-specific data be submitted for product chemistry guidelines. Rhone-Poulenc submitted product chemistry data for the asulam sodium salt. These data were reviewed in the Asulam Registration Update, dated January 15, 1991, which required additional data concerning the following guidelines (GLNs): 61-1, 61-3, 62-2, 62-3, 63-5, 63-8, 63-10, 63-13, 63-17, and 63-20. We note although asulam sodium salt data were originally reviewed in the Update for the 86.4% asulam T, subsequent Agency reviews applied these data to data requirements for the asulam sodium salt, and re-evaluated the outstanding data requirements for asulam and asulam sodium salt.

The following product chemistry guidelines have not been fully satisfied for the Rhone-Poulenc Ag Company asulam 86.4% technical (EPA Reg. No. 264-451): GLN 61-1 product identity and disclosure of ingredients, GLN 61-2 starting materials and manufacturing process, GLN 61-3 discussion of formation of impurities, GLN 62-1 preliminary analysis, GLN 62-2 certification of ingredient limits, GLN 62-3 analytical methods to verify the

certified limits, GLN 63-5 melting point, GLN 63-13 stability, GLN 63-17 storage stability, and GLN 63-20 corrosion characteristics. Guidelines 62-2, 63-17 and 63-20 have not been fully satisfied for the Rhone-Poulenc Ag Company asulam sodium salt technical (EPA File Symbol No. 264-LNL).

The registrant must submit the data summarized above for the 86.4% asulam T (EPA Reg. No. 264-451) and the asulam sodium salt T (EPA Reg. No. 264-LNL), and either certifies that the suppliers of the starting materials and the manufacturing process for the asulam and asulam sodium salt technical products have not changed since the last comprehensive product chemistry review or submit a complete updated product chemistry data package.

B. Human Health Assessment

1. Hazard Assessment

The toxicological data base required to support the reregistration of asulam is adequate.

a. Acute Toxicity

Acute toxicity values and categories for asulam are summarized in the following table.

Table I: Acute Toxicity of Asulam

TEST	RESULTS	CATEGORY
Oral LD_{50} - Rat	> 5000 mg/kg	IV
Dermal LD_{50} - Rabbit	> 4000 mg/kg	III
Inhalation LC_{50} - Rat	> 5 mg/L	IV
Eye Irritation - Rabbit	Mild Irritation	III
Dermal Irritation - Rabbit	Not an Irritant	IV
Dermal sensitization - Guinea Pig	No Sensitization	--

* Note: Data pertaining to acute eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented only for informational purposes.

Asulam technical displayed very low toxicity in acute toxicity tests. The LD_{50} for 87.6% - 88% asulam in acute oral rat studies

exceeded 5000 mg/kg (category IV toxicity; GLN 81-1; MRID 42110001, 40960501). The LD_{50} for 88% asulam in an acute rabbit dermal study exceeded 4000 mg/kg (highest dose tested) (category III toxicity; GLN 81-2; MRID 40960501). The LC_{50} for a rat inhalation study with 88% asulam was greater than 5 mg/liter (category IV toxicity; GLN 81-3; MRID 40960502).

Application of technical asulam to rabbit eyes produced mild chemosis, irritation, and redness which cleared by day seven post-treatment (category III toxicity; GLN 81-4; MRID 00098534). Asulam was not an irritant in a primary skin irritation study in rabbits (category IV toxicity; GLN 81-5; MRID 00098535). It did not cause dermal sensitization in guinea pigs (GLN 81-6; MRID 00098535).

b. Subchronic Toxicity

No adverse systemic effects occurred in a 21-day dermal study conducted at the limit dose of 1,000 mg/kg/day (only dose tested) using New Zealand white rabbits. Although transient and slight skin irritation was observed in a small number of treated females, the 1,000 mg/kg/day dose was considered a NOEL. (GLN 82-2; MRID 41076901)

c. Chronic Toxicity and Carcinogenicity

A two-year combined chronic feeding/carcinogenicity study was conducted using CD rats administered asulam at dose levels of 0, 1,000, 5,000 or 25,000 ppm (equivalent to 0, 36, 180 and 953 mg/kg/day in males and 0, 47, 243 and 1,280 mg/kg/day in females, respectively). The systemic NOEL was 36 mg/kg/day. Hyperplastic changes were observed in the adrenal medulla and in thyroid follicular cells of males at the LOEL of 180 mg/kg/day and the high dose. There was a statistically significant increase in thyroid gland c-cell carcinomas and in adenomas and carcinomas combined in both the low- and mid-dose males. There was a statistically-significant increase in benign adrenal medullary pheochromocytomas at the high dose in males. (GLNs 83-1(a) and 83-2; MRID 00098543)

In a six-month feeding study of asulam in beagle dogs, doses of 0, 60, 300 or 1,500 mg/kg/day were administered. The systemic NOEL was 60 mg/kg/day, the lowest dose tested. Higher doses of asulam at 300 mg/kg/day (LOEL) and 1,500 mg/kg/day (highest dose tested) were associated with reductions in food consumption, body weight gain, emesis, diarrhea, and reductions in red blood cells, hemoglobin and

packed cell volume. There were also elevated thyroid and kidney weights and reduced testicular weights. (GLN 83-1(b); MRID 00098536)

In a two-year carcinogenicity study with Charles River CD-1 mice, asulam was administered in the diet at 0, 500, 5,000 or 50,000 ppm. The systemic toxicity NOEL was 5,000 ppm or 750 mg/kg/day. The systemic LOEL was 50,000 ppm or 7,500 mg/kg/day, based on increased spleen weight in males and decreased brain weight and survival in females. There was no increase in the incidence of any tumors. (GLN 83-2(b); MRID 42338201)

d. Developmental Toxicity

Doses of 0, 500, 1,000 or 1,500 mg/kg were given by gavage on gestation days 5-17 in a developmental toxicity study with CD rats. The NOELs for maternal and developmental toxicity in rats were 1,000 mg/kg/day. The highest dose tested showed decreased body weight gain and a slight increase in resorptions. (GLN 83-3(a); MRID 00098538)

A study in New Zealand white rabbits evaluated asulam at 0, 150, 300 or 750 mg/kg/day by gavage on gestation days 5-20. The maternal and developmental NOELs were 750 mg/kg/day. At 750 mg/kg/day, a borderline maternal toxic effect of decreased body weight gain was seen, which may have been compound-related. An additional group of animals was included in this study at 1,500 mg/kg/day which either died or were sacrificed in extremis, leading to a maternal LOEL of 1,500 mg/kg/day. No teratogenic effects were produced by asulam in either rats or rabbits. (GLN 83-3(b); MRID 00098539)

e. Reproductive Toxicity

Asulam was evaluated in a two-generation reproduction study at 0, 1,000, 5,000, or 25,000 ppm in the diet of CD rats. The study found a NOEL of 1,000 ppm (50 mg/kg/day) for reproductive effects (lowest level tested) with a reduction in the number of live births per litter being noted at 5,000 ppm (250 mg/kg/day) and 25,000 ppm (1,250 mg/kg/day). The parental NOEL was 250 mg/kg/day, with body weight and organ weight decreases at 1250 mg/kg/day. The developmental toxicity NOEL exceeded 1250 mg/kg/day. (GLN 83-4; MRID 00098540)

f. Mutagenicity

Asulam was not mutagenic in the studies that have been performed. The Ames Assay which is used to detect gene mutation with S. typhimurium was negative (MRID 40415302). Mutagenicity assays which detect structural chromosome aberrations included the dominant lethal test in mice (MRID 00082250) and an in vitro cytogenetics assay in human lymphocytes were negative for asulam (MRID 40415301). In addition, the C3H/10T1/2 cell transformation assay when performed with asulam was also negative (MRID 00098542). (GLN 84 series)

g. Metabolism

Metabolism studies were conducted in male and female Sprague-Dawley rats. The tests used a single oral or i.v. dose, or repeated i.v. doses for 14 days. The pharmacokinetics of asulam were similar after all dose regimens in both sexes. Peak blood levels were attained at 0.5 hours. No unusual localization of asulam occurred in tissues and all tissue levels were low at 72 hours. Asulam was rapidly eliminated, mostly within 24 hours. 76.5% to 101.5% of the administered dose was eliminated in the urine, and 1.4% to 25.3% of the dose in feces. The major excretory product was unchanged parent compound (70% to 80%), with acetylasulam (3% to 8%) and acetylsulphanilamide (<3%) being the two major metabolites. (GLN 85-1; MRID 41345601)

h. Neurotoxicity

An acute delayed neurotoxicity study in hens is not required. Although asulam is chemically classified as a carbamate compound, it differs structurally from cholinesterase inhibiting carbamates, and both acute and other toxicity studies with asulam have produced no signs of cholinergic or neurotoxic effects (EPA, 1987; Taylor, 1992).

i. Reference Dose

The HED RfD Peer Review Committee met on June 17, 1993 and established the RfD at 0.36 mg/kg/day based on results of a chronic dietary feeding study in rats (MRID 00098543). The NOEL in this study was 36 mg/kg/day, based on thyroid follicular hyperplasia at 180 and 953 mg/kg/day. An uncertainty factor of 100 was used.

There has been no WHO RfD determination to date.

j. Other Toxicological Considerations

On November 12, 1987 the HED Carcinogenicity Peer Review Committee (HED-CPRC) classified asulam as Group C, a possible human carcinogen, based on thyroid and adrenal tumors in the rat study (MRID 00098543). They also recommended the mouse study be repeated and agreed to reconsider the cancer classification upon receipt and evaluation of the new mouse study. On September 22,1994 the HED RfD Peer Review Committee met to review the new mouse study (MRID 42338201). The Committee concluded that the findings of the new mouse study have no impact on the current classification of the chemical as a "Group C", possible human carcinogen. They determined that a low dose linear extrapolation risk model was not appropriate for asulam.

The HED Metabolism Committee determined on December 13, 1994 that although the metabolites hydroquinone/quinone are of toxicological concern, these compounds are naturally occurring plant constituents and the levels of hydroquinone/quinone present in the treated sugarcane, cane sugar, and molasses do not represent a significantly different risk than naturally occurring levels of hydroquinone/quinone. A new plant metabolism study, conducted on sugarcane, is required to confirm the presence and quantity of radiolabeled hydroquinone/quinone.

There are no concerns for developmental or reproductive toxicity associated with oral exposure to asulam. There is no acute dietary toxicological endpoint of concern (the NOEL in the developmental toxicity study in rats is 1000 mg/kg/day). There is no toxicological endpoint of concern for short term or intermediate term occupational or residential exposure (the NOEL in the 21-day dermal toxicity is 1000 mg/kg/day).

k. Other Adverse Effects

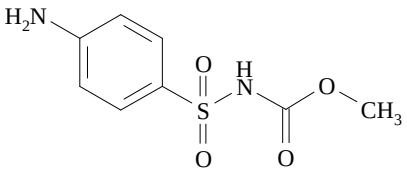
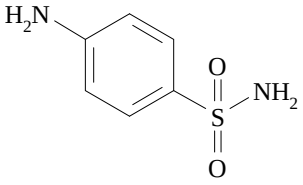
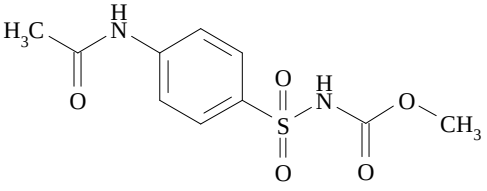
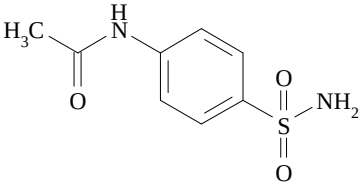
There have been no reported incidents for asulam in the Pesticide Incident Monitoring System (PIMS), by California during 1982-89, from the American Association of Poison Control Centers, in the National Pesticide Telecommunication Network reports from 1984-1991 inclusive, or in the EPA Incident Data System (June, 1992 to July, 1994).

2. Exposure Assessment

a. Dietary

The current tolerance for residues of asulam *per se* in/on sugarcane is 0.1 ppm *[Source: 40 CFR §180.360]*. The Agency is requiring that the tolerance expression be revised to include all metabolites containing the sulfanilamide moiety. Initially, the tolerance expression recommendation included the metabolites hydroquinone/ quinone. Subsequently, the HED Metabolism Committee determined on 12/13/94 that although hydroquinone/quinone are of toxicological concern, these compounds are naturally occurring plant constituents and the levels of hydroquinone/quinone present in the treated sugarcane, cane sugar, and molasses do not represent a significantly different risk than naturally occurring levels of hydroquinone/quinone. No food/feed additive regulations have been established. The chemical structures of the metabolites for regulation are presented in Figure A. An adequate enforcement method is available for the determination of combined residues of asulam and all metabolites containing the sulfanilamide moiety in/on sugarcane.

Figure A. The chemical structures of the metabolites of concern of asulam.

Structure **Metabolite**: Chemical name	Structure **Metabolite**: Chemical name
 **asulam**: methyl-4-sulfanilylcarbamate	 **sulfanilamide**: 4-aminobenzenesulfonamide
 **N_4-acetylasulam**: methyl 4-acetamido-benzenesulfonylcarbamate	 **N_4-acetylsulfanilamide**: N-acetyl-4-aminobenzenesulfonamide

Directions for Use

There is one asulam end-use product (EP) is currently registered by Rhone-Poulenc AG Company for use on food/feed crops. The 3.34 lb ai/gal SC/L formulation (ASULOX® Herbicide, EPA Reg. No. 264-447, accepted 8/5/93) is registered for one or two postemergence broadcast or band applications or as a postemergence spot treatment to sugarcane at a maximum rate of 3.34 lb ai/A/application. Ground and aerial applications are permitted in water spray volumes of 15-100 gal/A and 3-5 gal/A, respectively. Aerial applications in Hawaii are permitted in a water spray volume of 5-10 gal/A. The grazing or feeding of forage and fodder to livestock is prohibited. A 90-day PHI has been established. A one-year plantback interval for all crops other than sugarcane has been established.

Previously submitted field trial data indicate that residues in excess of tolerance will occur in/on sugarcane following treatment at the maximum registered rates. The registrant has committed to amending labels to reflect lower maximum application rates and/or longer PHI's and to submit supporting field trial data in order to support a lower tolerance level for sugarcane.

Plant Metabolism

The qualitative nature of the residue in plants is adequately understood based on acceptable sugarcane metabolism studies. The data indicate that asulam is metabolized via a complex pathway involving hydrolysis of the carbamate ester, hydroxylation, and subsequent incorporation into naturally occurring plant constituents. The major metabolites in sugarcane are unchanged parent (asulam) and its sulfanilamide-containing metabolites (sulfanilamide, sulfanilic acid, N_4-acetyl asulam, N_4-acetylsulfanilamide), and quinone and hydroquinone. Additionally, methyl 4-methoxybenzenesulfonyl carbamate, 4-amino-2-hydroxybenzenesulfonic acid, and benzenesulfonic acid were found in a nature of the residue in alfalfa study. A new metabolism study, conducted on sugarcane, is required to confirm the presence and quantity of radiolabeled hydroquinone/quinone. This study is considered confirmatory.

The Metabolism Committee of the Health Effects Division has determined that, in addition to asulam and its sulfanilamide-containing metabolites, the asulam plant metabolite quinone/hydroquinone is of

toxicological concern, but based on known concentrations of quinone and hydroquinone in other food items, probably occurs at levels comparable to background concentrations. The existing nature of the residue in the sugarcane study indicates that 20% of the total radiolabeled residue could be quinone/hydroquinone, but the identification is equivocal. The new study is needed to determine if quinone and hydroquinone are asulam metabolites; and the extent of quinone/hydroquinone formation. The terminal residues of concern are free and conjugated asulam, sulfanilamide, N_4-acetylasulam, and N_4-acetylsulfanilamide determined as a common moiety. The chemical structures of these metabolites for regulation are presented in Figure A.

Animal Metabolism

The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies. Asulam is largely eliminated in the excreta; the major residues identified in milk, eggs, and animal tissues are the parent and N_4-acetylsulfanilamide.

In the poultry metabolism study, laying hens were dosed with ring-labeled [^{14}C]asulam at 22.5 ppm in the diet for 7 consecutive days. The maximum total radioactive residues were 0.027 ppm in egg yolks, 0.062 ppm in egg whites, 0.011 ppm in fat, 0.074 ppm in muscle, 0.444 ppm in kidneys, and 0.086 ppm in liver. The parent compound asulam, and its metabolite N_4-acetylsulfanilamide constituted the majority of the residues in poultry, comprising 63 and 44% of the TRR, respectively, in egg yolks, 21 and 52% of the TRR, respectively, in egg whites, 35 and 51% of the TRR, respectively, in muscle, and 83 and 14% of the TRR, respectively, in kidney. The parent was not identified in liver samples; N_4-acetyl sulfanilamide represented 81% of the TRR in liver samples. (MRID 41561102)

In the ruminant metabolism study, two goats were dosed with ring-labeled [^{14}C]asulam at 20 ppm in the diet for 7 consecutive days. The total radioactive residues were nondetectable (<0.005 ppm) in fat and muscle, 0.162 ppm in kidneys, 0.090 ppm in liver, and up to 0.021 ppm in milk. The parent compound, asulam, constituted the majority of the residues in milk (81% of TRR) and kidneys (100% of TRR) and its metabolite N_4-acetylsulfanilamide constitutes the majority of residues in liver (58% of TRR). The parent was not identified in liver samples. In

a previous study, sulfanilamide was found in ruminant liver and muscle, and N_4-acetylasulam was found in liver, kidney, milk, muscle, and fat. (MRID 41561101)

The terminal residues of concern for regulation are free and conjugated asulam, sulfanilamide, N_4-acetylasulam, and N_4-acetylsulfanilamide determined as a common moiety.

Residue Analytical Methods - Plants and Animals

Adequate methods for purposes of enforcement of asulam tolerances in/on sugarcane are available. The spectrophotometric method for determining free and bound asulam and other compounds containing the primary aromatic amine (sulfanilamide) moiety in/on sugarcane is described in the Pesticide Analytical Manual (PAM), Vol. II, as Method I. The limit of detection is 0.02 ppm in sugarcane. A TLC procedure is used for confirmation. HPLC/UV methods, Method Nos. 154 and 156, for determination of the combined residues of asulam and its metabolites containing the sulfanilamide moiety in animal and in/on plant commodities, respectively, have also undergone EPA validation and are adequate for enforcement purposes. By these methods, residues are converted to and determined as N_4-acetylsulfanilamide. Limits of detection for these HPLC methods have not been specified. (MRID 42292401)

Adequate spectrophotometric methods (Method Nos. 111 and 143) were used to collect residue data for sugarcane and its processed fractions that were discussed in the 1987 Residue Chemistry Science Chapter. Residue data submitted since the Science Chapter were collected using a modification of HPLC/UV Method No. 154, which is considered adequate for data collection and tolerance enforcement purposes.

In addition, the registrant has satisfied the requirements for data on the recovery of asulam and its sulfanilamide-containing metabolites using FDA Multiresidue Protocols A, D, and E (fatty and nonfatty). These data have been forwarded to FDA for review. The FDA's PESTDATA dated 11/6/90 (Pam Vol. I, Appendix) indicates that recovery of asulam using Multiresidue Protocols A, D, or E is unlikely. The updated PESTDATA dated 08/93 does not have an entry for asulam or its metabolites.

Storage Stability

A stability study (up to 18 months of storage) has been conducted using samples of sugarcane, sugarcane forage, bagasse, molasses, and sugar. These data indicate that residues of asulam *per se* are not stable in/on sugarcane and sugarcane forage. A 60% loss each of asulam and of sulfanilamide occurs in sugarcane during 15 months of storage, with most of the loss occurring in the first six months of storage. Residues of the metabolites (except sulfanilamide) are generally stable in/on sugarcane and sugarcane forage, and residues of both asulam and its metabolites are stable in the processed commodities. All existing field trial results for sugarcane must be corrected by a factor of 2.5X to account for the instability of asulam. (MRID 43234701)

Residues of asulam *per se* are stable under frozen conditions (-26 to -10°C) in/on alfalfa commodities for up to 13 months, in milk for 1 week, and in animal tissues for up to 1 month. Residues containing the sulfanilamide moiety are stable in milk and ruminant tissues for up to 21 months. (MRID 42806201)

Magnitude of the Residue in Plants

Field residue data reflecting the current maximum registered use patterns have been reviewed. These data indicate that residues of asulam and its sulfanilamide-containing metabolites in/on sugarcane will exceed the established tolerance with residues as high as 15 ppm (6 ppm corrected for 60% storage loss). The current RAC tolerance is 0.1 ppm. However, the registrant is submitting further additional data reflecting longer PHI's and more accurate timing of applications which will likely result in a tolerance level lower than 15 ppm. After reviewing these data, the Agency will establish a new sugarcane tolerance. (MRID 42088801)

Magnitude of the Residue in Processed Food/Feed

Acceptable sugarcane processing studies have been submitted and reviewed. The sugarcane processing data indicate that asulam and its metabolites concentrated in first strike molasses (16x). A factor of 3X is considered adequate for concentration from first strike to blackstrap molasses. Therefore, the concentration factor for blackstrap molasses is 48X. A feed additive tolerance for residues of asulam in blackstrap molasses is needed. (MRID 42201501)

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

Feeding studies with ruminants and poultry were discussed in the 1987 Residue Chemistry Science Chapter of the Registration Standard; however, the adequacy of these studies was not assessed because field trial and processing data for sugarcane remained outstanding. Although some field trial data for sugarcane and storage stability data to support the processing data remain outstanding, sufficient data are available to assess the adequacy of these feeding studies.

Based on the reevaluated tolerance of 15 ppm for sugarcane, and the 48x concentration factor for molasses, the maximum theoretical dietary burden for ruminants is estimated to be about 100 ppm (based on a diet consisting of 10% molasses) and the maximum theoretical dietary burden for poultry is estimated to be nil. Molasses is not considered a poultry feed item.

In a ruminant feeding study lactating dairy cows were dosed with asulam *per se* at 50, 200, or 800 ppm in the diet (50x, 200x, or 800x the maximum theoretical dietary burden, respectively, based on established tolerances) for 28 days. Milk samples were collected in the morning and evening on days 4, 7, 13, and 28 of the study. Half the test animals were sacrificed within 24 hours of the final dose and the remaining animals were sacrificed after a 14- or 21-day withdrawal period. All milk and tissue samples were frozen after collection. Residues of asulam and its metabolites containing the sulfanilamide moiety were determined using an adequate HPLC method (Method No. 154) in fat, kidney, liver, muscle, and milk on days 4, 7, 13, and 28. At the 50 ppm dose level, residues ranged from 0.04 - 0.11 ppm in milk and from <0.05 - 0.34 ppm in the tissues; at the 200 ppm dose level residues ranged from 0.10 - 0.32 ppm in milk and from <0.05 - 1.03 ppm in tissues; and at the 800 ppm dose level residues ranged from 0.48 - 1.16 ppm in milk and from <0.05 - 3.56 ppm in tissues. The residue level plateaued in milk on day 13. Kidney tissue had the highest residue levels (>4X) as compared to the other tissues. (MRID 00098553)

In a second ruminant feeding study, lactating dairy cows were dosed with asulam *per se* at 0.5, 5, 50, 200, or 800 ppm in the diet (0.5x, 5x, 50x, 200x, or 800x, respectively, the maximum theoretical dietary burden based on existing tolerances) for 28 days. Milk samples were collected in the morning and evening at regular intervals during the study. Animals were sacrificed within 24 hours of the final dose and tissue samples were collected. All milk and tissue samples were stored

frozen (-15°C) until analyzed. Residues of asulam were determined using an adequate spectrophotometric method. Residues were nondetectable (<0.025 ppm) in milk from cows dosed at 0.5x-50x (0.5-50 ppm). Residues were nondetectable (<0.05 ppm) in all tissues of cows dosed at 0.5x (0.5 ppm) and in the fat of cows from all feeding levels. In cows fed at 5x (5 ppm), residues were nondetectable (<0.05 ppm) in all tissues except kidney (0.06-0.12 ppm). In cows fed at 50x (50 ppm), residues were nondetectable in all tissues except kidney (0.11-0.13 ppm) and heart (0.06 ppm). In cows fed at 200x (200 ppm), residues were nondetectable in all tissues except kidney (0.32-0.34 ppm) and heart (0.07 ppm). In cows fed at 800x (800 ppm), residues were 1.19-1.39 ppm in kidney, 0.10-0.11 ppm in liver, 0.08-0.10 ppm in muscle, 0.13-0.17 ppm in heart, and 0.07 ppm in brain. (MRIDs 00052047, 00084805, and 00113833)

In a poultry feeding study, laying hens were dosed with asulam *per se* at 50, 150, and 200 ppm in the diet for 28 days. Eggs were collected daily and pooled. The test animals were sacrificed after 2, 3, or 4 weeks of feeding. Residues of asulam and its metabolites containing the sulfanilamide moiety were determined using an adequate HPLC method (Method No. 154) in eggs, kidney, gizzard, blood, heart, liver, muscle (leg and breast), and skin. At the 50 ppm dose level residues ranged from 0.1 - 1.0 ppm; at the 150 ppm dose level residues ranged from 0.3 to 2.5 ppm; and at the 500 ppm dose level residues ranged from 1.0 - 10.7 ppm. The lowest residue levels were generally in the skin, muscle, and eggs. The highest residue levels were found in the kidney tissue. It should be noted that there are no significant dietary sources of asulam for poultry. (MRID 00098554)

Interpolating the 50 ppm and 200 ppm feeding studies to a 100 ppm diet, the Agency concluded that finite residues of asulam and its sulfanilamide-containing metabolites may occur. Probable concentrations are 0.18 ppm in milk, 0.57 ppm in kidney, 0.12 ppm in liver, and 0.07 ppm in muscle. No residue (< 0.05 ppm) is expected in fat. Therefore, tolerances will be required for ruminant meat, meat byproducts, and milk. No tolerances are needed for poultry commodities because there are currently no poultry feed items with asulam residues.

Confined/Field Rotational Crops

An acceptable limited rotational crops study has been conducted. No residues of asulam, acetylasulam, sulfanilamide, and/or

acetylsulfanilamide were found in/on lettuce, carrots, and wheat grain, wheat forage, and wheat straw rotated with sugar cane treated at the maximum label rate with asulam. The data support a minimum plantback interval of 6 months. (MRID 42980801)

A confined rotational crop study utilizing radiolabeled asulam is required as confirmatory data. It is conceivable that the residue of concern could contain metabolites of toxicological concern not covered by the tolerance expression for primary crops.The study is essential to determine the nature of the residue in secondary crops and to determine total residue levels at various plantback intervals. The presence/absence of quinone and hydroquinone in the radiolabeled residue must be established.

Anticipated Residues for Dietary Exposure Assessment

Anticipated residues in sugarcane and its processed commodities and in ruminant commodities for use in acute and chronic risk assessment are given in Table IIa and Table IIb. The calculations are based on the most recent field trials for plant commodities and on animal feeding studies for the ruminant commodities.

Note that the anticipated residues for plant commodities are derived from the most recent mainland field trials. Residues were substantially lower on HI cane than on mainland cane. Presumably this is related to the longer growing season in HI, where canopy formation is complete before the 90 day PHI used for the trials.

Table IIa: Anticipated Residues of Asulam and Its Sulfanilamide-Containing Metabolites in Plant Commodities

Commodity	Reassessed Tolerance (ppm)	Asulam Plus Sulfanilamide-Containing Metabolites Field Trial Results (ppm)		Anticipated Residue Asulam Plus Sulfanilamide-Containing Metabolites (ppm)	
		Max[1]	Avg[2]	Acute	Chronic
Sugarcane	15[3]	15[6]	5.8[6]	15	5.8[6]
Refined Sugar	15[4]			15	5.8[6]
Molasses (Blackstrap)	720[5]			720	280

[1] The maximum residue encountered in 14 mainland field trials.
[2] The average of the average residues encountered at each of 14 mainland field trials, range 0.67 ± 0.31 ppm - 5.34 ± 0.50 ppm (MRID 42088801).
[3] Based on mainland field trial data, HI data excluded.
[4] No concentration (1 - 1.3X) from RAC to refined sugar.
[5] 48X concentration from RAC to blackstrap molasses (16X to first strike molasses).
[6] Adjusted for a 60% loss during storage.

Table IIb: Anticipated Residues of Asulam and Its Sulfanilamide-Containing Metabolites in Animal Commodities

Commodity	Reassessed Tolerance (ppm)	Anticipated Residue Asulam Plus Sulfanilamide-Containing Metabolites (ppm)	
		Acute	Chronic[1]
Milk	0.2	0.2	0.2
Cattle, meat	0.1	0.1	0.1
Cattle, mbyp	0.6	0.6	0.6
Goats, meat	0.1	0.1	0.1
Goats, mbyp	0.6	0.6	0.6
Hogs, meat	0.1	0.1	0.1
Hogs, mbyp	0.6	0.6	0.6
Horses, meat	0.1	0.1	0.1
Horses, mbyp	0.6	0.6	0.6
Sheep, meat	0.1	0.1	0.1
Sheep, mbyp	0.6	0.6	0.6

[1]DRES adjusted chronic anticipated residues by 70% to reflect % crop treated.

b. Occupational and Residential

Handler (Mixer, Loader, Applicator) Exposure

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, etc.) during use or to persons entering treated sites after application is complete.

The Agency has determined that there is an exposure potential for mixers, loaders, applicators, or other handlers during the usual use-patterns associated with asulam. The mixing, loading, and application methods include open pouring, broadcast (aerial and ground) application and application with hand-held equipment.

Asulam (TGAI) is in acute toxicity category IV for acute oral toxicity, inhalation toxicity, and primary dermal irritation; and in category III for acute dermal and eye irritation. Asulam is not a skin sensitizer. These toxicity categories for asulam do not trigger the acute battery of testing. For asulam, the Agency has determined that the toxicology criteria are not triggered. No endpoints of concern regarding dermal toxicity, inhalation toxicity or other adverse effects have been identified. Therefore, an occupational exposure assessment is not required. There are no residential uses for asulam.

Post-Application Exposures

The Agency has determined that the potential exposure to persons entering treated sites after application triggers the post-application criteria. However, as indicated above, no endpoints of concern regarding dermal toxicity, inhalation toxicity or other adverse effects have been identified. Therefore, a post-application occupational exposure assessment is not required.

Occupational-use products and homeowner-use products

There are no products containing asulam that provide directions intended for homeowner use. Current labelling provides the statement "for agricultural or commercial use only, not for use by homeowners."

3. Risk Assessment

a. Dietary

Asulam was classified as a Group C, possible human carcinogen, by the HED Carcinogenicity Peer Review Committee with the recommendation not to quantify the carcinogenic risk by low dose linear extrapolation. Two plant metabolites, hydroquinone and quinone, have also been identified as carcinogens. Based upon the determination by the Metabolism Committee on 12/13/94 that hydroquinone/quinone are naturally occurring plant constituents, and the levels of hydroquinone/quinone present in the treated sugarcane, cane sugar, and molasses *may* not represent a significantly different risk than naturally occurring levels of hydroquinone/quinone, the dietary risk assessment does not include the metabolite quinone/hydroquinone. A new plant metabolism study is required to confirm that radiolabeled quinone/hydroquinone levels are in the range of naturally occurring background levels.

Chronic Dietary Risk

The chronic dietary exposure analysis used a Reference Dose (RfD) of 0.36 mg/kg/day. The RfD was based on the NOEL of 36 mg/kg/day from a 2-year chronic toxicity study in rats in which thyroid follicular cell hyperplasia was observed at the mid and high doses (180 and 953 mg/kg/day, respectively) in males. An uncertainty factor of 100 was applied to account for interspecies extrapolation and intraspecies variability.

Food uses evaluated in this analysis are the published uses of asulam as listed in 40 CFR §180.360 plus ruminant commodities milk, meat, and meat byproducts. The existing tolerance for sugarcane is 0.1 ppm. Based upon results of field trials this tolerance may be exceeded. The reassessed tolerance for sugarcane is 15 ppm. There are currently no food/feed additive tolerances for asulam, but studies indicate that a tolerance of 720 ppm is needed for blackstrap molasses.

Anticipated residues (AR) have been determined for asulam (see Table IIa and Table IIb) and its metabolites containing the sulfanilamide moiety. The AR of 5.8 ppm on sugarcane was based upon the average of the residue levels detected in field trials. The 10/94 usage estimate of 70% sugarcane crop treated annually with asulam was used in this assessment.

The chronic dietary risk analysis for asulam and its metabolites containing the sulfanilamide moiety was conducted for sugarcane as cane sugar and sugar-molasses and for ruminant commodities. The analysis assumed the higher reassessed tolerance level of 15 ppm and 100% crop treated for all commodities for the overall U.S. population and 22 population subgroups. The exposure estimates were then compared to the RfD for asulam to calculate estimates of chronic dietary risk.

The ARC from the use of asulam on sugarcane for the overall U.S. population of the 48 states is 1.39×10^{-2} mg/kg body weight/day which represents 3.85% of the RfD. The ARCs for the two highest exposed subgroups, children (1-6 years old) and non-nursing infants (<1 year old), are 3.48×10^{-2} and 2.64×10^{-2} mg/kg body weight/day, respectively. These exposure values represent 9.7% and 7.3% of the RfD, respectively.

Therefore, the Agency does not have a concern for chronic dietary exposure to asulam since the RfD is not exceeded for either the general population or any subgroup.

b. Occupational and Residential

There is the potential for handler (mixers/loaders/applicators, etc.) exposure and post-application exposure for the usual use-patterns associated with asulam; however, there are no toxicological endpoints of concern for the short to intermediate term occupational exposure. Therefore, minimal risk from the occupational use of asulam is expected.

There are no residential uses for this chemical; therefore, no exposure or risk is expected from asulam.

C. Environmental Assessment

1. Ecological Toxicity Data

The following ecological effects guideline requirements have not been fulfilled for asulam: a freshwater aquatic invertebrate life-cycle study (72-4b), a seedling emergence study - with soybean and radish (123-1a), and a vegetative vigor study - with cucumber and onion (123-1b). The ecotoxicological data base, however, is adequate to characterize the acute

toxicity of asulam to nontarget terrestrial and aquatic organisms when used on terrestrial food, feed and nonfood sites.

a. Toxicity to Terrestrial Animals

In order to establish the toxicity of asulam to birds, the following tests are required using the technical grade material: two subacute dietary studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant), and one avian single-dose oral (LD_{50}) study on one species (preferably mallard duck or bobwhite quail).

Wild mammal testing is required on a case-by-case basis, depending on results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure.

(1) Birds, Acute and Subacute

<u>Avian Acute</u>

No acceptable avian acute oral toxicity studies on technical asulam have been submitted for review. However, the collection of data on the 40 percent formulated product will satisfy the requirement.

The acceptable acute oral toxicity tests for the 40 percent formulated product are listed in the following table:

Avian Acute Oral Toxicity Findings - Formulated Product							
Species	**% A.I.**	**LD_{50}**	**Author**	**Date**	**MRID**	**Category**	**Conclusions**
Mallard	40	>4000 ppm (product)	Ingham et al.	1971	56417	Supplemental[2]	Practically nontoxic
Partridge	40	>4000 ppm (product)	Ingham et al.	1971	56417	Supplemental[1,2]	Practically nontoxic
Pheasant	40	>4000 ppm (product)	Ingham et al.	1971	56417	Supplemental[1,2]	Practically nontoxic
Pigeon	40	>4000 ppm (product)	Ingham et al.	1971	56417	Supplemental[1,2]	Practically nontoxic

1. Not a recommended test species.
2. Test material is not technical.

The existing data demonstrate that a 40 percent formulation of asulam is practically nontoxic to waterfowl and upland game birds. Although none of the above studies were classified as core, the **collection** of studies taken as a whole can be used to satisfy the guideline requirement for an avian acute oral study. (MRID 00056417)

Avian Subacute Dietary

No acceptable avian dietary toxicity studies on technical asulam have been submitted for review. However, the collection of studies taken as a whole on a 60 percent formulation of asulam will satisfy the requirement.

The acceptable avian dietary toxicity tests for a 60 percent formulation are listed in the following table:

Avian Subacute Dietary Toxicity Findings Formulated Product							
Species	**% A.I.**	**LC_{50} (ppm)**	**Author**	**Date**	**MRID**	**Category**	**Conclusions**
Mallard	60	>75,000 (product)	Heywood et al.	1970	56418	Supplemental[2]	Practically nontoxic
Pheasant	60	>75,000 (product)	Heywood et al.	1970	56419	Supplemental[1,2]	Practically nontoxic

1. Not a recommended test species.
2. Test material is not technical.

The existing data demonstrate that a 60 percent formulation of asulam is practically nontoxic to waterfowl and upland game birds. Although none of the above studies were

classified as core, the **collection** of studies taken as a whole can be used to satisfy the guideline requirement for an avian dietary study. (MRIDs 00056418 and 00056419)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications; or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of asulam allows several applications of the end-use product per growing season (specifically on sugarcane and possibly for the non-cropland and Christmas tree use sites). The Agency is not requesting avian reproduction studies at this time primarily due to the extremely short photolytic half-life (approximately 2 hours) and in acute studies, the practically non-toxic nature of asulam to birds and mammals.

(3) Mammals

The available mammalian data indicate that both asulam and the sodium salt of asulam are practically nontoxic to small mammals on an acute basis with LD_{50}s of greater than 5000 ppm for the rat. (MRID 00111761) On a chronic basis, testing with technical asulam in a two-generation reproduction study with rats produced a reproductive NOEL of 1000 ppm/day and a LOEL of 5000 ppm/day based on a decrease in live birth index. (MRIDs 00070776 and 00098540)

(4) Insects

The minimum data required to establish the acute toxicity to honey bees is an acute contact LD_{50} study with the technical material.

The acceptable honeybee study is listed in the following table:

Nontarget Insect Toxicity Findings - Formulated Product							
Species	**% A.I.**	**LD_{50}**	**Author**	**Date**	**MRID**	**Category**	**Conclusion**
Apis mellifera	formulation not reported	1.28% mortality at 36.26 ug/bee	Atkins et al.	1975	00036935	Core	Practically nontoxic

There is sufficient information to characterize asulam as practically nontoxic to bees. This study fulfills the data requirement for acute toxicity testing with honey bees. (MRID 00036935)

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of asulam to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout) and the other should use a warmwater species (preferably the bluegill sunfish).

Acute Studies - Technical

The acceptable acute fish toxicity studies are listed in the following table:

Freshwater Fish Acute Toxicity Findings - TGAI							
Species	**% A.I.**	**LC_{50}**	**Author**	**Date**	**MRID**	**Category**	**Conclusions**
Rainbow trout	88	>175 ppm	Manning	1988	40872001	Core	Practically nontoxic
Bluegill sunfish	96.6	>180 ppm	Vilkas	1979	98505	Core	Practically nontoxic

There is sufficient information to characterize technical asulam as practically nontoxic to both warmwater and coldwater fish. The guideline requirements, 72-1 (a) and (b), have been satisfied. (MRIDs 40872001 and 00098505)

Acute Studies - Formulated Product

Although formulated product testing on fish was not required for asulam, several studies were submitted and reviewed.

The acceptable fish toxicity data on the formulated products are listed in the following table:

Freshwater Fish Acute Toxicity Findings - Formulated Product

Species	% A.I.	LC_{50}	Author	Date	MRID	Category	Conclusions
Rainbow trout	60	> 5000 ppm (product)	Fraser et al.	1970	56421	Supplemental[1]	Practically nontoxic
Bluefish	60	> 5000 ppm (product)	Fraser et al.	1970	56421	Supplemental[1]	Practically nontoxic
Goldfish	60	> 5000 ppm (product)	Fraser et al.	1970	56421	Supplemental[1,2]	Practically nontoxic
Channel catfish	60	> 5000 ppm (product)	Fraser et al.	1970	56421	Supplemental[1,2]	Practically nontoxic

1. Formulated product was used instead of technical grade material.
2. Not a recommended test species.

These fish studies show that a 60 percent formulated product of asulam is practically nontoxic to both the warmwater and coldwater fish. However, these studies were not required and do not fulfill any guideline requirements. (MRID 00056421)

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater aquatic invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

The acceptable toxicity data are listed in the following table:

Freshwater Invertebrates Acute Toxicity Findings - TGAI							
Species	**% A.I.**	**EC_{50}**	**Author**	**Date**	**MRID**	**Category**	**Conclusions**
Daphnia magna	97	27 ppm	Roberts et al.	1977	98507	Core	Slightly toxic
Daphnia magna	88	67 ppm	Manning	1988	40977602	Core	Slightly toxic

There is sufficient information to characterize technical asulam as slightly toxic to aquatic invertebrates. The guideline requirement for an aquatic invertebrate EC_{50} study has been satisfied. (MRIDs 00098507 and 40977602)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The use of asulam on sugarcane and turf may result in exposure to the estuarine environment through drift and runoff. The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

The acceptable acute estuarine and marine studies are listed in the following table:

Estuarine/Marine Acute Toxicity Findings							
Species	**% A.I.**	**LC_{50}**	**Author**	**Date**	**MRID**	**Category**	**Conclusions**
Eastern oyster	88 (asulam sodium salt)	>185 ppm	Manning	1989	41000701	Core	Practically nontoxic
Grass shrimp	97	>100 ppm	Vilkas	1979	98508	Core	Practically nontoxic
Fiddler crab	97	>100 ppm	Schneider et al.	1979	98509	Supplemental[1]	Practically nontoxic

1. The fiddler crab is not a recommended species.

There is sufficient information to characterize technical asulam as practically nontoxic to estuarine/marine species. The guideline requirement for testing with a marine or estuarine fish

species is waived due to the demonstrated low toxicity of asulam to freshwater fish as well as marine and freshwater invertebrates. The guideline requirements for estuarine/marine testing are satisfied. (MRID 41000701, 00098508 and 00098509)

c. Toxicity to Plants

(1) Terrestrial

Terrestrial plant testing (seed germination, vegetative vigor and seedling emergence) is required for asulam because it is registered for use on terrestrial food (sugarcane) and terrestrial nonfood sites (turf, rights-of-way, Christmas tree plantations) and it may be aerially applied (sugarcane and Christmas tree plantations). Also, Tier II terrestrial plant testing is automatically required for herbicides, such as asulam, which are aerially applied.

The acceptable Tier II terrestrial phytotoxicity data on the technical material (sodium salt of asulam) are listed below:

Tier II Terrestrial Phytotoxicity Findings - TGAI

Species	% A.I	EC_{25}	Author	Date	MRID No.	Category
Seed germination (10 species)	89.5 % asulam sodium salt	lowest EC_{25} = 0.095 lbs a.i./A for oat radicle length **(see below)**[1]	Christensen	1992	42613801	Partial[4]
Seedling emergence (10 species)		lowest EC_{25} = 0.08 lbs a.i./A for lettuce shoot length **(see below)**[2]				Partial[5]
Vegetative vigor (10 species)		lowest EC_{25} = 0.0002 lbs a.i./A for cucumber root weight **(see below)**[3]				Partial[6]

4. The results from oat and radish were supplemental as the EC_{25} was determined to be lower than the lowest level tested. These species need to be retested at lower test concentrations.
5. The results from soybean and radish were supplemental as the EC_{25} was determined to be lower than the NOEL. These species must be retested to obtain an adequate dose-response.
6. The results from cucumber and onion are supplemental as the EC_{25} was determined to be lower than the lowest concentration tested. These species need to be retested at lower concentration levels.

[1]**Tier II seed germination test results: lowest observed EC values**
rl = radical length; pg = percent germination

Plant Species	**EC_{25} lbs a.i./A**
Cabbage	0.20 (rl)
Corn	5.40 (rl)
Cucumber	>6.5 (pg,rl)
Lettuce	1.10 (rl)
Oat	0.095 (rl)
Onion	3.80 (rl)
Ryegrass	0.16 (rl)
Radish	0.21 (rl)
Soybean	>6.5 (rl,pg)
Tomato	>6.5 (rl,pg)

[2]**Tier II seedling emergence test results:**
lowest observed EC_{25} values = shoot length for all test species

Plant Species	**EC_{25} lbs a.i./A**
Cabbage	0.10
Corn	0.86
Cucumber	3.60
Lettuce	0.08
Oat	0.15
Onion	0.26
Ryegrass	0.14
Radish	0.11
Soybean	0.26
Tomato	0.86

[3]Tier II vegetative vigor test results: lowest observed EC values
sl = shoot length; sw = shoot weight; rw = root weight

Plant Species	EC_{25} lbs a.i./A
Cabbage	0.02 (sw)
Corn	>5.3 (sl,sw,rw)
Cucumber	0.0002* (rw)
Lettuce	0.07 (sw)
Oat	1.4 (sw)
Onion	0.07 (sl)
Ryegrass	4.2 (sw)
Radish	0.16 (rw)
Soybean	1.3 (sw)
Tomato	0.54 (rw)

* EC value was extrapolated beyond treatment range.

Guideline requirements for terrestrial plant testing with asulam have been **partially fulfilled**. Additional data are required for seedling emergence - soybeans and radish and vegetative vigor - cucumber and onion tests. (MRID 42613801)

(2) Aquatic

Aquatic plant testing is required for asulam because it is registered for use on terrestrial food/nonfood sites and may be aerially applied. The following species should be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom. Also, Tier II aquatic plant testing is automatically required for herbicides, such as asulam, which are aerially applied.

The acceptable Tier II aquatic phytotoxicity data on the technical material (sodium salt of asulam) are listed below:

Tier II Aquatic Phytotoxicity Findings - TGAI						
Species	**% AI**	**EC_{50}**	**Author**	**Date**	**MRID No.**	**Category**
Anabaena flos-aquae	89.5 asulam sodium	5-Day EC_{50} = 0.70 ppm	Hoberg	1992	42613802	Core
Skeletonema costatum	89.5 asulam sodium	5-Day EC_{50} = 0.44 ppm	Hoberg	1992	42560302	Core
Navicula pelliculosa	89.5 asulam sodium	5-Day EC_{50} = 2.3 ppm	Hoberg	1992	42631301	Core
Lemna gibba	89.5 asulam sodium	14-Day EC_{50} = 0.14 ppm	Hoberg	1992	42611701	Core
Selenastrum capricornutum	89.5 asulam sodium	5-Day EC_{50} = 0.18 ppm	Hoberg	1992	42560301	Core

Guideline requirements for aquatic plant testing with asulam have been fulfilled. (MRIDs 42613802, 42560302, 42631301, 42611701, and 42560301)

2. Environmental Fate

At this time, the following environmental fate guidelines are not fulfilled for asulam: an aerobic soil metabolism study (162-1), an anaerobic soil and aquatic metabolism study (162-2) (to include a laboratory study investigating asulam and its degradate (sulfanilamide) in soil under freezing conditions), and a spray drift (droplet size spectrum) and drift field evaluation (201-1 and 202-1). Although the studies to support the soil/aquatic metabolism data requirements can be upgraded and other data requirements have been fulfilled, the lack of acceptable field dissipation data and the concerns about the integrity of data from the laboratory studies limit the Agency's ability to assess with confidence the environmental fate of asulam. The following assessment of the environmental fate of asulam is, in part, based on *unreliable* data. As a result, the fate, ground and surface water assessments of asulam may change after review of the additional data being required.

a. Environmental Fate Assessment

Based on available data, the major routes of dissipation are leaching into ground water and biotic degradation under aerobic conditions. Asulam also dissipates by irreversible binding to soil organic matter, and the binding appears to increase with time. However, there is a time lag of up to 120 days during which asulam residues can move through the soil profile under aerobic conditions.

Because of its solubility in water, rain occurring immediately following application may increase the amount of chemical getting into ground water. Sediment-bound residues or solubilized asulam may run off to surface water. Therefore, surface runoff could be another major route of dissipation.

Based on the laboratory studies, photolysis in water and on soil appear to be major routes of degradation for asulam. However, the role of photolysis may be less significant in the natural field conditions than in the laboratory. This was demonstrated by the detection of low levels of asulam residues (0.1 ppb) in a surface water study.

Based on acceptable data, the Agency concludes that asulam is very soluble in water, with a water solubility of 4,000 ppm. One end-use product contains the sodium salt of asulam which is very highly soluble.

Asulam is stable to hydrolysis at pH's of 5, 7, and 9 in the absence of light. Although this chemical photodegrades very rapidly in aqueous solution at pH 9, with a half-life of 2 hours, no degradation products were present at levels greater than 10 percent of the applied. On sandy loam soil, asulam was found to be readily photodegradable with a half-life of 1.5 hours.

Sulfanilamide, the major degradation product formed on soil, was present at 27.4 percent of the applied two hours after exposure to light. Based on the low vapor pressure of asulam, volatilization from soils will not be an important dissipation route. The low octanol/water partition coefficient suggests that asulam will have a low tendency to accumulate in fish.

Based on supplemental data, asulam is much less persistent under aerobic than anaerobic soil and aquatic conditions. If asulam moves into anaerobic conditions, then biotic metabolism is greatly

reduced and leaching potential is enhanced. Asulam degraded with half-lives of 8 days in sand, 28 days in sandy loam, and 23 days in loam soils under aerobic conditions whereas it degraded very slowly in sandy loam soil under anaerobic conditions, where the half-life was greater than 1 year. Asulam degraded with a half-life of 105 days in an aerobic aquatic metabolism study.

Sulfanilamide was the major degradate detected in the aerobic/anaerobic soil, and anaerobic/aerobic aquatic metabolism studies. Acetyl asulam (14.3% of the applied at 7 days) was only found in the soil incubated under anaerobic soil/aquatic environment.

Asulam is expected to be very mobile due to its low soil adsorption coefficients (K_{ads}=0.6-1.0; or K_{oc}=18-115). Results from the column leaching studies for unaged and aged asulam residues showed that the parent compound has a high potential for leaching. Although no mobility studies were conducted for the major degradate (sulfanilamide), based on the aged leaching study for asulam, sulfanilamide showed low mobility.

In the unaged leaching study, asulam residues in the leachates of all four soils totaled 88.7-to-98.4 percent of the applied; the residues remaining in the soil columns averaged 0.5-to-4.1 percent of the applied, and were evenly distributed throughout the length of the columns. Asulam was the only compound isolated from the leachates.

In the aged leaching study, asulam was the only compound identified in the leachates, which contained 77 percent of the applied to the sand soil column, 60-to-61 percent of the applied to the sandy loam, 47-to-52 percent of the applied to the sandy clay loam, and 52-to-55 percent of the applied to the clay loam. Asulam residues remaining in the soil ranged from 14-to-17 percent in the sand to 44-to-46 percent in the sandy clay loam columns. Small amounts of asulam and sulfanilamide were detected in the leached soil columns.

The dissipation of asulam in the field cannot be confirmed at this time because the registrant has not submitted any acceptable field dissipation data. Asulam has the physical/chemical characteristics in common with those pesticides that are known to leach to ground water or run off to surface water.

The field dissipation/small-scale prospective ground-water monitoring study provided little conclusive information due to the

problems of residue analysis in the soil; however, it is adequate to allow the Agency to conclude that asulam will likely reach ground water especially under the shallow ground-water conditions associated with sugarcane usage. Results from an asulam drinking water survey of surface water indicates the presence of low levels of asulam (0.1 ppb) at the intakes to community water systems. This demonstrates the ability of the compound to move offsite into surface water.

Although the studies to support the soil/aquatic metabolism data requirements can be upgraded and other data requirements have been fulfilled, the lack of acceptable field dissipation data and the concerns about the integrity of data from the laboratory studies limit the Agency's ability to assess with confidence the environmental fate of asulam. The above assessment of the environmental fate of asulam was, in part, based on unreliable data. As a result, the fate, ground and surface water assessments of asulam may change after review of the additional data being required.

Based on the available data (including those from unreliable studies), asulam has the following characteristics: 1) highly to very highly soluble, 2) stable in water without light, 3) unstable in water and on soil under light; however, small amounts of asulam were detected in surface water, 4) relatively unstable in soil under aerobic conditions, 5) very stable in soil and sediment under anaerobic conditions, 6) very mobile in soil, 7) not volatile, and 8) does not accumulate in fish. With these properties, it appears that asulam is highly mobile and has a strong potential to leach into ground water or move offsite into surface water.

The Agency has concluded from the small-scale prospective ground-water studies that asulam will likely reach ground water especially under the shallow ground-water conditions associated with sugarcane usage.

Level of Concern (LOC) criteria for asulam were exceeded for both mobility and persistence. A weight-of-evidence evaluation for the occurrence of low levels of asulam in the surface and ground-water samples, and its low human and aquatic toxicity indicated that the risk posed will likely not be significant.

b. Environmental Fate and Transport

(1) Degradation

Hydrolysis

Asulam does not hydrolyze in basic and neutral sterilized water, but does hydrolyze very slowly in acidic environments. Uniformly ring-labeled [^{14}C]asulam was stable in pH 7 and 9 sterile aqueous buffered solutions that were incubated in the dark at 25° (+/- 1°) Celsius for 31 days. Asulam degraded slightly in pH 5 solution; by 31 days posttreatment, one unidentified compound increased in formation, comprising 4.4 to 4.9 percent of the applied radioactivity. The requirement for hydrolysis data (161-1) has been satisfied. (MRID 40997901)

Photodegradation in water

Asulam is unstable to photolysis in water. Uniformly ring-labeled [^{14}C]asulam photodegraded with a half-life of 2 hours in sterile aqueous pH 9 buffer solution that was irradiated with artificial light (xenon arc lamp) continuously for 22 days. No degradation products were present in greater than 10 percent of the applied during the course of the study. The half-life of asulam under dark conditions was not calculated by the registrant because degradation was not significant. The requirement for photolysis in water data (161-2) has been satisfied. (MRID 41326001)

Photodegradation on soil

Uniformly ring-labeled [^{14}C]asulam photodegraded rapidly (half-life = 1.5 hours) on sandy loam soil samples that were continuously irradiated with an artificial light source (xenon lamp) at 25-28^{o}C for up to 9 hours. The half-life of asulam in the dark control samples was 83 hours. Sulfanilamide, the major degradation product detected in the study, was present at 27.6 percent of the applied two hours after exposure to light. The requirement for photodegradation on soil data (161-3) has been satisfied. (MRID 41326002)

Aerobic soil metabolism

The submitted aerobic soil metabolism study was reviewed and found to be unacceptable for the following reasons:

* The results of the study could not be evaluated by the Agency at this time because information on the storage conditions (such as temperature) and length of storage of the soil samples prior to extraction were not provided. Based on the storage stability experiment for a field dissipation/small-scale prospective ground water monitoring study, the recovery of soil-spiked asulam and sulfanilamide decreased with time under storage at freezing conditions. Recoveries from soils analyzed immediately after spiking were good and reproducible. However, the recoveries of asulam and sulfanilamide from the soil samples from freezing storage were very poor. Only 9 and 45 percent of the spiked asulam and sulfanilamide, respectively, were recovered 14 days after freezing storage. After 75 days of storage at freezing temperature, the recoveries were less than 2 percent and 31 percent for the applied asulam and sulfanilamide, respectively. It appears that the decline of recovery for soil-spiked asulam and sulfanilamide does not have a linear relationship with the length of time during freezing storage.

* Results from this storage stability study suggested that the length of storage of the soil samples at freezing temperature would significantly affect the ratio between the extractable and unextractable residues, and subsequently affect the percentage of residues to be characterized and identified.

* Theoretically, the soil-spiked asulam should be recovered readily in the storage stability study based on the following reasons: (1) chemicals are usually metabolically stable at freezing temperature due to the lack of active microorganisms; (2) asulam is unsusceptible to hydrolysis; (3) asulam has a low tendency to bind with soil (K_d=0.6-1.0; or K_{oc}=18-115). Although asulam was reportedly photolytically unstable

in water and on the surface of soil, these routes are unlikely to have a significant role in the low recovery of asulam in freezing storage because the soil samples are usually kept in the dark in the refrigerator/freezer.

However, this study is upgradable. The registrant must: 1) submit adequate soil storage data for this study, and 2) evaluate and validate the findings in this study, based on results from the required storage stability study.

Results from this study are summarized below:

The degradation of asulam in soil appears to be microbiologically mediated under aerobic conditions (with half-lives ranging from 8-to-28 days). Asulam degraded with half-lives of 8 days in sand, 28 days in sandy loam, and 23 days in loam soils that were incubated in the dark at 20 °C and 75 percent of field moisture capacity. Three major compounds other than asulam were isolated from the soils. These included sulfanilamide and two compounds which were only characterized as the ionic or conjugated form of asulam. The registrant did not explain what was meant by ionic or conjugated form of asulam. However, since harsh measures (acid-base extraction) were taken to extract these degradates, data on the structural identity of these degradates would be of little value. Therefore, no additional data on the identity of these degradates is required.

In the sandy soil, asulam was 56.5-to-63.5 percent of the applied immediately posttreatment, and decreased to 2.8 percent at 37 days. Between 0 and 37 days posttreatment, the alternative ionic form of asulam decreased from an average of 22.7-to-0.5 percent of the applied, and the conjugated form of asulam ranged from 0.8-to-6.2 percent. Sulfanilamide was 1.4-to-3.6 percent of the applied between 0 and 18 days posttreatment. Conjugated acetyl asulam, conjugated acetyl sulfanilamide, and methylbenzenesulfonyl carbamate were identified in the soil in trace amounts. (MRID 41326002)

Anaerobic soil and aquatic metabolism

The submitted anaerobic aquatic soil metabolism study was reviewed and found to be unacceptable for the same reasons as described above in the aerobic soil metabolism section. However, this study is upgradable using the same procedure as noted above in the aerobic soil metabolism section.

Results from this study are summarized below:

Asulam appears to be relatively stable in sandy loam soil under anaerobic conditions (estimated half-life greater than 1 year). Asulam was relatively stable in sandy loam soil that had been incubated in the dark at 20 °C under anaerobic conditions (estimated half-life greater than 1 year). Five compounds other than asulam were detected in this study. These included sulfanilamide, acetyl asulam, and three compounds which were only characterized as the ionic or conjugated form of asulam. The registrant did not explain what was meant by ionic or conjugated form of asulam. However, since harsh measures (acid-base extraction) were taken to extract these degradates, data on the structural identity of these degradates would be of little value. Therefore, no additional data on the identity of these degradates is required.

The conjugated form of asulam was a maximum of 23.8 percent of the applied at 1 day posttreatment, then decreased to an average of 9.4 percent by 366 days. The first alternative ionic form of asulam (designated as Metabolite 2) was a maximum of 10.7 percent of the applied at 30 days, and the other alternative ionic form (designated as Metabolite 3) was a maximum of 2.9 percent at 260 days. Acetyl asulam was a maximum of 14.3 percent of the applied at 7 days. Sulfanilamide was a maximum of 3.6 percent of the applied at 366 days. (MRID 41767802)

Aerobic aquatic metabolism

The submitted aerobic aquatic soil metabolism study was reviewed and found to be unacceptable for the same reasons as described above in the aerobic soil metabolism section.

In the 1987 Registration Standard for asulam, aerobic aquatic metabolism (162-4) studies were required because, at

that time, it was used on ditch banks. Since the registrant has deleted the ditch bank use on the label (EPA Registration Number 264-447), this data requirement is no longer applicable. However, the above study was still reviewed by the Agency because it would provide additional information about the fate of asulam in the aquatic environment.

If the registrant decides to add the aquatic use of asulam on the label in the future, he/she can submit additional storage information to upgrade this study.

Results from this study are summarized below:

Asulam appears to be relatively stable in the loam soil/water system under anaerobic conditions (with a half-life of 105 days). Asulam degraded with a half-life of approximately 105 days in an aerobic sandy loam soil/water system that was incubated in the dark at 20 °C. Four compounds other than asulam were detected in this study. These included sulfanilamide, and three compounds which were only characterized as the ionic or conjugated form of asulam. The study report did not explain what was meant by ionic or conjugated form of asulam. However, since harsh measures were taken (acid-base extraction) to extract these degradates, data on the structural identity of these degradates would be of little value. Therefore, no additional data on the identity of these degradates are required.

The conjugated form of asulam increased from 2.8 percent of the applied immediately posttreatment, to 4.9 percent at 30 days, and to a maximum of 6.1 percent at 273 days. Two alternative ionic forms of asulam were present at a maximum of 7.8 and 19.8 percent, respectively, at 30 days. Sulfanilamide was not found until day 15; it reached a maximum of 2.2 percent at 273 days posttreatment. (MRID 41767801)

(2) Mobility

Leaching and adsorption/desorption

Information on the mobility of asulam in an aquatic sediment required by the Agency prior to November 8, 1989, is no longer needed because the registrant has deleted the ditch

bank use of asulam on the label (EPA Registration Number 264-447). However, these studies were reviewed by the Agency because of their value in providing additional understanding of the fate of asulam in the environment.

Results from these studies are summarized below:

Asulam is highly mobile in soil and has a strong potential to leach into ground water or move offsite into surface water. Data from the batch equilibrium study (Godward, 1988) indicate that asulam is very mobile in autoclaved sand, clay loam, sandy clay loam, and sandy loam soils, with Freundlich K_{ads} values of 0.4-1.0 (K_{oc}=18-115). Freundlich K_{des} values ranged from 0.5-1.6 (K_{oc}=20-127).

The mobility of asulam and its aged residues was further confirmed in the column leaching study (Reeves, et al., 1988). Following leaching, asulam was the only compound identified in the leachates, which contained 77 percent of the radioactivity applied to the sandy soil column, 60-to-61 percent of the applied to the sandy loam, 47-to-52 percent of the applied to the sandy clay loam, and 52-to-55 percent of the applied to the clay loam. Residues remaining in the soil ranged from 14-to-17 percent in the sand to 44-to-46 percent in the sandy clay loam columns; the majority of the residues remaining in the soil were located in the upper 6 cm of the soil columns and were unextractable with acetone.

The batch equilibrium study and the column leaching study are found to be acceptable to support the Leaching-Adsorption/Desorption data requirements. However, the Agency has concerns about the use of autoclave for sterilization of soils. The Agency believes that physical or chemical sterilization may indirectly alter the soil chemistry, thus complicating the interpretation of the results obtained in the batch equilibrium study.

Because the soil samples for the above studies were combusted to determine the total residues (including extractable as well as unextractable residues), the length of freezing storage of these samples is unlikely to affect the findings. The concentration of asulam and sulfanilamide in the aqueous

samples did not appear to decline during the storage in the refrigerator.

Results from the column leaching study along with the batch equilibrium study have clearly demonstrated the potential for asulam to leach in the environment. The leaching and adsorption/desorption data requirement has been satisfied by the submitted column leaching and batch equilibrium studies. No additional information on the mobility of asulam and its degradation products in soil is needed at this time. (MRIDs 41215101 and 40965001)

(3) Accumulation

Accumulation in Irrigated Crops

Regarding accumulation in irrigated crops (165-3), no data are required. There are no registered aquatic uses for asulam.

Bioaccumulation in Fish

Because the octanol/water partition coefficient for asulam is very low (K_{ow}=1.01), a bioaccumulation in fish study (165-4) is waived.

Accumulation in Aquatic NonTarget Organisms

At this time, there are no registered aquatic uses for asulam; therefore an accumulation in aquatic nontarget organism study (165-5) is not required.

(4) Field Dissipation

Terrestrial

Three progress reports for the field dissipation/small-scale prospective ground-water monitoring studies (164-1 and 166-1, respectively) were reviewed. These progress reports are found to be unacceptable to support the Field Dissipation (164-1) data requirement. Reasons are presented below:

* The soil residue data were invalid because the analytical methods (including the primary Analytical Method #7 and many other modified methods) could not effectively extract and recover asulam and sulfanilamide in the soil samples which were stored in the freezer for more than 10 months.

* Claims made in the submitted information were that the residues of asulam and sulfanilamide in soil were either very strongly bound or rapidly degraded (a claim contradictory to the results of other laboratory studies), resulting in poor method recoveries. However, no information has been provided to explain why the recoveries of asulam and sulfanilamide were so low, even for the spiked soil which was kept at freezing temperature for a relatively short period of time.

Since the field dissipation/small-scale prospective ground-water monitoring studies are unlikely to provide any additional information to support the Field Dissipation Data Requirement (164-1), the final report does not need to be submitted.

Aquatic

At this time, the aquatic field dissipation data requirement (164-2) is not applicable because there are no registered aquatic uses for asulam.

Forestry

At this time, the forestry field dissipation data requirement (164-3) is not applicable because there are no registered forestry uses for asulam.

Combination and Tank Mixes

At this time, combination and tank mixes data requirement (164-4) is not applicable because there are no registered combination and tank mix uses for asulam.

Long-Term

At this time, long-term field dissipation data (164-5) are not required because the Agency believes that the required storage stability study (to investigate the fate of asulam residues in soil under freezing storage) along with the field dissipation/small-scale prospective ground-water monitoring study will provide sufficient information for the understanding of the fate of asulam in the field.

(5) Spray Drift

The registrant is required to submit data to support the Spray Drift data requirements because aerial application of asulam (EPA Registration Number 264-447) can cause damage to nontarget plants due to spray drift. Rhone-Poulenc Ag Company is a member of the Spray Drift Task Force (SDTF), and therefore, may elect to satisfy these data requirements through the SDTF. If the registrant wishes to satisfy these data requirements in this manner, the procedures outlined in PR Notice 90-3 should be followed.

c. Water Resources

(1) Ground Water

Although the small-scale prospective ground-water monitoring (166-1) data requirement has not been satisfied, no additional prospective ground-water studies will be required at this time. Additional prospective ground-water study requirements will be placed in reserve. Should long-term monitoring demonstrate that unacceptable contamination of ground water by asulam occurs in some use areas, further restrictions on use could be necessary.

Three small-scale prospective ground-water studies were required to determine the circumstances under which asulam might leach into ground water. These reports detail the results of three small-scale prospective ground-water studies and one drinking water study for asulam (MRIDs 41561103, 42224701, 42534501, 41803901, 42704901).

The ground-water studies were conducted at three sites in the United States: a turf site in Florida, a sugarcane site in Florida, and a sugarcane site in Louisiana. Due to the serious problems of residue analysis in the soils, and dry wells at the Louisiana site, little conclusive information concerning the potential leaching of asulam into ground water was derived from the studies. However, they are adequate to allow the Agency to conclude that asulam will likely reach ground water especially under the shallow ground-water conditions associated with sugarcane usage.

(2) Surface Water

Results from the drinking water survey (pertaining to drinking water derived from surface water sources) indicate the presence of asulam (0.1 ppb) at the intakes to the community water systems. Earlier data indicated that asulam residues would degrade in aerobic aquatic conditions and not be carried far from the site of application in surface water. This study demonstrates asulam may move offsite into surface water.

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk
acute RQ>	0.2	Risk that may be mitigated through restricted use
acute RQ>	0.1	Endangered species may be affected acutely
chronic RQ> 1		Chronic risk, endangered species may be affected chronically,

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ>	0.5	High acute risk
acute RQ>	0.1	Risk that may be mitigated through restricted use
acute RQ>	0.05	Endangered species may be affected acutely
chronic RQ> 1		Chronic risk, endangered species may be affected chronically

Plants

IF THE	LOC	PRESUMPTION
RQ>	1	High risk
RQ>	1	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Terrestrial Animals Acute Risk

Avian and mammalian organisms may be exposed to asulam through the consumption of food items (i.e. grasses, insects, seeds and fruit) containing asulam residues. Calculations of expected environmental residues are based on the work by Hoerger and Kenaga (1972).

A maximum application of 6.7 lbs asulam on non-cropland (i.e. rights-of way) is expected to produce maximum residues on avian and mammalian food items of 47 ppm (fruit) to 1608 ppm (short grass) and typical residues of 10 ppm to 837 ppm.

As neither data on acute oral nor subacute dietary testing are available for technical asulam, the avian dietary LC_{50} for the 60 percent formulation (75,000 ppm) was adjusted to 100 percent a.i. (45,000 ppm). As the maximum expected residue of 1608 ppm falls short of the high level of concern (0.5 LC_{50} = 22,500), adverse acute effects to nontarget avian species are not expected from the proposed reregistration of asulam.

The mammalian LC_{50} value can be estimated using the following formula:

LC_{50} = LD_{50} x body weight (g)/ daily food consumption (g)

LC_{50} = 5,000 mg/kg x 0.10 kg/10 g = 50,000 ppm (young rat)

Therefore, an LD_{50} of 5,000 for the rat would convert to an LC_{50} of 50,000 ppm. As the maximum expected residue of 1608 ppm falls short of the high level of concern (0.5 LC_{50} = 25,000), adverse acute effects to nontarget mammalian species are not expected from the proposed reregistration of asulam.

(b) Terrestrial Animals Chronic Risk

Chronic effects to avian species cannot be assessed at this time due to lack of avian reproduction

data. However, the Agency believes there is little potential for adverse effects to avian reproduction as the available environmental fate information indicates that photolysis in water and soil is very rapid -- approximately 2 hours. Although asulam may be applied more than once to sugarcane and Christmas tree plantations, a scenario reflecting the decline of residues on long grass treated at 3.3 lbs ai/A showed maximum residues of 367 ppm immediately after application dissipating to less than 1 ppm within one day. Even allowing for a repeat application after 14 days, the average residues would only be 23 ppm. Furthermore, any residue not exposed to sunlight but subjected to rainfall will rapidly move from the area through either leaching or surface runoff due to asulam's high mobility. In addition, asulam has a very low potential for bioaccumulating in birds based on the K_{ow} of 1.0. Lastly, the major degradate -- sulfanilamide -- need not be tested as it comprised only 27.6% of the applied parent in the soil photodegradation study. Therefore, avian reproduction studies on the bobwhite quail and mallard duck (71-4 a,b) are not required at this time.

Based on the overlap between the LOEL range of 1000 ppm to 5000 ppm for mammalian reproduction and the maximum expected residues on mammalian food items (1608 ppm on short grass), use of asulam on noncropland (maximum 6.7 lbs a.i./A) may exceed levels of concern (EEC/LOEL range) for mammalian reproduction (risk quotient range of 0.32 to 1.6). The LOC for mammalian reproduction is not surpassed when compared to the typical (i.e. average) residues on short grass (837 ppm). In addition, rights-of-way are more likely to have long grass than short grass (typical for turf sites). Even when compared to the maximum expected residues on long grass (737 ppm), the LOC for mammalian reproduction is not exceeded. Therefore, the Agency concludes that the use of asulam on noncropland at the maximum use rate, or any other use site, is not likely to adversely affect mammalian reproduction.

(c) Insects

Asulam may be applied during the flowering time of a variety of nontarget plants. Thus, there is the potential of exposure to honey bees from asulam use. However, minimal risk to these organisms is expected as asulam is practically nontoxic to honey bees (LD_{50} > 36.26 ug/bee).

(2) Exposure and Risk to Nontarget Aquatic Animals

(a) Acute Risk

Aquatic fauna may be exposed to asulam residues via runoff and/or drift to water bodies or through an inadvertent direct application to water. A direct application of asulam to water would result in an estimated environmental concentration (EEC) of 408 ppb in six feet of water [61 ppb x 6.7 lbs ai/A = 408 ppb].

As the aquatic EEC does not surpass the high level of concern (0.5 LC_{50}) for the most sensitive fish species (0.5 LC_{50} = >87 ppm for the rainbow trout) or the most sensitive aquatic invertebrate species (0.5 LC_{50} = 13 ppm for *Daphnia magna*), acute risk to aquatic fauna are not expected from the proposed reregistration of asulam.

(b) Chronic Risk

Chronic effects to fish and aquatic invertebrates cannot be assessed at this time due to lack of data. However, the Agency is concerned with adverse effects to these organisms as the available environmental fate information indicates that asulam is possibly persistent and has a high potential to move to ground and surface water. In addition, the unrefined aquatic EEC for a direct application to 6 feet of water (408 ppb) exceeds 0.01 EC_{50} (270 ppb) for *Daphnia magna*. Asulam may also be applied more than once to sugarcane and possibly to Christmas tree plantations and non-cropland areas (label does not specify). Therefore, a life-cycle aquatic invertebrate study with *Daphnia magna* (72-4b) is required at this time. The early life-stage fish study (72-

4a) is in reserve status pending results of the daphnia life-cycle study.

(3) Exposure and Risk to Nontarget Plants

Exposure of nontarget terrestrial and aquatic plants to asulam is based on expected runoff from ground applications and from runoff and drift from aerial applications (sugarcane and Christmas tree plantations).

(a) Terrestrial and Semi-aquatic

Terrestrial plant EEC's are calculated by estimating the runoff from one acre treated at the maximum application rate to an adjacent one acre site. Semi-aquatic plant EEC's are calculated by estimating the runoff from a 10 acre site treated at the maximum application rate to an adjacent one acre wetland area. For example, at a maximum ground application rate of 6.7 lbs a.i./A (non-cropland) and anticipated 5 percent runoff of applied pesticide, runoff into areas adjacent to treated sites is expected to be 0.33 lbs. a.i./A (see table below). Runoff into a wetland area (i.e., moist, saturated or flooded soils) away from treated sites is expected to be approximately 3.3 lbs a.i./A.

Estimated Environmental Concentrations and Risk Quotients								
USE SITE	**MAX. APPL. RATE (LBS A.I./A)**	**LEVEL OF CONCERN**[1]	**TERR. PLANTS ADJACENT TO USE SITE**		**SEMI-AQUATIC PLANTS IN WET AREAS AWAY**		**AQUATIC PLANTS**	
			EEC[2] **(lbs ai/A)**	**Risk Quot.**	**EEC**[2] **(lbs ai/A)**	**Risk Quot.**	**EEC**[2] **(ppm)**	**Risk Quot.**
Noncrop (rights-of-way, industrial,fences)	6.68	EC_{25} = 0.08 EC_{25} = 0.0002 EC_{50} = 0.14	0.33	4.1	3.3	41	0.2	1.5
Sugarcane, Christmas tree plantations, ornamentals	3.34	EC_{25} = 0.08 EC_{50} = 0.14	0.17 0.27[3] 0.17[4]	2.1 3.8[3] 850[4]	1.7 1.2[3] 0.17[4]	21 17[3] 850[4]	0.10 0.07[3]	0.73 0.51[3]
Turf	2.10	EC_{25} = 0.08 EC_{50} = 0.14	0.10	1.2	1.0	12	0.064	0.46
Rights-of-way (Sec. 24C PA)	1.67	EC_{25} = 0.08 EC_{50} = 0.14 EC_{25} = 0.0002	0.08 0.13[3] 0.08[4]	1.1 1.8[3] 400[4]	0.8 0.58[3] 0.08[4]	11 8[3] 400[4]	0.05 0.03[3]	0.35 0.21[3]

1. Levels of Concern: a) terrestrial plants - lowest EC_{25} value (lettuce shoot length) = 0.08 lbs a.i./A for seedling germination and emergence tests; this value is compared to runoff alone and runoff plus drift calculations; lowest EC_{25} value (cucumber root weight) = 0.0002 lbs a.i./A for vegetative vigor; this value is compared to drift calculations; b) aquatic plants - lowest EC_{50} value from aquatic plant studies (*Lemna gibba* EC_{50} = 0.14 ppm).
2. EEC values are based on runoff from ground applications, except where noted for aerial applications to sugarcane and Christmas tree plantations.
3. EEC value and corresponding risk quotient for aerial application (runoff and drift).
4. EEC value and corresponding risk quotient for aerial application (drift only).

A high level of concern exists for both endangered and non-endangered terrestrial and semi-aquatic plants if the EEC exceeds the EC_{25} value for the most sensitive plant species tested or, in other words, the risk quotient is greater than 1.0. In the above table, the shaded areas indicate that the high level of concern for endangered and non-endangered terrestrial and semi-aquatic plants has been exceeded for all use patterns.

The Agency has a fairly high degree of certainty concerning these LOC exceedences for terrestrial and semi-aquatic plants. Asulam is an herbicide which is designed to kill plants. Therefore, it is almost a given that LOC's will be exceeded. By how many times the LOC's are exceeded is another question. There is an even higher certainty that the use of asulam will adversely

affect nontarget semi-aquatic plants as the risk quotients are higher. Drift from aerial applications will certainly pose a hazard to nontarget terrestrial and semi-aquatic plants as the risk quotients are 400 - 850. The EC_{25} value (cucumber root weight) used for the drift calculations was extrapolated from the data because the laboratory failed to test at sufficiently low concentrations to determine an EC_{25}. When this test is repeated it is expected that the EC_{25} value may be even lower, thus, increasing the magnitude by which the LOC's are surpassed.

(b) Aquatic

Aquatic EECs are calculated using the estimated runoff from 10 acres treated at the highest registered rate flowing into a 1 acre water body, six feet deep. For example, at a maximum application rate of 6.7 lbs a.i./A (non-cropland) to a 10 acre watershed with anticipated 5 percent runoff of applied pesticide, the concentration of asulam in six feet of water is expected to be 0.2 ppm.

A high level of concern exists for both endangered and non-endangered aquatic plants if the EEC exceeds the EC_{50} value for the most sensitive plant species tested or, in other words, the risk quotient is greater than 1.0. In the above table, the shaded areas beneath the aquatic plants heading indicate that the high level of concern for endangered and non-endangered aquatic plants has been exceeded for the non-cropland use pattern only. Because the risk quotient is fairly low (1.5), a refined aquatic risk assessment will most likely reduce the EEC below the level of concern.

(4) Endangered Species

Based on the conclusions in the preceding sections of this risk assessment, all registered uses of asulam might pose a significant risk to endangered terrestrial and semi-aquatic plant species inhabiting areas adjacent to treated sites and those in wet, low-lying areas farther away from treated sites. Use of asulam on non-cropland areas (i.e., rights-of-way, fence rows) might pose a risk to nearby endangered aquatic plant species as well.

All endangered plant species inhabiting certain target areas (i.e., rights-of-way) are likely to be jeopardized as they will receive a direct application of asulam.

The Endangered Species Protection Program is expected to be implemented in the future. Limitations on the use of asulam will be required to protect endangered and threatened species, but these limitations have not yet been defined (and may be formulation specific). OPP anticipates that consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county bulletins.

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 the generic (i.e., active ingredient specific) data required to support reregistration of products containing asulam and its sodium salt as active ingredients. The Agency has completed its review of these generic data, and has determined that based on the information currently available, there are data to support reregistration of all products containing asulam and its sodium salt; however, a reregistration eligibility decision on products registered for use on sugarcane cannot be made at this time for reasons discussed in Section IV.A.1. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of asulam and its sodium salt, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of asulam and its sodium salt. The Agency has determined that except for the use on sugarcane, asulam and its sodium salt can be used without resulting in unreasonable adverse effects to humans and the environment. To ensure that the potential risks of asulam are not unreasonable, the Agency is requiring the registrant to implement certain risk mitigation measures. Provided these risk mitigation measures are implemented, the Agency finds that all products containing asulam and its sodium salt as the sole active ingredient are eligible for reregistration

for all uses with the exception of sugarcane. The reregistration of particular products is addressed in Section V of this document.

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, published scientific literature, etc. and the data identified in Appendix B. The Agency has found that all uses of asulam and its sodium salt, except for sugarcane, 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 the registration of products containing asulam and its sodium salt, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients asulam and its sodium salt, the Agency has sufficient information on the health effects of asulam and its sodium salt and on its potential for causing adverse effects in fish and wildlife and the environment. Although levels of concern are exceeded for endangered and non-endangered plant species and surfacewater and groundwater quality, the Agency concludes that products containing asulam and its sodium salt for all uses, with the exception of sugarcane, once amended to reflect the risk mitigation measures imposed in this RED, are eligible for reregistration.

The Agency is unable to make a reregistration eligibility decision on the use of asulam and its sodium salt on sugarcane because data show that asulam concentrates in the processed animal feed commodity, blackstrap molasses. Under current policies, the establishment of the necessary feed additive regulation (tolerance) to cover residues in this commodity may be barred by the Delaney clause of Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) because asulam may induce cancer in animals within the meaning of the Delaney clause.

2. Eligible and Ineligible Uses

The Agency has determined that the use of asulam and its sodium salt on the following use sites are eligible for reregistration: Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass), and non-cropland (boundary fences, fencerows, hedgerows, lumberyards, storage areas, industrial plant sites, and warehouse lots). The decision for the use of asulam and its sodium salt on sugarcane cannot be made at this time because a feed additive regulation for blackstrap molasses may be required.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR §180.360

The tolerances listed in 40 CFR §180.360 are for residues of asulam *per se* on sugarcane. The tolerance expression must be revised to include all metabolites containing the sulfanilamide moiety. A summary of the asulam tolerance reassessment is presented in Table III.

The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies. The residue of concern in milk, eggs, and animal tissues is asulam and its metabolites containing the sulfanilamide moiety. The only ruminant feed item containing asulam is molasses; there are no poultry feed items. Magnitude of the residue studies in ruminants conducted at a slightly exaggerated rate (2X) show that quantifiable residues of asulam and its sulfanilamide-containing metabolites in ruminant commodities from a 1X dietary exposure do occur in meat, meat byproducts, and milk, but not in fat. Therefore, ruminant commodity tolerances are needed, as presented in Table III.

Processed Food (40 CFR §185) and Feed (40 CFR §186) Tolerances

No food/feed additive tolerances have been established for asulam. An adequate processing study has been conducted with sugarcane for asulam and its metabolites containing the sulfanilamide moiety. A tolerance proposal is needed for residues of asulam and its metabolites containing the sulfanilamide moiety in the sugarcane processed commodity blackstrap molasses at 48X the reevaluated tolerance. An appropriate tolerance would be 720 ppm, based on the revised tolerance of 15 ppm for sugarcane.

However, as noted previously, the Agency may be barred from establishing a food or feed additive tolerance for blackstrap molasses because of the Delaney clause of FFDCA. This clause prohibits the establishment of a regulation for any food/feed additive that is found to induce cancer in man or animals. The Ninth Circuit Court of Appeals has ruled that EPA must interpret this provision strictly. Therefore, since asulam may be found to be an animal carcinogen within the meaning of the Delaney clause, EPA may not be able to establish a processed feed tolerance for blackstrap molasses. Further, under

current Agency policy if a food/feed additive tolerance cannot be established due to the Delaney clause, EPA will neither establish nor continue in effect a tolerance for the associated raw agricultural commodity. As part of the settlement agreement in a recent court case challenging the Agency's implementation of the Delaney clause (California vs. Browner), the Agency committed to a schedule for determining whether revocation was warranted for raw agricultural commodity tolerances where a food/feed additive tolerance was needed or established and the pesticide at issue possibly was a carcinogen within the meaning of the Delaney clause. These decisions are to be made in three groups beginning in October 1995, with final revocation, if necessary, for all three groups scheduled for no later than 2000.

Because final revocation, if necessary, is likely to be several years away, the Agency believes it would be important to revise the existing raw agricultural commodity tolerance for sugarcane from the current 0.1 ppm to 15 ppm consistent with new cropfield trial data and to establish new meat, milk and meat by-product tolerances. Current residue data suggest the existing tolerance should be raised to 15 ppm from 0.1 ppm. However, the registrant is submitting further additional data reflecting longer PHI's and more accurate timing of application which will likely result in a tolerance level lower than the 15 ppm. After reviewing these data, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk, and meat by-product tolerances.

These tolerances once established may ultimately be revoked as part of the commitment to review the underlying raw agricultural tolerance for sugarcane. The Agency recently announced certain modifications in its policies concerning which pesticide uses require a food/feed additive regulation (response to the NFPA Petition June 14, 1995; 60 FR 31300). These changes may effect the need for a feed additive regulation for asulam on blackstrap molasses. One of the policy decisions concerned "ready-to-eat" animal feeds and under what circumstances these feeds will need a food/feed additive regulation. Under this policy, it is possible that residues of asulam in blackstrap molasses may be adequately covered by the tolerance in the raw agricultural commodity (sugarcane) so that establishing a feed additive tolerance will be unnecessary. If it can be shown that blackstrap molasses is unpalatable when fed "as is," EPA will not categorize it as "ready-to-eat." Further, if EPA determines that once blackstrap molasses is mixed with other feed items before feeding and this mixing dilutes the asulam residues such that

they are below the raw agricultural commodity tolerance level, it will not be necessary to establish a feed additive regulation.

By amending and establishing tolerances for what may be an interim period, the Agency believes it is providing appropriate and responsive regulatory measures to avoid production of adulterated food which could be subject to possible crop and food commodity seizures. The Agency also believes this action will help keep any public misunderstanding or misconception regarding dietary risk from asulam to a minimum.

Table III. Tolerance Reassessment Summary

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerance listed under 40 CFR §180.360			
Sugarcane	0.1	15	Existing studies show that the current tolerance is exceeded and that residues are as great as 15 ppm (150X).
Milk	None	0.2	Based on evaluation of 50 ppm and 200 ppm feeding studies and a ruminant diet containing a maximum of 100 ppm asulam.
Cattle, meat	None	0.1	
Cattle, mbyp	None	0.6	
Goats, meat	None	0.2	
Goats, mbyp	None	0.6	
Hogs, meat	None	0.1	
Hogs, mbyp	None	0.6	
Horses, meat	None	0.1	
Horses, mbyp	None	0.6	
Sheep, meat	None	0.1	
Sheep, mbyp	None	0.6	

CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of asulam. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

2. Risk Mitigation

The Agency has determined that the current uses of asulam exceed levels of concern for endangered and nonendangered terrestrial and semi-aquatic plants for all uses. For noncropland uses, asulam exceeds LOCs for

endangered and nonendangered aquatic plants. Several risk mitigation measures proposed by the technical registrant, Rhone Poulenc, and accepted by the Agency are being required. These risk mitigation measures include reducing application rates, reducing number of applications per season, prohibiting aerial uses for noncropland and Christmas tree use sites, and adding groundwater and surface water label advisories. These risk mitigation measures are required for all asulam registrants.

The technical registrant, Rhone-Poulenc, has withdrawn the Pennsylvania SLN issued under FIFRA section 24(c) - aerial application on rights-of-way. Likewise, Rhone Poulenc is prohibiting the aerial uses of asulam for noncropland and Christmas trees use sites by voluntarily cancelling aerial application. Rhone-Poulenc is clarifying the noncropland use to be limited to 1 gallon/A rate, 1 application/season; clarifying the Christmas tree uses to be limited to 1 application/season; and clarifying the turf use to limit use to sod farms use only and 1 application/season. In addition, Rhone-Poulenc also agreed to clarify the environmental fate assessment methodology and the uncertainty associated with the extraction technique and recovery of asulam from the laboratory versus the field studies. The clarification of the recovery methodology will reduce the uncertainty associated with the environmental fate assessment.

Ground water and Surface water concerns: Due to ground water and surface water quality concerns, the following mitigation steps are required:

- Asulam has the potential to leach to ground water. Therefore all product labels must carry a ground water advisory. The label language for this advisory can be found in Section V of this document.

- Rhone-Poulenc is required to initiate long-term monitoring to determine if unacceptable contamination of ground water occurs in some use areas. Therefore, long-term monitoring in cooperation with the States and USGS is necessary.

- Asulam has the potential to move offsite to surface water. Therefore all product labels must carry a surface water advisory. The label language for this advisory can be found in Section V of this document.

3. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered plant species to asulam. Based on the conclusions discussed in the preceding sections of this risk assessment, endangered species LOCs are exceeded for terrestrial and semi-aquatic plants for all uses. Also, asulam exceeds the level of concern for endangered aquatic plants for noncropland uses.

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 eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species in the county. 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 in the Federal Register a description of the program and have available enforceable 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 requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

4. Labeling Rationale

a. Worker Protection

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7, which reflect the requirements of EPA' s labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR

Notice complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

Uses within the scope of the Worker Protection Standard

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, flowers, shrubs, ornamentals, and seedlings). Uses within the scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

Some of the registered uses of asulam are within the scope of the Worker Protection Standard (WPS) and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS include use:

- on plants grown for other than commercial or research purposes, which may include plants in home lawns, home gardens and home greenhouses,
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms are covered by the WPS).
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other noncrop areas.

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

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

1. If the Agency has no special concerns about the acute 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 will be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If the Agency has special concerns about an active ingredient due to 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, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational 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 each 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.

There are no special toxicological concerns about asulam that warrant the establishment of active-ingredient-based minimum PPE requirements.

Entry Restrictions

Entry Restrictions for Occupational-Use Products (WPS Uses)

Some of the registered uses of asulam are within the scope of the Worker Protection Standard (WPS).

Restricted Entry Interval -- Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. The WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-

specific REI's established on the basis of adequate data and (2) interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing asulam as an active ingredient, the Agency is maintaining the current a 12 hour REI pertaining to each use of the product that is within the scope of the Worker Protection Standard. The 12 hour REI is the minimum acceptable REI for asulam.

The WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. These existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with asulam. The WPS REI in effect until now was 12 hours.

Early Entry PPE -- The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval if the entry involves contact with treated surfaces. Among those restrictions, are a prohibition of routine entry to perform hand labor tasks and requirement that PPE be worn. Personal protective equipment requirements for persons who enter areas that remain under a restricted-entry interval and contact treated surfaces are based on the toxicity concerns about the active ingredient. The requirements are set in one of two ways.

1. If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements based on the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient or the minimum early-entry requirements specified under the Worker Protection Standard. The more protective PPE is to be used. These minimum WPS requirements are: coveralls, chemical resistant gloves, and shoes plus socks.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects, such as allergic effects, cancer, developmental toxicity, or reproductive effects, it may establish early entry PPE requirements that are more stringent than would be established otherwise.

The personal protective equipment for early entry is the minimum required under the WPS: coveralls, chemical resistant gloves, and shoes plus socks.

Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Some registered uses of asulam are outside the scope of the Worker Protection Standard (WPS). For nonWPS uses the Agency is requiring the following.

"Do not enter or allow others to enter the treated area until sprays have dried."

Homeowner-Use Products

There are no products containing asulam that provide directions intended for homeowner use. Current labelling provides the statement "for agricultural or commercial use only, not for use by homeowners." This statement is to be maintained.

b. Environmental Hazard

The Agency is requiring labeling to address risk to wetland areas. (Refer to Section V).

c. Spray Drift Advisory

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Spray Drift Task Force completes their studies, submits data, and the Agency evaluation is completed, there may be further refinements in spray drift management practices.

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 asulam and its sodium salt for the above eligible uses has been reviewed and determined to be substantially complete.

In summary, based on the information currently available to the Agency, all uses of asulam are eligible for reregistration, with the exception of **sugarcane.** Furthermore, the Agency is requiring that additional confirmatory data be submitted to fulfill the generic data requirements for reregistration of asulam.

Chronic Aquatic Invertebrate Toxicity - *Daphnia Magna*
Aerobic Soil Metabolism
Anaerobic Soil and Aquatic Metabolism
Droplet Size Spectrum
Drift Field Evaluation

Directions for Use - Label amendment (lower application rate and/or longer PHI)
Plant Metabolism Study
Magnitude of Residue - Sugarcane
Confined Rotational Crop

After reviewing additional field trial data for sugarcane, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk and meat by-product tolerances.

Certain data are not part of the reregistration target database for asulam, but are also required:

Seedling emergence - soybeans and radish
Vegetative vigor - cucumber and onion

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 herbicide for the following uses(s): _ _____ (fill blank only with those uses that are being supported by MP registrant)."

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, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such uses(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 uses(s) and the Agency has registered the end-use products being produced."

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 G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) 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. Worker Protection

(1) Personal Protective Equipment/Entry Restrictions; Labeling

<u>Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)</u>

The PPE for mixer/loader/applicators is to be based on the acute toxicity of the end-use product.

Entry Restrictions for Occupational-Use Products (WPS Uses)

Based on the assessment of human health risks, the Agency does not believe an increase in the REI above what is required in the Worker Protection Standard (WPS) is warranted. The current 12 hour REI, pertaining to each use of the product that is within the scope of the WPS, is to be maintained. This 12 hour REI is the minimum acceptable REI for asulam.

Early Entry PPE: The PPE for early entry are the minimum that would be required under the WPS. These are: coveralls, chemical-resistant gloves, shoes, and socks.

Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Some registered uses of asulam are outside the scope of the Worker Protection Standard (WPS). For nonWPS uses the Agency is requiring the following.

"Do not enter or allow others to enter the treated area until sprays have dried."

(2) Other Labeling Requirements

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

(a) Products Intended Primarily for Occupational Use

Engineering Controls Used

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard for Agricultural Pesticides (WPS) [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS. However, full PPE must be available in the event that the handler exits the aircraft, enclosed cab, etc. prior to the REI."

User Safety Requirements

"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 Statements

"Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users must leave the treated area, and remove clothing immediately if pesticide gets inside."

"Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing."

Application Restrictions

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

(b) Homeowner-Use Products

There are no products containing asulam that provide directions intended for homeowner use. Current labelling provides the statement "for agricultural or commercial use only, not for use by homeowners." This statement is to be maintained.

b. Environmental Hazard Statements

The labels of all asulam end-use products must be revised to bear the following under the **Environmental Hazard Section**:

Wetland Statement

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash water or rinsate."

Ground Water Advisory

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Surface Water Advisory

"Surface water contamination may occur in areas with poorly draining soils and little or no buffers or in areas where drainage systems flow directly to surface water."

c. Application Restrictions

The labels of all asulam end-use products must be revised to bear the following application restrictions under the **Directions for Use Section:**

For noncropland and Christmas tree uses:
"Aerial application is prohibited"

For turf uses:
"For sod farm use only"

d. Application Rates

The labels of all asulam end-use products must be revised to bear the following application rates under the **Crop Uses Section** for the respective crops:

For asulam use on noncropland sites:
A maximum application rate of 1 gallon/A with use limited to single application per year.

For asulam use on Christmas trees:
A maximum application of 1 gallon/A with use limited to single application per year.

For asulam use on turf (sod farm use only):
A maximum application of 1 gallon/A with use limited to single application per year.

e. Spray Drift

The following language must be placed on each asulam product label that can be applied aerially:

"AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR."

"The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions."

"The following drift management requirements must be followed to avoid off-target movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations."

1. "The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor."

2. "Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees."

"Where states have more stringent regulations, they should be observed."

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory below.

AERIAL DRIFT REDUCTION ADVISORY

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supercede the mandatory label requirements].

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (See Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle

types, narrower spray angles produce larger droplets. Consider using low- drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator should compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.).

WIND

Drift potential is lowest between winds speeds of 2 -10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g, when wind is blowing away from the sensitive areas).

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

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 asulam and its sodium salt 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

APPENDIX A. Table of Use Patterns Subject to Reregistration

ALL OF THESE USES WILL BE ELIGIBLE FOR REREGISTRATION PROVIDED CHANGES ARE MADE IN ACCORDANCE WITH THIS RED DOCUMENT.

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps Max. Rate unless noted otherwise)/A] Max. /crop /year cycle		Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
THESE ARE CURRENT USES.											
NON-FOOD/NON-FEED											
CHRISTMAS TREE PLANTATIONS				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Spray., Delayed dormant., Aircraft.	SC/L	NA	3.34 lb A	*	NS	NS	NS	NS	NS .5		C46, C92, CAL, G74
Spray., Delayed dormant., Ground.	SC/L	NA	3.34 lb A	*	NS	NS	NS	NS	NS .5		C46, C92, CAL, G74
INDUSTRIAL AREAS (OUTDOOR)				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Spot treatment., When needed., Ground.	SC/L	NA	3.34 lb A	*	NS	NS	NS	NS	NS .5	HI	C46, C92, CAL
Spray., When needed., Ground.	SC/L	NA	6.68 lb A	*	NS	NS	NS	NS	NS .5		C46, C92, CAL
NONAGRICULTURAL RIGHTS-OF-WAY/FENCEROWS/HEDGEROWS				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Spot treatment., When needed., Ground.	SC/L	NA	3.34 lb A	*	NS	NS	NS	NS	NS .5	HI	C46, C92, CAL
Spray., When needed., Ground.	SC/L	NA	6.68 lb A	*	NS	NS	NS	NS	NS .5		C46, C92, CAL
NONAGRICULTURAL UNCULTIVATED AREAS/SOILS				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Spot treatment., When needed., Ground.	SC/L	NA	3.34 lb A	*	NS	NS	NS	NS	NS .5	HI	C46, C92, CAL
Spray., When needed., Ground.	SC/L	NA	6.68 lb A	*	NS	NS	NS	NS	NS .5		C46, C92, CAL
ORNAMENTAL AND/OR SHADE TREES				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Broadcast., Postemergence., Ground.	SC/L	NA	3.34 lb A	*	1	NS	NS	NS	NS .5		C46, C92, CAL
ORNAMENTAL LAWNS AND TURF				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Spray., Postemergence., Ground.	SC/L	NA	2.088 lb A	*	1	NS	NS	NS	NS .5		C46, C92, CAL
ORNAMENTAL WOODY SHRUBS AND VINES				**Use Group: TERRESTRIAL NON-FOOD CROP**							
Broadcast., Postemergence., Ground.	SC/L	NA	3.34 lb A	*	1	NS	NS	NS	NS .5		C46, C92, CAL

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. @ Max. Dose	Max. # Apps /crop cycle	Max. Rate unless noted otherwise)/A] /crop cycle	/year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USE FOR WHICH A REREGISTRATION ELIGIBILITY DECISION HAS NOT BEEN MADE DUE TO DELANEY CLAUSE												
FOOD/FEED USES												
SUGARCANE				**Use Group: TERRESTRIAL FOOD+FEED CROP**								
Band treatment., Cane grown for stubble., Ground.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Band treatment., Cane., Ground.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Broadcast., Cane grown for stubble., Aircraft.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Broadcast., Cane grown for stubble., Ground.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Broadcast., Cane., Aircraft.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Broadcast., Cane., Ground.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Spot treatment., Cane grown for stubble., Ground.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)
Spot treatment., Cane., Ground.	SC/L	NA	3.34 lb A	*	2	NS	NS	NS	NS .5			C46, C92, CAL, GI9, H01(90)

LEGEND
444444

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
SC/L : SOLUBLE CONCENTRATE/LIQUID

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"

USE LIMITATIONS CODES
C46 : Do not apply through any type of irrigation system.
C92 : For terrestrial uses, do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark.
CAL : Do not contaminate water, food or feed.
G74 : Do not feed treated foliage to livestock or graze treated areas.
GI9 : Do not graze or feed fodder and forage to livestock.
H01 : __ day(s) preharvest interval.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

GEOGRAPHIC CODES
HI : Hawaii

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Asulam covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Asulam 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 ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	**DATA GAP**
61-2A	**Start. Mat. & Mnfg. Process**	All	**DATA GAP**
61-2B	**Formation of Impurities**	All	**DATA GAP**
62-1	**Preliminary Analysis**	All	**DATA GAP**
62-2	**Certification of limits**	All	42485801, 42485802 - **DATA GAP**
62-3	**Analytical Method**	All	**DATA GAP**
63-2	**Color**	All	40751501
63-3	**Physical State**	All	40751501
63-4	**Odor**	All	**DATA GAP**
63-5	**Melting Point**	All	**DATA GAP**
63-6	**Boiling Point**	All	**WAIVED**
63-7	**Density**	All	40751501
63-8	**Solubility**	All	40751501
63-9	**Vapor Pressure**	All	40751501
63-10	**Dissociation Constant**	All	42342004
63-11	**Octanol/Water Partition**	All	40751501
63-12	**pH**	All	40751501
63-13	**Stability**	All	**DATA GAP**

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,B,C	00056417
71-1B	**Acute Avian Oral - Quail/Duck TEP**	N/A	
71-2A	**Avian Dietary - Quail**	A,B,C	00056419
71-2B	**Avian Dietary - Duck**	A,B,C	00056418
71-3	**Wild Mammal Toxicity**	N/A	
71-4A	**Avian Reproduction - Quail**	N/A	
71-4B	**Avian Reproduction - Duck**	N/A	
71-5A	**Simulated Field Study**	N/A	
71-5B	**Actual Field Study**	N/A	
72-1A	**Fish Toxicity Bluegill**	A,B,C	00056421, 00098505
72-1B	**Fish Toxicity Bluegill - TEP**	N/A	
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C	00056421, 40872001
72-1D	**Fish Toxicity Rainbow Trout- TEP**	N/A	
72-2A	**Invertebrate Toxicity**	A,B,C	00098507, 40977602
72-2B	**Invertebrate Toxicity - TEP**	N/A	
72-3A	**Estuarine/Marine Toxicity - Fish**		**WAIVED**
72-3B	**Estuarine/Marine Toxicity - Mollusk**	A,B,C	41000701

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
72-3C	**Estuarine/Marine Toxicity - Shrimp**	A,B,C	00098508, 00098509
72-3D	**Estuarine/Marine Toxicity Fish- TEP**	N/A	
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**	N/A	
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**	N/A	
72-4A	**Early Life Stage Fish**	A,B,C	**RESERVED** pending results of life cycle invertebraate
72-4B	**Life Cycle Invertebrate**	A,B,C	**DATA GAP**
72-5	**Life Cycle Fish**	N/A	
72-6	**Aquatic Organism Accumulation**	N/A	
72-7A	**Simulated Field - Aquatic Organisms**	N/A	
72-7B	**Actual Field - Aquatic Organisms**	N/A	
122-1A	**Seed Germination/Seedling Emergence**		**RESERVED**
122-1B	**Vegetative Vigor**		**RESERVED**
122-2	**Aquatic Plant Growth**		**RESERVED**
123-1A	**Seed Germination/Seedling Emergence**	A,B,C	42613801 - **DATA GAP**
123-1B	**Vegetative Vigor**	A,B,C	42613801 - **DATA GAP**

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
123-2	**Aquatic Plant Growth**	A,B,C	42560301, 42560302, 42611701, 42613802, 42631301
124-1	**Terrestrial Field**		**RESERVED** pending results of Tier II testing
124-2	**Aquatic Field**		**RESERVED** pending results of Tier II testing
141-1	**Honey Bee Acute Contact**	A,B,C	00036935
141-2	**Honey Bee Residue on Foliage**	N/A	
141-5	**Field Test for Pollinators**	N/A	
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C	40960501, 42110001
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C	40960501
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C	40960502
81-4	**Primary Eye Irritation - Rabbit**	A,B,C	00098534
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C	00098535
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C	00098535
81-7	**Acute Delayed Neurotoxicity - Hen**	N/A	
82-1A	**90-Day Feeding - Rodent**	A,B,C	00098543
82-1B	**90-Day Feeding - Non-rodent**	A,B,C	**RESERVED**
82-2	**21-Day Dermal - Rabbit/Rat**	A,B,C	41076901

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
82-3	**90-Day Dermal - Rodent**	N/A	
82-4	**90-Day Inhalation - Rat**	N/A	
82-5A	**90-Day Neurotoxicity - Hen**	N/A	
82-5B	**90-Day Neurotoxicity - Mammal**		**WAIVED**
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,C	00098543
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C	00098536
83-2A	**Oncogenicity - Rat**	A,B,C	00098543
83-2B	**Oncogenicity - Mouse**	A,B,C	42338201
83-3A	**Developmental Toxicity - Rat**	A,B,C	00098538
83-3B	**Developmental Toxicity - Rabbit**	A,B,C	00098539
83-4	**2-Generation Reproduction - Rat**	A,B,C	00098540
84-2A	**Gene Mutation (Ames Test)**	A,B,C	40415302, 41457501?,
84-2B	**Structural Chromosomal Aberration**	A,B,C	00082250, 40415301
84-4	**Other Genotoxic Effects**	A,B,C	00098542, 40415301, 41457501
85-1	**General Metabolism**	A,B,C	41345601
85-2	**Dermal Penetration**	N/A	
86-1	**Domestic Animal Safety**	N/A	
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**	N/A	

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
132-1B	**Soil Residue Dissipation**	N/A	
133-3	**Dermal Passive Dosimetry Exposure**	N/A	
133-4	**Inhalation Passive Dosimetry Exposure**	N/A	
231	**Estimation of Dermal Exposure at Outdoor Sites**	N/A	
232	**Estimation of Inhalation Exposure at Outdoor Sites**	N/A	
233	**Estimation of Dermal Exposure at Indoor Sites**	N/A	
234	**Estimation of Inhalation Exposure at Indoor Sites**	N/A	
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	N/A	
161-1	**Hydrolysis**	A,B,C	40997901
161-2	**Photodegradation - Water**	A,B,C	41326001
161-3	**Photodegradation - Soil**	A,B,C	41326002
161-4	**Photodegradation - Air**	N/A	
162-1	**Aerobic Soil Metabolism**	A,B,C	41767801 - **DATA GAP**
162-2	**Anaerobic Soil Metabolism**	A,B,C	41767802 - **DATA GAP**
162-3	**Anaerobic Aquatic Metabolism**	A,B,C	41767802 - **DATA GAP**

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
162-4	**Aerobic Aquatic Metabolism**	N/A	41767803 - **WAIVED**
163-1	**Leaching/Adsorption/Desorption**	A,B,C	00098525, 41215101, 40965001
163-2	**Volatility - Lab**	N/A	
163-3	**Volatility - Field**	N/A	
164-1	**Terrestrial Field Dissipation**	A,B,C	**RESERVED**
164-2	**Aquatic Field Dissipation**	N/A	
164-3	**Forest Field Dissipation**	N/A	
164-5	**Long Term Soil Dissipation**	N/A	
165-1	**Confined Rotational Crop**	A,B,C	41857701 - **DATA GAP**
165-2	**Field Rotational Crop**	A,B,C	42980801
165-3	**Accumulation - Irrigated Crop**		**WAIVED**
165-4	**Bioaccumulation in Fish**	N/A	
165-5	**Bioaccumulation - Aquatic NonTarget**	N/A	
166-1	**Ground Water - Small Prospective**	A,B,C	41561103, 42224701, 42534501, 41803901, 42704901
166-2	**Ground Water - Small Retrospective**	N/A	
166-3	**Ground Water - Irrigated Retrospective**	N/A	
201-1	**Droplet Size Spectrum**	A,B,C	**DATA GAP**
202-1	**Drift Field Evaluation**	A,B,C	**DATA GAP**

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-3	**Directions for Use**	A,B,C	**DATA GAP**
171-4A	**Nature of Residue - Plants**	A,B	00024737, 00044583, 00052044, 00056424, 00056425, 00113828 - **DATA GAP**
171-4B	**Nature of Residue - Livestock**	B	00044580, 00056422, 00098551, 41561101, 41561102
171-4C	**Residue Analytical Method - Plants**	A,B	00004821, 00004822, 00044584, 00052047, 00056432, 00056435, 00056436, 00056438, 00056439, 00056440, 00084790, 00084804, 00098545, 00098547, 00098548, 00098552, 00098553, 00113827, 00113831, 41239701, 42292401
171-4D	**Residue Analytical Method - Animal**	B	00052047, 00098549, 00098551, 42806201, 43234701
171-4E	**Storage Stability**	A,B	43234701
171-4F	**Magnitude of Residues - Potable H2O**	N/A	
171-4G	**Magnitude of Residues in Fish**	N/A	
171-4H	**Magnitude of Residues - Irrigated Crop**	N/A	
171-4I	**Magnitude of Residues - Food Handling**	N/A	
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	00052047, 00084805, 00098553, 00098554, 00113833

Data Supporting Guideline Requirements for the Reregistration of ASULAM AND ITS SODIUM SALT

REQUIREMENT		USE PATTERN	CITATION(S)
171-4K	**Crop Field Trials - Sugarcane**	A,B	00004821, 00004823, 00004824, 00056441, 00056442, 00113830, 00113831, 00113836, 00113837, 00136346, 42088801, 42201501, 42292401, 42806201 - **DATA GAP**
171-4L	**Processed Food - Sugarcane**	A,B	00056441, 00113831, 00113836, 00136346, 42201501, 42292401, 42806201

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of Asulam

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.

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41857701 Billings, T. (1991) A Confined Rotational Crop Study with carbon 14-Asulam Using Radishes (Raphanus sativa, Spinacia oleracea), and Wheat (Triticum aestivum): Lab Project Number: EC90-104. Unpublished study prepared by Rhone Poulenc Ag Co. 70 p.

42088801 Williams, R. (1991) Analysis of Sugarcane and Processed Sugarcane Products for Asulam Residues: Interim Report: Lab Project Number USA88UO5. Unpublished study prepared by Rhone-Poulenc Ag. in coop. with Rhone-Poulenc Ag Ltd. 149 p.

42110001 Cummins, H. (1987) FR 1398/1: Acute Oral Toxicity Study in the Rat: Lab Project Number: 87/MBL071/011. Unpublished study prepared by Life Science Research Ltd. 20 p.

42201501 Williams, R. (1991) Analysis of Sugarcane and Processed Sugarcane Products for Asulam Residues: Final Report: Lab Project Number: USA88UO5. Unpublished study prepared by Rhone-Poulenc Ag Co., and Rhone-Poulenc Agric., Ltd. 166 p.

42224701 Norris, F. (1992) A Small Scale Prospective Groundwater Monitoring Study With Asulam-Sodium, the Active Ingredient of Asulox Brand Herbicide, Applied to Sugar Cane and to Turf: Progress Report: Lab Project Number: EC-89-068: EC-89-069: R081-102. Unpublished study prepared by Rhone-Poulenc Ag Co., A & L Eastern Ag Labs, Inc., and Analytical Development Corp. 228 p.

42292401 Williams, R. (1992) A Common Moiety Method for the Analysis of Asulam Residues on Sugarcane and Sugarcane Processed Fractions Using High Performance Liquid Chromatography: Final Report: Lab Project Number: EC-91-154. Unpublished study prepared by Rhone-Poulenc Ag Co. 41 p.

42806201 Williams, R. (1993) Stability of Asulam and Its Principal Metabolites on Sugarcane and Sugarcane Processed Fractions During Frozen Storage:

BIBLIOGRAPHY

MRID **CITATION**

Preliminary Report: Lab Project Number: EC-91-151. Unpublished study prepared by Rhone-Poulenc Ag Co. 18 p.

42292401 Williams, R. (1992) A Common Moiety Method for the Analysis of Asulam Residues on Sugarcane and Sugarcane Processed Fractions Using High Performance Liquid Chromatography: Final Report: Lab Project Number: EC-91-154. Unpublished study prepared by Rhone-Poulenc Ag Co. 41 p.

42338201 Blair, M. (1992) Two Year Dietary Oncogenicity Study in Mice: Asulam Sodium Salt: Lab Project Number: 347-036. Unpublished study prepared by International Research and Development Corp. 2959 p.

42342004 Cicotti, M.; Weidenauer, M.; Mollard, L. (1992) Determination of the Dissociation Constant of Asulam-Sodium Salt: Final Report: Lab Project Number: BE-P-1-91-PK-01-BG. Unpublished study prepared by Battelle Europe, Geneva Research Centres. 29 p.

42485801 Buddle, G. (1992) Methyl(4-aminophenyl)sulphonylcarbamate, monosodium salt (Asulam sodium): Product Chemistry: Lab Project Number: P-87-110. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 30 p.

42485802 Gomez, F. (1992) Asulam-sodium Technical Grade: Analysis and Certification of Ingredients Identification of Two Impurities: Lab Project Number: 92-17: AG/CRLD/AN9216163. Unpublished study prepared by Rhone-Poulenc Secteur Agro. 67 p.

42534501 Norris, F. (1992) A Small Scale Prospective Groundwater Monitoring Study with Asulam-Sodium, the Active Ingredient of Asulox Brand Herbicide Applied to Sugar Cane and to Turf: Progress Report: Lab Project Number: EC-89-068: EC/89/069: 920105. Unpublished study prepared by Rhone-Poulenc. 17 p.

42560302 Hoberg, J. (1992) Asulam Sodium--Toxicity to the Marine Diatom, Skeletonema costatum: Final Report: Lab Project Number: 92-8-4395: 10566.0292.6221.450. Unpublished study prepared by Springborn Labs, Inc. 59 p.

BIBLIOGRAPHY

MRID	CITATION
42611701	Hoberg, J. (1992) Asulam Sodium--Toxicity to the Duckweed Lemna gibba: Final Report: Lab Project Number: 92-9-4397: 10566.0292.6222.410. Unpublished study prepared by Springborn Labs, Inc. 64 p.
42613801	Christensen, K. (1992) Asulam Sodium--Determination of Effects on Seed Germination, Seedling Emergence and Vegetative Vigor of Ten Plant Species: Final Report: Lab Project Number: 92-9-4431: 10566.0292.6217.610. Unpublished study prepared by Springborn Labs., Inc. 214 p.
42613802	Hoberg, J. (1992) Asulam Sodium--Toxicity to the Freshwater Alga, Anabaena flos-aquae: Final Report: Lab Project Number: 92-10-4457: 10566.0292.6218.420. Unpublished study prepared by Springborn Lab., Inc. 60 p.
42631301	Hoberg, J. (1992) Asulam Sodium--Toxicity to the Freshwater Diatom, Navicula pelliculosa: Final Report: Lab Project Number: 92-12-4519: 10566.0292.6219.440. Unpublished study prepared by Springborn Labs, Inc. 60 p.
42704901	Gustafson, D. (1993) Drinking Water Monitoring for Residues of Asulam in High-use Areas of the United States: Lab Project Number: 41293: EC-91-153. Unpublished study prepared by Alta Analytical Laboratory, Inc. 164 p.
42980801	See, R. (1993) Asulox Rotational Crop-Field: Lab Project Number: 1143: USA90U03: 41351. Unpublished study prepared by Colorado Analytical Research & Development Corp. 783 p.
43234701	Williams, R. (1994) Stability of Asulam and Its Prinicipal Metabolites on Sugarcane and Sugarcane Processed Fractions During Frozen Storage: Final Report: Lab Project Number: EC/91/151. Unpublished study prepared by Rhone-Poulenc Ag Co. 65 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Asulam. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Asulam and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. Asulam RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS
AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the

entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an

application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE.** An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

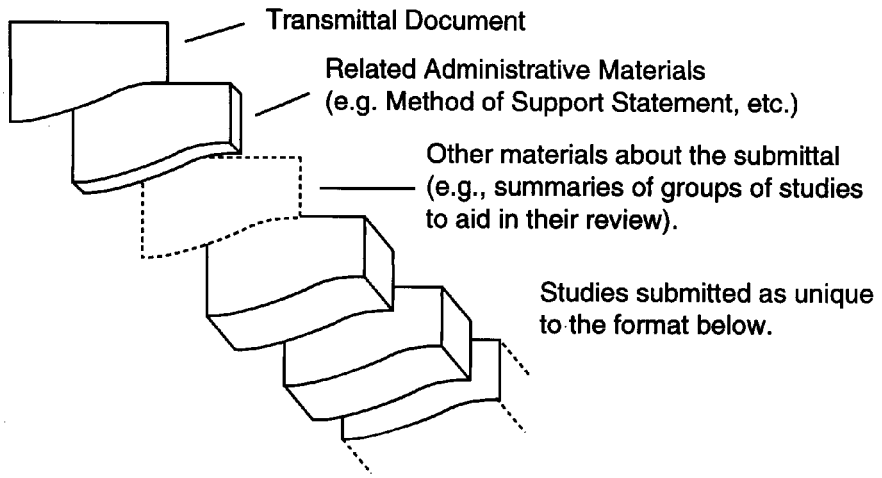
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

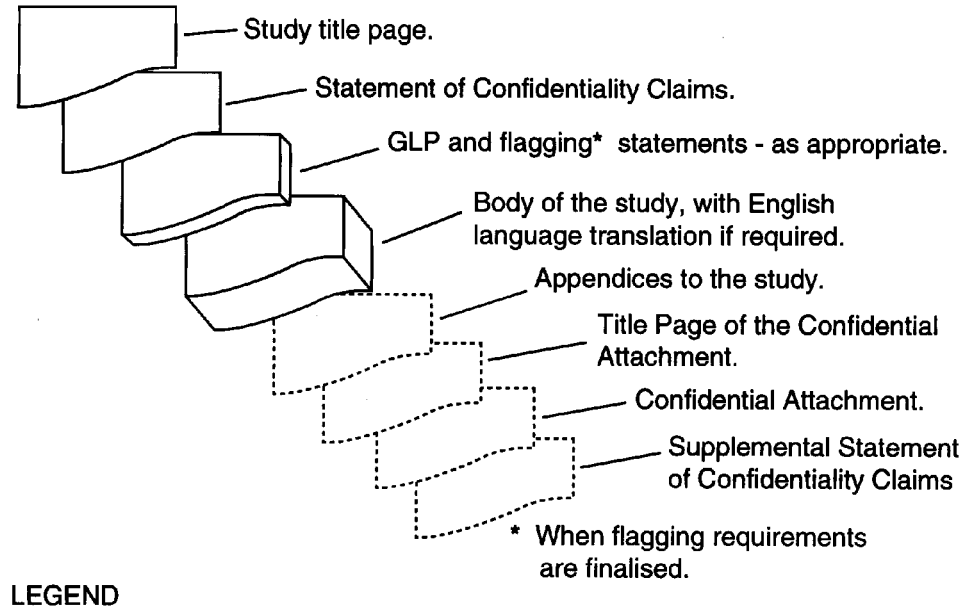
Submitter_____

ATTACHMENT 7.

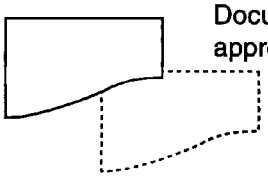
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Combined Generic and Product Specific Data Call-In

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 6).

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
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 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms

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 Registrant'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 Registrant'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 A. Rossi, 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 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

Attachment 1. Chemical Status Sheets

ASULAM DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Asulam. 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 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Asulam Generic Data Call-In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Asulam are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry, ecological effects, environmental fate, spray drift, and residue chemistry data on asulam are needed. These data are needed to fully complete the reregistration of all eligible asulam 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 Karen Jones at (703) 308-8047.

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

Karen Jones, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Asulam

ASULAM DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Asulam. 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) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Asulam Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Asulam are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Asulam 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 Asulam products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Asulam, please contact Karen Jones at (703) 308-8047.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008. (703) 308-8004.

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

Jeffrey Billingslea
Chemical Review Manager, Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **Asulam**

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

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.

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.

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.

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

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 Reqistrant's Response Form.

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

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF PRODUCTS CONTAINING ASULAM AS THE ACTIVE INGREDIENT 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 the active ingredient Asulam (methyl sulfanilylcarbamate and methyl sulfanilylcarbamate, sodium salt), the Agency has batched products which can be considered similar in terms of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

Table 1 displays the batch for the active ingredient Asulam.

Table 1.

EPA Reg. No.	Active Ingredient	Formulation Type
264-447	Sodium Salt of Asulam ... 36.2%	liquid
57242-5	Sodium Salt of Asulam ... 36.2%	liquid
64764-3	Sodium salt of Asulam ... 36.2%	liquid

Table 2 lists the product the Agency was unable to batch. This product was considered not to be similar to other products for purposes of acute toxicity. The registrant of this product is responsible for meeting the acute toxicity data requirements for this product.

Table 2.

EPA Reg. No.	Active Ingredient	Formulation Type
264-451	Asulam ... 96%	solid

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at $\geq$ 0.1%.
2.____ Degree of accountability or closure $\geq$ ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert alon g with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at $\geq$ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision an d accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25° C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in °C
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in °C
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25° C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20° C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25° C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25° C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25° C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25° C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25° C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4.*___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22° C ($\pm 2^{\circ}$), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration o f respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\leq$2 or $\geq$11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of $\leq$2 or $\geq$11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of $\leq$2 or $\geq$11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*___ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share, Data Compensation Forms, Confidential Statement of Formula Form and Instructions

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

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.

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 G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-021 September 1995

R.E.D. FACTS

Asulam

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0265, methyl sulfanilylcarbamate and sodium salt of methyl sulfanilylcarbamate, commonly known as asulam.

Use Profile

Asulam is a selective postemergent systemic carbamate herbicide used to control a variety of annual grasses and broadleaf weeds on sugarcane, Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass) and non-cropland uses (boundary fences, fencerows, hedgerows, lumberyards, storage areas and industrial plant sites, and warehouse lots). Its major use site is sugarcane. The only end-use formulation of asulam is soluble/concentrate liquid (sodium salt of asulam). Asulam is applied by aerial or ground spray, broadcast, band, and spot treatment.

Use practice limitations prohibit applying asulam through any type of irrigation system; discharging into bodies of water; using treated plants for feed or forage; and treating crops/sites within 90 days of harvest.

Regulatory History

Asulam was first registered as a pesticide in the U.S. in 1975. EPA issued a Registration Standard for Asulam in December 1987 (PB88-168588). A 1991 Data Call-In (DCI) required additional neurotoxicity, plant protection, animal feeding, dermal mixer/loader exposure and

inhalation exposure data. Currently, 1 technical asulam product and 3 sodium salt of asulam products are registered.

Human Health Assessment

Toxicity

Asulam technical is of relatively low acute toxicity. It is practically non-toxic by the oral and inhalation routes; technical asulam is in Toxicity Category IV (the lowest of four categories) for these effects. It is slightly toxic by the dermal route (Toxicity Category III). It causes slight eye irritation in rabbits (Toxicity Category III) and is not a skin sensitizer.

In a subchronic dermal study using rabbits, no treatment-related effects were observed.

Asulam is carcinogenic in rats based on thyroid and adrenal tumors in males. It has been classified as a Group C carcinogen --- that is, a possible human carcinogen for which there is limited animal evidence.

In a chronic toxicity study using beagle dogs, reductions in food consumption, body weight gain, vomiting, diarrhea, and reduction in red blood cells, increase in thyroid and kidney weights and reduced testicular weights were noted in the high dose groups. A carcinogenic study using mice cause increased spleen weights in males and decreased brain weights and decreased survival in females.

In a developmental toxicity study using rats, the highest dose level caused maternal toxic effects of decreased body weight gain and slight increase in resorptions. In a study using rabbits, asulam caused maternal effects of decreased body weight.

A 2-generation reproduction study showed a reduction in the number of live births per litter, and decreases in body weight and organ weights. Asulam is not mutagenic.

Dietary Exposure

People may be exposed to residues of asulam through the diet. Tolerances or maximum residue limits have been established for asulam in sugarcane (please see 40 CFR 180.360).

Residue data show that sugarcane concentrates in the processed feed commodity, blackstrap molasses. Under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA may be barred from establishing a feed additive regulation (tolerance) for blackstrap molasses because asulam may be found to be an animal carcinogen within the meaning of the Delaney clause. The Delaney clause prohibits the establishment of a regulation for any food/feed additive that is found to induce cancer in man or animals. Further, under current policy, EPA would not issue these food and feed additive tolerances, and would not continue in effect a tolerance for the associated raw agricultural commodity, sugarcane.

The Agency has committed to revoking the underlying raw agricultural commodity tolerance where food/feed additive tolerances have been established or need to be established but cannot because of Delaney. As part of a settlement agreement in a recent lawsuit, the Agency agreed to complete these revocations by the year 2000. During the 5 years before final revocation, the Agency believes it is important to amend the existing raw agricultural commodity tolerance on sugarcane to reflect new residue data.

The Agency will also establish new meat, milk, and meat by-product tolerances. Current residue data suggest the existing sugarcane tolerance should be raised to 15 ppm from 0.1 ppm. However, the registrant is submitting additional data reflecting longer pre-harvest intervals (PHIs) and more accurate timing of applications which will likely result in a tolerance level lower than the 15 ppm. After reviewing these data, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk, and meat by-product tolerances. By amending and establishing tolerances for what may be an interim period, the Agency believes that these actions will prevent possible overtolerance situations and should reduce any public confusion regarding dietary risks associated with a crop or commodity seizure.

In addition, the Agency will also review blackstrap molasses as part of its new policy regarding implementation of Delaney that was recently published in the Federal Register as a response to the National Food Processors Association petition (June 14, 1995; 60 FR 31300). The Agency will determine if blackstrap molasses is "ready-to-eat" as an animal feed. If dilution with other feed items is necessary before animal consumption, and subsequent dilution lowers the level of asulam in the diluted feed mixture to the level of the raw agricultural commodity tolerance, then a processed feed tolerance will not be necessary. Then the new sugarcane tolerance and new meat, milk and meat by-product tolerances will not be revoked.

EPA has assessed the dietary risk posed by asulam. The chronic dietary risk analysis assumed the higher reassessed tolerance level of 15 ppm and 100% crop treated. The Anticipated Residue Concentration (ARC) for the overall U.S. population represents 3.85% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposures for the two highest exposed subgroups, children (1-6 years old) and non-nursing infants (<1 year old), are 3.48×10^{-2} and 2.64×10^{-2} mg/kg body weight/day, respectively. These exposure values represent 9.7% and 7.3% of the RfD, respectively. This low fraction of the allowable RfD is acceptable dietary risk.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to asulam during and after applications in agricultural and other settings. However, there are no toxicological

endpoints of concern for short to intermediate term occupational exposure. There are no residential uses for asulam; therefore, no exposure or risk is expected from asulam to homeowners.

The Agency is requiring that the current restricted entry interval (REI) of 12 hours for uses within the scope of the Worker Protection Standards (WPS) be maintained. This 12 hour REI is the minimum acceptable REI for assulam. There are no special toxicological concerns about asulam that warrant the establishment of active-ingredient-based minimum personal protective equipment (PPE) requirements. The Agency is also requiring the following early-entry PPE, which is the minimum required under the WPS: coveralls, chemical-resistant gloves, and shoes plus socks.

Human Risk Assessment

Asulam generally is of low acute toxicity, but it is classified as a non-quantifiableGroup C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence), and shows some evidence of developmental and reproductive toxicity. The only food crop use is sugarcane. However, dietary exposure to asulam residues in foods is extremely low, as is the cancer risk posed to the general population.

Application and post-application risks to workers and others are minimal because asulam has no toxicological endpoints of concern for the short to intermediate term occupational exposure. Post-application reentry workers will be required to observe a 12-hour restricted entry interval (REI). The following early-entry PPE is the minimum required under the WPS: coveralls, chemical-resistant gloves, and shoes plus socks.

Environmental Assessment

Environmental Fate

The environmental fate assessment is considered preliminary because of contradictory data. Although there is a lack of acceptable terrestrial field dissipation data and the Agency has concerns about the integrity of data for key laboratory studies, based on the supplemental data, it appears that asulam is highly mobile and has a strong potential to leach into ground water or move offsite into surface water. Also, based on available data (including those from unreliable studies), asulam has the following characteristics: 1) highly to very highly soluble, 2) stable in water without light, 3) unstable in water and on soil under light; however, small amounts of asulam were detected in surface water, 4) relatively unstable in soil under aerobic conditions, 5) very stable in soil and sediment under anaerobic conditions, 6) very mobile in soil, 7) not volatile, and 8) does not accumulate in fish.

The Agency is requiring additional storage stability data (aerobic soil metabolism and anaerobic soil/aquatic metabolism) to validate the results of the laboratory studies and to assess the need for the field dissipation study.

In addition, a groundwater label advisory and a surface water label advisory are required. Due to concerns about off-target damage by the aerial application of asulam, spray drift data (droplet size spectrum and drift field evaluation) and a label advisory are also required.

Ecological Effects

Technical asulam is practically nontoxic to freshwater fish and slightly toxic to freshwater invertebrates. Also, asulam is practically nontoxic to estuarine/marine species, honeybees, and small mammals. Chronic effects to avian species and aquatic invertebrate cannot be fully assessed due to lack of adequate data. However, based on the overall low risk asulam poses to aquatic and avian species, the Agency does not expect that asulam will pose a high chronic risk to aquatic invertebrates or avian species. The Agency is requiring a confirmatory aquatic invertebrate life cycle study. The Agency is not requiring avian reproduction studies due to the extremely short photolytic half-life (approximately 2 hours) and, in acute studies, the practically non-toxic nature of asulam to birds and mammals.

Levels of concern from all uses of asulam have been exceeded for endangered and non-endangered terrestrial and semi-aquatic plants. For non-cropland uses, asulam exceeds levels of concern for endangered and non-endangered aquatic plants. A comprehensive risk assessment for nontarget plants cannot be determined due to the lack of adequate data. High isk to nontarget plants is likely, based on the herbicidal properties of asulam. The Agency is requiring additional phytotoxicity data to complete the nontarget plants risk assessment for asulam.

Ecological Effects Risk Assessment

Asulam poses minimal risk to honeybees. Chronic risk to birds cannot be assessed at this time due to the lack of avian reproduction data. However, the Agency believes there is little potential for adverse effects to avian reproduction as the available environmental fate information indicates that photolysis in water and soil is very rapid -- approximately 2 hours.

Regarding mammals, the use of asulam on noncropland at the maximum use rate, or any other use site, is not likely to adversely affect mammalian reproduction.

Regarding aquatic risks, acute effects are low for aquatic invertebrates. However, chronic effects to fish and aquatic invertebrates cannot be fully assessed without further data.

Endangered and non-endangered species levels of concern are exceeded for terrestrial and semi-aquatic plants for all uses of asulam. For the noncropland use of asulam, endangered and non-endangered species are exceeded for aquatic plants. A comprehensive risk assessment cannot be determined for nontarget plants without further data. When the Endangered

Species Program goes into effect, limitation on the use of asulam will be required to protect endangered and threatened species.

Risk Mitigation

Since the current uses of asulam and its sodium salt exceed ecological effects levels of concern, EPA is requiring the following risk mitigation measures.

◦ Prohibiting the aerial uses of asulam for non-cropland and Christmas trees use sites;

◦ Clarifying the non-cropland use to state 1 gallon/acre rate, 1 application per season;

◦ Clarifying the Christmas tree uses to state 1 application per season;

◦ Clarifying the turf use to state sod farms use only and 1 application per season;

◦ Ground water label advisory;

◦ Surface water label advisory; and

◦ Long term ground water monitoring in and near asulam use areas.

The registrant also is required to clarify the environmental fate assessment methodology and the uncertainty associated with the extraction technique and recovery of asulam from the laboratory versus the field studies.

Additional Data Required

EPA is requiring the following additional generic studies for asulam and its sodium salt to confirm its regulatory assessments and conclusions:

Acute Aquatic Invertebrate Toxicity - *Daphnia magna*;

Aerobic Soil Metabolism;

Anaerobic Soil and Aquatic Metabolism;

Droplet Size Spectrum;

Drift Field Evaluation;

Directions for Use - Label amendment (lower application rate and/or longer PHI);

Plant Metabolism Study;

Magnitude of Residue - Sugarcane; and

Confined Rotational Crop

After reviewing additional field trial data for sugarcane, the Agency will establish a new sugarcane tolerance and require the registrant to petition for new meat, milk and meat by-product tolerances.

Certain data are not part of the reregistration target database for asulam, but are also required:

Seedling emergence - soybeans and radish

Vegetative vigor - cucumber and onion

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All asulam end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

Worker Protection

Personal Protective Equipment/Entry Restrictions; Labeling

Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

The PPE for mixer/loader/applicators is to be based on the acute toxicity of the end-use product.

Entry Restrictions for Occupational-Use Products (WPS Uses)

Based on the assessment of human health risks, the Agency does not believe an increase in the REI above what is required in the Worker Protection Standard (WPS) is warranted. The current 12 hour REI, pertaining to each use of the product that is within the scope of the WPS, is to be maintained. This 12 hour REI is the minimum acceptable REI for asulam.

Early Entry PPE: The PPE for early entry are the minimum that would be required under the WPS. These are: coveralls, chemical-resistant gloves, shoes, and socks.

Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Some registered uses of asulam are outside the scope of the Worker Protection Standard (WPS). For nonWPS uses the Agency is requiring the following.

"Do not enter or allow others to enter the treated area until sprays have dried."

Other Labeling Requirements

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

Products Intended Primarily for Occupational Use

Engineering Controls Used

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard for Agricultural Pesticides (WPS) [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS. However, full PPE must be available in the event that the handler exits the aircraft, enclosed cab, etc. prior to the REI."

User Safety Requirements

"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 Statements

"Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users must leave the treated area, and remove clothing immediately if pesticide gets inside."

"Users must remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing."

Application Restrictions

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

Homeowner-Use Products

There are no products containing asulam that provide directions intended for homeowner use. Current labelling provides the statement, *"For agricultural or commercial use only, not for use by homeowners."* This statement must be maintained.

Environmental Hazard

The labels of all asulam end-use products must be revised to bear the following under the **Environmental Hazard Section**:

Wetland Statement

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment wash water or rinsate."

Ground Water Advisory

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Surface Water Advisory

"Surface water contamination may occur in areas with poorly draining soils and little or no buffers or in areas where drainage systems flow directly to surface water."

Application Restrictions

The labels of all asulam end-use products must be revised to bear the following application restrictions under the **Directions for Use Section:**

For noncropland and Christmas tree uses

"Aerial application is prohibited"

For turf uses

"For sod farm use only"

Application Rates

The labels of all asulam end-use products must be revised to bear the following application rates under the **Crop Uses Section** for the respective crops:

For asulam use on noncropland sites

A maximum application rate of 1 gallon/A with use limited to single application per year.

For asulam use on Christmas trees

A maximum application of 1 gallon/A with use limited to single application per year.

For asulam use on turf (sod farm use only)

A maximum application of 1 gallon/A with use limited to single application per year.

Spray Drift

The following language must be placed on each asulam product label that can be applied aerially:

"AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR."

"The interaction of many equipment and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions."

"The following drift management requirements must be followed to avoid off-target movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations."

1. "The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor."

2. "Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees."

"Where states have more stringent regulations, they should be observed."

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory below.

AERIAL DRIFT REDUCTION ADVISORY

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements].

Information on Droplet Size

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (See Wind, Temperature and Humidity, and Temperature Inversions).

Controlling Droplet Size

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.
- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.
- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.
- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.
- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low- drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

Boom Length

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

Application Height

Applications should not be made at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

Swath Adjustment

When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator should compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.).

Wind

Drift potential is lowest between winds speeds of 2 -10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

Temperature and Humidity

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

Temperature Inversions

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

Sensitive Areas

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g, when wind is blowing away from the sensitive areas).

Regulatory Conclusion

Although levels of concern are exceeded for endangered and non-endangered plant species and surfacewater and groundwater quality, the Agency concludes that the current registered products containing asulam and its sodium salt for all uses, with the exception of sugarcane, once amended to reflect the risk mitigation measures imposed in this RED, are eligible for reregistration. Therefore, products containing asulam and its

sodium salt for uses on Christmas tree plantations, ornamentals, turf (St. Augustinegrass and Bermudagrass), and non-cropland (boundary fences, fencerows, hedgerows, lumberyards, storage areas, industrial plant sites, and warehouse lots) are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision regarding the use of asulam and its sodium salt on **sugarcane** because data show that asulam concentrates in the processed animal feed commodity, blackstrap molasses. Under current policies, the establishment of the necessary feed additive regulation (tolerance) to cover residues in this commodity may be barred by the Delaney clause of Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) because asulam may induce cancer in animals within the meaning of the Delaney clause.

Asulam and its sodium salt products with eligible uses will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for asulam during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet 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*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the asulam RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the asulam RED, or reregistration of individual products containing asulam and its sodium salt, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.