United States Environmental Protection Agency
Office of Prevention, Pesticides And Toxic Substances (7508W)
EPA 738-R-95-040
April 1996

Reregistration Eligibility Decision (RED)

Trifluralin

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 0179 which includes the active ingredient trifluralin. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, 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 is due 90 days from the date of this letter. The second set of required responses is 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 Moana Appleyard (703) 308-8175. Address any questions on required generic data to the Special Review and Reregistration Division representative Connie Childress at (703) 308-8076.

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

TRIFLURALIN

LIST A

CASE 0179

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

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TRIFLURALIN REREGISTRATION ELIGIBILITY DECISION TEAM

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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
NPDES	National Pollutant Discharge Elimination System

GLOSSARY OF TERMS AND ABBREVIATIONS

NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
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

This Reregistration Eligibility Decision (RED) document addresses the reregistration eligibility of the pesticide trifluralin, α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine. Trifluralin was first registered in the United States in 1963 for use as a selective preemergent herbicide. A Registration Standard for trifluralin was issued in April, 1987 (NTIS# PB87-201935) and a Data Call-In (DCI) for products used on turf was issued in March, 1995.

Trifluralin is a pre-emergent herbicide used to control annual grasses and broadleaf weeds on a variety of food crops and is also currently registered for non-food uses, including residential use sites. The herbicide is formulated as a liquid, emulsifiable concentrate, granular, flowable concentrate, impregnated material, soluble concentrate/liquid, soluble concentrate/solid, and water dispersible granules (dry flowable). Trifluralin is typically applied dormant, semi-dormant, preplant, pre-transplant, postplant, preemergence, postemergence, layby, or postharvest as a soil incorporated treatment. It can be applied by aerial equipment, tractor-drawn groundbooms, tractor-drawn granular spreaders, push-type spreaders, "whirly-bird" spreaders, and commercial granular turf spreaders.

Reregistration Eligibility

The Agency has determined that none of the currently registered uses of trifluralin will cause unreasonable risk to humans or the environment. All uses are eligible for reregistration with the exception of nongrass forage/fodder/straw/hay and dill. If residue data are not generated to support these uses, they must be deleted from all labels. Additional generic data are required for product chemistry, ecological effects, environmental fate, occupational and residential exposure, and residue chemistry. These data will be considered confirmatory and are listed in the attached Data Call-In notice and in Section V of this Reregistration Eligibility Decision (RED) document.

Product and Residue Chemistry

Additional data remain outstanding for all of the trifluralin technical products. A possible contaminant in the production of trifluralin is N-nitroso-di-n-propylamine, also known as NDPA or nitrosamine. Nitrosamine is a carcinogen and the Agency has required that its levels not exceed 0.5 ppm in any technical or manufacturing-use product containing trifluralin. All current technical registrations reflect the 0.5 ppm level in trifluralin CSFs, however, further nitrosamine analysis data are being required as part of the DCI included with this RED.

Tolerances are established for residues of trifluralin in or on numerous agricultural commodities. Available enforcement methods are adequate for the determination of trifluralin residues in/on plant commodities. Tolerances for residues of trifluralin in animal commodities have not been established and are not needed. The residue chemistry data

battery is substantially complete and a tolerance reassessment summary is included in Section IV of this RED document. Additional confirmatory residue chemistry data are required to support the reregistration of trifluralin.

Peppermint and spearmint are the only crops in which trifluralin has been shown to concentrate in processed foods (mint oils) at levels above the tolerance established for the raw agricultural commodity (RAC). The Delaney Clause of Section 409 of FFDCA prohibits the establishment of food additive regulations (tolerances) for processed commodities that contain substances that have been shown to cause cancer in "man or animals." Trifluralin has been classified as a "possible" human carcinogen, thus suggesting that the establishment of a processed food additive regulation (tolerance) for peppermint and spearmint oil be prohibited. However, the Agency also recognizes that not all processed foods are "ready to eat." In the case of peppermint and spearmint oils, they are not consumed in their concentrated form, but rather diluted as additives to other food products.

Available data show that residues of trifluralin in foods prepared with mint oil will not exceed the existing raw agricultural commodity tolerance. A food additive regulation is therefore not required and the existing peppermint and spearmint food additive regulations will be revoked. The Agency will, however, use its general rule-writing authority under the Federal Food Drug and Cosmetic Act (FFDCA) section 701 to establish Maximum Residue Limits (MRLs) for peppermint and spearmint oils at 2.0 ppm. In addition, new peppermint and spearmint processing data are required to determine the factor by which trifluralin concentrates in these commodities. Establishing an MRL at 2.0 ppm will help ensure that the levels in food commodities containing mint oil do not exceed the raw agricultural commodity tolerance of 0.05 ppm.

Toxicology

Trifluralin technical is classified under category IV for acute oral toxicity and dermal irritation, toxicity category III for acute dermal toxicity, acute inhalation toxicity and eye irritation potential, and toxicity category IV for dermal irritation. Trifluralin is also classified as a dermal sensitizer.

The Reference Dose (RfD) for chronic oral exposure is 0.024 mg/kg/day as determined from a one-year feeding study in dogs. The NOEL was 2.4 mg/kg/day, using a safety factor of 100. Trifluralin was classified as a group C, possible human carcinogen by the OPP Carcinogenicity Peer Review Committee on April 4, 1986. The Q_1^* for quantitation of human risk is 0.0077 $mg/kg/day^{-1}$.

Dietary Risk

Anticipated residue data were developed for trifluralin residues of concern in/on carrots, wheat, tomatoes and sugarcane crop and processed food commodities for

carcinogenic risk assessment purposes and were used for the Dietary Risk Evaluation System (DRES) analysis. With all of the DRES population subgroups having Theoretical Maximum Residue Contribution (TMRC) and Anticipated Residue Contribution (ARC) values well below the Reference Dose (RfD), the chronic non-carcinogenic dietary risk from exposure to trifluralin has been determined to be of minimal concern. When using refinements in residues and percent of crop treated information, the upper bound carcinogenic risk of trifluralin, 1.0 x 10^{-6} (viz. 0.96 x 10^{-6}) does not exceed the level of concern for excess lifetime dietary cancer risk.

Occupational and Residential Exposure and Risk

The Agency has identified a potential for exposure to trifluralin for mixers, loaders, applicators, or other handlers during usual use pattern practices associated with this chemical. However, the occupational/residential cancer exposure/risk assessment for all uses indicates a level of risk that does not exceed 10^{-5} for occupational handlers or 10^{-7} for residential handlers.

No data are available to calculate post-application exposures and risks following trifluralin treatments, however, the dermal absorption value is very low (one percent) and inhalation exposures are not a concern for post-application scenarios. These factors suggest that occupational and residential post-application exposures will probably be no higher than exposures to occupational handlers. Since the occupational/residential cancer exposure/risk assessment for all uses indicates a level of risk that does not exceed 10^{-5} for occupational handlers or 10^{-7} for residential handlers, the Agency does not anticipate that the exposure/risk assessment for post-application scenarios would exceed these levels for occupational or residential exposures.

A Data Call-In was issued in March, 1995 requiring generic turf exposure data. This DCI was sent to all technical and manufacturing-use registrants of products registered for use on home lawns or grass, that are applied by homeowners or professionals. Data were called in for foliar residue dissipation, dermal exposure upon reentry, dermal exposure from mixing/loading/applying and inhalation exposure from mixing/loading/applying. The data generated will allow the Agency to more accurately estimate homeowner exposure from pesticides applied to home lawns and turf.

For occupational end-use products containing trifluralin as an active ingredient, the Agency believes that the 12-hour restricted-entry interval (REI), currently on the labels with uses within the scope of the WPS, is appropriate. The PPE required for early entry is the minimum PPE established under the WPS for early entry: coveralls, chemical-resistant gloves, shoes, and socks.

Environmental Fate and Risk to Water Resources

Available information on the properties of trifluralin in the environment suggest that it is moderately persistent and non-mobile in a vital (microbially active) soil environment. In general, high persistence and high mobility promote movement into ground water. Detections of trifluralin in ground water have been reported to the Agency, however, the validity and significance of these detections is questionable on several grounds and the information is not being considered by the Agency to be a basis for risk reduction measures. Because annual average surface water concentrations are not likely to exceed the lifetime health advisory level (2 ug/L) and peak/short term averages are not likely to exceed 1 day and 10 day health advisory levels, exposure/risk from trifluralin in drinking water is expected to be minimal. Although trifluralin has no direct aquatic applications, contamination of surface water may occur by spray drift and under some circumstances, runoff.

Ecological Effects Assessment

Trifluralin ranks as practically non-toxic to birds and mammals on an acute basis, using a simple hazard classification scheme. Nontarget acute risk quotients (the estimated environmental concentration divided by the toxicity test effect level) do not suggest a concern for terrestrial vertebrates in general. However, the more sensitive endangered species risk quotients are exceeded for terrestrial vertebrates. Also, two of four laboratory bird studies indicate chronic risk, as evidenced by egg shell cracking.

For aquatic animals (fish and invertebrates), trifluralin ranked as moderate to high toxicity according to the hazard classification scheme. Risk quotients for acute effects do not indicate concerns for nonendangered species, but the more sensitive endangered species risk quotients are exceeded (for freshwater fish, RQ 0.03 to 0.08 versus Level of Concern 0.05). (Levels of Concern (LOCs) are criteria used to indicate potential risk to nontarget organisms.) In addition, laboratory and field studies suggest exposure-related abnormalities in vertebral development, at concentrations below those where acute effects are anticipated. Also, the LOC determination is based on trifluralin dissolved in the water column and does not take into account trifluralin adsorbed to sediment. Trifluralin adsorbed to sediment may pose a risk for fish species that forage by feeding from sediment, particularly since trifluralin has a moderate tendency to bioaccumulate. The Agency will explore further monitoring efforts or additional analyses with the registrants of technical trifluralin in order to obtain more refined characterization of the risk to fish.

For terrestrial and semi-aquatic plants the Agency does find a concern for the semi-aquatic category: risk quotients were obtained that exceeded the "high risk" level of concern (RQ 0.7 to 1.3 versus LOC 1). The Agency does not find concerns for effects on aquatic plants resulting from use of trifluralin. For control of adverse effects caused by spray drift, the Agency will require precautionary labelling described in section V, which is standard for pesticides with aerial applications.

Before reregistering the products containing trifluralin, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each registered product. After reviewing 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. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that, in Phase 5, "the Administrator shall determine whether pesticides containing such active ingredients 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 trifluralin. The document consists of six sections. Section I is the introduction. Section II describes trifluralin, 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 trifluralin. Section V discusses the reregistration requirements for trifluralin. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

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

- **Common Name:** Trifluralin
- **Chemical Name:** α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine
- **Chemical Family:** Dinitroaniline
- **CAS Registry Number:** 1582-09-8
- **OPP Chemical Code:** 036101
- **Empirical Formula:** $C_{13}H_{16}F_3N_3O_4$
- **Trade and Other Names:** Treflan, L-36352, Crisalin, Su Seguro Carpidor, Trefanocide, Treficon, TR-10, Triflurex, Trim, Ipersan, Sinflouran, Ipifluor
- **Basic Manufacturers:** DowElanco, Makhteshim-Agan, Industria Prodotti Chimici S.P.A (I.Pi.Ci.), Tri Corporation, Albaugh Inc.

B. Use Profile

The following is information on the current registered trifluralin uses with an overview of use sites and application methods. A detailed table of these uses can be found in Appendix A, which is available upon request.

Multiple active ingredient products contain:

078802 - triallate
084301 - benfluralin
090501 - alachlor
101101 - metribuzin
105501 - tebuthiuron
125401 - clomazone
125851 - isoxaben
128848 - imazaquin

128982 - imazethapyr
129016 - flumetsulam
059101 - chlorpyrifos
032501 - disulfoton

Mode of Action:

Trifluralin is a dinitroaniline herbicide that enters plants through developing roots and stops plant cells from dividing and elongating (meristematic inhibitor).

Type of Pesticide for Single Active Ingredient:

Herbicide

Additional Type of Pesticide for Multiple Active Ingredient:

Acaricide; Insecticide

Use Sites:

TERRESTRIAL FOOD CROPS (Note: Dill is ineligible for reregistration)

* Apricot
* Asparagus
* Broccoli
* Brussels Sprouts
* Cabbage
* Cabbage, Chinese
* Carrot (including tops)
* Prune
* Cauliflower
* Celery
* Chicory
* Walnut (english/black)
* Crambe
* Cucumber
* Cucurbit Vegetables
* ~~Dill~~ (ineligible)
* Eggplant
* Endive (escarole)
* Kale
* Kohlrabi
* Lentils
* Melons, Cantaloupe
* Melons, Water
* Mustard
* Nectarine
* Collards
* Onions (green)
* Onions (scallions)
* Onions(spring)
* Peach
* Pecan
* Pepper
* Pepper (chili type)
* Plum
* Lettuce
* Radish
* Stone Fruits
* Turnip
* Okra

TERRESTRIAL FOOD AND FEED CROPS

* Almond
* Barley
* Beans
* Beans, Dried-type
* Bean , Mung
* Beans, Succulent (lima, snap)
* Lemon
* Lupine
* Mint
* Mint (Pepper and Spear)
* Mustard
* Orange
* Sugar Beet
* Sugarcane
* Sunflower
* Tangelo
* Tangerines
* Tomato

* Citrus Fruits
* Cole Crops
* Corn (field)
* Cotton
* Cowpea/Blackeyed Pea
* Flax
* Grapefruit
* Grapes
* Guar
* Hops
* Peanuts
* Peas, Dried-type
* Peas, Field
* Peas, Southern
* Peas, Succulent
* Potato, White/Irish
* Rape
* Safflower
* Sorghum
* Soybeans
* Tree Nuts
* Turnip
* Wheat

TERRESTRIAL FEED CROPS (Note: Nongrass: Forage/Fodder/Straw/Hay are ineligible for reregistration)

* Alfalfa
* Barley
* Bermudagrass
* Clover
* Corn
* Cotton
* Wheat
* ~~Nongrass Forage/Fodder/Straw/Hay~~ (ineligible)
* Peanuts
* Rape
* Soybeans
* Sugar Beets (incl. tops)

TERRESTRIAL NON-FOOD CROPS

* Agricultural Rights-Of-Way/Fencerows/ Hedgerows
* Airports/Landing Fields
* Almond (non-bearing)
* Apple (non-bearing)
* Apricot (non-bearing)
* Avocado (non-bearing)
* Blackberry (non-bearing)
* Blueberry (non-bearing)
* Boysenberry (non-bearing)
* Cables/Cable Coverings
* Nonagricultural Rights-Of-Way/ Fencerows/Hedgerows
* Cherry (non-bearing)
* Nonagric. Uncultivated Areas/Soils
* Citrus Fruits (non-bearing)
* Commercial/Industrial Lawns
* Currant (non-bearing)
* Dewberry (non-bearing)
* Elderberry (non-bearing)
* Grapes (non-bearing)
* Industrial Areas (outdoor)
* Kenaf
* Kiwi Fruit (non-bearing)
* Lemon (non-bearing)
* Lesquerella
* Loganberry (non-bearing)
* Macadamia Nut (bushnut; non-bearing)
* Nectarine (non-bearing)
* Nonagric. Outdoor Buildings/Structures
* Castor Bean
* Christmas Tree Plantations
* Olive (non-bearing)
* Orange (non-bearing)
* Ornamental and/or Shade Trees
* Ornamental Ground Cover
* Ornamental Herbaceous Plants

* Fig (non-bearing)
* Filbert (hazelnut; non-bearing)
* Golf Course Turf
* Gooseberry (non-bearing)
* Grapefruit (non-bearing)
* Pistachio (non-bearing)
* Plum (non-bearing)
* Pomegranate (non-bearing)
* Prune (non-bearing)
* Raspberry (black, red; non-bearing)
* Recreation Area Lawns
* Recreational Areas
* Ornamental Woody Shrubs and Vines
* Paved Areas (private roads/sidewalks)
* Peach (non-bearing)
* Pear (non-bearing)
* Pecan (non-bearing)
* Refuse/Solid Waste Sites (outdoor)
* Sewage Disposal Areas
* Stone Fruits (non-bearing)
* Tangelo (non-bearing)
* Tangerines (non-bearing)
* Tree Nuts (non-bearing)
* Walnut (english/black; non-bearing)

TERRESTRIAL NON-FOOD AND OUTDOOR RESIDENTIAL

* Nonagricultural Rights-Of-Way/Fencerows/Hedgerows
* Ornamental and/or Shade Trees
* Ornamental Ground Cover
* Ornamental Herbaceous Plants
* Ornamental Lawns and Turf
* Ornamental Nonflowering Plants
* Ornamental Woody Shrubs and Vines
* Paths/Patios
* Paved Areas (private roads/sidewalks)
* Swimming Pools (impregnated nodules on fabric placed in soil to protect pools from root encroachment; an in-soil barrier plane)

FORESTRY

* Cottonwood (forest/shelterbelt)
* Poplar (forest/shelterbelt)

OUTDOOR RESIDENTIAL

* Ornamental and/or Shade Trees
* Ornamental Ground Cover
* Ornamental Herbaceous Plants
* Ornamental Woody Shrubs and Vines
* Soil, Preplant/Outdoor

Target Pests for Single Active Ingredient:

annual bluegrass, bottlegrass, bristlegrass, bromegrass, broncograss, burgrass, carelessweed, carpetweed, cheat, chess, chickweed, Coloradograss, crabgrass,

cupgrass, field morningglory, Florida pusley, German millet, giant foxtail, goathead, goosefoot, guineagrass, hairy crabgrass, henbit, johnsongrass, jointed goatgrass, junglerice, knotweed, lambsquarters, lovegrass, Mexican fireweed, nettle, panicum, pigeongrass, pigweed, pusley, red rice, rough pigweed, Russian thistle, silver crabgrass, small crabgrass, spiny pigweed, sprangletop, spreading pigweed, stinging nettle, watergrass, wild barley, wild oat, wiregrass, woolly cupgrass

Types/Formulations Registered:
Technical Grade Active Ingredient
- Product Solid (95.6% - 98%)
Manufacturing Products
- Emulsifiable Concentrate 44.5%
- Liquid 50.8%
End Use Products
- Emulsifiable Concentrate 3.9 to 50.8%
- Flowable Concentrate 10.9%
- Form Not Identified/Liquid 36.35 to 50.8%
- Granular 0.17 to 10.0%
- Impregnated Material 18.9%
- Soluble Concentrate/Liquid 43.8%
- Soluble Concentrate/Solid 14.0%
- Water Dispersible Granules (dry flowable) 0.75 to 80.0%

Methods and Rates of Application:
See Appendix A

Types of Treatment:
Barrier treatment; Broadcast; Chemigation; Containerized plant treatment; Golf course treatment; Ground spray; Prepaving treatment; Soil broadcast treatment; Soil incorporated treatment; Soil treatment; Spray

Equipment:
Aircraft; Boom sprayer; By hand; Center pivot irrigation; Drip irrigation; Fixed-wing aircraft; Glove; Granule applicator; Ground; Hand held sprayer; Hand held; Hand move irrigation; Helicopter; Low pressure ground sprayer; Not on label; Overhead sprinkler irrigation; Pneumatic (compressed air) applicator; Shaker can; Solid set irrigation; Sprayer; Spreader; Sprinkler can; Sprinkler irrigation; Wrap

Timing:
April; At planting; August; Bearing; Containerized; Dormant; Early fall; Early preplant; Early spring; Early summer; Established plantings; Fall; Foliar; July; June; Late spring; Late summer; Late winter; Layby; May; Nonbearing; Not on label; Plant bed; Postemergence; Postharvest; Postplant; Posttransplant; Preemergence; Preharvest;

Preplant (Fall); Preplant (Spring); Preplant; Pretransplant; Seed piece; Seed; Seedling stage; Semi-dormant; September; Spring; Summer; Transplant; When needed; Winter

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of trifluralin. 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.

Trifluralin is an herbicide used on a wide range of foods crops. It is also registered for some non-food crop uses. Of the approximately 25,000,000 pounds of active ingredient annually used on agricultural crops, 64% is used on soybeans with another 19% used on cotton. The remaining 17% is used on a wide range of crops. Crops with more than 50% of the planted acres receiving an application of trifluralin include green beans, broccoli, tomatoes, and cotton. Other crops with more than 20% of the planted acres treated with trifluralin include collards, cabbage, sunflowers, dry beans, cauliflower, okra, soybeans, carrots, flax, Brussels sprouts, asparagus, and sweet peppers.

For non-food crops, trees and ornamentals appear to be the most significant sites with approximately 150,000 pounds of active ingredient used annually. Little use of trifluralin on turf was reported.

The table below summarizes trifluralin's uses by site:

TRIFLURALIN USAGE

Crop	Acres Planted (000's acres)	% of Site Treated	Likely Maximum % Treated	Total Active Ingredient (000's lbs)	Likely Maximum (000's lb)	Acres Treated (000's acres)	Likely Maximum (000's acres)
Alfalfa	24,835	2	4	778	1,425	584	1,030
Almonds	389	2	4	7	14	9	14
Apricots	19	Limited individual crop data. Very little usage reported on stone fruits as a group.					
Asparagus	55	22	57	14	38	12	31
Barley	8,190	5	7	192	309	410	531
Beans, Dry	1,809	37	52	417	558	676	937
Beans, Green	319	85	93	158	179	271	298
Broccoli	27	32	26	14	17	19	23

TRIFLURALIN USAGE							
Crop	**Acres Planted (000's acres)**	**% of Site Treated**	**Likely Maximum % Treated**	**Total Active Ingredient (000's lbs)**	**Likely Maximum (000's lb)**	**Acres Treated (000's acres)**	**Likely Maximum (000's acres)**
Brussels Sprouts	4	25	30	<1	<1	1	<2
Cabbage	84	35	35	30	36	38	46
Canola	170	7	14	5	10	11	22
Carrots	65	28	43	14	20	18	28
Cauliflower	44	55	43	11	13	15	18
Celery	34	6	12	2	4	2	4
Cherries	95	No usage observed					
Clover	No information available						
Collards	15	47	60	5	7	7	9
Corn	76,200	<1	1	212	359	275	457
Cotton	13,595	52	62	5,379	7,188	7,009	8,412
Cucumbers	151	3	5	2	2	4	8
Dill	No information available						
Eggplant	3	Information limited, no usage observed.					
Endive & Escarole	5	No information available.					
Flax	244	28	43	32	60	69	105
Grapefruit	139	3	7	6	16	4	10
Grapes	745	3	10	25	81	20	71
Hay, Other	35,988	<1	<1	15	43	22	61
Hops	42	2	5	<1	1	1	2
Kale	6	No information available.					
Lemons	62	No usage observed.					
Lentils	131	No information available.					
Lettuce	275	3	9	3	11	7	24
Limes	No usage observed for citrus other than oranges and grapefruit.						
Lots/farmsteads/etc.	--	--	--	--	11	--	62
Lupines	No information available.						
Melons, Canteloupe	79	18	35	20	48	14	28
Melons, Honeydew	15	3	7	<1	<2	<1	1

TRIFLURALIN USAGE							
Crop	**Acres Planted (000's acres)**	**% of Site Treated**	**Likely Maximum % Treated**	**Total Active Ingredient (000's lbs)**	**Likely Maximum (000's lb)**	**Acres Treated (000's acres)**	**Likely Maximum (000's acres)**
Mint	146	<1	1	<1	1	<1	2
Mustard greens	10	No information available.					
Nectarines	27	Limited individual crop data. Very little usage reported on stone fruits as a group.					
Oats	4,364	<1	<1	15	24	12	22
Okra	6	33	67	1	2	2	4
Onions	149	12	12	11	11	17	17
Oranges	646	<1	1	6	14	4	8
Parsley	5	No usage observed.					
Pasture/Rangeland	--	--	--	2	8	7	38
Pasture/Rangeland, Other	No usage observed.						
Peaches	179	<1	<2	<1	<2	<1	<2
Peanuts	1,690	11	16	106	135	194	258
Peas, Dry	166	19	27	20	26	32	45
Peas, Green	321	17	19	33	37	56	62
Pecans	453	1	2	4	9	6	9
Peppers, Hot	34	No usage observed					
Peppers, Sweet	67	22	39	12	20	15	26
Plums & Prunes	130	<1	<2	1	2	1	2
Potatoes	1,373	7	10	58	100	89	139
Pumpkins	41	2	5	<1	1	<1	2
Rape (see also Canola)	12	No information available.					
Safflower	323	8	16	21	42	25	50
Seed Crops	--	--	--	4	4	4	4
Setaside acres	--	--	--	118	204	192	336
Sorghum	11,611	1	2	77	148	119	226
Soybeans	58,909	33	38	17,985	23,305	19,494	22,091
Squash	58	7	14	3	6	4	8
Sugar beets	1,434	8	11	73	92	120	153

TRIFLURALIN USAGE							
Crop	**Acres Planted (000's acres)**	**% of Site Treated**	**Likely Maximum % Treated**	**Total Active Ingredient (000's lbs)**	**Likely Maximum (000's lb)**	**Acres Treated (000's acres)**	**Likely Maximum (000's acres)**
Sugarcane	926	15	20	248	308	143	184
Summer fallow	--	--	--	79	203	157	382
Sunflower	2,580	44	49	838	1,050	1,135	1,271
Sweet Corn	748	<1	1	1	3	3	9
Tangelos	--	No usage observed for citrus other than oranges and grapefruits.					
Tangerines	--	No usage observed for citrus other than oranges and grapefruits.					
Tomatoes	456	53	63	164	244	240	286
Turnip greens (tops)	10	No information available					
Watermelon	239	5	12	16	39	12	28
Wheat	71,464	3	5	945	1,502	2,410	3,722
Agricultural Total	--	--	--	28,182	37,990	33,992	41,616
Trees, Ornamentals & Turf	--	--	--	150	--	--	<300
Not in the Reference Files System (REFS) but usage reported:							
Tobacco	762	0	1	4	5	3	6
In the Reference Files System (REFS) and no usage:							
Pomegranates	--	--	--	--	--	--	--
Tolerances exist for the following crops, however, no usage is reported. Beet greens (tops); Buckwheat; Cabbage, Chinese; Casaba (muskmelon); Cashew; Chestnut; Cowpeas; Crenshaw melon; Dandelion; Fennel, Florence; Filbert; Hazelnut; Hickory nut; Honey balls (melons); Kohlrabi; Kumquats; Lespedezas; Macadamia nuts; Millet; Muskmelon; Pawpaws; Pea vine hay; Persian melon; Pimentos; Popcorn; Rhubarb; Salsify tops; Spinach; Swiss chard; Velvet beans (for forage); Walnuts; Watercress							
The following imported crops were listed in the tolerance or Reference Files System (REFS) files. No usage information is provided: Brazil nuts, Palm oil.							
Other crops appeared only in the Reference Files System (REFS) listing and not in the tolerance file. For these crops no usage was observed. Fescue; Walnuts, black; Herbaceous flavoring.							

Sources: Doane, RFF, NASS, State surveys. 1987 to 1993 data

D. Data Requirements

Data requested in the April, 1987 Registration Standard for trifluralin included studies on product and residue chemistry, toxicology, ecological effects and environmental fate. These data were required to support the uses listed in the Registration Standard. A Data Call-In was issued by the Agency in March, 1995 for reentry protection data and mixer/loader/applicator exposure monitoring data on trifluralin and other chemicals used on turf. These data are due in 1996 and 1997, respectively. Appendix B of this RED document includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Trifluralin was first registered in the United States in 1963 for use as a selective preemergent herbicide. A Registration Standard for trifluralin was issued in April, 1987 (NTIS# PB87-201935). This Reregistration Eligibility Decision reflects a reassessment of all data submitted in support of trifluralin reregistration.

A Special Review was initiated in August, 1979 because trifluralin products contained N-nitroso-di-n-propylamine (NDPA or nitrosamine) at levels that met or exceeded the oncogenic risk criterion. The Agency's Position Document (PD 1/2/3) proposed cancellation of all trifluralin product registrations unless registrants modified their labels and Confidential Statements of Formula (CSFs) to reflect an upper limit for NDPA of 1 ppm.

In 1982, the Agency revised its position on nitrosamine requirements for trifluralin and issued the Trifluralin PD-4, reducing the allowable nitrosamine level to 0.5 ppm. The Agency also withdrew the requirement that product labels state the level of NDPA contamination. The PD-4 required registrants to list a 0.5 ppm upper certified limit for nitrosamines on CSFs for all technical products. For formulated products, the upper limit for total N-nitrosamine content is to be calculated on a percentage basis including a multiplication factor of 2 (e.g., for a 25% FI: 0.5 ppm nitrosamine in TGAI x 0.25% ai x 2 - 0.25 ppm maximum nitrosamine). The Confidential Statements of Formula (CSFs) for all currently registered trifluralin technical products list nitrosamine levels at or below the 0.5 ppm level. As specified in the PD-4, registrants are required to advise the Agency of quality control procedures and maintain quality control records.

Although the trifluralin technical product CSFs state that nitrosamine levels are at or below 0.5 ppm, the Agency is requiring that all technical and manufacturing-use registrants confirm this by submitting nitrosamine analysis data for each of their technical and/or manufacturing-use products. The issue of nitrosamine levels in

trifluralin end-use products is addressed in the product-specific Data Call-In included in this RED.

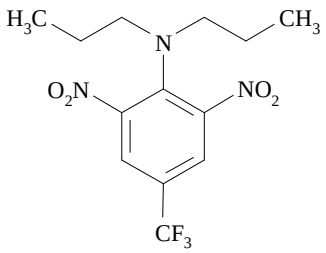
Currently, there are 172 active products containing trifluralin which are registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). They consist of technicals, formulation intermediates, impregnated materials, granulars, soluble concentrates, emulsifiable concentrates, wettable powders, dusts, pressurized dusts, and water dispersible granules.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Description of Chemical

Trifluralin (α,α,α-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine) is a selective preemergence herbicide registered for weed control primarily on soybeans and cotton, as well as on various vegetable crops.



Empirical Formula: $C_{13}H_{16}F_3N_3O_4$

Molecular Weight: 335.3

CAS Registry No.: 1582-09-8

Shaughnessy No.: 036101

2. Identification of Active Ingredient

Trifluralin is a yellow-orange crystalline solid with a melting point of 42-49° C. Trifluralin is practically insoluble in water (<1 ppm), but is readily soluble in organic solvents such as acetone, xylene, or aromatic naphthas.

3. Manufacturing-Use Products

The table below summarizes the currently registered manufacturing-use trifluralin products. At the time of the Trifluralin Reregistration Standard (4/87), the DowElanco products listed below were registered to Elanco Products Company. When Elanco merged with Dow Chemical to become DowElanco, EPA registration numbers for the products were changed.

Formulation	EPA Reg. No. (Date of Registration)	Registrant
98% T	11603-13 (2/73)	Agan Chemical Manufacturers, Ltd.
96% T	19713-384 (5/95)	Drexel
96.3% T	33660-3 (5/76)	Industria Prodotti Chimici S.P.A (I.Pi.Ci.)
95.6% T	42750-30 (10/94)	Albaugh, Inc.
96.3% T	62719-99 (12/89) [a]	DowElanco
50.8% FI	62719-172 (6/90) [b]	
44.5% FI	62719-101 (12/89) [c]	
97.47% T	67959-1 (6/94)	Tri Corporation
96.3% T	68156-3 (9/94)	Dintec Agrichemicals

[a] Previously registered to Elanco Products Company, EPA Reg No. 1471-70 (4/70).
[b] Previously registered to Elanco Products Company, EPA Reg No. 1471-120 (12/81).
[c] Previously registered to Elanco Products Company, EPA Reg No. 1471-72 (4/70).

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for trifluralin is adequate and will support reregistration eligibility for all trifluralin uses.

a. Acute Toxicity

Acute toxicity values and categories for trifluralin are summarized in the table below:

Gdln	Test	Citation (MRID)	Results	Category
81-1	Oral LD_{50} - Rat	00157486	>5000 mg/kg	IV
81-2	Dermal LD_{50} - Rat	00157482	>2000 mg/kg	III
81-3	Inhalation LC_{50} - Rat	00155261	>4.66 mg/L	III
81-4*	Eye Irritation - Rabbit	00157483	slight irritation	III
81-5*	Dermal Irritation - Rabbit	00157485	no irritation	IV
81-6*	Dermal Sensitization - Guinea Pig	00157484	sensitizer	-
81-7	Acute Delayed Neurotoxicity - Leghorn Hens	00159616	>5000 mg/kg	-

* 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 for informational purposes.

b. Subchronic Toxicity

90-Day Feeding - Rodent: A subchronic oral toxicity study was performed in Fischer 344 rats using concentrations of 0.005, 0.02, 0.08, 0.32 or 0.64 % in the diet. The NOEL was 0.005% (50 ppm or 2.5 mg/kg/day). The LOEL was 0.02% (10 mg/kg/day) based on increased hyaline droplet formation in cortical cells, increased total urinary protein excretion, and changes in urine color and clarity. Many of the effects were reversible within a six-week recovery period (MRID 40138301).

A second subchronic oral toxicity study, using Wistar rats and higher trifluralin doses of 0, 800, 2000, or 5000 ppm, indicated that the NOEL was less than 800 ppm (40 mg/kg/day, lowest dose tested), due to reductions in relative liver and pituitary gland weights at all dose levels tested (MRID 00151906).

31-Day Dermal Toxicity - Rodent: A 31-day dermal toxicity study was performed with trifluralin in Wistar rats using doses of 0, 40, 200 or 1000 mg/kg/day for six hours/day for a total of 23 applications. The NOEL was 200 mg/kg/day based upon increased liver weight at the highest dose tested (MRID 00153171).

c. Chronic Toxicity and Carcinogenicity

Chronic Toxicity - Non-Rodent: Beagle dogs were fed trifluralin by capsule at doses of 0, 0.75, 2.4 or 40 mg/kg/day for one year. The

NOEL was 2.4 mg/kg/day and the LOEL was 40 mg/kg/day based upon reduced body weight, decreased red cells and hemoglobin levels, increased thrombocyte, methemoglobin, cholesterol and triglyceride levels, and increased liver weight (MRID 42447001).

In a second beagle dog study, doses of 0, 30, 150 or 750 ppm were fed in the diet for one year. The NOEL was 30 ppm (the lowest dose tested, 0.75 mg/kg/day). The LOEL was 150 ppm (3.75 mg/kg/day) based upon increases in liver weight and methemoglobin. At the high dose, there were also decreased weight gain, decreased RBC, increased methemoglobin, increased serum lipids, triglycerides, and cholesterol (MRID 00151908, 00159618).

Chronic Toxicity/Oncogenicity - Rodent: Several long-term carcinogenicity studies were conducted with trifluralin in rodents. One study was performed in Fischer 344 rats using dietary doses of 0, 813, 3250 or 6500 ppm for two years. The highest dose (325 mg/kg/day) resulted in significant increases of combined malignant and benign urinary bladder tumors in females. An increase in the incidence of carcinomas of the renal pelvis was seen in all dose groups of males. In addition, an increase in the incidence of thyroid gland follicular cell tumors (adenomas plus carcinomas combined) in males was found. (MRID 00044337).

The other rat bioassays were: a two-year study in Sprague Dawley rats at doses of 0, 200, 1000 or 2000 ppm; a 78-week study in Osborne-Mendel rats at doses of 0, 3250 or 6500 ppm, conducted by the National Cancer Institute; and a two-year study in Wistar rats at doses of 0, 200, 800 or 3200 ppm (MRID 00162456, 00162457, 00162458). In the last study, the systemic LOEL was 800 ppm (40 mg/kg/day) based on body weight changes.

Oncogenicity - Mouse: There were three mouse carcinogenicity bioassays of trifluralin. A 78-week study was conducted by the National Cancer Institute with $B6C3F_1$ mice at doses of 0, 2375 or 5000 ppm. The test compound was contaminated with N-nitroso-di-n-propylamine, which was considered to be the cause of the liver carcinomas, alveolar-bronchiolar adenomas, and squamous-cell carcinomas of the forestomach in the female mice (Jaeger, 1986).

A two-year study, conducted in $B6C3F_1$ mice at doses of 0, 563, 2250 or 4500 ppm, found no tumors due to the test compound (MRID 00044338).

A two-year study in NMRI mice used purified test compound at doses of 0, 50, 200 or 800 ppm. There were increased liver weights in males at 200 or 800 ppm (30 and 120 mg/kg/day) and in females at the high dose. The systemic NOEL was 50 ppm (7.5 mg/kg/day) in male mice and 200 ppm in females. No tumors due to the test compound were found (MRID 00158935, 40392313).

The available mouse carcinogenicity studies showed that trifluralin did not induce increases in tumor incidence in any of the mouse studies.

Carcinogenicity Classification: The OPP Carcinogenicity Peer Review Committee evaluated all the available carcinogenicity data on trifluralin (April 4, 1986), and it concluded that there is limited evidence of carcinogenicity in male and female rats based upon an increase in combined malignant and benign urinary bladder tumors in females, renal pelvis carcinomas in male rats, and thyroid gland follicular cell tumors (adenomas plus carcinomas combined) in males. Trifluralin has been classified as a Group "C", possible human carcinogen with a Q_1* of 0.0077 mg/kg/day^{-1}.

d. Developmental Toxicity

Teratogenicity - Rat: Charles River rats were given gavage doses of 0, 100, 225, 475 or 1000 mg/kg/day of trifluralin on gestation days 6-15. The maternal toxicity NOEL was 225 mg/kg/day due to reduced weight gain and food consumption at higher dose levels. The developmental toxicity NOEL was 475 mg/kg due to reduced mean fetal body weight at 1000 mg/kg/day (MRID 00152419).

Teratogenicity - Rabbit: Dutch Belted rabbits were given oral doses of 0, 100, 225 or 500 mg/kg/day of trifluralin on gestation days 6-28. The maternal toxicity NOEL was 100 mg/kg/day due to anorexia, cachexia and resulting abortion at higher dose levels. The developmental toxicity NOEL was 225 mg/kg/day based on depressed fetal weight and an increased number of fetal runts at higher doses (MRID 00152421).

No teratogenic effects occurred in rats or rabbits.

e. Reproductive Toxicity

2-Generation Reproduction - Rat: A reproductive NOEL of greater than or equal to 2000 ppm (i.e. 0.2% in the diet) was established in a two-generation study in which trifluralin was fed to CD rats at dietary levels of 0, 200, 630 or 2000 ppm (15, 47, or 148 mg/kg/day). The systemic NOEL was 200 ppm. The systemic LOEL was 630 ppm due to reduced body weights in parental animals (MRID 00162543).

Another two-generation study was conducted with Wistar KFM-Han rats, using doses of 0, 200, 650, or 2000 ppm in the diet. There were increased relative kidney weights at all dose levels tested, and thus the parental LOEL was 200 ppm (10 mg/kg/day). The two higher doses showed renal lesions and increased relative liver weights. The NOEL for reproductive and developmental toxicity was 200 ppm. The LOEL was 650 ppm (32.5 mg/kg/day) based on reduced weanling body weights at 650 and 2000 ppm, and reduced litter sizes at the highest dose (MRID 00151901, 00151902, 00151903).

f. Mutagenicity

Trifluralin was negative for genotoxicity in the Ames test (MRID 00153173, 00126660) and an assay of mammalian cells in culture to assess forward mutations at the TK locus of L5178Y mouse lymphoma cells (MRID 00126661). The compound also displayed negative activity in tests to detect chromosome aberrations, including dominant lethal tests in rats and mice (MRID 00129059), and a mouse micronucleus assay (Last, et al., 1981). Trifluralin was also negative in another mutagenicity assay for the in vivo induction of sister chromatid exchange in Chinese hamster bone marrow (MRID 00126662).

g. Metabolism

General Metabolism: Studies in rats using radioactive trifluralin have indicated that the compound is not readily absorbed from the gastrointestinal tract after oral intake. However, of the trifluralin that is absorbed, essentially all of it is completely metabolized and eliminated within 3 days after oral administration. About 80% of the administered dose was eliminated in the feces and the remainder in the urine. About 30 to 40 different metabolites are excreted in the urine, each one representing less than 1% to 2% of the total radioactivity in the urine (MRID 41218901).

h. Dermal Penetration

The estimated approximate rate of dermal absorption is 1% of the applied dose based on available data that indicates that less than 1% of the applied dose is dermally absorbed (Toxicology Endpoint Selection Document 9/9/94).

i. Other Toxicity Endpoints

Reference Dose: The RfD for trifluralin is 0.024 mg/kg/day as determined from the one-year feeding study in dogs. The NOEL was 2.4 mg/kg/day (MRID 42447001). A safety factor of 100 was applied to account for the inter-species extrapolation (factor of 10) and intra-species variability (factor of 10).

Carcinogenicity Classification: Trifluralin has been classified as a Group C, possible human carcinogen by the OPP Carcinogenicity Peer Review Committee (4/4/86). The Q_1* for quantitation of risk is 0.0077 $mg/kg/day^{-1}$.

Additional Toxic Endpoints: No acute dietary, short term occupational or residential nor intermediate term occupational or residential endpoints were identified.

2. Exposure Assessment

a. Dietary

Plant metabolism data for trifluralin are adequate. Except for alfalfa forage, alfalfa hay, flax straw, and sunflower forage, the field trial data are adequate. The residue study on corn forage, fodder, and silage is adequate pending submission of acceptable data validating the analytical method (Method No. GRM92.11) at or below the established 0.05 ppm tolerance level. Adequate processing studies have been submitted for field corn, cottonseed, grapes, hops, citrus, peanuts, plums, potatoes, sorghum grain, soybeans, sugar beets, sugarcane, sunflower seed, tomatoes, and wheat. Based on these data, food/feed additive tolerances for residues of trifluralin are not required for the processed commodities of barley, field corn, cottonseed, flax, grapes, hops, citrus, peanuts, plums, potatoes, rape seed, safflower seed, sorghum grain, soybeans, sugar beets, sugarcane, sunflower seed, tomatoes, and wheat. Peppermint and spearmint processing data remain outstanding. Test sample storage information remains outstanding for

asparagus, peppermint, and spearmint. Due to test sample storage stability concerns, one additional field trial should be conducted on carrots, grapes, and barley/wheat forage, hay, and straw. Acceptable storage stability studies have been conducted on numerous commodities matrices. The existing data indicate that the established tolerances and/or the revised tolerance recommendations made in this report are supported.

The qualitative nature of the residue in animals is adequately understood. Based on available ruminant and poultry metabolism data, the Agency has concluded that there is no reasonable expectation of finite residues of trifluralin in animal commodities. Therefore, there is no need for tolerances for trifluralin residues in meat, milk, poultry and eggs.

The dietary exposure assessment for trifluralin is based on tolerance level residues and proposed tolerance levels as specified in the tolerance reassessment summary with the exception of carrots, wheat, tomatoes, and sugarcane. Anticipated residue estimates for carrots, wheat, tomatoes, and sugarcane, as well as for their processed food commodities, will be used for the carcinogenic risk assessment. Though confirmatory, receipt of the required sample storage information and bridging field trials will increase confidence with respect to the risk assessment.

Plant Metabolism: The qualitative nature of the residue in plants is adequately understood based on acceptable field corn and mustard green metabolism studies supported by supplemental carrot, cotton, peanut, soybean, and sweet potato metabolism data. The residue of concern in plants is trifluralin *per se* and the current tolerance expression for plants is adequate (MRID 00024731, 00026054, 00093553, 00105720, 00105759, 00124905, 00125299, 41179001, 41179002, 41396801, 41396802).

Animal Metabolism: The qualitative nature of the residue in animals is adequately understood based on acceptable poultry and ruminant metabolism studies reflecting oral exposure. Studies conducted at various feeding levels (including exaggerated levels) indicate that finite trifluralin residues are not expected to occur in animal commodities (MRID 00093636, 00105690, 00105772, 41233101, 41233102, 41286101).

The Agency concludes that although radioactive residues in animal tissues, milk, and eggs from exaggerated feeding levels were incompletely characterized, further analytical work is not required given the low levels of radioactive residues expected to result from the current maximum theoretical dietary exposure estimates. Further, the Agency concludes that there is no reasonable expectation of finite residues of trifluralin in animal commodities. Therefore, there is no need for tolerances for trifluralin residues in meat, milk, poultry and eggs as prescribed under 40 CFR §180.6(a)(3).

Residue Analytical Methods - Plants and Animals: The reregistration requirements for residue analytical methods are fulfilled. Adequate methods are available for data collection and enforcement of tolerances for residues of trifluralin *per se* in/on plant commodities. The requirement for analytical method(s) for animal commodities has been waived (MRID 00022793, 00047591, 00047639, 00059532, 00067371, 00067435, 00080320, 00105646, 00105689, 00105695, 00105720, 00105759, 00125303).

Storage Stability: The requirements for storage stability data are not fully satisfied. Information concerning sample storage intervals and conditions for asparagus and peppermint/spearmint magnitude of the residue studies previously submitted and reviewed in the Trifluralin Registration Standard remains outstanding.

In addition, due to test sample stability concerns, one additional field trial must be conducted as bridging data at exaggerated rates on each of the following crops in the major growing area: (i) barley or wheat forage, hay and straw; (ii) carrots; and (iii) grapes.

Outstanding field trials and processing studies must have supporting storage stability data. The Agency prefers that concurrent storage stability studies be conducted with the field trials.

Magnitude of the Residue in Plants: The reregistration requirements for magnitude of the residue in plants are fulfilled for the following commodities: almonds (hull and nutmeats); apricots; asparagus; barley (forage, grain, hay, and straw); beans (succulent, seed, forage, and straw/hay); broccoli; Brussels sprouts; cabbage; cantaloupes; cauliflower; carrots; celery; cherries; chicory (roots and tops); collards; corn (grain and aspirated grain fractions); cotton (seed); cucumbers; endive; flax (seed); garlic; grapefruit; grapes; hops; kale; lemons; lupin (seed), mustard (greens and seed); nectarines; okra; onions (bulb and

green); oranges; peaches; peanuts (nutmeats, hay, and hulls); peas (succulent, seed, vines, and hay); pecans; peppermint (hay); peppers; plums; potatoes; radishes (roots and tops); rape (seed); safflower (seed); sorghum (forage, grain, fodder, and aspirated grain fractions); soybeans (seed, forage, hay, and aspirated grain fractions); spearmint (hay); squash (summer), sugar beets (roots and tops); sugarcane; sunflower (seed); tangelos; tangerines; tomatoes; turnips (roots and tops); walnuts; watermelon; and wheat (forage, grain, hay, straw, and aspirated grain fractions). Adequate field trial data depicting residues of trifluralin following treatments according to the maximum registered use patterns have been submitted for the commodities listed above or have been translated where appropriate.

Residue data for corn forage, fodder and silage are adequate pending submission of acceptable method validation data. Additional alfalfa forage and hay data are required to support the reregistration of trifluralin. Residue data are no longer required for sunflower forage; however, residue data are now required for rape forage. Alternatively, sunflower forage data, if available, would be translated to rape forage.

Existing Special Local Needs (SLN) registrations for the uses of trifluralin on clover and bermudagrass grown for seed production only may be deemed non-feed uses by the Agency, if, like Washington state, the states needing these SLN registrations ensure that adequate legal/regulatory mechanisms are in place to prevent feed uses of the seed crop(s) and forages, hays, straws from the seed crop(s). Otherwise, residue data are required depicting residues of trifluralin in/on clover forage and hay and bermudagrass forage and hay resulting from the maximum use rates permitted to clover and bermudagrass to establish tolerances on clover forage and hay and bermudagrass forage and hay.

There are two uses for which the Agency has no data, non-grass forage/fodder/straw/hay and dill. These uses are unsupported and will be deleted from the labels unless data are generated.

Based on changes to the Livestock Feeds Table, the Agency currently recognizes cotton gin byproducts (commonly called gin trash) as a raw agricultural commodity of cotton and residue data are required depicting residues of trifluralin in/on cotton gin byproducts resulting from the maximum registered use rate to cotton. A minimum of six (6) field trials are required. These data will be considered confirmatory to the reregistration eligibility decision for trifluralin.

For additional guidance on sampling and geographical locations for field trials the registrant should consult "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances" issued 6/2/94. The need for additional tolerances and revisions to the exposure/risk assessments will be made upon receipt and evaluation of required data.

Magnitude of the Residue in Processed Food/Feed: Adequate processing studies have been conducted on the processed commodities of the following RACs: cottonseed, field corn, oranges, peanuts, potatoes, grain sorghum, soybeans, sugar beets, sugarcane, sunflower seed, and wheat. The available processing data indicate that residues in the processed commodities will not exceed the currently established tolerance on the associated RAC.

Available wheat processing data have been translated to barley processed commodities.

Available cottonseed processing data have been translated to flax processed commodities.

Available sunflower seed processing data have been translated to rape seed and safflower processed commodities.

Acceptable field trials have been conducted at exaggerated application rates (up to 5x) which are adequate to demonstrate that residues of trifluralin are not likely to concentrate in the processed commodities of the following RACs: grapes, hops, plums, and tomatoes.

Potato processing data (MRID 42514501) have previously been reviewed by the Agency and deemed adequate to satisfy data requirements. These data demonstrate that residues of trifluralin do not concentrate in flakes and chips but do concentrate in wet peel (5x) and dried peel (280x). Based on the submitted study, the Agency recommended that a feed additive tolerance for residues of trifluralin in processed potato waste should be established using the maximum theoretical concentration of residues in dry peel. However, since that time, the Agency has updated the Livestock Feeds Table for Subdivision O and now establishes feed additive tolerances for processed potato waste based on the maximum concentration factor observed for residues in/on wet peel. Because the potato processing study was conducted at exaggerated application rates (up to 5x)

resulting in trifluralin residue levels in/on processed wet potato peel samples (ranging from <0.05 ppm to 0.05 ppm) equal to or below the currently established tolerance for potatoes (0.05 ppm), the Agency concludes that a feed additive tolerance for residues of trifluralin in/on processed potato waste is not required. The currently established tolerance for residues of trifluralin in/on potatoes will apply to processed potato waste.

The Agency no longer recognizes any processed commodities of alfalfa and beans. No alfalfa or bean processing data are required.

Processing studies conducted on peppermint oil and spearmint oil showed that residues of trifluralin concentrated in both commodities. Because the actual concentration factors could not be determined, new peppermint and spearmint processing data are required on a confirmatory basis. It should be noted that the available processing data are sufficient for the purposes of determining that residues in ready-to-eat foods prepared from the mint oil will not exceed the existing 408 tolerances.

Magnitude of the Residue in Meat, Milk, Poultry, and Eggs: The data requirements for magnitude of trifluralin residue in meat, milk, poultry, and eggs have been waived based on the low levels of radioactive residues from the animal metabolism studies. This is considered to be a 40 CFR §180.6 category 3 with respect to the need for tolerances for trifluralin residues in meat, milk, poultry and eggs. Category 3 of 40 CFR §180.6 states that "it is not possible to establish with certainty whether finite residues will be incurred, but there is no reasonable expectation of finite residues."

Confined/Field Rotational Crops: Confined rotational crop data are deemed adequate to satisfy reregistration data requirements. Limited field rotational crop studies are not required and tolerances are not needed for trifluralin residues in rotational crops (MRID 41661102).

b. Occupational and Residential

Handler (Mixer/Loaders and Applicators) Exposure: The Agency has determined that there is potential for exposure to mixers, loaders, applicators, or other handlers during usual use patterns associated with trifluralin. The Agency is concerned specifically about potential exposures arising from mixing and loading liquids and granulars, aerial application, groundboom application, granular application at planting,

granular spreader cultivator mounted, residential push-type spreaders, whirly-bird spreaders, hand-held sprayers, and backpack sprayers.

Post Application Exposure: The Agency has determined that there is potential exposure to persons entering treated sites after application is complete. The Agency is specifically concerned about potential post-application exposure arising from re-entering treated turf (e.g.,residential lawns, recreational areas, and sod farms), ornamental (especially nursery), and established food/fiber crop sites.

Post-application exposure data were not required previously by the Agency, since no toxicological concerns were identified at that time. No post-application exposure data are available to conduct an exposure/risk assessment, however, trifluralin was one of the chemicals included in a generic Data Call-In Notice requiring exposure data for pesticides used on residential lawns. The data generated will allow the Agency to more accurately estimate both professional and homeowner exposure to pesticides applied to the home lawn.

Exposure values can be found in the combined exposure/risk table in section III.B.3.b.

3. Risk Assessment

a. Dietary

Using anticipated residues and percent of crop treated data, the Agency has concluded that the chronic dietary risk posed by trifluralin is not of concern. The upper bound cancer risk does not exceed the level of concern for excess lifetime dietary cancer risk.

The Dietary Risk Evaluation System (DRES) chronic analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Refinements in residue information were considered in calculating the Anticipated Residue Contribution (ARC) for those same population groups. Anticipated residues were estimated for carrots, wheat, tomatoes and sugarcane. Percent of crop treated information was included in the estimation of the anticipated residue contribution. These exposure estimates were then compared to the RfD for trifluralin.

Using Tolerances: The Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and highest exposed subgroup from published tolerances supported in reregistration are listed below.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.000724	3
Non-nursing Infants	0.002438	10

Using Anticipated Residues and Percent of Crop Treated Data: The Anticipated Residue Contribution (ARC) for the overall U.S. population from published uses is listed below.

Subgroup	Exposure(mg/kg/day)	% Reference Dose
U.S. population	0.000126	1
Non-nursing Infants	0.000429	2

For all the DRES subgroups the %RfD appears to be within a safe margin, even when considering tolerance levels and 100% crop treated. The chronic dietary risk posed from trifluralin is not of concern.

Upper Bound Carcinogenic Exposure: The upper bound carcinogenic risk from food uses of trifluralin for the general U.S. population was calculated using the following equation:

Upper Bound Cancer Risk = Dietary Exposure (ARC) x Q_1^*

Based on a Q_1^* of 0.0077 $(mg/kg/day)^{-1}$, when using refinements in residues and percent of crop treated information, the upper bound cancer risk was calculated to be 1.0×10^{-6} (viz. 0.96×10^{-6}), contributed through all the published uses for trifluralin, including mung beans, which are not being supported for reregistration. The upper bound risk does not exceed the level of concern for excess lifetime dietary cancer risk.

b. Occupational and Residential

Handler (Mixer/Loader/Applicator): Based on the use patterns and potential exposures, nine major handler exposure scenarios were identified for trifluralin:

(1) mixing/loading the liquid formulation
(2) loading granulars for ground and aerial application
(3) aerial application of liquids
(4) groundboom application of liquids
(5) granular row planter application
(6) granular spreader cultivator application
(7) mixing/loading and applying using a residential push-type spreader
(8) mixing/loading and applying with a residential "whirly-bird" spreader.
(9) application using backpack sprayer

The exposure scenarios are presented in the table below along with the corresponding exposure/risk assessment. Each exposure assessment in the table below is based on the assumption that workers wear long pants, shoes and socks, long sleeved shirts and no gloves, except handlers on granular 6 and 8-row planters who were wearing double layered clothing (coveralls, over long sleeved shirt and long pants) and chemical resistant gloves and were located inside enclosed cabs), and mixer/loaders of liquids who were wearing chemical resistant gloves.

The Agency has calculated the exposure and resulting risk values for the exposure scenarios. The occupational/residential cancer exposure/risk assessment for all uses indicates a level of risk that does not exceed 10^{-5} for occupational handlers or 10^{-7} for residential handlers.

Post-Application: No data are available to calculate post-application exposures and risks following trifluralin treatments. A March, 1995 Data Call-In Notice for trifluralin pesticide products' use on residential lawns will generate data that will allow the Agency to more accurately estimate both professional and homeowner exposure to pesticides applied to lawns.

Although the Agency has no data, the dermal absorption value is very low (one percent) and inhalation exposures are not a concern for post-application scenarios. These factors suggest that occupational and residential post-application exposures probably would be no higher than exposures to occupational handlers. Since the occupational/residential cancer exposure/risk assessment for all uses indicates a level of risk that does not exceed 10^{-5} for occupational handlers or 10^{-7} for residential handlers, the Agency does not anticipate that the exposure/risk assessment for post-application scenarios would exceed 10^{-5} for

occupational post-application exposures or 10^{-7} for residential post-application exposures.

Table 1. Summary Exposure/Risk Values for Trifluralin

Exposure Scenario (Scen. #)	Dermal Exposure[a] (mg/lb ai)	Inhalation Exposure[b] (mg/lb ai)	Maximum Label Application Rate[c] (lb ai/acre)	Daily Max. Treated[d] (acres)	Potential Daily Dermal Dose[e] (mg/kg/day)	Potential Daily Inhalation Dose[e] (mg/kg/day)	Total Absorbed LADD[f] (mg/kg/day)		Risk[i]	
							Private Appl.[g]	Commercial Appl.[h]	Private Appl.[g]	Commercial Appl.[h]
Mixer/Loader Exposure										
Liquids (I)	0.04[*]	0.0012	2	800	0.91	0.027	0.00016	0.0016	1.2×10^{-6}	1.2×10^{-5}
Granulars (II)	0.01	0.0017	2	800	0.23	0.04	0.000087	0.00087	6.7×10^{-7}	6.7×10^{-6}
Applicator Exposure										
Aerial (III)	0.05	0.0003	2	800	1.14	0.007	NA	0.0016	NA	1.2×10^{-5}
Groundboom (IV)	0.01	0.0007	2	80	0.02	0.0016	0.000005	0.000049	3.8×10^{-8}	3.8×10^{-7}
Granular 8-row Planter (V)	0.003[**]	0.0004	2	80	0.007	0.0009	0.000002	0.000022	1.7×10^{-8}	1.7×10^{-7}
Granular Spreader Cultivator Mounted (VI)	0.002[***]	0	2	80	0.005	0	0	0.000007	5.0×10^{-9}	5.0×10^{-8}
Mixer/Loader Applicator										
Residential Push-type Spreader (VII)	2.9	0.0063	3	1	0.12	0.0003	0.000016	NA	1.2×10^{-7}	NA
Whirly-bird Spreader (VIII)	10.4	0.0618	3	1	0.45	0.003	0.000066	NA	5.1×10^{-7}	NA
Backpack Sprayer (IX)	2.5	0.03	0.83 (lb ai/gallon)	(H) 5 gallons (O) 40 gallons	(H) 0.15 (O) 1.19	(H) 0.002 (O) 0.01	0.000024	0.003	1.9×10^{-7}	2.3×10^{-5}

[a] Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeved shirts, and no gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for lognormal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. Protection factors were not used to calculate dermal unit exposure values because sufficient data are available for PPE in these scenarios.

[b] Inhalation Exposure Values are reported as geometric means (lognormal distributions). No adjustment has been made to simulate workers wearing dust/mist respirators.

[c] Team 1.15 Lawn Weed and Feed Label, EPA Reg # 228-208; Treflan M.T.F. Label, EPA Reg # 62719-116; Treflan TR-10 Label, EPA Reg # 62719-131; Treflan 5 Label, EPA Reg # 62719-118; Treflan E.C. Label, EPA Reg # 62719-93; Trilin 5 label, EPA Reg # 1812-353.

[d] Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.

[e] Potentially Daily Dose (mg/kg/day) $= \frac{\text{Exposure (mg/lb ai)} * \text{Max. Appl. Rate (lb ai/cycle)} * \text{Max. Treated}}{70 \text{ kg}}$

[f] Absorbed LADD mg/kg/day = [Daily Dermal Dose (mg/kg/day) * (Work Days Per Yr/365 Days Per Year) * (35 Yrs/70 Yrs) * (0.1 Dermal Absorption)] + [Daily Inhalation Dose (mg/kg/day) * (Work Days Per Yr/365 Days Per Year) * (35 yrs/70 yrs)]

[g] Private applicator is defined as a short term exposed individual (i.e., one day)

[h] Commercial applicator is defined as an intermediate exposed individual (i.e. 10 days)

[I] Risk = [Absorbed LADD (mg/kg/day)] * [Q (0.0077 mg/kg/day)]

[*] Long pants, long sleeved shirt, chemical resistant gloves.

[**] Double layer of clothing and gloves were worn during this scenario.

[***] Enclosed cab, long pants, long sleeve shirt, no gloves.

Table 2. Exposure Scenario Descriptions for Trifluralin

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario[a]	Equipment	Standard Assumptions[b]	Comments[c]
Mixer/Loader Exposure					
Liquids (I)	PHED V1.1	Long pants, long sleeves, chemical resistant gloves	Open mixing for aerial or chemigation applications	800 acres	Acceptable grades; Dermal = 53 to 122 replicates; Inhalation = 85 replicates; High confidence in dermal and inhalation data.
Granular (II)	PHED V1.1	Long pants, long sleeves, no gloves	Open mixing for aerial applications	800 acres	All grades for dermal; Acceptable grades for inhalation; Dermal = 10 to 78 replicates Inhalation = 58 replicates; Low confidence in dermal and high confidence for inhalation data.
Applicator Exposure					
Aerial (III)	PHED V1.1	Long pants, long sleeves, no gloves	Aircraft; all cab types	800 acres	Dermal grades A,B,C; Inhalation all grades; Dermal = 1 to 17 replicates Inhalation = 17 replicates; Low confidence in dermal and inhalation data.
Groundboom (IV)	PHED V1.1	Long pants, long sleeves, no gloves	Open Cab	80 acres	Dermal and inhalation grades = acceptable grades; Dermal = 23 to 33 replicates; Inhalation = 22 replicates; High confidence in dermal and inhalation data.
Granular 8-row Planter (V)	PHED V1.1	Two layers of clothing; chemical resistant gloves	6 and 8-row planters, enclosed cab	80 acres	Acceptable grades; Dermal = 2 to 17 replicates; Inhalation = 17 replicates Low confidence in dermal data. High confidence in inhalation data.
Granular Spreader Cultivator Mounted (VI)	PHED V1.1	Long pants, long sleeves, no gloves	Cultivator mounted or pull-behind; Ag or Turf; closed cab	80 acres	Acceptable grades; Dermal = 24 to 25 replicates; Inhalation = 25 replicates; High confidence in dermal and inhalation data.
Mixer/Loader/Applicator					
Residential Push-type Spreader (VII)	PHED V1.1	Long pants, long sleeves, no gloves	Rotary spreader	1 acre	Dermal grade C; inhalation acceptable grades; Dermal = 15 replicates; Inhalation = 15 replicates; Medium confidence in dermal data, high confidence for inhalation data.
Whirly-bird Spreader (VIII)	PHED V1.1	Long pants, long sleeves, no gloves	Belly grinder	1 acre	Dermal grades = 9A and 36C; Inhalation grades = acceptable; Dermal = 23 to 45 replicates; Inhalation = 40 replicates; Medium confidence in dermal data, high confidence for inhalation data.
Backpack Sprayer (IX)	PHED V1.1	Long pants, long sleeves, no gloves	Backpack Sprayer	(H) 5 gallons (O) 40 gallons	Dermal grades = A,B,C; Inhalation grades = acceptable; Dermal = 9 to 11 replicates; Inhalation = 11 replicates; low confidence in dermal and inhalation data.

[a] Clothing scenario represents actual monitored exposure data. The dermal exposure values on Table 1 have not been altered for simulate clothing protection factors.

[b] Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

[c] "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B for dermal and inhalation, and grade C for hand rinse method. All grades that do not meet OREB's SOP are listed individually.

C. Environmental Assessment

1. Ecological Toxicity Data

The Agency has adequate data to assess the risk of trifluralin to nontarget terrestrial organisms. However, the Agency does not currently have data to assess the toxicity of trifluralin on seedling emergence. A seedling emergence study has been required and is considered confirmatory.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the acute and subacute toxicity of trifluralin to birds, the following tests are required using the technical grade material:

* one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail)
* 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)

Avian Acute Oral Toxicity Findings

Species	% a.i.	LD_{50} mg/kg	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	96.7	> 2000	00137573	Practically nontoxic	Yes
Mallard	96.7	> 2000	Reported in Hudson et.al, 1984	Practically nontoxic	Yes

Avian Subacute Dietary Toxicity Findings

Species	% a.i.	LC_{50} ppm	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	99.96	> 5000	00138857	Practically nontoxic	Yes
Mallard	99.96	> 5000	00138858	Practically nontoxic	Yes

These results indicate that trifluralin is practically nontoxic to birds on an acute oral and subacute dietary basis. The guideline requirements are fulfilled (MRID 00137573, 00138857, 00138858).

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or when mammalian reproduction tests indicate reproductive hazard. Current product labeling of trifluralin allows several applications of the end-use product per growing season. Also, the chemical is known to be persistent and nonmobile in a vital (microbially active) soil environment.

Avian Reproduction Findings

Species	% a.i.	NOEC ppm	LOEC ppm	Endpoints affected	Citation (MRID)	Fulfills Guideline Requirement
Northern Bobwhite	99.6	Not determined	Not determined	None - Long term exposure at levels <50 ppm will not significantly affect reproductive success	00131134	Yes
Mallard Duck	99.6	Not determined	Not determined	Although there was increased cracked eggs at 50 ppm it was not enough of a difference (2.4%) to be able to determine an LOEC.	00131132	Yes
Northern Bobwhite	96.0	452.3	910.5	Cracked eggs as a percentage of eggs laid	40334706	Unreviewed data*
Mallard Duck	96.0	910.5	Not determined	None	40334704	Unreviewed data*

* The test appears to be scientifically sound based on cursory review; however, the NOEC and LOEC are subject to change resulting from further study review.

The results indicate that adverse reproductive effects may occur as low as 910.5 ppm. The guideline requirements are fulfilled (MRID 00131132, 00131134, 40334704, 40334706).

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Acute toxicity studies show that trifluralin is not acutely toxic to the animals tested. The herbicide has been tested in animals via oral, dermal inhalation and ocular routes of exposure, and the results show only minor effects. Based on these conclusions and expected exposure, wild animal testing was not required for trifluralin.

(4) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. Based on the use pattern, which includes outdoor terrestrial uses, honey bee exposure to trifluralin was expected and therefore acute testing was required.

Nontarget Insect Toxicity Findings

Species	% a.i.	LD_{50} μg/bee	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	Not reported	24-hour contact > 100 24-hour oral > 50	05001991	Practically nontoxic	Yes

There is sufficient information to characterize trifluralin as practically nontoxic to bees. The guideline requirement is fulfilled (MRID 05001991).

b. Toxicity to Aquatic Animals

(1) Freshwater Fish - Acute Toxicity

In order to establish the toxicity of trifluralin 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).

Freshwater Fish Acute Toxicity Findings

Species	% a.i.	LC_{50} ppb	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	95.9	41	40094602	very highly toxic	Yes
Bluegill sunfish	95.9	58	40094602	very highly toxic	Yes
Fathead minnow	95.9	105	40094602	highly toxic	Yes
Channel Catfish	95.9	2200	40094602	moderately toxic	Supplemental
Largemouth bass	95.9	75	40094602	very highly toxic	Supplemental
Goldfish	46	145	40094602	highly toxic	Supplemental

The results of the acute toxicity studies indicate that trifluralin is highly to very highly toxic to both cold and warmwater fish. The guideline requirements are fulfilled (MRID 40094602).

Early Life-Stage Fish: An early life-stage test for fish is required if the product is applied directly to water or expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is greater than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g., half-life greater than 4 days). Several of these scenarios apply to trifluralin, therefore, the fish early life-stage test was required.

Fish Early Life-Stage Toxicity Findings

Species	% a.i.	NOEC ppb	LOEC ppb	MATC ppb	Citation (MRID)	Endpoints Affected	Fulfills Guideline Requirement
Rainbow trout	99.86	1.14	2.18	1.58	41386202	larval fish length	Yes

The results indicate that trifluralin may result in adverse chronic effects to fish at levels as low as 2.18 ppb. The guideline requirement is fulfilled (MRID 41386202).

Fish Life-Cycle: The fish life-cycle test is required when an end-use product is intended to be applied directly to water or is expected to be transported to water from the intended use site, when any of the following conditions apply: the EEC is equal to or greater than one-tenth of the NOEL in the fish early life-stage or invertebrate life-cycle test; or if studies of other organisms indicate the reproductive physiology of fish may be affected. Because many of these conditions apply to trifluralin, fish life-cycle testing was required.

Fish Life-Cycle Toxicity Findings

Species	% a.i.	NOEC ppb	LOEC ppb	MATC ppb	Citation (MRID)	Endpoints Affected	Fulfills Guideline Requirement
Fathead minnow	97	1.9	5.1	3.5	05008271	Not reported	Yes

The results indicate that chronic effects to fish may occur from the use of trifluralin at levels as low as 5.1 ppb. The guideline requirement is fulfilled (05008271).

Field Monitoring: Vertebral dysplasia has been related to trifluralin exposure in a study using sheepshead minnow (Couch et al. 1979). Therefore vertebral dysplasia was evaluated in an aquatic field monitoring study submitted to the Agency (MRID 00155972, 00155973, 00155974, 00155975, 00155978). Results of that study indicate that, when used on soybeans, trifluralin will be transported to aquatic habitat where it will be biologically available to aquatic organisms. Incidence of vertebral anomalies was found to be related to trifluralin exposure, despite the fact that concentrations were less than NOEL values from life-cycle tests with aquatic organisms.

Trifluralin may also contribute at non-detectable residues along with other environmental or chemical influences to the increased evidence of vertebral anomalies in fish. The significance to fish populations of this contribution is not clear. Some doubt still remains as to whether trifluralin poses a serious threat to fish in areas of high trifluralin usage. The results of the field trial do not negate the presumption of risk for which the requirement was proposed.

The Agency will explore monitoring efforts with the technical registrants of trifluralin to further evaluate vertebral developmental abnormalities in fish.

Vertebral Lesion Study: Based on the results from the field monitoring study, the Agency required a fish vertebral lesion study. The study submitted has been classified as invalid because of an inadequate control group, however, additional data are not required. Trifluralin contamination in both the acetone and water controls led to detectable concentrations in the fish at termination. Also, the stock fish that were used as a negative control were three to four weeks older than the test organisms at the time of radiographic exams. The stock fish had high incidence of wavy ribs (27.5%) and vertebral anomalies (23.8%). The Trifluralin Data Development Consortium (TDDC) has submitted a rebuttal to the review that classified this study as invalid. This rebuttal is currently being evaluated by the Agency. The Agency will explore with TDDC the appropriateness of a field monitoring study following the review of the rebuttal submission (MRID 42439601).

(2) Freshwater Invertebrates

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

Freshwater Invertebrate Toxicity Findings

Species	% a.i.	EC_{50} ppb	Citation (MRID)	Toxicity Category	Fulfills Guideline Requirement
Daphnia magna	95.9	560	40094602	highly toxic	Yes
Daphnia pulex	95.9	625	40094602	highly toxic	Yes
Simocephalus	95.9	900	40094602	highly toxic	Supplemental
G. fasciatus	95.9	LC_{50} = 2200	40094602	moderately toxic	Supplemental
Pteronarcys	95.9	LC_{50} = 2800	40094602	moderately toxic	Supplemental

There is sufficient information to characterize trifluralin as moderately to highly toxic to aquatic invertebrates. The guideline requirement is fulfilled (MRID 40094602).

Life-Cycle Aquatic Invertebrates: Data from life-cycle tests with aquatic invertebrates are required if the product is applied directly to water or is expected to be transported to water from the site of intended use, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is greater than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate that the reproductive physiology of fish or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g. half-life greater than 4 days). Because several of these scenarios apply to trifluralin, the invertebrate life cycle test was required.

Aquatic Invertebrate Life-Cycle Toxicity Findings							
Species	**% a.i.**	**NOEC ppb**	**LOEC ppb**	**MATC ppb**	**Citation (MRID)**	**Endpoints Affected**	**Fulfills Guideline Requirement**
Daphnia magna	99.86	50.7	N/A	> 50.7	41386201	None	Yes
Daphnia magna	97	2.4	7.2	4.8	05008271	Survival	Yes

The results indicate that chronic effects to aquatic invertebrates may occur from the use of trifluralin at levels as low as 7.2 ppb. The guideline requirement is fulfilled (MRID 41386201, 05008271).

(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 or estuarine environment or when the intended use is such that the pesticide is expected to reach that environment in significant concentrations.

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 mollusks.

Estuarine/Marine Acute Toxicity Findings					
Species	**% a.i.**	**LC_{50}/EC_{50} ppb**	**Citation (MRID)**	**Toxicity Category**	**Fulfills Guideline Requirement**
Bay mussel embryo larvae	99	EC_{50} = 240 (survival) -Shell growth inhibition at 96 ppb	42449902	highly toxic	Yes
Grass shrimp	96.4	LC_{50} = 638.5	40674801	highly toxic	Yes - formulated product
Sheepshead minnow	99	LC_{50} = 190	42449901	highly toxic	Yes

There is sufficient information to characterize trifluralin as highly toxic to estuarine and marine organisms. The guideline requirement is fulfilled (MRID 42449902, 42449901, 40674801).

c. Toxicity to Plants

(1) Terrestrial

Currently, terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides that have terrestrial non-residential outdoor use patterns and that appear to move off site of application through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mm Hg at 25°C) or drift (aerial or irrigation); or which may have endangered or threatened plant species associated with the site of application. Tier II vegetative vigor toxicity data on the technical material for the three most sensitive species is listed below:

Nontarget Terrestrial Plant Toxicity Findings - Vegetative Vigor

Species	% a.i.	Height		Fresh Weight		Citation (MRID)	Fulfills Guideline Requirement
		EC_{25} lb a.i./A	NOEL lb a.i./A	EC_{25} lb a.i./A	NOEL lb a.i./A		
Dicot - cucumber	95.7	0.800	0.50	0.796	0.25	41934503	Yes
Monocot - corn	95.7	1.47	0.125	1.09	0.50	41934503	Yes
Dicot - radish	95.7	0.936	0.25	1.23	0.50	41934503	Yes

The results indicate that terrestrial plants may be adversely affected at levels as low as 0.796 lb a.i./A, which is far below the maximum label rate of 4 lb a.i./A for sugarcane and 2 lb a.i./A for all other crops. The guideline requirement for vegetative vigor is fulfilled (MRID 41934503).

Tier I Seed Germination testing (MRID 41934501) indicated that, of the ten species tested, greater than 25% inhibition occurred in the onion and cabbage tests, therefore, Tier II seed germination testing was required on these two species. Tier II toxicity data for these two species is summarized in the following table:

Tier II Seed Germination Toxicity Findings

Species	% a.i.	NOEC lb a.i./A	LOEC lb a.i./A	EC_{25} lb a.i./A	EC_{50} lb a.i./A	Citation (MRID)	Fulfills Guideline Requirement
Onion - radicle length	95	0.13	0.25	0.33	4.3	42695601	Yes
Cabbage	95	2	Not reported	4	> 4	42695601	Yes

These results indicate that nontarget terrestrial plants may be adversely affected at levels as low as 0.25 lb a.i./A, which is far below the maximum label rate of 4 lb a.i./A for sugarcane and 2 lb a.i./A for all other crops. The guideline requirement for tier II seed germination testing is fulfilled (MRID 42695601).

The Agency does not currently have data to assess the toxicity of trifluralin on seedling emergence. Although toxicity to nontarget terrestrial plants can be estimated from the available data, a comprehensive plant risk assessment cannot be completed without seedling emergence data. Seedling shoot effects as well as root effects are expected from trifluralin exposure, based upon the following:

- The publication developed from the 1989 Purdue University Herbicide Action Course (Warren and Hess, 1989) states that trifluralin is a mitotic poison that stops the growth of roots *and shoots* of seedlings, as is the case for most dinitroanaline chemicals. The section of that publication entitled "Inhibitors of Roots Only in Seedlings" does not include trifluralin; also,

- Literature has been provided by the registrant which states that trifluralin controls weeds by interrupting the development of new cells in roots and shoots of susceptible seedlings.

(2) Aquatic

Currently, aquatic plant testing is required for any herbicide which has outdoor non-residential terrestrial uses that may result in off-site movement of pesticide by runoff or by drift (aerial or irrigation). The following species are to be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Tier II toxicity data on the technical material is listed below:

Nontarget Aquatic Plant Toxicity Findings

Species	% a.i.	EC_{50} ppb	NOEC ppb	Citation (MRID)	Fulfills Guideline Requirements
Navicula pelliculosa	97.92	15.3	undetermined	42834102	Yes
Lemna gibba	95	43.5	undetermined	42834104	Yes

Nontarget Aquatic Plant Toxicity Findings					
Species	**% a.i.**	**EC_{50} ppb**	**NOEC ppb**	**Citation (MRID)**	**Fulfills Guideline Requirements**
Selenastrum capricornutum	99.86	7.52	5.37	41934502	Yes
Skeletonema costatum	97.92	28	4.6	42834101	Yes
Anabaena flos-aquae	97.92	>339	89	42834103	Yes

In the studies listed above, the concentrations of trifluralin decreased to non-detectable levels between day 1 and day 5. Because of this, the toxicity values may be conservative in determining the full degree of toxicity to aquatic plants. The plants in these studies may have been exposed to concentrations of trifluralin much lower than the values used to determine the toxicity estimates reported, therefore, trifluralin is likely to be more toxic to these species than these studies report (MRID 42834103, 42834102, 41934502, 42834101, 42834104).

2. Environmental Fate

a. Environmental Fate Assessment

The available information on the properties of trifluralin in the environment suggest that the chemical is expected to be moderately persistent. It is not expected to be mobile, as a consequence of adsorption to soil. Risks to water resources, ground water and surface water are discussed in detail in Section "c." below. Trifluralin may contaminate surface water by spray drift, and under some circumstances by runoff. Despite the low mobility of trifluralin, the USEPA Pesticides in Ground Water Data Base indicates detections in 10 states. However, the validity and significance of the detections is questionable on several grounds which are discussed below in section c.(1).

The available data, represented by supplemental and acceptable studies, suggest the following conclusions regarding mechanisms of dissipation in the field. Although trifluralin is volatile, in the field it dissipates primarily by soil binding and (secondarily) by biotic degradation. For trifluralin to be effective, it has to be incorporated into the soil at the time of application. Incorporation limits dissipation via surface active processes, primarily volatilization and photodegradation. Once incorporated, soil binding is the initial route of dissipation. This is followed by biotic degradation processes with a half life of 116 to 201 days. A number of transitional degradates have been identified.

Laboratory data indicate that trifluralin is not mobile in sandy loam, loam, and clay loam soils. Surface volatilization of trifluralin is controlled by soil moisture and temperature. Results based on laboratory data appear to be confirmed by supplemental field data which indicate trifluralin dissipates with a field half life of 29 to 149 days with no detection of trifluralin below six inches depth.

In order for the submitted studies to fulfill guideline data requirements, confirmation of analytical procedures should be submitted. It is not likely that the additional information requested will change the overall qualitative assessment. However, the additional information may bear on the confidence in the data, and is expected to provide a better understanding of the environmental fate properties of the chemical. Also, the additional information could be relevant for a quantitative assessment of trifluralin exposure.

b. Environmental Fate and Transport

In order for the submitted laboratory and field studies to be acceptable to fulfill the data requirements, confirmatory analysis (preferably MS) is needed. Separations such as those based on TLC should be confirmed by another analytical method.

(1) Degradation

Hydrolysis: The data requirement is not fulfilled at this time. The registrant is supporting a study (MRID 00131135) that was found to be acceptable in 1984-1985. Comparison of that study to a study of photodegradation in water (MRID 40560101) indicates a discrepancy. Trifluralin was reported to be substantially more stable in the hydrolysis study than for the dark controls in the study of photodegradation in water. In order to fully understand the degradation and dissipation of trifluralin, this apparent discrepancy needed to be addressed. The registrant has submitted information addressing the discrepancy which is currently under review.

Photodegradation in Water: The submitted study supplies supplemental data and is scientifically valid. However, it cannot be used to fulfill the data requirement at this time, but may be upgradable when the following points are adequately addressed:

- As described for the hydrolysis data requirement, there is a discrepancy between the dark control half life (about 20 days) and the relative stability reported for the hydrolysis

study. The reason for the difference is not apparent at this time.

- Trifluralin appears to volatilize in preliminary testing. For a complete environmental fate assessment, measurements are needed of the fractions of volatile and nonvolatile parent and degradates over the course of the test.

The study reports that trifluralin degraded with a half-life of 8.93 hours in a sterile pH 7 aqueous buffer solution when exposed to a light source. In the dark control, trifluralin degraded with a half-life of 485 hours (or about 20 days). The major degradates identified in the samples exposed to light (with maximum percent of applied) were:

(47.4%) 2-ethyl-7-nitro-5-trifluoromethylbenzimidazole;
(9.6%) 5-trifluoromethyl3-nitro-1,2-benzene diamine; and
(53.8%) 2-ethyl-7-nitro-1-propyl-5-trifluoromethylbenzimidazole

The fraction of applied radioactivity recovered as volatile residue was about 55% for control samples and about 70% for light-exposed samples. The registrant has submitted information to address the cited deficiencies that is currently under review (MRID 40560101).

Photodegradation on Soil: The available study of photodegradation on soil is scientifically valid and can be used as supplemental data, but cannot be used to fulfill the data requirement. In order to validate the analytical data, a confirmatory analysis (preferably MS) is needed in addition to comparison to the Rf of reference standards. There are guideline concerns [soil moisture and sieve size were not furnished and a discrepancy in the half-life for photodegradation on soil control samples (66 days) and for aerobic soil metabolism data (189 days)] in the study methodology, as well. However, the Agency believes that repeating this study will not provide significant new information. If information is furnished to the Agency confirming the analytical procedures the study can be used to fulfill the data requirement.

The study reports that trifluralin degraded with a reported half-life of 41 days when exposed to a light source on sandy loam soil. The half-life of dark control samples of trifluralin was reported to be 66 days. Two degradates, 2,6-dinitro-N-propyl-4 -trifluoromethylbenzenamine, and 2-ethyl-7nitro-5-trifluoromethyl-benzimidazole-3-oxide, were identified in the light exposed samples at

maximum concentrations of 6.0% and 7.1% of applied radioactivity in the soil extract, respectively. Unidentified residues made up a maximum of <9.6% of soil extract at 29.8-day following treatment. At 29.8 days following treatment, 11.2% of the applied radioactivity was not extracted. Also, carbon dioxide was reported to reach 5.79% of applied radioactivity in the exposed samples and 0% for the dark control samples during the testing period. The Agency is currently reviewing information submitted by the registrant to fulfill this requirement (MRID 40597801, 40751301).

Aerobic Soil Metabolism: The aerobic soil metabolism study is scientifically valid and can be used for supplemental data but cannot be used to fulfill the data requirement. A complete environmental fate assessment of the degradation of trifluralin under aerobic conditions cannot be made at this time for the following reason: Degradates present in the organic extracts at up to 7.6% of the applied (0.119 ppm) and in the aqueous extracts at up to 6.9% of the applied (0.108 ppm) were not characterized.

Trifluralin degraded with registrant-calculated half-lives of 189, 201, and 116 days in sandy loam, clay loam, and loam soils, respectively, when incubated aerobically in the dark at 22°C for 364 days. Seven degradates were identified. With maximum percentages of applied radioactivity in the test samples, the seven degradates are:

1) α,α,α-trifluoro-2,6-dinitro-N-propyl-p-toluidine
2) α,α,α-trifluoro-5-nitro-4-propyl-toluene- 3,4-diamine
3) 2-ethyl-7-nitro-1-propyl-5-(trifluoromethyl) benzimidazole-3-oxide
4) 2-ethyl-7-nitro-1-propyl-5-(trifluoromethyl) benzimidazole
5) 2-ethyl-7-nitro-5-(trifluoromethyl)benzimidazole
6) α,α,α-trifluoro-2,6-dinitro-p-cresol
7) 2,2'azoxybis(α,α,α-trifluoro-6-nitro-N-propyl-p- toluidine

These degradates were identified in test samples at maximum concentrations (% applied radioactivity) 2.8 to 4.6%, 1.5 to 2.1%, 0.1 to 0.3%, 0.5 to 1.0%, 2.1 to 2.6%, 0.1 to 2.7%, and 0.8 to 3.0%. During the testing period of about one year trifluralin parent declined to less than 25% of applied radioactivity in all soils. At the same time volatile and unextractable residues increased to 21.7% and about 45% of applied radioactivity. The registrant has submitted degradate information that is currently under Agency review (MRID 41240501).

Anaerobic Soil Metabolism: The anaerobic soil metabolism study is scientifically valid and can be used as supplemental data. The data cannot be used to fulfill the guideline requirement but may be upgradable. A complete assessment of trifluralin degradation under anaerobic conditions cannot be made at this time because important degradates were not identified: Degradates were not characterized that were present in organic extracts at up to 6.1% of applied radioactivity (0.099 ppm) and in aqueous extracts at up to 12.1% of applied (0.182 ppm).

Based on the study available, trifluralin degraded with registrant-calculated half-lives of 25-59 days in sandy loam, loam, and clay loam soils incubated anaerobically in the dark at 22°C for 60 days following an aerobic incubation period of 30 days. The major degradates identified were:

1) α,α,α-trifluoro-5-nitro-N4,N4-dipropyl-toluene- 3,4-diamine (which reached a maximum concentration of 5.4% and 13.2% of the applied radioactivity in the sandy loam soil and clay loam soil, respectively, at Day 60 following flooding, and 11.6% in the loam soil at Day 30 following flooding);
2) 7-amino-2-ethyl-1-propyl-5-(trifluoromethyl) benzimidazole (which reached 7.3% in the sandy loam soil and 8.3% in the loam and clay loam soils at Day 60 following flooding);
3) α,α,α-trifluoro-N4,N4-dipropyltoluene-3,4,5-triamine (which reached 0.3% in the sandy loam soil, 4.1% in the loam soil, and 2.6% in the clay loam soil).

Four other degradates identified were:

1) α,α,α-trifluoro-2,6-dinitro-N-propyl-p-toluidine;
2) α,α,α-trifluoro-5-nitro-N4-propyl-toluene-3,4-diamine;
3) 2-ethyl-7-nitro-1- propyl-5-(trifluoromethyl) benzimidazole;
4) 2,2'-azoxybis (α,α,α-trifluoro-6-nitro-N-propyl- p-toluidine)

each present at concentrations up to 2.1% of the initial radioactivity.

The following three degradates:

1) 2-ethyl-7-nitro-1-propyl-5-(trifluoromethyl);
2) benzimidazole-3-oxide;
3) 7-amino-2-ethyl-5-(trifluoromethyl)benzimidazole;

were each present at up to 1% of the initial radioactivity. Uncharacterized degradates in the organic extracts were at maximum concentrations of 6.1% (0.099 ppm) of the initial radioactivity in the sandy loam soil, 6.2% (0.093 ppm) in the loam soil, and 6.3% (0.090 ppm) in the clay loam soil. Uncharacterized degradates in the aqueous extracts were maximums of 6.4% (0.104 ppm) of applied radioactivity in the sandy loam soil, 12.1% (0.182 ppm) in the loam soil, and 9.6% (0.138 ppm) in the clay loam soil. An increase of unextractable trifluralin residues (9.4 to 60%) indicated that binding of residues to soil organic matter is the major route of anaerobic dissipation for trifluralin. The registrant has submitted degradate information that is currently under Agency review (MRID 41240502).

(2) Mobility

Leaching and Adsorption-Desorption: The mobility study, an unaged batch equilibrium and aged column study, is scientifically valid and can be used as supplemental data. It cannot be used to fulfill the data requirement. Degradates that were detected in the soil segments extracts and the leachate were not quantified and characterized, as needed to predict the leaching of trifluralin residues.

Unaged trifluralin appears not to be mobile in sandy loam, loam, and clay loam soils (Freundlich K_{ads}, values of 54.8-155.6). However, aged trifluralin residues appear to be slightly mobile in columns of sand and loam soils: About 90% of the applied radioactivity remained in the upper 6 cm; 0.65-2.57% leached from the column. The degradates identified were:

1) α,α,α-trifluoro-2,6-dinitro-N-propyl-toluidine (TR-2) (present at 3.01-3.05% of the extracted radioactivity);
2) 2-ethyl-7-nitro-1-propyl-5-(trifluoromethyl)-benzimidazole (present at 0.77-0.87% of extracted radioactivity);
3) 2,2'-azoxybis(α,α,α-trifluoro-6-nitro-N-propyl-p- toluidine) (present at 0.38-0.40% of extracted radioactivity).

Degradates remaining at the TLC origin were 0.88 to 1.31% of the extracted radioactivity. Also, radioactivity in other TLC zones ranged from 0.01 to 0.54% of extracted radioactivity. Uncharacterized residues in the aqueous extract averaged 0.76% of the applied radioactivity with unextracted residues averaging 6.79% of the applied radioactivity. Volatile residues extracted from the charcoal trap averaged 3.40% of the applied radioactivity. The extracted radioactivity

in the charcoal trap was identified as essentially all trifluralin with some TR-2, and residues remaining at the TLC origin. The registrant has responded to the study deficiencies and this submission is currently under Agency review (MRID 40673501).

Laboratory Volatility: Three laboratory volatility studies were submitted and provide supplemental data. They cannot be used to fulfill the data requirement. These data were taken from published articles and were not originally designed to satisfy Subdivision N data requirements. Therefore, it is difficult to draw conclusions needed for an environmental fate assessment. However, published laboratory and field volatility data submitted (MRID 40673601A-G) do indicate the following:

1) Volatility may be a major route of dissipation for trifluralin above the soil surface.
2) Trifluralin appears to volatilize (25 to 60% of applied in 11 days).
3) Data are needed to determine relative rate of dissipation due to volatility in relation to other routes of dissipation.

In the data submitted, the concentration of trifluralin in air and soil was not reported. Also, application rate and material balances could not be confirmed, and the concentration of trifluralin residues in the air could not be related to the concentration of trifluralin residues in the soil. Furthermore, the study was terminated before the pattern of decline of the test substance was established. The registrant has committed to conduct a new laboratory field volatility study (MRID 40673601A, 40673601B, 40673601C).

Field Volatility: Four field volatility studies were submitted and provide supplemental data. They cannot be used to fulfill the data requirement.

These data were taken from published articles and were not originally designed to satisfy Subdivision N data requirements. Therefore, it is difficult to draw the conclusions needed for an environmental fate assessment. However, published volatility data submitted do indicate the following:

1) Volatility may be a major route of dissipation for trifluralin above the soil surface.

2) Trifluralin appears to volatilize: 25% to 60% of applied trifluralin volatilizes in 11 days).
3) Laboratory volatility data are needed to determine the contribution of volatilization to dissipation, relative to other dissipation mechanisms.
4) No further field volatility data are needed until evaluation of acceptable laboratory volatility data are completed.

In the data submitted the concentration of trifluralin in the soil immediately following treatment was not reported. Therefore, the application rate was not confirmed and the concentration of trifluralin in the air could not be related to the amount of trifluralin in the soil. Furthermore, the study was terminated before the pattern of decline of the test substance was established. The registrant has requested that the need for a new study be determined upon receipt and review of the laboratory volatility study (MRID 40673601D, 40673601E, 40673601F, 40673601G).

(3) Accumulation

Bioaccumulation in Fish: A single study submitted was determined to be scientifically valid and to provide supplemental information. That study cannot be used to fulfill the data requirement. Accumulation and depuration in fish cannot be fully assessed because radioactive residues in the fish tissues were not completely characterized. Radioactivity attributed to a total of 10 metabolites at a maximum of 0.804 ppm was not identified; up to 1.273 ppm was described only as polar radioactivity. Also, up to 1.8% of the total radioactivity in the aqueous phase of the tissue extracts was not characterized. Trifluralin residues accumulated in bluegill sunfish exposed to 0.0059 ppm of trifluralin, with maximum mean bioconcentration factors of 2041x, 9586x, and 5674x for edible, nonedible, and whole fish tissues, respectively. Depuration occurred with 86.34-88.01% of the [^{14}C]residues eliminated from the fish tissues after 14 days of exposure to pesticide free water. The registrant has responded to the study deficiencies. This submission is currently under Agency review (MRID 40673801).

(4) Field Dissipation

Terrestrial Field Dissipation: The submitted studies of terrestrial field dissipation are scientifically valid and can be used as supplemental data. However, they cannot be used to fulfill the data requirement because degradates identified in laboratory data were not analyzed for in field

samples, and the degradation pathway of trifluralin in the field could not be determined from this study.

In order to fulfill the data requirement, acceptable data must be submitted for two sites treated at the maximum registered application rate for each trifluralin formulation type.

Granular trifluralin dissipated with a reported half-life of 49 days in the top 6 inches of soil when applied to loamy sand soil in California. Pretreatment sample analysis indicated there were low levels (0.07-0.16 ppm) of trifluralin present at depths less than 6 inches. Immediately following treatment, concentrations ranged from 1.30 to 6.30 ppm and from 1.80 to 5.00 ppm for applications 1 and 2, respectively. By days 14 and 42 following treatment the average recovery was 1.14 ppm (range of 0.88-1.30 ppm) and 0.74 ppm (range of 0.38-1.90), respectively. With the exception of one sample, trifluralin was not detected at depths greater than 6 inches (MRID 41781901).

Trifluralin (EC formulations) dissipated with reported half-lives of 149 days from California loam soil and 93 days from Alabama clay soil. Immediately following treatment, the recoveries on 8 samples ranged from 2.10 to 6.70 ppm and from 1.40 to 2.90 ppm at depths to 6 inches for the CA and AL sites, respectively. By termination of the study (Day 494 following treatment for CA site and day 482 following treatment for AL site) the recovery of applied material had declined to 0.22 and 0.04 ppm, respectively. Trifluralin did not appear to leach to below 6 inches depth. However, one sample at 24 to 30 inches depth did contain trifluralin at 0.06 ppm, 494 days following treatment at the California site (MRID 41661101).

Emulsifiable concentrate trifluralin formulations were reported to dissipate with a half-life ranging from 29 to 35 days when applied to coarse (sandy loam soil at Shellman, GA site) and fine (silty clay loam soil at Mansfield, IL site) soils, respectively. However, granular trifluralin formulation was reported to dissipate with a half-life ranging from 15-to 86 days when applied to sandy loam soil in Shellman, GA. These half-lives were calculated from nonlinear dissipation curves. Furthermore, since trifluralin was not discernible in soil segments below the top 6 inches of soil, trifluralin did not demonstrate any leaching potential.

Mean recoveries immediately following treatment for the emulsifiable concentrate at the Georgia and Illinois sites were 0.94 ppm

(132% of applied) and 0.99 ppm (200% of applied) at depths less than 6 inches, respectively. For the granular formulation the mean recoveries immediate following treatment at the Georgia and Illinois sites were 0.85 ppm (113% of applied) and 0.67 ppm (134% of applied), respectively. By termination of study, the mean recoveries for the emulsifiable concentrate were 0.04 ppm at 398 following treatment at the Illinois site and 0.09 ppm at Day 193 following treatment at the Georgia sites. For the granular formulation, at termination of study the mean recoveries were 0.04 ppm (Day 573 posttreatment) and 0.10 ppm (Day 549 posttreatment) for the Illinois and Georgia sites, respectively. There was an increase in the mean at Day 7 posttreatment at the Georgia site for the emulsifiable concentrate formulation (1.91 ppm which is 400% of applied) and at the Illinois site for the granular formulation (1.01 ppm which is 135% of applied)(MRID 42309101).

(5) Spray Drift

No studies have been submitted to the Agency for spray drift droplet size (201-1) or field drift (202-1). These studies are held in reserve pending the results of work currently being conducted by the Spray Drift Task Force. Registrants who are not members of Task Force or do not have the permission to cite Task Force data will have to independently develop these data.

c. Water Resources

(1) Ground Water

Trifluralin has a very low propensity to leach in the vast majority of soils because of its strong adsorption to soil colloids and organic matter. Trifluralin is, however, a persistent pesticide with an aerobic soil metabolism half-life of 116-201 days in guideline studies (other studies have been published in the technical literature; half-lives have generally been in the same range, although it is a little less persistent in some soils). Its field dissipation half-life has been reported as low as 29 days and as high as 149 days in guideline studies. Published field dissipation half-lives range from 60 to 132 days (Wauchope et al., 1992). Trifluralin is very immobile with Kd values ranging from 18 to 156 L/kg in four test soils. The average K_{oc} value for trifluralin has been estimated to be anywhere from 1200 to 13700 (Wauchope et al., 1992). Considering the nature of the chemical; i.e., often persistent for many months but very immobile in nearly all if not all soils, trifluralin

would only be expected to affect ground water under special circumstances.

Pesticides in Ground Water Data Base indicates that for the years 1971-1991 trifluralin has been detected in well water in ten states at concentrations of 0.01 to 14.89 ppb. The states for which detections are indicated in the DataBase are IA, IL, IN, MD, MO, MS, ND, NE, SD, and VA. Several considerations call into question the value or significance of the detections for purposes of risk assessment. The detections were for the most part unconfirmed analytically, from very shallow ground water, from point sources, or at very low concentrations. No ground water label advisory or management plan is recommended for trifluralin at this time.

Evaluation of Ground Water Residue Data: Trifluralin has been detected at from 0.002 to 14.9 ppb in 59 of 5590 well water samples from 21 states (Hoheisel et al., 1992 and 12/23/93 errata). The high detection of 14.9 ppb, in Iowa, was traced to an incident of direct spill of the formulated product into a well (Kross et al., 1990).

By far the largest numbers of wells with trifluralin detections were from Illinois (26 of 542 wells), Missouri (10 of 324 wells), and Virginia (9 of 138 wells). A description of the studies with most of the detections follows.

Illinois Data: About eighteen (the exact number cannot be determined from the original study report) of the wells with detections in Illinois in the PGWDB were from a single study covering an area of about 42 square miles adjacent to the Illinois River in Mason county (McKenna et al., 1988). This study evaluated pesticide concentrations in shallow (usually 3 to 7 meters or 10 to 23 feet) monitoring wells plus existing wells (usually domestic drinking water wells 7 to 12 meters in depth) finished in a surficial aquifer overlain by sandy soils.

The detection limit for trifluralin in the McKenna et al. study was 0.004 ppb, which is extremely low for a compound which is normally applied to the soil surface at about 0.5 to 1 lb ai/A. The maximum apparent trifluralin concentration among 49 samples with detectable levels was 0.14 ppb. The analytical method utilized gas chromatography with electron capture detection (GC-ECD), confirming residues only by running the GC analyses with two different separation columns. This is inadequate because GC-ECD is a very non-specific detection method which is sensitive to a vast number of halogenated

organic compounds. Confirmation of these sub-ppb residue levels should have been performed with GC-mass spectrometry. Apparent detections were all below 0.2 ppb except for a well in Gallatin county which had up to 1.7 ppb.

Trifluralin was "detected" in 8 of 25 wells set up for monitoring vulnerable ground water in four "high risk regions" of Illinois (Felsot, 1988). These wells were all in locations with very sandy soils. These data are of even poorer quality than from the other study with apparent trifluralin detections, with no attempt at all to confirm the identity of peaks eluted from the sample with the GC electron capture detection method used.

Missouri Data: Apparently all of the detections in Missouri were from a single study, although the author's written report clearly identifies only eight different wells with trifluralin detections (Mesko and Carlson, 1988). Evaluation of the reliability of these data is impossible because the report does not describe the analytical methods used. Some samples were split and analyzed by two or more separate facilities, however, the authors note that detections by one laboratory were sometimes not confirmed in the other laboratory that analyzed a portion of the same sample (details of these quality control efforts were not provided). The study area was the Mississippi alluvial plain in several counties in extreme southeastern Missouri. Most of the wells were sampled from shallow alluvial aquifers. Trifluralin detections were in the range of 0.006 to 0.14 ppb.

Virginia Data: Eight of the nine trifluralin detections reported in the PGWDB were from a single study of a 3700 acre watershed in Westmoreland County. Little background information is available on these detections. Pesticide detections were apparently confirmed with two different GC detection systems (but not by mass spectrometry). Some pesticides not normally analyzable at environmental concentrations with the instrumentation used were included as analytes, the authors did not explain how this was done. Most of the wells sampled from were monitoring wells installed specifically for the purposes of this study. A wide variety of pesticides were found in many of these wells, often at concentrations much higher than for trifluralin. Other pesticides with relatively low leaching potential were also detected in ground water, including disulfoton (K_{oc} = 600, t½ = 30 days), paraquat (K_{oc} = 1000000, t½ = 1000 days), malathion (K_{oc} = 1800, t½ = 1 day), linuron (K_{oc} = 400, t½ = 60 days), carbaryl (K_{oc} = 200, t½ = 10 days), fenvalerate (K_{oc} = 5300, t½ = 35 days), and

permethrin (K_{oc} = 100000, t½ = 30 days) (the values for K_{oc} and t½ are taken from Wauchope et al., 1991; values from guideline studies are similar to these).

Summary of Ground Water Monitoring Data: Trifluralin appears to only very rarely contaminate ground water except for shallow and extremely vulnerable surficial aquifers which would be contaminated by virtually any pesticide that was used in the area. Extremely sensitive analytical methodology is available for analysis of trifluralin residues in ground water (usually down to a few parts per trillion), this is more than adequate considering the application rates used and the level of the lifetime health advisory for trifluralin. It appears unlikely that trifluralin use would rarely if ever result in ground water contamination at levels approaching a few tenths of a ppb, except for extremely vulnerable areas.

(2) Surface Water

Trifluralin can contaminate surface water by spray drift. Also, under some circumstances trifluralin may contaminate surface water by runoff, mostly via transport of contaminated sediment. Contamination of drinking water is not expected to result in a substantial risk to humans: The limited monitoring data for surface water as well as the results of Tier 2 modelling suggest that annual average concentrations are not likely to exceed the lifetime health advisory levels, and that peak/short term averages are not likely to exceed 1 day and 10 day health advisory levels. Also, most primary treatment procedures applied to surface water are likely to be effective in removing trifluralin, particularly given the relatively high soil/water partitioning of the chemical.

Substantial trifluralin could be available for runoff to surface waters for several weeks to months following application, based on measurements of aerobic soil metabolism (half-life 115 days), photodegradation on soil (half-life 41 days), and terrestrial field dissipation (half-life 15 to 149 days). Under some conditions, volatilization from soil may contribute significantly to the overall dissipation rate.

The relatively high soil/water partitioning of trifluralin (SCS/ARS database K_{oc} of 8000; K_{ads} = 18-19 for sandy soil and 53-156 for finer soils) indicates that the concentration of trifluralin adsorbed to eroding soil will be 1 to over 2 orders of magnitude greater than the

dissolved concentration in runoff water. However, the sediment yield off many fields varies anywhere from 1 to > 3 orders of magnitude less than the mass equivalent of the runoff volume. Therefore, the mass percentage of trifluralin runoff occurring via dissolution in runoff water may be somewhat comparable to or sometimes greater than that occurring via adsorption to eroding soil in cases where the sediment yield is 1 to > 3 orders of magnitude less than the runoff volume.

Trifluralin is susceptible to direct aqueous photolysis (half-life 8.9 hours) and to volatilization (Henry's Law constant = 1.6×10^{-4} $atm \cdot m^3/mol$) which should limit its persistence in the water column of well mixed, shallow surface water. However, its resistance to abiotic hydrolysis, only moderate susceptibility to aerobic metabolism and only slightly greater susceptibility to anaerobic metabolism (anaerobic soil metabolism half-life of 25-59 days) should make it more persistent in other types of surface water, particularly those with relatively long hydrological residence times. Its relatively high soil/water partitioning indicates that the concentration of trifluralin adsorbed to suspended and bottom sediment will be substantially greater than its dissolved concentration in the water column. Surface waters will be adsorbed to suspended and bottom sediment as opposed to dissolved in the water column.

Trifluralin and/or its major degradates appear to have some potential for bioconcentration as evidenced by total ^{14}C residue BCF factors of 2040X to 9590X.

There is insufficient data on the several major degradates (see fate section) of trifluralin to adequately assess their persistence and mobility. However, they appear to have similar persistence and mobility to trifluralin in the environment.

Surface Water Monitoring and Detection: The State of Illinois (Moyer and Cross 1990) sampled 30 surface water sites for pesticides at various times from October 1985 through October 1988. Substantial use in Illinois was a criterion for pesticides being included in the analyses. Total trifluralin (dissolved plus adsorbed to suspended sediment) was detected in 18 of 580 samples collected (detection limit 0.01 ug/L) . The 18 detections were from 13 of the 30 sites sampled. Concentrations ranged from 0.015 to 0.73 ug/L. Three of the 18 detections were at concentrations greater than 0.2 ug/L (0.23, 0.54, and 0.73 ug/L).

The USGS (Squillace and Engberg 1985) sampled 7 surface water sites in the Cedar River Basin (Iowa) from May 1984 through November 1895. Samples were collected monthly except in June 1984 when they were collected bimonthly. Total trifluralin and dissolved trifluralin were not detected in any of the samples collected from any of the 6 sites (detection limits 0.05 or 0.10 ug/L).

The USGS sampled 7 widely spread locations within the Mississippi Basin at frequent intervals from April 1991 to April 1992 (Goolsby and Battaglin, 1993). Dissolved trifluralin was detected at concentrations between approximately 0.003 and 0.03 ug/L in 81 of the 316 samples collected (level of quantification approximately 0.003 ug/L). Trifluralin was detected at all 7 locations with percentage detections ranging from 7% in the White River to 42% in the Mississippi River at Thebes IL and 47% in the Missouri River at Hermann MO.

Illinois sampled 128 to 129 surface water source supply systems in 1991 and 1992 (Taylor 1992). In 1991, one sample was collected in April-July from each system, and an additional sample was collected in September from some of the systems. Trifluralin was detected in one or more samples collected from 30 of the 129 systems sampled at concentrations ranging from 0.02 ug/L to 0.2 ug/L. In 1992, one sample was collected in April to June from each of 128 systems. Trifluralin was detected in samples collected from 7 of the 128 samples at concentrations ranging from 0.05 ug/L to 0.36 ug/L. The detection limit was not provided.

Tier 2 Surface Water Modelling: The Agency has calculated Tier 2 estimated environmental concentrations (EECs) for assessing risk to aquatic organisms. EECs assume a body of water with 1 ha surface area and depth 2 m draining a 10 ha file of sugarcane or soybeans. Sites were a Louisiana Commerce silt loam site (thought to represent a reasonable high runoff site for sugarcane) and an Illinois Hosmer silt loam site (thought to represent a reasonable high runoff site for soybeans). For each site the concentrations were simulated over 36 years. Assuming conventional tillage, two ground applications of 4 lb ai/acre at 6 month intervals with 3 inch incorporation, and 1% ground application spray drift, estimated 1 in 10 year concentrations for the Louisiana sugarcane site were 3.44 ug/L (initial), 2.06 ug/L (96 hour average), 0.78 ug/L (21 day average), 0.49 ug/L (60 day average), and 0.39 ug/L (90 day average). Based on the same assumptions except assuming a single application at 2 lb ai/acre, estimated 1 in 10 year

concentrations for the Illinois soybean site were 2.89 ug/L (initial), 2.01 ug/L (96 hour average), 0.81 ug/L (21 day average), 0.41 ug/L (60 day average), and 0.31 ug/L (90 day average).

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. To determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOCs. 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 below along with the corresponding LOCs.

Levels of Concern (LOC) and Associated Risk Presumption

Mammals and 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 and 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

Plants do not have separate criteria for restricted use or chronic effects.

(1) Exposure and Risk to Nontarget Terrestrial Animals

Birds: Residues found on dietary food items following trifluralin application may be compared to acute LC_{50} values to predict hazard. Chronic hazard is predicted by comparing the residues to either the NOEC or the LOEC from a valid avian reproduction study. In this case, the NOEC used to calculate the RQ is from unreviewed data; however, the studies appear to be scientifically sound based on cursory review. Although it is not expected, both the NOEC and the LOEC are subject to change once the studies have been reviewed comprehensively.

Therefore, the RQs may also be subject to change once these studies have been reviewed and validated.

The maximum concentration of residues of trifluralin and the corresponding risk quotients which may be expected to occur on selected avian dietary food items following a single application rate of 2.0 lb. a.i./A (maximum application rate for all crops except sugarcane in Hawaii) and 4.0 lb a.i./A (maximum application rate on sugarcane in Hawaii) are provided in the table below:

Dietary Concentrations (ppm) and Risk Quotients for Birds						
Food items	**EEC for 2.0 lb a.i./A**	**RQ**		**EEC for 4.0 lb a.i./A**	**RQ**	
		Acute	**Chronic**		**Acute**	**Chronic**
Range Grasses (short)	480 ppm	0.096	1.06	960 ppm	0.192	2.12
Fruit/Vegetable Leaves (other than legumes)	250	0.05	0.55	500	0.1	1.1
Forage Legumes and Insects	116	0.023	0.26	232	0.05	0.51
Seeds	24	0.005	0.05	48	0.009	0.11
Fruits	14	0.003	0.03	28	0.006	0.06

The LOC for endangered species has been exceeded on range grasses and for fruit and vegetable leaves for the 4.0 lb a.i./A label rate. Therefore, the use of trifluralin may cause adverse acute effects to endangered and threatened avian species.

The chronic LOC has been exceeded on range grasses for both maximum labeled rates, also on fruit and vegetable leaves for the 4.0 lb a.i./A label rate. Therefore, use of trifluralin may affect reproduction in birds adversely.

Mammals: Small mammal exposure is addressed using acute oral LD_{50} values converted to estimate an LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50} \times \text{body weight (g)}}{\text{food cons. per day (g)}}$$

Small Mammal Food Consumption (Based on an LD_{50} = 2,000 mg/kg)				
Small Mammal	**Body Weight in Grams**	**% of Weight Eaten Per Day**	**Food Consumed Per Day in Grams**	**Estimated LC_{50} Per Day**
Meadow vole	46	61 %	28.1 gms	3,274 ppm
Adult field mouse	13	16 %	2.1 gms	12,381 ppm
Least shrew	5	110 %	5.5 gms	1,818 ppm

The above table is based on information contained in Principles of Mammology by D. E. Davis and F. Golly, published by Reinhold Corporation, 1963.

The estimated LC_{50} is then compared to the EECs calculated as for birds (section (a) above) to calculate a risk quotient (EEC/LC_{50}). The table below indicates the risk quotients for each of the following application rates:

Dietary Risk Quotients for Mammals (based on Dietary RQ = EEC/Estimated LC_{50})		
Small Mammal	**RQ Application Rates in lb. a.i./A**	
	2.0	**4.0**
Meadow vole consuming range grasses	0.15	0.29
Adult field mouse consuming seeds	0.002	0.004
Least shrew consuming forage and insects	0.06	0.13

The LOC for endangered species has been exceeded for the meadow vole consuming range grasses at the 2.0 lb application rate and the least shrew consuming forage and insects at the 4.0 lb application rate. The LOC for restricted use has also been exceeded for the meadow vole at the 4.0 lb application rate. This would indicate that small mammals, including endangered and threatened species, feeding on grasses, insects or seeds could be adversely affected by the use of trifluralin.

Insects: Trifluralin is practically nontoxic to honey bees. Adverse impact to honey bees is not expected from the use of trifluralin.

(2) Exposure and Risk to Nontarget Aquatic Animals

Expected Aquatic Concentrations: Trifluralin displays very high toxicity to most aquatic organisms tested to date. A refined (Tier 2) EEC has been calculated for ground application to soybeans and

sugarcane. This EEC is determined using environmental fate and transport computer models. The Pesticide Root Zone Model (PRZM2) was used to simulate pesticides in field runoff and the Exposure Analysis Modeling System (EXAMS II) to simulate pesticide fate and transport in an aquatic environment. The soils selected for modeling are class C (moderately high runoff potential) and represents high exposure but reasonable sites. Use sites simulated were a Louisiana Commerce silt loam site thought to represent a reasonable high runoff site for sugarcane and an Illinois Hosmer silt loam site thought to represent a reasonable high runoff site for soybeans. The average amounts of rainfall were 58 and 33 inches per year for Louisiana and Illinois sites, respectively. The application rate assumed is the highest recommended label rate. The EECs represent a body of water with surface area 1 ha and depth 2 m, receiving runoff from a 10 ha field of sugarcane or soybeans. It was assumed that 1% of applied trifluralin reached the water by spray drift.

Results of the simulation are displayed below. The 1 in 10 year maximum initial, 96 hour acute, 21 day chronic, maximum 60 day and maximum 90 day average dissolved trifluralin concentrations are also displayed.

Estimated Environmental Concentrations (EECs) for Nontarget Aquatic Animal Risk

Crop	Application Method	Application Rate in lb a.i./A (# of applications)	Maximum Initial EEC (ppb)	4-day EEC (ppb)	21-day EEC (ppb)	60-day EEC (ppb)	90-day EEC (ppb)
Sugarcane	Ground	2.0 (2) (total application equals 4.0 lb a.i./A)	5.69	2.75	0.89	0.57	0.48
Soybeans	Ground	2.0 (1)	7.01	3.15	0.91	0.50	0.39

The total annual trifluralin losses (as % of applied) were 2.43% for soybeans and 1.51% for sugarcane. Part of this difference is due to dissimilarities between the sites in soil characteristics, environmental conditions, and agronomic practices. These results also indicate that most of trifluralin loss from both sites was due to spray drift and runoff. Losses due to the assumed spray drift played a major role and had greater impact on the fractional loss for Louisiana sugarcane than for Illinois soybeans (64.7% versus 40.3%). These results also indicate that trifluralin dissolved in runoff water accounted for 26.7% of the total trifluralin loss from the Louisiana sugarcane site, and 54.6% from the Illinois soybean site. Trifluralin bound to eroding soil contributed much less to the overall trifluralin loss than spray drift or trifluralin dissolved

in runoff water. These results indicate that mitigation practices that reduce spray drift and runoff volume will be effective in reducing trifluralin transport to aquatic environments.

Freshwater Fish: The following table lists the acute and chronic risk quotients for freshwater fish:

Risk Quotients (RQ) for Freshwater Fish

Crop/application rate	Species	Acute RQ (96-hr)	Chronic RQ (60-day)
Sugarcane/2.0 lb a.i./A applied two times for a total of 4.0 lb a.i./A	Bluegill	0.05	
	Rainbow trout	0.07	0.5
	Fathead minnow	0.03	0.3
Soybeans/2.0 lb a.i./A	Bluegill	0.05	
	Rainbow trout	0.08	0.4
	Fathead minnow	0.03	0.3

The LOCs have not been exceeded. However, a sheepshead minnow study (Couch et.al., 1979) related occurrence of vertebral dysplasia in the fish to low level exposures to trifluralin. A subsequent field study showed that trifluralin will transport to receiving waters and is bioavailable to aquatic organisms. Trifluralin may also contribute at non-detectable residue levels with other environmental or chemical influences to increase evidences of vertebral anomalies in finfish. Therefore, based on these findings, it is likely that freshwater finfish may be adversely affected from the use of trifluralin.

It is important to note that the estimated environmental concentration (EEC), on which the LOC determination is based, represents only the pesticide dissolved in the water column and does not take into account pesticide which may be adsorbed to suspended and bottom sediment. Trifluralin's relatively high soil/water partitioning indicates that the concentration of trifluralin adsorbed to suspended and bottom sediment will be substantially greater than its dissolved concentration in the water column. Also, trifluralin has a relatively high tendency to bioaccumulate in fish (bioconcentration factors of 2041x to 9586x). This, along with the fact that the fish will be exposed to trifluralin while scavenging or foraging, is also evidence that finfish may be adversely affected from exposure to trifluralin.

Freshwater Invertebrates: The following table lists the acute and chronic risk quotients for freshwater invertebrates:

Risk Quotients (RQ) for Freshwater Invertebrates			
Crop/application rate	Species	Acute RQ (96-hr)	Chronic RQ (21-day)
Sugarcane/2.0 lb a.i./A applied two times for a total of 4.0 lb a.i./A	*Daphnia magna*	0.005	0.2
Soybeans/2.0 lb a.i./A	*Daphnia magna*	0.006	0.2

The LOCs have not been exceeded. Freshwater invertebrates may not be adversely affected by the use of trifluralin.

Estuarine and Marine Animals: The following table lists the acute and chronic risk quotients for estuarine and marine organisms:

Risk Quotients (RQ) for Estuarine and Marine Organisms		
Crop/application rate	Species	Acute RQ (96-hr)
Sugarcane/2.0 lb a.i./A applied two times for a total of 4.0 lb a.i./A	Sheepshead minnow Bay mussel Grass shrimp	0.01 0.01 0.004
Soybeans/2.0 lb a.i./A	Sheepshead minnow Bay mussel Grass shrimp	0.02 0.01 0.005

The LOCs have not been exceeded, however, sheepshead minnow have been shown to be sensitive to trifluralin in laboratory studies. In this study (Couch et.al., 1979) minnows showed vertebral dysplasia after exposure to low levels of trifluralin. A subsequent field study showed that trifluralin will transport to receiving waters and is bioavailable to aquatic organisms. Trifluralin may also contribute at non-detectable residue levels with other environmental or chemical influences to increase evidences of vertebral anomalies in finfish. Therefore, based on these findings, it is likely that estuarine and marine finfish may be adversely affected from the use of trifluralin.

(3) Exposure and Risk to Nontarget Plants

Terrestrial and Semi-Aquatic: Non-target terrestrial plants inhabit non-aquatic areas. Non-target "semi-aquatic" plants are plants that usually inhabit low-lying wet areas that may or may not be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. The terrestrial and "semi-aquatic" plants are exposed to pesticides from runoff, drift or volatilization.

Runoff exposure is determined from a generic EEC. This runoff is characterized as a one acre to one acre sheet runoff to an adjacent acreage that affects terrestrial plants or a channelized runoff from 10 acres to a low lying area some distance away that affects "semi-aquatic" and terrestrial plants.

Spray drift exposure is determined by assuming 5% of the pesticide application will drift over to an adjacent acreage or to a much longer distance.

The following EECs have been determined for non-target plants which may be exposed from the application of trifluralin:

Risk Quotients (RQ) for Terrestrial and Semi-Aquatic Plants

Use Site	App. Rate (Lbs a.i./A)	Level of Concern[1]	Terrestrial Plants Adjacent to Use Site		Semi-Aquatic Plants in Wet Areas	
			EEC (lbs ai/A)	RQ	EEC (lbs ai/A)	RQ
Soybeans	2.0	EC_{25} = 0.33 EC_{25} = 0.796 EC_{50} = 7.52	0.004[2] 0.112[3] 0.1[4]	0.013 0.34 0.13	0.04[2] 0.22[3] 0.1[4]	0.13 0.7 0.13
Sugarcane	4.0	EC_{25} = 0.33 EC_{25} = 0.796 EC_{50} = 7.52	0.0082[2] 0.044[3] 0.02[4]	0.02 0.13 0.03	0.082[2] 0.44[3] 0.2[4]	0.25 1.3 0.3

1. Levels of Concern: a) terrestrial plants - lowest EC_{25} value (onion radicle length) = 0.33 lbs a.i./A for seedling germination test; this value is compared to runoff alone and runoff plus drift calculations; lowest EC_{25} value (cucumber fresh weight) = 0.796 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 (*Selenastrum capricornutum* EC_{50} = 7.52 ppb).
2. EEC value and corresponding risk quotient for runoff from incorporated ground applications.
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).

The LOCs for terrestrial plants adjacent to the use sites have not been exceeded, however, the LOC for runoff and drift has been exceeded for semi-aquatic plants for the sugarcane site. Therefore, nontarget semi-aquatic plants may be adversely affected by direct or indirect exposure to trifluralin.

Aquatic Plants: For aquatic plants exposures were calculated as described for aquatic animals in Section C.3.a.(2) above. The following table summarizes RQ values for aquatic plants:

Risk Quotients (RQ) for Aquatic Plants				
Use Site	Application Rate (lbs a.i./A)	Level of Concern*	Aquatic Plants	
			4-day EEC (ppb)	RQ
Soybeans	2.0	1	2.75	0.4
Sugarcane	4.0	1	3.15	0.4

* Measure of toxicity: lowest EC_{50} value (*Selenastrum capricornutum*) = 7.52 ppb.

The LOCs for aquatic plants, including endangered species, have not been exceeded for either use site. Therefore, nontarget aquatic plants are not likely to be affected by direct or indirect exposure to trifluralin.

(4) Endangered Species

The endangered species LOCs have been exceeded for birds, mammals, and semi-aquatic plants. Although the LOCs have not been exceeded for endangered freshwater and marine or estuarine fish, these species may be adversely affected based on laboratory and field studies which revealed vertebral dysplasia after exposure to very low levels of trifluralin.

The Endangered Species Protection Program will become final in the future. Limitations in the use of trifluralin will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a 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 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 trifluralin. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing trifluralin except for products with nongrass forage/fodder/straw/hay or dill uses. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of trifluralin, 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 trifluralin and to determine that trifluralin can be used without resulting in unreasonable adverse effects to humans and the environment. 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 and the data identified in Appendix B. Although the Agency has found that all uses of trifluralin are eligible for reregistration with the exceptions of nongrass forage/fodder/straw/hay and dill, 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 trifluralin, 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 trifluralin, the Agency has sufficient information on the health effects of trifluralin and on its potential for causing adverse effects in fish and wildlife and the environment. Therefore, the Agency concludes that products containing trifluralin are eligible for reregistration for all registered uses except for nongrass forage/fodder/straw/hay and dill provided the labeling changes and other requirements specified in this document are implemented.

The Agency has determined that trifluralin products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of trifluralin are eligible for reregistration with the exceptions of nongrass forage/fodder/straw/hay and dill.

B. Regulatory Position

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

1. Tolerance Reassessment

The tolerances listed in 40 CFR §180.207 are for the residues of trifluralin *per se*. The "(N)" designation should be deleted from all 40 CFR §180.207 entries.

Adequate Existing Tolerances Under 40 CFR §180.207:

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.207 (as defined) for the following commodities: asparagus; barley hay; barley straw; carrots; citrus fruits; corn grain (exc. popcorn); corn forage; corn fodder; cottonseed; cucurbits; flax seed; grapes; hops; nuts; peanuts; peppermint, hay; rape seed; safflower seed; sorghum forage; sorghum fodder; spearmint, hay; stone fruits; sugarcane; sunflower seed; vegetables, fruiting; wheat, grain; and wheat, straw. See "Tolerance Reassessment Summary" table for appropriate commodity definitions of some of these entries.

Tolerances to be Increased:

* **Wheat Straw, Barley Straw, and Barley Hay:** Available data for wheat straw and barley straw reflecting treatment at the maximum registered application rate indicate that the established tolerance for residues of trifluralin in/on wheat straw, barley straw, and barley hay should be increased to 0.1 ppm.

Tolerances to be Revoked:

* **Root Vegetables (exc. carrots) Crop Group:** The established crop group tolerance for the obsolete "root vegetables (exc. carrots)" should be revoked concomitant with the establishment of: (i) a tolerance for root and tuber vegetables (exc, carrots) at 0.05 ppm; and (ii) a tolerance for bulb vegetables group at 0.05 ppm. The available data for radish roots and sugar beet roots will be translated to chicory roots and turnip roots.

* **Leafy Vegetables Crop Group:** The established crop group tolerance for the obsolete "leafy vegetables" should be revoked concomitant with the establishment of: (i) separate tolerances for celery and endive, each at 0.05 ppm; (ii) a tolerance for leaves of root and tuber vegetables group at 0.05 ppm;

and (iii) a tolerance for Brassica (cole) leafy vegetables group at 0.05 ppm. The available data for celery will be translated to endive.

* **Seed and Pod Vegetables Crop Group:** The established crop group tolerance for the obsolete "seed and pod vegetables" should be revoked concomitant with the establishment of: (i) a tolerance for legume vegetables (succulent/dried) group at 0.05 ppm; and (ii) a separate tolerance for okra at 0.05 ppm.

* **Grain Crop (except fresh corn and rice grain) Crop Group:** The established crop group tolerance of 0.05 ppm in/on "grain crops (except fresh corn and rice grain)" is inappropriate because there are no registered uses for rice, a representative commodity of this group; furthermore, the use directions are not uniform for the representative commodities of this group. Therefore, the established crop group tolerance for "grain crops (except fresh corn and rice grain)" should be revoked concomitant with the establishment of individual tolerances, each at 0.05 ppm, for barley grain and sorghum grain. Separate adequate tolerances of 0.05 ppm already exist for corn and wheat grain. The available data for field corn grain will be translated to sorghum grain.

* **Forage Legumes Crop Group:** The established crop group tolerance for "forage legumes" should be revoked concomitant with the establishment of: (i) a tolerance for foliage of legume vegetables group at 0.05 ppm; and (ii) a separate tolerance for alfalfa forage at a level to be determined upon receipt of required magnitude of the residue data.

* **Mung Bean Sprouts:** The established tolerance for mung bean sprouts should be revoked because no registered uses exist for mung bean sprouts *per se*.

* **Upland Cress:** The established tolerance for upland cress should be revoked because no registered uses exist.

* **Barley Fodder, Barley Forage, Rape Straw, Flax Straw, and Peanut Hulls:** The Agency no longer considers barley fodder, barley forage, rape straw, flax straw, and peanut hulls as raw agricultural commodities (Livestock Feeds Table, 1995). The established tolerances for barley fodder, barley forage, rape straw, flax straw, and peanut hulls should be revoked.

Data Gaps:

Additional magnitude of the residue data are required before the established tolerance on alfalfa hay can be reassessed.

Tolerances That Need To Be Proposed Under 40 CFR §180.207:

* **Almond Hulls, Barley Grain, Celery, Okra, Peanut Hay, Sorghum Grain, and Wheat Forage:** Sufficient data are available to recommend the establishment of a tolerance for residues of trifluralin at 0.05 ppm in/on the following raw agricultural commodities: almond hulls, barley grain, celery, okra, peanut hay, sorghum grain, and wheat forage.

* **Endive:** Based on available celery data which have been translated to endive, a tolerance for the residues of trifluralin should be established in/on endive. A tolerance of 0.05 ppm would be appropriate.

* **Brassica (Cole) Leafy Vegetables, Bulb Vegetables, Foliage of Legume Vegetables, Leaves of Root and Tuber Vegetables, and Legume Vegetables (Dry and Succulent):** Sufficient data on representative commodities are available to recommend the establishment of the following crop group tolerances for residues of trifluralin at 0.05 ppm: Brassica (cole) leafy vegetables, bulb vegetables, foliage of legume vegetables, leaves of root and tuber vegetables, and legume vegetables (dry and succulent).

* **Mustard Seed:** Sufficient mustard seed data are available to recommend the establishment of a tolerance for residues of trifluralin at 0.01 ppm in/on mustard seed.

* **Wheat Hay:** A tolerance for residues of trifluralin in/on wheat hay must be established. Based on available barley straw and wheat straw data, a tolerance of 0.1 ppm would be appropriate.

* **Alfalfa Forage:** The registrant must propose a tolerance for alfalfa forage once adequate data have been submitted and evaluated.

* **Cotton Gin By-Products, Rape Forage:** The Agency currently recognizes cotton gin by-products as a raw agricultural commodity of cotton and has determined that label restrictions for rape forage are not appropriate (Livestock Feeds Table). Therefore, tolerances for cotton gin by-products and rape forage must be established. The registrant must propose tolerances for cotton gin by-products and rape forage once adequate data have been submitted and evaluated.

Tolerances Under 40 CFR §185.5900:

Food additive regulations (FAR) currently exist for residues of trifluralin in peppermint oil and spearmint oil at 2.0 ppm. The Agency reviewed the mint oil

tolerance in light of recent policies developed concerning "ready-to-eat" processed foods. The Agency believes that commodities such as mint oils are not "ready-to-eat" and once diluted, the residues of trifluralin in the "ready-to-eat" food would be lower than the raw agricultural commodity (RAC) tolerance. Based on this determination, the existing tolerance is sufficient to cover the residue levels of trifluralin in foods containing mint oil and a food additive regulation under Section 409 of the FFDCA is not necessary.

The Agency has therefore proposed to revoke the 2.0 ppm FAR for residues in/on peppermint oil and spearmint oil set under Section 409 of the FFDCA, and to withdraw the prior rule revoking these tolerances (60 FR 38781; 7/28/95). However, even though residues of trifluralin do not concentrate in finished foods containing mint oil above those found in the RAC, the Agency believes it appropriate to establish a maximum residue level (MRL) for the residues of trifluralin in mint oils per se for enforcement purposes. Establishing a MRL for mint oil will ensure that levels in finished food items do not exceed the RAC tolerance.

To set this tolerance, the Agency has decided to use its general rule-writing authority under the FFDCA Section 701 to establish Maximum Residue Limits (MRLs) for mint oils. Section 701 grants the Agency the authority "to promulgate regulations for the efficient enforcement of this Act." These maximum residue levels would be set no higher than the levels that could result in the processed food assuming legal residues in the raw food and that good manufacturing practices were followed. The MRLs on peppermint and spearmint oil will be established at 2.0 ppm.

Data Gaps:

Because actual concentration factors could not be determined in any of the submitted studies, additional processing data are required on peppermint and spearmint oil. It should be noted, however, that the available processing data are sufficient for the purpose of determining that residues in foods prepared from the mint oil will not exceed the Section 408 tolerance, and that the food additive regulations on the oils can be revoked. These data will be considered confirmatory.

TOLERANCE REASSESSMENT SUMMARY

TOLERANCES LISTED UNDER 40 CFR 180.207			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Alfalfa, hay	0.2 (N)	TBD [a]	
Asparagus	0.05	0.05	
Barley, fodder	0.05	Revoke	No longer considered a RAC.
Barley, forage	0.05	Revoke	No longer considered a RAC.
Barley, hay	0.05	0.1	

TOLERANCES LISTED UNDER 40 CFR 180.207			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Barley, straw	0.05	0.1	
Carrots	1.0	1.0	
Citrus fruits	0.05 (N)	0.05	*Citrus fruits group*
Corn, grain (exc. popcorn)	0.05 (N)	0.05	*Corn, field, grain*
Corn, grain (exc. popcorn), forage	0.05 (N)	0.05	*Corn, field, forage*
Corn, grain (exc. popcorn), fodder	0.05 (N)	0.05	*Corn, field, fodder*
Cottonseed	0.05 (N)	0.05	
Cucurbits	0.05 (N)	0.05	*Cucurbit vegetables group*
Flax, seed	0.05	0.05	
Flax, straw	0.05	Revoke	No longer considered a RAC.
Grain, crops (except fresh corn and rice grain)	0.05	Revoke	The tolerance should be revoked concomitant with the establishment of separate tolerances for individual members of the grain crop group.
Grapes	0.05 (N)	0.05	
Hops	0.05 (N)	0.05	
Legumes, forage	0.05 (N)	Revoke	The tolerance should be revoked concomitant with the establishment of: (i) a tolerance for *foliage of legume vegetables group* ; and (ii) a separate tolerance for alfalfa forage.
Mung bean sprouts	2.0	Revoke	No registered uses exist for mung bean sprouts *per se*.
Nuts	0.05 (N)	0.05	*Tree nuts group*
Peanut, hulls	0.1	Revoke	No longer considered a RAC.
Peanuts	0.05 (N)	0.05	
Peppermint, hay	0.05 (N)	0.05	
Rape, seed	0.05	0.05	
Rape, straw	0.05	Revoke	No longer considered a RAC.
Safflower seed	0.05 (N)	0.05	
Sorghum, fodder	0.05	0.05	
Sorghum, forage	0.05	0.05	
Spearmint, hay	0.05 (N)	0.05	
Stone fruits	0.05 (N)	0.05	*Stone fruits group*
Sugarcane	0.05 (N)	0.05	
Sunflower seed	0.05 (N)	0.05	
Upland Cress	0.05	Revoke	No registered uses exist.

TOLERANCES LISTED UNDER 40 CFR 180.207			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Vegetables, fruiting	0.05 (N)	0.05	*Fruiting vegetables (except cucurbits) group*
Vegetables, leafy	0.05 (N)	Revoke	The tolerance should be revoked concomitant with the establishment of: (i) separate tolerances for celery and endive; (ii) a tolerance for *leaves of root and tuber vegetables group* ; and (iii) a tolerance for *Brassica (cole) leafy vegetables group* .
Vegetables, root (exc. carrots)	0.05 (N)	Revoke	The tolerance should be revoked concomitant with the establishment of: (i) a tolerance for *root and tuber vegetables (except carrots) group* ; and (ii) a tolerance for *bulb vegetables group* .
Vegetables, seed and pod	0.05 (N)	Revoke	The tolerance should be revoked concomitant with the establishment of: (i) a tolerance for *legume vegetables (dry or succulent) group* ; and (ii) a separate tolerance for okra.
Wheat, grain	0.05 (N)	0.05	
Wheat, straw	0.05 (N)	0.1	

[a] TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

TOLERANCES THAT NEED TO BE PROPOSED UNDER 40 CFR 180.207			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Alfalfa, forage	None	TBD [a]	
Almonds, hulls	None	0.05	
Barley, grain	None	0.05	
Brassica (cole) leafy vegetables group	None	0.05	
Bulb vegetables group	None	0.05	
Celery	None	0.05	
Cotton, gin by-products	None	TBD [a]	
Endive	None	0.05	
Foliage of legume vegetables group	None	0.05	
Leaves of root and tuber vegetables group	None	0.05	

TOLERANCES THAT NEED TO BE PROPOSED UNDER 40 CFR 180.207			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Legume vegetables (dry or succulent) group	None	0.05	
Mustard seed	None	0.01	
Okra	None	0.05	
Peanuts, hay	None	0.05	
Rape forage	None	TBD [a]	
Root and tuber vegetables (exc. carrots)	None	0.05	
Sorghum, grain	None	0.05	
Wheat, forage	None	0.05	
Wheat, hay	None	0.1	

[a] TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

TOLERANCES UNDER 40 CFR 185.5900:			
Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Peppermint oil	2.0	Revoke	60 FR 38781; 7/28/95
Spearmint oil	2.0	Revoke	60 FR 38781; 7/28/95

MAXIMUM RESIDUE LIMITS (MRLs) TO BE PROPOSED UNDER SECTION 701 (FFDCA)		
Commodity	Maximum Residue Limit	Comment/*Correct Commodity Definition*
Peppermint oil	2.0	
Spearmint oil	2.0	

2. Codex Harmonization

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

3. Restricted Use Classification

Trifluralin is not currently classified for restricted use and the Agency has determined that trifluralin products should not be classified for restricted use at this time.

4. Reference Dose (RfD)

Trifluralin is not an RfD exceeder. The RfD for trifluralin is 0.024 mg/kg/day as determined from the one-year feeding study in dogs. The NOEL was 2.4 mg/kg/day (MRID 42447001). A safety factor of 100 was applied to account for the inter-species extrapolation (factor of 10) and intra-species variability (factor of 10).

Using tolerances, the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population from published uses is 0.000724 mg/kg/day (3% of the RfD). The TMRC for non-nursing infants, the highest exposed subgroup, is 0.002438 mg/kg/day (10% of the RfD).

Using percent of crop treated data the Anticipated Residue Contribution (ARC) for the overall U.S. population from published uses is 0.000126 mg/kg/day (1% of the RfD). The ARC for non-nursing infants, the highest exposed subgroup, is 0.000429 mg/kg/day (2% of the RfD).

5. Cancer Classification

The OPP Carcinogenicity Peer Review Committee evaluated all the available carcinogenicity data on trifluralin (April 4, 1986), and it concluded that there is limited evidence of carcinogenicity in male and female rats based upon an increase in combined malignant and benign urinary bladder tumors in females, renal pelvis carcinomas in male rats, and thyroid gland follicular cell tumors (adenomas plus carcinomas combined) in males. Trifluralin has been classified as a Group "C" possible human carcinogen with a Q_1^* of 0.0077 $(mg/kg/day)^{-1}$. The upper bound dietary cancer risk is is approximately 1.0×10^{-6}.

6. Water Resources - Implications for Human Health Risk

a. Ground Water

No ground water label advisory or management plan for trifluralin is needed at this time. No ground water monitoring studies are needed.

While some ground water detections of trifluralin have been reported, these are largely either (1) unconfirmed analytically, (2) from very shallow and extremely vulnerable ground water where every pesticide used (including immobile and nonpersistent compounds) is found, or (3) at levels much below 0.1 ppb. Consequently, the ground water detections reported to date do not provide an adequate basis for recommending regulation of trifluralin because of ground water contamination concerns. Furthermore, trifluralin, while fairly

persistent under aerobic conditions in soil, degrades relatively rapidly ($t_{1/2}$ < four weeks) under anaerobic conditions and is very immobile in the vast majority of agricultural soils. The leaching potential of trifluralin appears to be very low compared to other pesticides that are common ground water contaminants.

Relatively few data are available on the environmental fate of trifluralin degradates. If the Agency determines at some point that any degradation products are of toxicological concern, then additional data on the ground water contamination potential of trifluralin degradates may be needed.

b. Surface Water

Trifluralin is not currently regulated under the Safe Drinking Water Act. Therefore no maximum contaminant level (MCL) has been established and water supply systems are not required to sample and analyze for the chemical. It has a lifetime water health advisory level of 5 µg/L. The 1 day and the 10 day advisory levels are 80 µg/L. The limited data available to the Agency on trifluralin in surface water, as well as presumably conservative computer estimated EECs (Section C.2) suggests that it is probably unlikely that the annual average concentrations of trifluralin will exceed the lifetime health advisory or that peak or short term average concentrations will exceed the 1 day or 10 day health advisory in the actual surface water sources for drinking water. Furthermore, most drinking water supply systems that use surface water use primary treatment processes likely to be effective in removing trifluralin, because of the relatively high soil/water partitioning of the chemical. No surface water advisory is required.

7. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered plant and animal species to trifluralin as discussed above in the science assessment chapter. The endangered species LOCs have been slightly exceeded for birds, mammals, and semi-aquatic and aquatic plants. Although the LOCs have not been exceeded for endangered freshwater and marine or estuarine fish, these species may be adversely affected based on laboratory and field studies which revealed vertebral dysplasia after exposure to very low levels of trifluralin.

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 modifications or a generic product label statement, requiring users to consult county-specific bulletins.

These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in the near future. 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.

8. Aquatic Impact Labeling

Due to trifluralin's toxicity to fish, aquatic invertebrates and estuarine/marine organisms, the Agency is requiring aquatic impact labeling on all trifluralin end-use products. For specific language, refer to Section V. of this document.

9. Occupational/Residential Labeling Rationale/Risk Mitigation

a. 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 labels 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, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium that the plants are (or will be) grown in.

To the Agency's knowledge, some of the currently registered uses of trifluralin are within the scope of the Worker Protection Standard for Agricultural Pesticides (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 habitations, home fruit and vegetable 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).

b. Compliance with the Worker Protection Standard (WPS)

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.

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. Personal Protective Equipment (PPE) for Handlers (Mixer/Loaders and Applicators; WPS, Non-WPS, and Homeowners)

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 established 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 Agency 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, cancer, developmental toxicity, or reproductive effects:

   - 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.

Trifluralin risks (cancer) are low enough that the Agency believes that the establishment of active-ingredient-based handler PPE requirements is not warranted. The Agency notes that the only data available for assessing exposure for granular 6 and 8-row-planter equipment were studies in which the applicator was inside an enclosed cab and wearing coveralls over long-sleeved shirt and long pants and chemical-resistant gloves. However, since the risk values are quite low (8.0×10^{-9} for private applicators and 8.0×10^{-8} for commercial applicators) for this exposure scenario and no other exposure scenario for trifluralin presents unacceptable risk, the Agency has determined that no active ingredient based PPE should be required for handlers using granular-8-row-planter equipment or for any other trifluralin handlers.

d. Post-Application Restrictions

Restricted Entry Interval (REI): Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are 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. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, 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 trifluralin as an active ingredient, the Agency is requiring that the current WPS-established 12-hour restricted-entry interval (REI) for each use of the product that is within the scope of the WPS be maintained. The basis for this recommendation is that trifluralin is categorized as toxicity category III for acute dermal toxicity, category III for eye irritation potential, and category IV for dermal irritation. However, since trifluralin is classified as a category C carcinogen, the Agency has determined that the minimum acceptable REI is 12 hours.

Early Entry Personal Protective Equipment (PPE): The Agency has determined that potential for exposure exists for persons entering treated sites after application is complete, such as re-entering treated turf areas (e.g., residential lawns, recreational areas, and sod farms), treated ornamental sites (especially nursery sites), and treated established food/feed/fiber crop areas (such as tree fruits/nuts, grapes, and brambles). 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 is a prohibition of routine entry to perform hand labor tasks and the requirement that personal protective equipment be worn. Personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval 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.

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.

- 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.

Since trifluralin is classified as category IV for acute dermal toxicity and as category III for eye irritation potential and IV for dermal irritation, and the Agency has no concerns with regard to occupational exposure that warrant the establishment of active ingredient based PPE, the PPE required for early entry is the minimum post-application early entry PPE required under the WPS: coveralls, chemical-resistant gloves, shoes, and socks.

Entry Restrictions for Occupational-Use Products (Non-WPS Uses): The Agency is establishing entry restrictions for all non-WPS occupational uses of trifluralin liquid and granular end-use products. These requirements are specified in Section V.

Entry Restrictions for Home-Use Products: The Agency is requiring that home-use liquid and granular products carry the label statements specified in Section V.

Other Labeling Requirements: The Agency is requiring other labeling requirements pertaining to occupational and residential exposures. These requirements are specified in Section V.

10. Other Regulatory Restrictions

The Agency is concerned about trifluralin Special Local Needs (SLN) registrations for the uses of trifluralin on clover and bermudagrass grown for seed production only. These uses are eligible for reregistration provided that the registrant/state lead agencies either 1) reach an agreement within 6 months of the date of receipt of this RED which provides for adequate legal/regulatory mechanisms to prevent feed uses of the seed crop(s) and forages, hays, straws from the seed crops or 2) provide a formal commitment to generate residue data depicting residues of

trifluralin in/on clover forage and hay and bermudagrass forage and hay. See Section V.2.d.

V. ACTIONS REQUIRED OF 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 trifluralin for the above eligible uses has been reviewed and determined to be substantially complete. However, additional confirmatory data are needed to fulfill the requirements listed below. Some of these requirements were levied in the trifluralin Registration Standard and in previously issued Data Call-In Notices. Only the data requirements that have not been previously levied by the Agency will be included in the generic Data Call-In Notice (DCI) includes as an attachment to this RED document.

*	62-1	Preliminary Analysis for Nitrosamine
*	123-1a	Seed Germination/Seedling Emergence
*	132-1a	Foliar Residue Dissipation**
*	133-3	Dermal Exposure Upon Reentry**
*	231	Dermal Exposure from Mixing/Loading/Applying**
*	232	Inhalation Exposure from Mixing/Loading/Applying**
*	163-2	Lab Volatility
*	171-4e	Storage Stability (field trial data on (i) barley or wheat forage, hay and straw; (ii) carrots; and (iii) grapes)
*	171-4k	Corn, Field, Forage, Fodder, and Silage (method validation data)
*	171-4k	Alfalfa, Forage and Hay
*	171-4k	Cotton Gin Byproducts
*	171-4k	Rape Forage (Alternatively, the Agency would translate sunflower forage data, if available, to rape forage)
*	171-4k	Dill
*	171-4k	Non-Grass Forage/Fodder/Straw/Hay
*	171-4l	Peppermint/Spearmint Processing

** Levied in the March, 1995 turf DCI

2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing-use (MP) product labeling must be revised to comply with all current Agency 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 use(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 use(s)."

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix 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. Personal Protective Equipment (PPE)/Engineering Control Requirements for Pesticide Handlers (Mixers/Loaders and Applicators)

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

For **multiple-active-ingredient** end-use products that contain trifluralin, the handler PPE/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

(1) Products Intended Primarily for Occupational Use (WPS and Non-WPS)

Minimum (Baseline) PPE/Engineering Control Requirements: The Agency **is not** establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for trifluralin end-use products that are intended primarily for occupational use.

Determining PPE Requirements for End-use Product Labels: Any necessary PPE for each trifluralin occupational end-use product **will be established on the basis of the end-use product's acute toxicity category.**

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

(2) Products Intended Primarily for Homeowner Use

Minimum (Baseline) PPE/Engineering Control Requirements: EPA **is not** establishing active-ingredient-based minimum (baseline) handler PPE for trifluralin end-use products that are intended primarily for homeowner use.

Determining PPE Requirements for End-Use Product Labels: Any necessary PPE for each trifluralin end-use product intended primarily for homeowner use **will be established on the basis of the end-use product's acute toxicity category.**

Placement in Labeling: The personal protective equipment requirements must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

b. Entry Restrictions

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

For **multiple-active-ingredient** end-use products that contain trifluralin the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

(1) Products Intended Primarily for Occupational Use (WPS Uses)

Restricted-entry interval: A **12-hour restricted-entry interval (REI)** is required for uses within the scope of the WPS on all trifluralin end-use products.

(Registrant, place the following statement on the labeling, if some WPS uses may be soil-incorporated:)

"Exception: if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

Early-Entry Personal Protective Equipment (PPE): The PPE required for early entry is:

* Coveralls
* Chemical-resistant gloves
* Socks plus shoes

Placement in Labeling: The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7.

(2) Products Intended Primarily for Occupational Use (Non-WPS Uses)

Entry Restrictions: The Agency is establishing the following entry restrictions for non-WPS occupational uses of trifluralin end-use products:

For liquid applications:

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

For granular applications:

"Do not enter or allow others to enter the treated area until dusts have settled. If soil incorporation is required after the application, do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete. If the incorporation is accomplished by watering-in, do not enter or allow others to enter the treated area until the surface is dry after the watering-in."

Placement in Labeling: If WPS uses are also on the label, follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label, place the appropriate non-WPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

(3) Products Intended Primarily for Homeowner Use

Entry Restrictions: The Agency is establishing the following entry restrictions for all homeowner uses of trifluralin end-use products:

For liquid applications:

> "Do not allow people or pets to enter the treated area until sprays have dried."

For dry applications:

> "Do not allow people or pets to enter the treated area until dusts have settled. If watering-in is required after the application, do not enter or allow others to enter the treated areas (except those involved in the watering) until the watering-in is complete and the surface is dry."

Placement in Labeling: Place the appropriate entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

c. Other Labeling Requirements

(1) Products Intended Primarily for Occupational Use

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

Application Restrictions:

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

Engineering Controls:

> "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements: (Registrant, place the following statements on the labeling ONLY if coveralls are required for pesticide handlers:)

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

(Registrant, place the following statements on all labeling of end-use products intended primarily for occupational use:)

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

User Safety Recommendations:

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

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

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

Skin Sensitizer Statement:

"This product may cause skin sensitization reactions in some people."

(2) Products Intended Primarily for Home Use

Application Restrictions:

"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."

User Safety Recommendations:

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

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

d. Aquatic Impact Labeling

The following label statement is required on all end-use products:

"This pesticide is extremely toxic to freshwater marine, and estuarine fish and aquatic invertebrates including shrimp and oyster. Do not apply in a manner which will directly expose canals, lakes, streams, ponds, marshes or estuaries to aerial drift. Do not contaminate water when disposing of equipment washwaters."

For non-homeowner products: "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark."

For homeowner products: "Do not apply directly to water."

e. Spray Drift Labeling

The following language must be placed on each 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 and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift 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 Information.

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 largest 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 downward. Therefore, on the up and downwind edges of the field, the applicator must 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 wind 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).

3. Other Regulatory Requirements

In order for the Agency to consider trifluralin Special Local Needs registrations uses on clover and bermudagrass grown for seed production only eligible for reregistration, the registrant/state lead agencies must either 1) reach an agreement within 6 months of the date of receipt of this RED which provides for adequate legal/regulatory mechanisms to prevent feed uses of the seed crop(s) and forages, hays, straws from the seed crop(s) or 2) provide a formal commitment to generate data to support these uses.

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 trifluralin 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 for Use Patterns Subject to Reregistration

Appendix A is approximately 600 pages long and is not being included. Copies of Appendix A are available upon request per the instructions in Appendix D.

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case trifluralin covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to trifluralin 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 Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY Agan Chemical Manufacturers, Ltd. 98% T (11603-13)			
61-1	**Chemical Identity**	ALL	40454701; **Additional data are required**
61-2a	**Start. Mat. & Mnfg. Process**	ALL	40454701
61-2b	**Formation of Impurities**	ALL	40454701, 43032201; **Additional data are required**
62-1	**Preliminary Analysis**	ALL	40454701, 43079901; **Additional data are required**
62-2	**Certification of Limits**	ALL	40454701; **Additional data are required**
62-3	**Analytical Method**	ALL	40454701, 40692701, 42922501 **Additional data are required**
63-2	**Color**	ALL	40454701
63-3	**Physical State**	ALL	40454701
63-4	**Odor**	ALL	40454701
63-5	**Melting Point**	ALL	40454701
63-6	**Boiling Point**		N/A - Solid at room temperature
63-7	**Density**	ALL	40454701
63-8	**Solubility**	ALL	40454701
63-9	**Vapor Pressure**	ALL	40454701
63-10	**Dissociation Constant**	ALL	42922502
63-11	**Octanol/Water Partition**	ALL	40454701

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-12	**pH**	ALL	40454701
63-13	**Stability**	ALL	40454701, 42922503
63-14	**Oxidizing/Reducing Action**	ALL	42922504
63-15	**Flammability**		N/A - Solid at room temperature
63-16	**Explodability**	ALL	42922505
63-17	**Storage stability**	ALL	**Additional data are required**
63-18	**Viscosity**		N/A - Solid at room temperature
63-19	**Miscibility**		N/A - Solid at room temperature
63-20	**Corrosion characteristics**	ALL	42922506

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY Drexel 96% T (19713-384)			
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	Data Gap
62-3	**Analytical Method**	ALL	Data Gap
63-2	**Color**	ALL	Data Gap
63-3	**Physical State**	ALL	Data Gap
63-4	**Odor**	ALL	Data Gap
63-5	**Melting Point**	ALL	Data Gap
63-6	**Boiling Point**		N/A - Solid at room temperature
63-7	**Density**	ALL	Data Gap
63-8	**Solubility**	ALL	Data Gap
63-9	**Vapor Pressure**	ALL	Data Gap
63-10	**Dissociation Constant**	ALL	Data Gap
63-11	**Octanol/Water Partition**	ALL	Data Gap
63-12	**pH**	ALL	Data Gap
63-13	**Stability**	ALL	Data Gap
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap
63-15	**Flammability**		N/A - Solid at room temperature

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage stability**	ALL	Data Gap
63-18	**Viscosity**	ALL	Data Gap
63-19	**Miscibility**	ALL	Data Gap
63-20	**Corrosion characteristics**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY Industria Prodotti Chimici S.P.A (I.Pi.Ci.) 96.3% T (33660-3)			
61-1	**Chemical Identity**	ALL	40743901, 43233001, 43614001
61-2a	**Starting Materials & Manufacturing Process**	ALL	40743901, 43233001, 43614001
61-2b	**Formation of Impurities**	ALL	40743901, 43233001
62-1	**Preliminary Analysis**	ALL	40743902, 43233001
62-2	**Certification of limits**	ALL	40743902, 43233001, 43614001
62-3	**Analytical Method**	ALL	40743902, 43233001, 43614001
63-2	**Color**	ALL	40446902
63-3	**Physical State**	ALL	40446902
63-4	**Odor**	ALL	40446902
63-5	**Melting Point**	ALL	40446902
63-6	**Boiling Point**		N/A - Solid at room temperature
63-7	**Density**	ALL	40446902
63-8	**Solubility**	ALL	40446902
63-9	**Vapor Pressure**	ALL	40446902
63-10	**Dissociation Constant**	ALL	40446902
63-11	**Octanol/Water Partition**	ALL	40446902
63-12	**pH**	ALL	40446902
63-13	**Stability**	ALL	40446902
63-14	**Oxidizing/Reducing Action**	ALL	40446902

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**		N/A - Solid at room temperature
63-16	**Explodability**	ALL	40446902
63-17	**Storage stability**	ALL	40446902, 40834701
63-18	**Viscosity**		N/A - Solid at room temperature
63-19	**Miscibility**		N/A - Solid at room temperature
63-20	**Corrosion characteristics**	ALL	40446902, 40446902

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY Albaugh 95.6% T (42750-30)			
61-1	**Chemical Identity**	ALL	Data Gap
61-2a	**Starting Materials & Manufacturing 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	Data Gap
62-3	**Analytical Method**	ALL	Data Gap
63-2	**Color**	ALL	Data Gap
63-3	**Physical State**	ALL	Data Gap
63-4	**Odor**	ALL	Data Gap
63-5	**Melting Point**	ALL	Data Gap
63-6	**Boiling Point**		N/A - Solid at room temperature
63-7	**Density**	ALL	Data Gap
63-8	**Solubility**	ALL	Data Gap
63-9	**Vapor Pressure**	ALL	Data Gap
63-10	**Dissociation Constant**	ALL	Data Gap
63-11	**Octanol/Water Partition**	ALL	Data Gap
63-12	**pH**	ALL	Data Gap
63-13	**Stability**	ALL	Data Gap
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	ALL	Data Gap
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage stability**	ALL	Data Gap
63-18	**Viscosity**	ALL	Data Gap
63-19	**Miscibility**	ALL	Data Gap
63-20	**Corrosion characteristics**	ALL	

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY DowElanco 96.3% (62719-99)			
61-1	**Chemical Identity**	ALL	40453302, 41241301, 43186901
61-2a	**Starting Materials & Manufacturing Process**	ALL	40453302, IN REVIEW
61-2b	**Formation of Impurities**	ALL	40453302, IN REVIEW
62-1	**Preliminary Analysis**	ALL	40674702, 40674703; Additional data are required
62-2	**Certification of limits**	ALL	40453301, 41241301, 43186901 Additional data are required
62-3	**Analytical Method**	ALL	40674704, 43186901; Additional data are required
63-2	**Color**	ALL	40453303, 40453401
63-3	**Physical State**	ALL	40453303, 40453401
63-4	**Odor**	ALL	40453303, 40453401
63-5	**Melting Point**	ALL	40453401
63-6	**Boiling Point**		N/A - Solid at room temperature
63-7	**Density**	ALL	40453303, 40453401, 40453402
63-8	**Solubility**	ALL	40453401, 40453403; Additional data are required
63-9	**Vapor Pressure**	ALL	40453401, 40453404
63-10	**Dissociation Constant**	ALL	40453401
63-11	**Octanol/Water Partition**	ALL	40453401
63-12	**pH**	ALL	40453303, 40453401

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-13	**Stability**	ALL	40453401
63-14	**Oxidizing/Reducing Action**	ALL	40453303, 40453401
63-15	**Flammability**		N/A - Solid at room temperature
63-16	**Explodability**	ALL	40453303, 40453401
63-17	**Storage stability**	ALL	41792901
63-18	**Viscosity**		N/A - Product is a solid at room temperature
63-19	**Miscibility**		N/A - Product is a solid at room temperature
63-20	**Corrosion characteristics**	ALL	41792901

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY DowElanco 50.8% FI (62719-172)			
61-1	**Chemical Identity**	ALL	41251801, 43143001; Additional data are required
61-2a	**Starting Materials & Manufacturing Process**	ALL	41251801, 43143001; Additional data are required
61-2b	**Formation of Impurities**	ALL	43143001
62-1	**Preliminary Analysis**		N/A - Will be fulfilled by data for the technical source products
62-2	**Certification of Limits**	ALL	41251801, 43143001; Additional data are required
62-3	**Analytical Method**	ALL	40674602, 43194101
63-2	**Color**	ALL	40453502
63-3	**Physical State**	ALL	40453502
63-4	**Odor**	ALL	40453502
63-5	**Melting Point**		N/A - Will be fulfilled by data for the technical source products
63-6	**Boiling Point**		N/A - Will be fulfilled by data for the technical source products
63-7	**Density**	ALL	40453502
63-8	**Solubility**		N/A - Will be fulfilled by data for the technical source products
63-9	**Vapor Pressure**		N/A - Will be fulfilled by data for the technical source products

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-10	**Dissociation Constant**		N/A - Will be fulfilled by data for the technical source products
63-11	**Octanol/Water Partition**		N/A - Will be fulfilled by data for the technical source products
63-12	**pH**	ALL	40453502
63-13	**Stability**		N/A - Will be fulfilled by data for the technical source products
63-14	**Oxidizing/Reducing Action**	ALL	40453502
63-15	**Flammability**	ALL	40453502
63-16	**Explodability**	ALL	40453502
63-17	**Storage stability**	ALL	40453502, 43143002; Additional data are required
63-18	**Viscosity**	ALL	40453502
63-19	**Miscibility**		N/A - Product not diluted in petroleum solvents
63-20	**Corrosion characteristics**	ALL	40453502

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY DowElanco 44.5% FI (62719-101)			
61-1	**Chemical Identity**	ALL	40452701
61-2a	**Starting Materials & Manufacturing Process**	ALL	40452701; Additional data are required
61-2b	**Formation of Impurities**	ALL	40452701
62-1	**Preliminary Analysis**	ALL	N/A - Will be fulfilled by data for the technical source products
62-2	**Certification of limits**	ALL	40674201
62-3	**Analytical Method**	ALL	40674102
63-2	**Color**	ALL	40452702
63-3	**Physical State**	ALL	40452702
63-4	**Odor**	ALL	40452702
63-5	**Melting Point**	ALL	N/A - Will be fulfilled by data for the technical source products
63-6	**Boiling Point**		N/A - Will be fulfilled by data for the technical source products
63-7	**Density**	ALL	40452702
63-8	**Solubility**	ALL	N/A - Will be fulfilled by data for the technical source products
63-9	**Vapor Pressure**	ALL	N/A - Will be fulfilled by data for the technical source products
63-10	**Dissociation Constant**	ALL	N/A - Will be fulfilled by data for the technical source products

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-11	**Octanol/Water Partition**	ALL	N/A - Will be fulfilled by data for the technical source products
63-12	**pH**	ALL	40452702
63-13	**Stability**	ALL	N/A - Will be fulfilled by data for the technical source products
63-14	**Oxidizing/Reducing Action**	ALL	40452702
63-15	**Flammability**	ALL	40452702
63-16	**Explodability**	ALL	40452702
63-17	**Storage stability**	ALL	40452702
63-18	**Viscosity**	ALL	40452702
63-19	**Miscibility**		N/A - Product is not diluted in petroleum solvents
63-20	**Corrosion characteristics**	ALL	40452702

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY DowElanco 20.0% FI (62719-133)			
61-1	**Chemical Identity**	ALL	40453701
61-2a	**Starting Materials & Manufacturing Process**	ALL	40453701; Additional data are required
61-2b	**Formation of Impurities**	ALL	40453701
62-1	**Preliminary Analysis**		N/A - Will be fulfilled by data for the technical source products
62-2	**Certification of limits**	ALL	40675001
62-3	**Analytical Method**	ALL	40675002
63-2	**Color**	ALL	40453702
63-3	**Physical State**	ALL	40453702
63-4	**Odor**	ALL	40453702
63-5	**Melting Point**		N/A - Will be fulfilled by data for the technical source products
63-6	**Boiling Point**		N/A - Will be fulfilled by data for the technical source products
63-7	**Density**	ALL	40453702
63-8	**Solubility**		N/A - Will be fulfilled by data for the technical source products
63-9	**Vapor Pressure**		N/A - Will be fulfilled by data for the technical source products
63-10	**Dissociation Constant**		N/A - Will be fulfilled by data for the technical source products

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-11	**Octanol/Water Partition**		N/A - Will be fulfilled by data for the technical source products
63-12	**pH**	ALL	40453702
63-13	**Stability**		N/A - Will be fulfilled by data for the technical source products
63-14	**Oxidizing/Reducing Action**	ALL	40453702
63-15	**Flammability**		N/A - Product is a solid at room temperature
63-16	**Explodability**	ALL	40453702
63-17	**Storage stability**	ALL	40453702
63-18	**Viscosity**		N/A - Product is a solid at room temperature
63-19	**Miscibility**		N/A - Product is a solid at room temperature
63-20	**Corrosion characteristics**	ALL	40453702

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY Tri Corporation 97.47% T (67959-1)			
61-1	**Chemical Identity**	ALL	Data Gap
61-2a	**Starting Materials & Manufacturing 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	Data Gap
62-3	**Analytical Method**	ALL	Data Gap
63-2	**Color**	ALL	Data Gap
63-3	**Physical State**	ALL	Data Gap
63-4	**Odor**	ALL	Data Gap
63-5	**Melting Point**	ALL	Data Gap
63-6	**Boiling Point**		N/A - Solid at room temperature
63-7	**Density**	ALL	Data Gap
63-8	**Solubility**	ALL	Data Gap
63-9	**Vapor Pressure**	ALL	Data Gap
63-10	**Dissociation Constant**	ALL	Data Gap
63-11	**Octanol/Water Partition**	ALL	Data Gap
63-12	**pH**	ALL	Data Gap
63-13	**Stability**	ALL	Data Gap
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**		N/A - Solid at room temperature
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage stability**	ALL	Data Gap
63-18	**Viscosity**		N/A - Solid at room temperature
63-19	**Miscibility**	ALL	Data Gap
63-20	**Corrosion characteristics**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY Dintec (68156-3)			
61-1	**Chemical Identity**	ALL	Data Gap
61-2a	**Starting Materials & Manufacturing 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	Data Gap
62-3	**Analytical Method**	ALL	Data Gap
63-2	**Color**	ALL	Data Gap
63-3	**Physical State**	ALL	Data Gap
63-4	**Odor**	ALL	Data Gap
63-5	**Melting Point**	ALL	Data Gap
63-6	**Boiling Point**	ALL	Data Gap
63-7	**Density**	ALL	Data Gap
63-8	**Solubility**	ALL	Data Gap
63-9	**Vapor Pressure**	ALL	Data Gap
63-10	**Dissociation Constant**	ALL	Data Gap
63-11	**Octanol/Water Partition**	ALL	Data Gap
63-12	**pH**	ALL	Data Gap
63-13	**Stability**	ALL	Data Gap
63-14	**Oxidizing/Reducing Action**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	ALL	Data Gap
63-16	**Explodability**	ALL	Data Gap
63-17	**Storage stability**	ALL	Data Gap
63-18	**Viscosity**	ALL	Data Gap
63-19	**Miscibility**	ALL	Data Gap
63-20	**Corrosion characteristics**	ALL	Data Gap

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
ECOLOGICAL EFFECTS			
71-1a	**Acute Avian Oral - Quail/Duck**	A,B,C	00137573
71-2a	**Avian Dietary - Quail**	A,B,C	00138857
71-2b	**Avian Dietary - Duck**	A,B,C	00138858
71-4a	**Avian Reproduction - Quail**	A,B,C	00131134, 40334706
71-4b	**Avian Reproduction - Duck**	A,B,C	00131132, 40334704
72-1a	**Fish Toxicity Bluegill**	A,B,C	40094602
72-1c	**Fish Toxicity Rainbow Trout**	A,B,C	40094602
72-2a	**Invertebrate Toxicity**	A,B,C	40094602
72-3a	**Estuarine/Marine Toxicity - Fish**	A,B,C	42449901
72-3b	**Estuarine/Marine Toxicity - Mollusk**	A,B,C	42449902
72-3c	**Estuarine/Marine Toxicity - Shrimp**	A,B,C	40674801
72-4a	**Early Life Stage Fish**	A,B,C	41386202
72-4b	**Life Cycle Invertebrate**	A,B,C	05008271, 41386201
72-5	**Life Cycle Fish**	A,B,C	05008271
72-7a	**Simulated Field - Aquatic Organisms**	A,B,C	42439601
122-1a	**Seed Germination/Seedling Emergence**	A,B,C	41934501

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
123-1a	**Seed Germination/Seedling Emergence**	A,B,C	42695601; **Additional data are required**[1]
123-1b	**Vegetative Vigor**	A,B,C	41934503
123-2	**Aquatic Plant Growth**	A,B,C	42834101, 42834102, 42834103, 42834104 41934502
141-1	**Honey Bee Acute Contact**	A,B,C	00028772, 05001991

[1] **Seedling Emergence:** An EC_{25} was not determined in the submitted study. A new study must be conducted using higher concentrations of trifluralin to ensure an effect level.

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,K	00157486
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,K	00157482
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C,K	00155261
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,K	00157483
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,K	00157485
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,K	00157484
81-7	**Acute Delayed Neurotoxicity - Hen**	A,B,C,K	00159616
82-1a	**90-Day Feeding - Rodent**	A,B,C,K	40138301, 00151906
82-2	**31-Day Feeding - Rat**	A,B,C,K	00153171
83-1a	**Chronic Feeding Toxicity - Rodent**	A,B,C,K	00162456, 00162457
83-1b	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C,K	00151908, 00159618, 42447001
83-2a	**Oncogenicity - Rat**	A,B,C,K	00044337, 00162456, 00162458
83-2b	**Oncogenicity - Mouse**	A,B,C,K	00044338, 00158935, 40392313
83-3a	**Developmental Toxicity - Rat**	A,B,C,K	00152419
83-3b	**Developmental Toxicity - Rabbit**	A,B,C,K	00152421
83-4	**2-Generation Reproduction - Rat**	A,B,C,K	00162543, 00151901, 00151902, 00151903
84-2a	**Gene Mutation (Ames Test)**	A,B,C,K	00126660, 00126661, 00153173
84-2b	**Structural Chromosomal Aberration**	A,B,C,K	00129059
84-4	**Other Genotoxic Effects**	A,B,C,K	00126662

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
85-1	**General Metabolism**	A,B,C,K	41218901

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
161-1	**Hydrolysis**	A,B,H,D	00131135
161-2	**Photodegradation - Water**	A,B,H,D	40560101; **Partially satisfied**
161-3	**Photodegradation - Soil**	A,B,H	40597801, 40751301; **Partially satisfied**
161-4	**Photodegradation - Air**		**RESERVED**
162-1	**Aerobic Soil Metabolism**	A,B,H	41240501; **Partially satisfied**
162-2	**Anaerobic Soil Metabolism**	A,B,H	41240502; **Partially satisfied**
163-1	**Leaching/Adsorption/Desorption**	A,B,H,D	40673501; **Partially satisfied**
163-2	**Volatility - Lab**	A,B,H	40673601A-C; **Partially satisfied**
163-3	**Volatility - Field**	A,B,H	40673601D-G; **Partially satisfied**
164-1	**Terrestrial Field Dissipation**	A,B,H	41661101, 41781901, 42309101; **Partially satisfied**
165-1	**Confined Rotational Crop**	A,B,H	41661102
165-2	**Field Rotational Crop**		**WAIVED**[1]
165-4	**Bioaccumulation in Fish**	A,B,H,D	40673801; **Partially satisfied**
201-1	**Droplet Size Spectrum**	A,B	**Data Gap**[2]
202-1	**Drift Field Evaluation**	A,B	**Data Gap**[2]

[1] **Field Rotational Crop:** Trifluralin limited field rotational crop studies are not required and no tolerances are needed for trifluralin residues in rotational crops.
[2] **Droplet Size Spectrum, Drift Field Evaluation:** Data being generated by the Spray Drift Task Force.

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT		USE PATTERN	CITATION(S)
RESIDUE CHEMISTRY			
171-4a	**Nature of Residue - Plants**	A,B	00024731, 00026054, 00093553, 00105720 00105759, 00124905, 00125299, 41179001 41179002, 41396801, 41396802
171-4b	**Nature of Residue - Livestock**	B	00093636, 00105690, 00105772, 41233101 41233102, 41286101
171-4c	**Residue Analytical Methods - Plants**	A,B	00022793, 00047591, 00047639, 00059532 00067371, 00067435, 00080320, 00105646 00105689, 00105695, 00105720, 00105759 00125303
171-4d	**Residue Analytical Methods - Animals**		**WAIVED**[1]
171-4e	**Storage Stability**	A,B	00047639, 00105716, 00105720, 41335901 **Additional data are required**[2]
171-4j	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	00023105, 00080320, 00080322, 00093634 00093636, 00105772; **WAIVED**[3]
171-4k	**Crop Field Trials**		
	Root and Tuber Vegetables Group		
	- Carrots	A	00033087, 00093554
	- Potatoes	A	00022257, 00093574, 00105733, 00105734 00133939

[1] **Residue Analyticial Method Animal:** The requirement for residue analytical methods sutiable for data collection and tolerance enforcement for the determination of trifluralin in animal commodities is waived.

[2] **Storage Stability:** Information concerning sample storage intervals and conditions for numerous magnitude of the residue studies previously submitted and reviewed in the Trifluralin Registration Standard (7/12/85) remains outstanding.

[3] **Magnitude of the Residue in Meat/Milk, Poultry/Egg:** Waived based on the low levels of radioactive residues from the animal metabolism studies.

REQUIREMENT	USE PATTERN	CITATION(S)
- Radishes, Roots	A	42430802
- Sugar Beets, Roots	A	00057546, 00105648, 00105666, 00105757
Leaves of Root and Tuber Vegetables Group		
- Sugar Beets, Tops	A	00057546, 00105648, 00105666, 00105757
- Turnips, Tops	A	00105724
Bulb Vegetables Group		
- Garlic	A	00105678
- Onions, Dry Bulb	A	00120263
- Onions, Green	A	42448202
Leafy Vegetables Group (except Brassica Vegetables)		
- Celery	A	00093549, 00105670
Brassica (Cole) Leafy Vegetables Group		
- Broccoli	A	00105650, 00105749
- Brussels Sprouts	A	00105749
- Cabbage	A	00105650, 00105749
- Cauliflower	A	00105749
- Collards	A	00105724
- Kale	A	00105724
- Mustard Greens	A	00105724
Legume Vegetables (Dry or Succulent) Group		
- Beans, Dry	A	00022376, 00105669, 00105726

REQUIREMENT	USE PATTERN	CITATION(S)
- Field, Peas (Cowpeas, Black-Eyed Peas)	A	00105669
- Guar Beans	A	00105670
- Lima Beans	A	00033086, 00105669, 00105726
- Mung Beans	A	00105670
- Peas (Succulent and Dried)	A	00105669, 00105755
- Snap Beans	A	00022376, 00033086, 00057547, 00105669
- Soybeans and Aspirated Grain Fractions	A	00022793, 00030932, 00067433, 00094410 00096361, 00104423, 00105655, 00105669 00105717, 00105720, 00105725, 00105746 00124904, 00128308
Foliage and Legume Vegetables Group		
- Beans, Forage and Straw/Hay	A	00022376, 00105669
- Peas, Vines and Hay	A	00105669
- Soybeans, Forage, and Hay	A	00022793, 00030932, 00067433, 00096361 00105720
Fruiting Vegetables (Except Cucurbits) Group		
- Peppers	A	00105750
- Tomatoes	A	00105710, 00105726, 00105750
Cucurbit Vegetables Group		
- Cantaloupes	A	00093555, 00105726
- Cucumbers	A	00093555
- Squash, Summer	A	42354502

REQUIREMENT	USE PATTERN	CITATION(S)
- Watermelons	A	00105670
Citrus Fruits Group		
- Grapefruit	A	00105677
- Lemons	A	00105677
- Oranges	A	00105677
- Tangelos	A	00105677
- Tangerines	A	00105677
Stone Fruits Group		
- Apricots	A	00105667, 00105675
- Cherries	A	42430803
- Peaches	A	00105667, 00105675
- Plums	A	00105675, 00105735
Small Fruits and Berries Group		
- Grapes	A	00105678
Tree Nuts Group		
- Almonds, Nutmeat and Hulls	A	00105675, 00105726
- Pecans	A	00105675
- Walnuts	A	00105675
Cereal Grains Group		
- Barley, Grain	A	00070736, 00105704

REQUIREMENT	USE PATTERN	CITATION(S)
- Corn, Field, Grain and Aspirated Grain Fractions	A	00032811, 00105697, 00105726, 42448201 42779001
- Sorghum, Grain and Aspirated Grain Fractions	A	00105704, 00105726
- Wheat, Grain and Aspirated Grain Fractions	A	00070736, 00105681, 00105726
Forage, Fodder, and Straw of Cereal Grains Group		
- Barley Forage, Hay, and Straw	B	00070736, 00105704
- Corn, Field, Forage and Fodder	A	00032811, 00105726, 42472301 **Additional data are required**[1]
- Sorghum Forage and Fodder	A	00105704
- Wheat Forage, Hay, and Straw	A	00070736, 00105681
Non-grass Animal Feeds Group		
- Alfalfa, Forage and Hay	B	00093637, 00105691, 00105726, 00143667 00155395, 42466001, 42466002, 42466003 42466004, 42466005, 42466006, 42466007 42466008, 42466009, 42466010; **Additional data are required**[2]
Miscellaneous Commodities		
- Asparagus	A	00105696, 00105702

[1] **Corn, Field, Forage and Fodder:** The residue study (MRID 42472301) on corn forage, fodder, and silage is adequte pending submission of acceptable data validating the analytical method (Method No. GRM92.11) at or below the established 0.05 ppm tolerance level. Additionally, product labels must be amended to limit applications to clearly recognizable growth stages which assure at least a 6-week interval prior to harvesting forage and fodder.

[2] **Alfalfa, Forage and Hay:** The field trial studies submitted (MRID 42466001-42466010) are inadequate because geographic representation was insufficient and storage temperatures were not reported. Additional field trials are required for alfalfa forage and hay.

REQUIREMENT		USE PATTERN	CITATION(S)
	- Cotton, Seed and Gin Byproducts	B	00093190, 00105669, 00105713, 00105726 00105729, 00105731, 00105751, 00105759 00105780, 00105781, 00124904; **Additional data are required**[1]
	- Flax, Seed and Straw	B	00084581; **Additional data are required**[2]
	- Hops, Cones, Dried	A	00105678
	- Mustard Seed	A	00067371, 42430801
	- Okra	A	00105669
	- Peanuts, Nutmeat, Hay, and Hulls	A	00026049, 00059531, 00067222, 00105646 42472302
	- Peppermint, Tops	A	00105683
	- Rape, Seed and Forage	B	00047639
	- Safflower, Seed and Forage	A	00067371, 00105726, 00105750
	- Spearmint, Tops	A	00105683
	- Sugarcane	A	00105668, 00105674, 00105727, 00105730
	- Sunflower Seed and Forage	A	00057545, 00067371, 00067430, 00105673 **Additional data are required**[3]
171-4l	**Processed Food**		
	- Barley[4]	A	
	- Corn, Field	A	42403201, 42917801

[1] **Cotton, Seed and Gin Byproducts:** Data are required depicting residues of trifluralin in/on cotton gin byproducts resulting from the maximum registered use of trifluralin to cotton. A minimum of six field trials are required.

[2] **Flax, Seed and Straw:** The data requirement for flax staw remains outstanding.

[3] **Sunflower Seed and Forage:** The data requirement for sunflower forage remains outstanding.

[4] **Barley:** Available wheat processing data have been translated to barley processed commodities.

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT	USE PATTERN	CITATION(S)
- Cottonseed	A	42354501
- Flax[1]		
- Grapes	A	00105678
- Hops	A	00105678
- Citrus	A	42642601
- Peanuts	A	42430804, 42779001
- Peppermint	A	**Additional data are required**[2]
- Plums	A	00105675, 00105735
- Potato	A	42514501
- Rape Seed[3]		
- Safflower Seed[4]		
- Sorghum, Grain	A	42325001
- Soybeans	A	42448203, 42779001
- Spearmint	A	**Additional data are required**[5]
- Sugar Beets	A	42448204
- Sugarcane	A	41306701
- Sunflower Seed	A	42430805
- Tomatoes	A	00105710, 00105726, 00105750

[1] **Flax:** Cottonseed processing data have been translated ot flax processed commodities.
[2] **Peppermint:** Peppermint processing data remain outstanding.
[3] **Rape Seed:** The available sunflower processing data have been translated to rape seed.
[4] **Safflower Seed:** The available sunflower processing data have been translated to safflower seed.
[5] **Spearmint:** Searmint processing data remain outstanding.

Data Supporting Guideline Requirements for the Reregistration of Trifluralin

REQUIREMENT	USE PATTERN	CITATION(S)
- Wheat	A	42430806, 42779001

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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00022376	Shaw, A.; Thaemert, E.; Binning, L.K.; et al. (1975) Eptam 7-E + Treflan 4-E Tank Mix on Beans. (Unpublished study received Jul 20, 1976 under 476-2154; prepared in cooperation with Morse Laboratories, Inc. and Univ. of Wisconsin, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:224906-A)
00022793	Sckerl, M. (1978) Residue Data Treflan and Planavin Herbicides in Soybeans: TIR-24-305-76-C. (Unpublished study including TIR24-143-72-B, received Jul 18 1979 under 201-279; prepared in cooperation with Agri-Research, submitted by Shell Chemical Co., Washington, D.C.; CDL:098395-O)
00023105	Fisher, D.E.; St. John, L.E., Jr.; Guntenman, W.E.; et al. (1965) Fate of Banvel T, Ioxynil, Tordon and Trifluorilin in the dairy cow. Journal of Dairy Science 48(12):1711-1715. (Also in unpublished submission received Apr 8, 1976 under 876-203; submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:235226-Y)
00024731	Penner, D. (1971) Effect of temperature on phytotoxicity and root uptake of several herbicides. Weed Science 19(5):571-575. (Also in unpublished submission received Jul 19, 1978 under 201403; submitted by Shell Chemical Co., Washington, D.C.; CDL: 234470-AI)
00026049	Merkle, M.G.; Spears, B.R. (1969) Crop Residue Report: Vernam 6E Treflan 4E: FSDS No. B-0458. (Unpublished study including FSDS nos. B-0457, B-0456, B-0455..., received Dec 8, 1969 under 476-1807; prepared in cooperation with Texas A & M Univ., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:003788-B)
00026054	Golab, T.; Herberg, R.J.; Parka, S.J.; et al. (1967) Metabolism of Carbon-14 Trifluralin in carrots. Journal of Agricultural and Food Chemistry 15(4):638-641. (Also in unpublished submission received Jan 3, 1971 under 0F0981; submitted by Shell Chemical Co., Washington, D.C.; CDL:091687-C)

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00030932	Baychem Corporation (1973) Treflan plus Sencor--Soybeans. (Unpublished study received Feb 15, 1973 under 1471-EX-40; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:210010-B)
00032811	Elanco Products Company (1978) Trifluralin--Corn. (Unpublished study received Jun 23, 1980 under CO 80/9; CDL:242716-B)
00033086	Manning, P.B.; Kerr, T.W.; Olney, C.E.; et al. (1964) Residue Study. (Unpublished study including published data, received Jan 14, 1965 under 100-471; prepared by Univ. of Rhode Island, Agricultural Experiment Station and others, submitted by CibaGeigy Corp., Greensboro, N.C.; CDL:000459-E)
00033087	Manning, P.B.; Kerr, T.W.; Olney, C.E.; et al. (1964) Residue Study. (Unpublished study including published data, received Jan 14, 1965 under 100-471; prepared in cooperation with Univ. of Rhode Island, Agricultural Experiment Station and Gaspro, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 000459-F)
00044337	Emmerson, J.L.; Pierce, E.C.; McGrath, J.P.; et al. (1980) The Chronic Toxicity of Compound 36352 (Trifluralin) Given as a Component of the Diet to Fischer 344 Rats for Two Years: Studies R-87 and R-97. (Unpublished study received Sep 18, 1980 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:243289-A, 243290)
00044338	Emmerson, J.L.; Owen, N.V.; McGrath, J.D.; et al. (1980) The Chronic Toxicity of Compound 36352 (Trifluralin) Given as a Component of the Diet to the B6C3F1 Mouse for 24 Months: Studies M9067 and M-9077. (Unpublished study received Sep 18, 1980 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:243291-A; 243292; 243293)
00047591	Elanco Products Company (1967?) Determination of Trifluralin, Diphenamid and N-Methyl-2,2-diphenylacetamide in Tomatoes. Undated method no. 5800600. (Unpublished study received Aug 22, 1968 under 8F0717; CDL:093027-B)
00047639	Armock, I.; Knight, C.W.; Leavitt, R.A.; et al. (1979) Summary: Efficacy of Trifluralin for Weed Control in Rape. (Unpublished study including PR no. 1124, received Jul 29, 1980 under 0E2394; prepared in cooperation with

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00057545	Stauffer Chemical Company (1981) Eptam 7-E + Treflan 4-EC Tank Mix Applied Preplant Incorporated to Sunflowers. (Compilation; unpublished study received Feb 13, 1981 under 476-2154; CDL: 244420-A)
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00059532	Johnson, W.S. (1972) Determination of Trifluralin in Agricultural Crops and Soil. Method No. 5801616 dated Jul 20, 1972. (Unpublished study received Mar 13, 1975 under 1471-EX-47; submitted by Elanco Products Co., Div. of Eli Lilly & Co., Indianapolis, Ind.; CDL:224660-C)
00067222	Frank, R.; Johnson, W.S.; Sieck, R.F.; et al. (1978) Residue Data on Trifluralin and Vernolate in Peanuts When Preplant Incorporated as an EC Formulation. Includes procedure no. 5801616 dated May 24, 1977 and undated procedure no. 5801690. (Unpublished study received Jul 25, 1980 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:243059-A)
00067371	Danhaus, R.G.; Mestdagh, P.; Schreurs, R.; et al. (1980) Residues of Triallate, Trifluralin and EPTC in Oilseeds following Preemergent Applications of Fargo, Fargo + Treflan, and Fargo + Eptam Tank Mixes: Report No. MSL-1323. Final rept. Includes undated methods entitled: Analytical residue method for triallate and trifluralin in oilseed crops and Analytical residue method for EPTC in flax seed. (Unpublished study, including published data, received Dec 23, 1980 under 524-145; submitted by Monsanto Co., Washington, D.C.; CDL: 099852-A)

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00067433	Harrison, S.L.; Boros, E.J. (1980) Chloramben, Trifluralin & Metribuzin (+ DADK) Analyses of Soybeans Treated with Amiben + Treflan + Sencor or Lexone Tank Mix PPI: Project Report 10123/1280A. (Unpublished study received Dec 19, 1980 under 264-138; prepared in cooperation with Southern Illinois Univ., Plant & Soil Science Dept. and others, submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:243984-F)
00067435	Decker, O.D.; Griggs, R.D. (1980) Determination of Trifluralin in Agricultural Crops and Soil. Undated method AM-AA-CA-R023-AA755. (Unpublished study received Dec 19, 1980 under 264-138; prepared by Eli Lilly and Co., submitted by Union Carbide Agricultural Products Co., Inc., Ambler, Pa.; CDL:243984-I)
00070736	Frank, R.; Sieck, R.F.; Shuey, E.W. (1978) Trifluralin and Triallate on Barley and Wheat: Residue Data. (Unpublished study received Feb 20, 1981 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL: 244413-A)
00080320	Fisher, D.E.; St. John, L.E., Jr.; Gutenmann, W.H.; et al. (1965?) Fate of Banvel T, Ioxynil, Tordon, and Trifluralin in the Dairy Cow. (Unpublished study received Feb 7, 1967 under unknown admin. no.; prepared by Cornell Univ., Depts. of Engineering Physics, Entomology and Animal Husbandry, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:105544-D)
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00093190	Shell Chemical Company (1974) 1973--Residue Data for Treflan in Cottonseed from Stoneville, Mississippi: TIR-24-195-73 (Part II). (Unpublished study received Feb 28, 1975 under 5F1599; CDL:094364-O)
00093549	Manning, P.B.; Kerr, T.W.; Olney, C.E.; et al. (1964) Residue analysis of various fruits and vegetables treated with DCPA, prometryne and trifluralin for weed control. Pages 105-108,In Proceedings of the Northeastern Weed Control Conference: Volume 18; Jan 8,9,10, 1964, New York, N.Y. N.P. (Also in unpublished submission received Dec 1, 1964 under 7F0559; submitted by Geigy Chemical Co., Ardsley, N.Y.; CDL:090702-E)
00093553	Elanco Products Company (1966?) Radioactive Metabolic Studies. (Unpublished study received Jan 4, 1967 under 7F0555; CDL: 090690-B)
00093554	Elanco Products Company (1966) Summary of Residue Data. (Compilation; unpublished study received Jan 4, 1967 under 7F0555; CDL:090690-C; 090689)
00093555	Elanco Products Company (1966) Trifluralin--Cantaloupe and Cucumber. Includes procedure no. 5801000 dated Jul 1, 1964; procedure no. 5801110 dated Oct 15, 1964; procedure 5801210 dated Jan 1966. (Compilation; unpublished study received Jan 4, 1967 under 7F0555; CDL:090689-A)
00093574	Elanco Products Company (1966) Residue of Trifluralin--Irish Potatoes. (Compilation; unpublished study received Jan 24, 1967 under 7F0586; CDL:090752-A)
00093634	Van Duyn, R.L.; Berkman, R.N. (1965) Trifluralin Residues from a Dairy Cow: VPR-235-418. (Unpublished study received Jan 25, 1967 under 7F0565; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:090711-B)

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00094410	Union Carbide Agricultural Products Company, Incorporated (1975) Residue Studies on Chloramben, Trifluralin and Linuron in Soybeans. (Compilation; unpublished study received May 23, 1975 under 264-266; CDL:195120-A)
00096361	Decker, O.D.; Sieck, R.F.; Shuey, E.W. (1981) Residue Data on Trifluralin and Oryzalin When EL-5219 is Used for Preemergence Weed Control in Soybeans. (Unpublished study received Feb 10, 1981 under 1471-118; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:244283-A)
00104423	Frank, R.; Amundson, M.; Deal, P.; et al. (1978) Trifluralin and Chloramben on Soybeans: Residue Data. (Unpublished study received Feb 9, 1978 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:232828-A)
00105646	Elanco Products Co. (1965) Trifluralin Residue Data--Peanuts. (Compilation; unpublished study received Mar 23, 1965 under 1471-35; CDL:005968-B)
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00105650	Little, C.; Hunt, H. (1968) Supplemental Trifluralin Residue Data on Cole Crops Harvested in 1967 and 1968. (Unpublished study received Feb 10, 1969 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL: 006241-B)
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00105667	Elanco Products Co. (1966) Residue Data on Trifluralin in Citrus, Stone Fruit, Nuts, Vine Crops, and Pome Fruit. (Compilation; unpublished study received on unknown date under 7G0533; CDL: 090649-A)
00105668	Eli Lilly and Co. (1967) Residue Data on Trifluralin in Sugarcane. (Unpublished study received on unknown date under 7G0595; CDL: 090765-A)
00105669	Elanco Products Co. (1967) The Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: Trifluralin. (Compilation; unpublished study received Nov 28, 1967 under 8F0664; CDL:091163-A)
00105670	Eli Lilly and Co. (1967) Residue Data on Trifluralin in Watermelon, Celery, Mungbeans, and Guar Beans. (Unpublished study received Feb 14, 1968 under 8F0664; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:091164-A)
00105673	Eli Lilly and Co. (1967) Residue Data on Trifluralin in Sunflower Seed. (Compilation; unpublished study received Apr 5, 1968 under 8F0679; CDL:091186-A)
00105674	Eli Lilly and Co. (1968) Supplemental Residue Data on Trifluralin in Sugarcane. (Compilation; unpublished study received Apr 6, 1968 under 8F0715; CDL:091238-A)
00105675	Elanco Products Co. (1968) Trifluralin: Residues in Almonds and Other Nuts. (Compilation; unpublished study received Dec 1, 1968 under 8F0721; CDL:091243-A)
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00105683	Bundy, D.; Macy, T.; Hunt, H.; et al. (1969) Trifluralin: Peppermint and Spearmint. (Unpublished study received Aug 4, 1969 under 0F0862; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:091490-B)
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MRID	CITATION
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00105713	Elanco Products Co. (1963) Residues of Trifluralin in Cottonseed. (Compilation; unpublished study received May 13, 1963 under 1471-35; CDL:101591-A)
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00105720	Elanco Products Co. (1964) General Summary: Treflan E.C.. (Compilation; unpublished study received May 7, 1964 under 1471-35; CDL:101595-A)
00105724	Bundy, D.; Griggs, D.; Little, C.; et al. (1968) Residue Data on Trifluralin in Collard, Kale, Mustard, and Turnip Greens. (Unpublished study received Aug 26, 1968 under 1471-35; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN; CDL:101679-A)

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MRID	CITATION
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00105734	Johnson, W.; Oliva, M. (1973) Residue Data on Treflan Preplant and Postplant Application for Weed Control in Potatoes. (Unpublished study received Aug

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

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

iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

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

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

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

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

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

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

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

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

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

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

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

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

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

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

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

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

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

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Attachments:

The Attachments to this Notice are:

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

TRIFLURALIN DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 trifluralin. 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 trifluralin 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 trifluralin are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on trifluralin 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 trifluralin products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of trifluralin, please contact Connie Childress at (703) 308-8076.

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) 308-8172.

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

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: Trifluralin

trifluralin DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 trifluralin. 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 trifluralin Generic Data CallIn (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for trifluralin are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on trifluralin are needed. These data are needed to fully complete the reregistration of all eligible trifluralin 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 Connie Childress at (703) 308-8076.

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

Connie Childress, 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: Trifluralin

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

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and

incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

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

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

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

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

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

Generic and Product Specific Data Call-In

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

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

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

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

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

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

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

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

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

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

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

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the

agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

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

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

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

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

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

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I

may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

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

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

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

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

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

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

that the deadline for submission of data as specified by the original Data Call-In notice will not change.

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

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

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

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

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

EPA'S BATCHING OF PRODUCTS CONTAINING TRIFLURALIN 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 trifluralin (a,a,a-trifluoro-2,6-dinitro-N,N-dipropyl-p-toluidine) 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 statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

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

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

Table 1 displays the batches for the active ingredient trifluralin.

Table 1.

Batch	Registration Number	Percent Active Ingredient	Form
1	19713-226	Trifluralin ... 96.0%	powder
	33660-3	Trifluralin ... 96.0%	powder
	42750-30	Trifluralin ... 95.6%	powder
	62719-99	Trifluralin ... 96.3%	powder
	67959-1	Trifluralin ... 97.47%	powder
	68153-3	Trifluralin ... 96.3%	powder
2	1812-321	Trifluralin ... 80.0%	powder
	62719-216	Trifluralin ... 80.0%	powder
3	241-334	Trifluralin ... 46.0%	liquid
	241-343	Trifluralin ... 42.8%	liquid
	1386-609	Trifluralin ... 44.5%	liquid
	1812-355	Trifluralin ... 42.8%	liquid
	2749-513	Trifluralin ... 44.5%	liquid
	5481-172	Trifluralin ... 44.5%	liquid
	5905-519	Trifluralin ... 44.5%	liquid

Batch	Registration Number	Percent Active Ingredient	Form
	9779-303	Trifluralin ... 46.0%	liquid
	10163-101	Trifluralin ... 44.5%	liquid
	10163-181	Trifluralin ... 44.5%	liquid
	33660-33	Trifluralin ... 44.5%	liquid
	34704-241	Trifluralin ... 44.5%	liquid
	34704-242	Trifluralin ... 44.5%	liquid
	36480-33	Trifluralin ... 44.5%	liquid
	46193-6	Trifluralin ... 44.5%	liquid
	46193-10	Trifluralin ... 42.8%	liquid
	51036-106	Trifluralin ... 44.5%	liquid
	55467-2	Trifluralin ... 44.5%	liquid
	62719-93	Trifluralin ...44.5%	liquid
	62719-97	Trifluralin ...44.5%	liquid
	62719-101	Trifluralin ... 44.5%	liquid
	62719-241	Trifluralin ... 44.5%	liquid
4	241-332	Trifluralin ... 50.8%	liquid
	241-333	Trifluralin ... 41.2%	liquid
	1812-353	Trifluralin ... 50.8%	liquid
	2749-514	Trifluralin ... 41.2%	liquid
	9779-304	Trifluralin ... 41.2%	liquid
	10163-99	Trifluralin ... 50.8%	liquid
	33660-31	Trifluralin ... 50.8%	liquid

Batch	Registration Number	Percent Active Ingredient	Form
	33660-32	Trifluralin ... 41.2%	liquid
	34704-709	Trifluralin ... 50.8%	liquid
	34704-711	Trifluralin ... 41.2%	liquid
	51036-126	Trifluralin ... 41.2%	liquid
	62719-116	Trifluralin ... 41.2%	liquid
	62719-118	Trifluralin ... 50.8%	liquid
	62719-172	Trifluralin ... 50.8%	liquid
	66222-13	Trilfuralin ... 41.8%	liquid
5	1386-623	Trifluralin ... 10.0%	granular
	10163-120	Trifluralin ... 10.0%	granular
	34704-708	Trifluralin ... 10.0%	granular
	62719-131	Trifluralin ... 10.0%	granular
6	279-3104	Trifluralin ... 33.3% 2-(2-Chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone ... 26.7	liquid
	62719-143	Trifluralin ... 33.2% 2-(2-Chlorophenyl)methyl-4,4-dimethyl-3-isoxazolidinone ... 24.9%	liquid
7	572-324	Trifluralin ... 0.38% Benefin ... 0.77%	granular
	572-325	Trifluralin ... 0.38% Benefin ... 0.77%	granular
	10370-254	Trifluralin ... 0.31% Benefin ... 0.61%	granular

Batch	Registration Number	Percent Active Ingredient	Form
	34704-266	Trifluralin ... 0.38% Benefin ... 0.77%	granular
	62719-137	Trifluralin ... 0.67% Benefin ... 1.33%	granular
8	270-281	Trifluralin ... 1.75%	granular
	538-102	Trifluralin ... 2.65%	granular
	557-2001	Trifluralin ... 1.15%	granular
	572-200	Trifluralin ... 1.15%	granular
	961-280	Trifluralin ... 1.47%	granular
	961-335	Trifluralin ... 1.75%	granular
	961-405	Trifluralin ... 5.00%	granular
	2217-480	Trifluralin ... 1.47%	granular
	7401-349	Trifluralin ... 1.47%	granular
	8378-41	Trifluralin ... 1.47%	granular
	9198-60	Trifluralin ... 1.47%	granular
	9198-129	Trifluralin ... 5.00%	granular
	49585-25	Trifluralin ... 1.75%	granular
	62719-98	Trifluralin ... 5.00%	granular
9	9198-98	Trifluralin ... 0.38% Benefin ... 0.77% Chloropyrifos ... 0.57%	granular
	9198-99	Trifluralin ... 0.19% Benefin ... 0.38% Chloropyrifos ... 0.57%	granular

Batch	Registration Number	Percent Active Ingredient	Form
	9198-102	Trifluralin ... 0.28% Benefin ... 0.59% Chloropyrifos ... 0.58%	granular
10	8660-144	Trifluralin ... 14.00% Benefin ... 14.00%	powder
	8660-145	Trifluralin ... 10.89% Benefin ... 21.78%	powder
	9198-77	Trifluralin ... 10.89% Benefin ... 21.78%	powder
11	9779-308	Trifluralin ... 60.00%	granular
	46193-13	Trifluralin ... 60.00%	granular
12	59823-1	Trifluralin ... 18.9%	powder
	59823-3	Trilfuralin ... 18.9%	powder

Table 2 lists the products the Agency was unable to batch. These products were not batched because they were not considered to be similar to other products in terms of acute toxicity, or, the Agency lacked sufficient information about their chemical formulations. Registrants of this product are responsible for meeting the acute toxicity data requirements for this product.

Table 2.

Registration Number	Percent Active Ingredient	Form
228-259	Trifluralin ... 3.33% Benefin ... 6.67%	dust
241-307	Trifluralin 28.6% Ammonium salt of imazaquin ...4.72%	liquid

Registration Number	Percent Active Ingredient	Form
241-325	Trifluralin ... 27.5% Ammonium salt of imazethapyr ... 2.2%	liquid
524-375	Trifluralin ... 3.0% S (2,3,3-trichloroallyl) diisopropyl thiocarbamate ... 10.0%	granular
524-422	Trifluralin ... 3.9% Alachlor ... 31.7%	liquid
1812-325	Trifluralin ... 43.8%	liquid
2935-446	Trifluralin ... 0.17% Disulfoton ... 1.00%	granular
3125-375	Trifluralin ... 28% Metribuzin ... 14%	liquid
5905-521	Trifluralin ... 60.0%	liquid
9198-78	Trifluralin ... 14.0% Benefin ... 14.0%	liquid
62719-128	Trifluralin ... 4% Tebuthiuron ... 2%	granular
62719-175	Trifluralin ... 2.0% Isoxaben ... 0.5%	granular
62719-222	Trifluralin ... 36.35% Flumetsulam ... 2.67%	liquid

Table 3 displays a group of products that were not batchable, but were not placed into the "No Batch" group of products. Each of these products contains significant amounts of fertilizer. Many of these fertilizer components may change from time-to-time as the registrant sees fit. as much as 99% of these products' formulations may vary, PRS does not feel that it is possible to batch them. PRS is also concerned that since the formulation of these products may vary, a set of acute toxicity studies conducted on one of these products may not be consistently representative of that product's acute toxicity potential. Registrant of products is batch #3 that certify that they do not vary the inert composition of their product(s) may

request that their products be batched with other, similar, products. PRS does not believe that requesting acute toxicity data on all possible fertilizer combinations is sensible. The Agency has yet to develop a policy to address the labeling for these products.

Table 3.

Registration Number	Percent Active Ingredient	Form
228-208	Trifluralin ... 0.38% Benefin ... 0.77%	granular
228-254	Trifluralin ... 0.29% Benefin ... 0.59%	granular
228-255	Trifluralin ... 0.37% Benefin ... 0.74%	dust
228-256	Trifluralin ... 0.44% Benefin ... 0.89%	dust
228-257	Trifluralin ... 0.22% Benefin ... 0.45%	dust
228-258	Trifluralin ... 0.75% Benefin ... 0.75%	dust
538-83	Trifluralin ... 0.68%	granular
557-2013	Trifluralin ... 0.38% Benefin ... 0.77%	granular
961-283	Trifluralin ... 0.74%	granular
961-346	Trifluralin ... 0.385% Benefin ... 0.770%	granular
961-348	Trifluralin ... 0.515% Benefin ... 1.030%	granular
6133-13	Trifluralin ... 0.385% Benefin ... 0.765%	granular
8378-17	Trifluralin ... 0.38% Benefin ... 0.76%	granular
8378-18	Trifluralin ... 0.43% Benefin ... 0.84%	granular

Registration Number	Percent Active Ingredient	Form
8378-19	Trifluralin ... 0.50% Benefin ... 1.00%	granular
8378-20	Trifluralin ... 0.30% Benefin ... 0.62%	granular
8378-37	Trifluralin ... 0.49% Benefin ... 0.93%	granular
8590-667	Trifluralin ... 0.33% Benefin ... 0.67%	granular
8660-19	Trifluralin ... 0.43% Benefin ... 0.85%	granular
8660-143	Trifluralin ... 0.45% Benefin ... 0.90%	granular
8660-149	Trifluralin ... 0.45% Benefin ... 0.90%	granular
8660-151	Trifluralin ... 0.38% Benefin ... 0.76%	granular
9198-79	Trifluralin ... 0.38% Benefin ... 0.76%	granular
9198-91	Trifluralin ... 0.19% Benefin ... 0.38%	granular
9198-94	Trifluralin ... 0.30% Benefin ... 0.62%	granular
9198-101	Trifluralin ... 0.28% Benefin ... 0.59%	granular
9198-108	Trifluralin ... 0.33% Benefin ... 0.67%	granular
9198-130	Trifluralin ... 0.50% Benefin ... 1.00%	granular
9198-131	Trifluralin ... 0.515% Benefin ... 1.030%	granular

Registration Number	Percent Active Ingredient	Form
10404-53	Trifluralin ... 0.33% Benefin ... 0.67%	granular
10404-56	Trifluralin ... 0.38% Benefin ... 0.77%	granular
10404-57	Trifluralin ... 0.41% Benefin ... 0.84%	granular
32802-24	Trifluralin ... 0.38% Benefin ... 0.77%	granular
32802-33	Trifluralin ... 0.50% Benefin ... 1.00%	granular
32802-35	Trifluralin ... 0.29% Benefin ... 0.58%	granular
32802-40	Trifluralin ... 0.20% Benefin ... 0.38%	granular
43854-1	Trifluralin ... 0.38% Benefin ... 0.77%	granular
44561-7	Trifluralin ... 0.306% Benefin ... 0.613%	granular
44561-8	Trifluralin ... 0.383% Benefin ... 0.766%	granular
44561-9	Trifluralin ... 0.459% Benefin ... 0.919%	granular
52200-4	Trifluralin ... 0.29% Benefin ... 0.58%	granular
62719-150	Trifluralin ... 0.39% Benefin ... 0.76%	granular
62719-151	Trifluralin ... 0.31% Benefin ... 0.61%	granular
62719-152	Trifluralin ... 0.43% Benefin ... 0.82%	granular

The following is a list of available documents related to trifluralin. 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 trifluralin 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. trifluralin 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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

EPA

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

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

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

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

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

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

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

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

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

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)