United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA 738-R-95-006 April 1995

Reregistration Eligibility Decision (RED)

Metolachlor

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 metolachlor which includes the active ingredient metolachlor. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from receipt of this letter. The second set of required responses are due 8 months from 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 Veronica Dutch at (703) 308-8585. Address any questions on required generic data to the Special Review and Reregistration Division representative, Jane Mitchell at (703) 308-8061.

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 receipt 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

METOLACHLOR

LIST A

CASE 0001

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

TABLE OF CONTENTS

METOLACHLOR REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Division

Art Grube	Economic Analysis Branch
Neil Anderson	Biological Analysis Branch

Environmental Fate and Effects Division

Kathy Monk	Science Analysis and Coordination Staff
Concepcion Rodriguez	Ecological Effects Branch
George Tompkins	Environmental Fate and Groundwater Branch
Estella Waldman	Environmental Fate and Groundwater Branch

Health Effects Division

Linda Kutney	Risk Characterization and Analysis Branch
Susan Hummel	Chemistry Branch, Reregistration Support
Pat McLaughlin	Toxicology Branch II
Jeff Evans	Occupational and Residential Exposure Branch

Registration Division

Eugene Wilson	Fungicide-Herbicide Branch

Special Review and Reregistration Division

Jane Mitchell	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for refernce dose (RfD).
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
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
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed 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

GLOSSARY OF TERMS AND ABBREVIATIONS

PPE	Personal Protective Equipment
ppb	Parts Per Billion
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
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

Background

This Reregistration Eligibility Decision document (RED) addresses the reregistration eligibility of the pesticide metolachlor, 2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide.

Metolachlor, a broad spectrum herbicide, was first registered in 1976 for general weed control in noncrop areas. Metolachlor is manufactured by Ciba-Geigy Corporation, the sole producer and primary registrant. Since first registered for use on turf, it is now also registered for use on corn, cotton, peanuts, pod crops, potatoes, safflowers, sorghum, soybeans, stone fruits, tree nuts, nonbearing citrus, nonbearing grapes, cabbage, peppers (bell, chili, Cubanelle, tabasco), buffalograss, guymon bermudagrass for seed production, nurseries, hedgerows/fencerows and landscape plantings. Metolachlor's major use sites are corn, soybeans, and sorghum. The emulsifiable concentrate formulation is the most commonly used formulation on all sites. Ground application is the method of choice for all sites. Some formulations may be applied by chemigation with special use directions.

The first registration standard for metolachlor was issued in 1980 and a second standard was issued in 1987. The Agency has now completed its review of the metolachlor target data base including data submitted in response to the 1987 standard.

Reregistration Eligibility

The Agency has determined that all uses of metolachlor with the exception of potatoes, soybeans and peanuts as currently registered will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. An eligibility decision for use on potatoes, soybeans, and peanuts cannot be made at this time because under current policies section 409 tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA) are needed because metolachlor concentrates in some of the processed fractions of these crops and such tolerances may be barred by the Delaney Clause. The Agency has recently required additional data to confirm this decision. (Data Call-In Notices dated 12/10/93, 2/15/94 and 5/10/94). Also, additional confirmatory data (foliar soil dissipation and dermal passive dosimetry) are required for residential lawn and turf uses.

Health Effects

The Agency's Office of Pesticide Program's Carcinogenicity Peer Review Committee has classified metolachlor in Group C (possible human carcinogen) under EPA's Cancer Assessment Guidelines with no cancer risk quantification. The Committee recommended that chronic exposure to metolachlor be addressed by margin of exposure estimates. A RfD of 0.1 mg/kg body weight/day has been established based on a NOEL of 9.7 mg/kg/day and an

uncertainty factor of 100. The NOEL was based on a one year feeding study in dogs that demonstrated a decreased body weight gain.

A tolerance reassessment was performed and is included in this document. Data for cottonseed, peanuts (EC formulation at layby), fresh corn and safflower processing are required for the continued registration of metolachlor. Food additive tolerances are needed for potato granules and feed additive tolerances are needed for potato dry peel, wet peel, and waste from processing, soybean hulls and peanut meal. However, such tolerances may be barred by the Delaney Clause of FFDCA which provides that a food/feed additive regulation for a processed food may not be established for a pesticide which induces cancer in man or animals. The Agency is unable to make a reregistration decision for these uses because EPA is currently evaluating legal challenges related to the coordination of actions under FFDCA section 409's Delaney Clause and FFDCA section 408 in FIFRA.

Occupational and Residential Exposure

No toxicological endpoints of concern for acute or short term exposure to metolachlor through occupational or residential exposure have been identified.

Toxicological endpoints are of concern for workers exposed ten days or longer (intermediate exposure). A 21-day rabbit dermal toxicity study demonstrated systemic NOELS of 100 mg/kg/day for both sexes, based on increased bilirubin, increased liver weights in males and increased kidney weights in females. Using the NOEL of 100 mg/kg/day, the corresponding margin of exposure (MOE) for intermediate duration of occupational exposure was calculated. The MOEs range from 30 to 3890. The lower MOE's represent exposure scenarios for aerial mixer/loaders using open pour systems. The Agency is requiring that aerial mixer/loaders use closed systems. This requirement provides MOE's of approximately 300 or greater.

Postapplication worker exposure and risk to residues from preemergent applications to agricultural crops is likely to be minimal. Postapplication worker exposure and risk from postemergent applications to agricultural crops is also likely to be minimal since the target crops or weeds are small at the time of application, and harvesting or other maintenance activities are likely to be limited. However, there is a greater potential for postapplication exposure and risk following turf treatment. A foliar residue dissipation study and dermal passive dosimetry study are required as confirmatory data to better refine the risk for residential turf.

A foliar dissipation study submitted on weeds and ornamental turf grass gave exposure estimates that do not pose an unreasonable risk to individuals reentering treated areas. These estimates assume a 24-hour restricted entry interval (REI).

The Worker Protection Standard (WPS) for Agricultural Pesticides--40 CFR Parts 156 and 170--established an interim restricted-entry interval (REI) of 12 hours for metolachlor,

because the acute toxicity categories of metolachlor for acute dermal toxicity, skin irritation potential, and eye irritation potential are Toxicity Category III and IV. However, since metolachlor has been shown to have intermediate effects and is classified as a group C carcinogen, a REI of 24 hours for all sites within the scope of the WPS is required.

Environmental Fate and Ecological Effects

Metolachlor appears to be moderately persistent to persistent and mobile to highly mobile. Metolachlor is stable to hydrolysis under normal environmental conditions. Metolachlor degradation appears to be dependent on microbially mediated and abiotic processes. It appears to have a low potential to bioaccumulate in fish. Additional information on terrestrial field dissipation is required to fully satisfy the guideline requirement; however this additional information is not expected to change the overall fate assessment for metolachlor. The additional information for terrestrial field dissipation will help determine the efficiency and precision of extraction and analysis for metolachlor and several of its metabolites. Five major degradates have been identified for metolachlor.

Metolachlor residues exceed the following levels of concern for ground water: (l) Ground-water quality - Metolachlor has been detected in ground water in 20 states, although generally below thresholds of concern for humans and animals. Considering the widespread use of metolachlor, the Agency is concerned about the degradation of water quality in metolachlor use areas. (2) Human health - Metolachlor residues have been detected in three states above the lifetime Human Health Advisory (HAL) of 100 ppb. In five other states detections exceeded 10% of the HAL; (3) Nontarget plants - No data are currently available to assess the effect of metolachlor on aquatic or terrestrial plants. However, because metolachlor is a herbicide, potential risk to non-target plants is likely. In areas where irrigation water is contaminated with metolachlor, or where ground water discharges to surface water, metolachlor residues could present a threat to non-target plants.

Substantial amounts of metolachlor could be available for runoff to surface water for several months post-application. Metolachlor is among the top five pesticides in terms of frequency of detection and greatest concentrations in samples of both raw and finished surface water in the mid-western corn belt. It is detected in a high percentage of surface water samples collected from numerous locations within the corn belt for several months post-application. In streams and rivers of the corn belt, metolachlor concentrations typically increase rapidly from pre-application concentrations of below one ppb to post-application peak concentrations of typically several ppb.

Based upon the available results it appears highly unlikely that maximum or short term average metolachlor concentrations in surface water will exceed the 1-10 day HALs of 2000 ppb or that annual average metolachlor concentrations will exceed the lifetime HAL (potentially the MCL) of 100 ppb anywhere. Although not formally regulated by the Safe Drinking Water Act, water supply systems are required to sample and analyze for metolachlor. The Agency will review such data when they become available.

To address ground-water concerns, the registrant is conducting two small-scale prospective ground water studies for metolachlor and its metabolites. The registrant has also proposed additional labeling statements to mitigate point source contamination, i.e. mixing/loading sites and precautionary label language which will reduce potential for off-target movement due to spray drift, run-off or wind erosion. The registrant is presently monitoring for metolachlor as part of the 19-state atrazine monitoring program. The wells being monitored were selected by the states and are representative of vulnerable areas. The registrant will provide the Agency with the metolachlor analyses from this program in 1995.

No chronic effects are expected for freshwater and estuarine/marine fish. The roadside (rights-of-way) use pattern poses an acute risk for endangered freshwater fish in shallow water.

The levels of concern for acute effects to non-endangered birds are not exceeded for any application rate. At an application rate of 6 lbs. ai/A the level of concern for acute risk to endangered birds is exceeded for non-granular formulations. Based on a supplementary study for waterfowl, the level of concern for chronic effects is exceeded at the 6 lb. ai/A application rate. Because this study is supplementary, new avian reproduction studies have been required. These studies, which are due May 10, 1996, could result in changes in the avian risk assessment.

A risk assessment using maximum and typical estimated environmental concentrations (EECs) was done for acute effects to small mammals. The endangered species level of concern is exceeded, using the maximum EEC, for small mammals eating short grass at an application rate of 2 lbs. ai/A. The endangered species level of concern is exceeded, using typical EEC's, for small mammals eating short grass, at application rates of 4 lbs. ai/A and higher. The Agency is developing a program to identify all pesticides whose use may cause adverse effects on endangered plants/animals. Any label changes or use modifications will be implemented through the Endangered Species Program.

Because metolachlor is a herbicide, risk to non-target plants is expected. Toxicity data for non-target plants were required on 12/10/93 in a Data Call-In Notice. Once these data have been submitted, a risk assessment will be performed.

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

Before reregistering the products containing metolachlor, 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 registration. 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 subject to reregistration are determined to be eligible for reregistration.

I. INTRODUCTION

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

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of metolachlor. The document consists of six sections. Section I is the introduction. Section II describes metolachlor, 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 metolachlor. Section V discusses the reregistration requirements for metolachlor. 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(s) are covered by this Reregistration Eligibility Document:

- **Common Name:** Metolachlor
- **Chemical Name:** 2-chloro-N-(2-ethyl-6-methylphenyl)-N-2-methoxy-1-methylethyl) acetamide
- **Chemical Family:** Chloroacetanilide
- **CAS Registry Number:** 51218-45-2
- **OPP Chemical Code:** 108801
- **Empirical Formula:** $C_{15}H_{22}ClNO_2$
- **Trade and Other Names:** Dual
- **Basic Manufacturer:** Ciba-Geigy

B. Use Profile

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

Type of Pesticide: Herbicide

Mode of Action: Chloracetanilide inhibits seedling development.

Use Sites: Terrestrial Food Crops -cabbage, pepper (bell, chile, tabasco), radish, stone fruits

Terrestrial Food and Feed Crops -corn (field, pop, sweet), cotton,

legume vegetables, peanuts, peas, potato (white/Irish), safflower, sorghum, soybeans, tree nuts

Terrestrial Feed Crops -alfalfa

Terrestrial Non-Food Crops -agricultural rights-of-way/fencerows/hedgerows, airports/landing fields, Christmas tree plantations, commercial/industrial lawns, golf course turf, nonagricultural rights-of-way/fencerows/hedgerows, nonagricultural uncultivated areas/soils, ornamental and/or shade trees, ornamental lawns and turf, ornamental woody shrubs and vines, recreation area lawns, recreational areas, nonbearing fruits (apples, cherries, citrus fruits, crabapples, grapes, pears)

Terrestrial Non-Food and Outdoor Residential -ornamental and/or shade trees, ornamental herbaceous plants, ornamental nonflowering plants, ornamental woody shrubs and vines

Forestry -forest trees (softwoods, conifers)

Outdoor Residential -residential lawns

Pests:

Grass and Grasslike Weeds -barnyardgrass, browntop panicum, crabgrass, crowfootgrass, fall panicum, giant foxtail, goosegrass, green foxtail, red rice, signalgrass, southwestern cupgrass, witchgrass, yellow foxtail, foxtail millet, prairie cupgrass, yellow nutsedge

Broadleaf Weeds -Eastern black nightshade, carpetweed, Florida pusley, galinsoga, pigweed

Formulation Types Registered:

Single Active Ingredient Products

Granular--5 to 25%
Emulsifiable concentrate--84.4 to 86.4%
Technical/liquid--95%

Multiple Active Ingredient (AI) Products

Granular--4% + 1 other AI
Emulsifiable concentrate--22 to 70% + 1 other AI

Methods and Rates of Application:

Granular - Use from 1.95 to 4.05 pounds active ingredient per acre as a band, broadcast, soil incorporated, or no-till or minimum-till soil treatment. Apply with either a granule or pneumatic compressed air applicator postemergence, post transplant, layby, postplant, preemergence, preplant, ground crack, pre transplant, or when needed.

Emulsifiable Concentrate - Use from 1.2 to 5 pounds active ingredient per acre as a band, soil incorporated, broadcast, directed spray, or in-furrow soil treatment. Use also as a no-till or minimum-till soil treatment and through chemigation. Apply with ground, low volume ground, aircraft, center pivot irrigation, or sprinkler irrigation. Application timings include preplant, preemergence, early postemergence, postemergence, Fall, Spring, non-bearing, post-plant, layby, when needed, at-planting, non-bearing nurserystock, post-transplant, pre-transplant, and containerized.

Use Practices Limitations:

- Do not use in greenhouses or other enclosed structures.
- Do not use on muck or peat soils.
- Do not use on sweet potatoes or yams.
- Do not apply to trees or vines transplanted less than 30 days and only after depressions around the trees and vines have been filled in.
- Do not use on sand or loamy sand soils.
- Do not apply to trees or vines that will bear harvestable fruit within 12 months of application.
- Do not graze livestock in treated areas.
- Do not apply to Taloka Silt Loam.
- Do not use on English peas in Northeastern U.S.
- Do not use on sorghum grown under dry-mulch tillage.
- Do not feed or graze cover crops grown in treated orchards.
- Do not graze or feed peanut forage or fodder to livestock for 30 days following application.

C. Estimated Usage of Pesticide

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

The table below summarizes the pesticides use by site.

Estimated Metolachlor Usage
Based on data from 1987 to 1993

Use Site	Lbs. Used On Site (000's)	Percent Of Total Use On This Site	Percent Of Site Treated
Alfalfa	< 10	< 0.5	.
Almonds	< 10	< 0.5	.
Apples	< 10	< 0.5	.
Barley	< 10	< 0.5	.
Cole crops	20	< 0.5	.
Corn	41,000	69	25-30
Cotton	550	1	2-6
Cropland for pasture	< 10	< 0.5	.
Crp acres-long term	< 10	< 0.5	.
Cucurbits	< 10	< 0.5	.
Dry Beans	320	1	7-13
Dry Peas	< 10	< 0.5	0
Eggplant	< 10	< 0.5	.
Green Beans	170	< 0.5	80-100
Green Peas	37	< 0.5	5-9
Melons	< 10	< 0.5	.
Oats/Rye	< 10	< 0.5	.
Onions	< 10	< 0.5	.
Other hay	< 10	< 0.5	.
Pasture & Rangeland (Other)	< 10	< 0.5	.
Peanuts	1,300	2	25-35
Pecans	0	< 0.5	.
Peppers	< 10	< 0.5	.
Potatoes	690	1	20-35
Rice	< 30	< 0.5	.
Safflower	100	< 0.5	.
Setaside acres	< 20	< 0.5	.

Sorghum	3,000	5	15-19
Soybeans	11,000	19	5-10
Sugar beets	< 10	< 0.5	.
Summer fallow	< 10	< 0.5	.
Sunflowers	< 10	< 0.5	.
Sweet Corn	380	1	20-30
Tobacco	< 10	< 0.5	.
Tomatoes	< 10	< 0.5	.
	= = = = = = = = =	= = = = = = = = = = = =	
	58,651	100	

*These are agricultural sites for which usage was reported. Misreporting may have occurred and/or usage may have occurred on non-registered sites. Most numbers are rounded estimates and actual usage may differ. Based on USDA, proprietary and Resources for the Future (RFF) data from 1987 to 1993.

D. Data Requirements

Data requested in the 1987 Registration Standard for metolachlor included studies on product chemistry, residue chemistry, toxicology, and environmental fate. These data were required to support the uses listed in the Registration Standard. Also, two Data Call-In Notices were issued on 12/10/93 and 5/10/94 which required data to be submitted for ground water, phytoxicity, and ecotoxicity requirements. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Metolachlor, a broad spectrum herbicide, was first registered in 1976 for general weed control in noncrop areas. Metolachlor is manufactured by Ciba-Geigy Corporation, who is the sole producer and primary registrant. Since first registered for use on turf, it is now registered also for use on food/feed and non-food crops. Metolachlor's major use sites are corn, soybeans, and sorghum.

Metolachlor was the first Registration Standard document issued by the EPA in March 1980. In Janaury 1987, a second standard was issued. Additional Data Call-In Notices were issued in December 1993 and May 1994. The following data gaps were identified in these standards and subsequent Data Call-In Notices:

1980 and 1987 Standards

Toxicology

Mutagenicity
General metabolism
Effect on coagulation

Environmental Fate

Hydrolysis
Photodegradation
Metabolism
Mobility
Accumulation
Ground and Surface Water Monitoring

Product/Residue Chemistry

Product Chemistry
Plant Metabolism
Storage Stability
Crop Field Trials

1993 and 1994 Data Call-In Notices

Ecological Effects

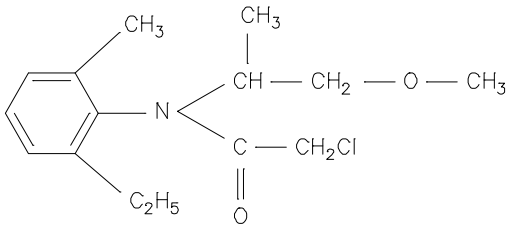
Avian Reproduction
Phytotoxicity
Fish and Marine Organisms Toxicity
Ground Water

III. SCIENCE ASSESSMENT

A. Product Chemistry

1. Identification of the Active Ingredient

Metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide] is a chloracetanilide herbicide. The molecular structure of metolachlor is:



Other identifying characteristics and codes are:

Empirical Formula:	$C_{15}H_{22}ClNO_2$
Molecular Weight:	283.8
CAS Registry No.:	51218-45-2
Shaughnessy No.:	108801
Basic Manufacturer:	Ciba-Geigy

Technical metolachlor is an odorless white to tan-colored liquid with a boiling point of 100 EC at 0.001 mm mercury. Its bulk density is 1.12 g/mL at 20 EC. Metolachlor's solubility in water at 20 EC is 530 mg/L. Metolachlor technical is miscible in xylene, toluene, ethylene dichloride, and cyclohexanone. It is classified as a Class IIIb combustible liquid.

2. Other Product Chemistry Considerations

There is one technical product for metolachlor, the 95% technical (T) (EPA Reg. No. 100-587). All pertinent product chemistry data requirements for the metolachlor 95% T (EPA Reg. No. 100-587) have been satisfied, with the exception of analytical methods to verify certified limits (Guideline Ref. No. 62-3).

B. Human Health Assessment

1. Toxicology Assessment

a. Acute Toxicity

Table 1 summarizes acute toxicity results and categories for metolachlor.

Table 1: Acute Toxicity Results and Categories for metolachlor

TEST	MRID	RESULTS	CATEGORY
Oral LD_{50} - Rat	00015523	2780 mg/kg	III
Dermal LD_{50} - Rabbit	00015526	> 10 g/kg	III
Inhalation LC_{50} - Rat	00015535	> 1.75 mg/L	III
W4444444444444444444		**W4444444**	**W44444U**
Eye Irritation - Rabbit	00015528	Non-irritating	IV
Dermal Irritation - Rabbit	00015530	Non-irritating	IV
Dermal Sensitization - Guinea Pig	00015631	Positive	

Metolachlor displayed a low level of toxicity in acute tests. Studies using technical metolachlor showed an oral LD_{50} of 2780 mg/kg in rats (Category III Toxicity) and a dermal LD_{50} in excess of 10 g/kg in rabbits (Category III Toxicity). The inhalation LC_{50} in rats was greater than 1.75 mg/L (Category III Toxicity). Neither eye nor dermal irritation was seen in rabbits (Category IV Toxicities, Document No. 000428). Metolachlor was positive in a study for dermal sensitization in guinea pigs (MRID 00015631).

b. Subchronic Toxicity

A three-month feeding study in beagle dogs displayed no effects at the doses of 500 and 1000 ppm; the NOEL for toxicity was equal to or greater than 1000 ppm (equivalent to 25 mg/kg/day) (guideline 82-1; MRID No. 00017690). Beagle dogs fed 0, 100, 300, or 1000 ppm for six months displayed a NOEL of 300 ppm (equivalent to 7.5 mg/kg/day) (MRID 00032174). The LOEL was 1000 ppm (equivalent to 25 mg/kg/day) based upon reduced body weight gains and food consumption in the high dose dogs (Document Number 010251).

A 21-day dermal toxicity study was performed on New Zealand white rabbits with 0, 10, 100, or 1000 mg/kg/day of metolachlor (guideline 82-2, MRID 418331-01). The systemic NOEL was 100 mg/kg/day for both sexes. The systemic LOELs was 1000 mg/kg/day based

upon increased bilirubin in both sexes, increased relative and absolute liver weights in males and increased kidney weights in females.

c. Chronic Toxicity

The requirement for a chronic feeding study in rodents is satisfied by the chronic carcinogenicity study in rats (see discussion below).

Metolachlor was fed to beagle dogs at dose levels of 0, 100, 300, or 1000 ppm for up to 52 weeks (guideline 83-1; MRID 409807-01). The systemic NOEL for male dogs was 1000 ppm (32.7 mg/kg/day). The systemic NOEL for female dogs was 300 ppm (9.7 mg/kg/day) and the LOEL was 1000 ppm (33 mg/kg/day) based on decreased body weight gain (Document Number 010088).

d. Carcinogenicity

Metolachlor has been evaluated for carcinogenic activity in both rats and mice. No treatment-related carcinogenic effects were observed in two acceptable chronic studies in mice. Both Charles River CD-1 mouse studies were two years in duration. One utilized dietary concentrations of 0, 30, 1000, or 3000 ppm and the other used 0, 300, 1000, or 3000 ppm (450 mg/kg/day) (Guideline 83-1, 83-2; 248722; MRID 000015634, 00042725, and 00084003, 00117597).

Metolachlor was fed to CD-Crl:CD (SD) BR albino rats from Charles River for 2 years at 0, 30, 300, or 3000 ppm (0, 1.5, 13.5 or 150 mg/kg/day) (MRID 00129377, Study 80030) as part of a combined chronic toxicity and carcinogenity study. The NOEL was 300 ppm (15 mg/kg/day) for systemic toxicity. The LOEL was 3000 ppm (150 mg/kg/day) based on decreased body weight gain and increased liver weights in high dose males. A significant increase in liver neoplastic nodules was observed in females at the highest dose level (equivalent to 150 mg/kg/day) (Guideline 83-1, -2; MRID 00129377). This study satisfies the requirement for a chronic toxicity study in rats (MRID 00129377) (Guideline 83-1a). Increases of neoplastic modules and hepatocellular carcinomas were found in high dose females (MRID 00244166).

The 1991 HED Peer Review Committee recommended that metolachlor be classified as a Group C (possible human) carcinogen, with a Q_1* of 9.2×10^{-3} $(mg/kg/day)^{-1}$). The classification of Group C was based on increases in liver tumors in the female rat, by both pair-wise and trend analysis and the replication of the finding of tumors in the female rat in a second study. However, the Peer Review conducted July 27, 1994, recommended an MOE approach since there was no supportable mutagenicity concern and in light of new information on the relative metabolism of metolachlor, quinone imine is presumed to be the ultimate carcinogen for 2,6-dimethylaniline. Because of steric hindrance (provided by the additional alkyl group about the nitrogen atom), the nitrogen atom is significantly less susceptible to amide dealkylation and extremely stable to metobolic hydrolysis of the amide so that formation

of the disubstituted aniline is presumably very low (if any).

e. Developmental Toxicity

Metolachlor was given to New Zealand white rabbits at 0, 36, 120, or 360 mg/kg/day by gavage on gestation days 6-18. Under the conditions of the study, it was not a developmental toxicant, with the NOEL for developmental toxicity equal to or greater than 360 mg/kg/day (highest dose tested) (guideline 83-3; MRID 00041283). The NOEL for maternal toxicity was 120 mg/kg/day. The maternal LOEL was 360 mg/kg/day, based on lacrimation, miosis, and reduced body weight gain.

In one developmental toxicity study in Sprague-Dawley rats, both the maternal and developmental toxicity NOELs were greater than 360 mg/kg/day (highest dose tested). The doses were 0, 60, 180, or 360 mg/kg/day, given by gavage on gestation days 6-15 (guideline 83-3; Ciba Geigy Report 227625). In a second study in CD rats, the gavage doses on gestation days 6-15 were 0, 30, 100, 300, or 1000 mg/kg/day. The maternal and developmental toxicity NOELs were 300 mg/kg/day (MRID 00151941). Both LOELs were 1000 mg/kg/day, and the LOEL for maternal toxicity was based on deaths, salivation, lacrimation, convulsions, reduced body weight gain and food consumption. The LOEL for developmental toxicity was based on reduced mean fetal body weight, reduced number of implantations per dam with resulting decreased litter size, and a slight increase in resorption s per dam with resulting increase in post-implantation loss (guideline 83-3, Document Number 009509).

f. Reproduction

A two-generation reproduction study in albino CD rats, with doses of 0, 30, 300 or 1000 ppm in the diet, revealed a reproductive NOEL of 300 ppm (23.5-26.0 mg/kg/day) (MRID 00080897). This NOEL was derived from reduced pup weights in the F_{1a} and F_{2a} litters at the highest dose tested, i.e., 1000 ppm (75.8-85.7 mg/kg/day). The NOEL for parental toxicity was 1000 ppm (Guideline 83-4; Document Number 010088).

g. Mutagenicity

Metolachlor was not found to be mutagenic in several tests. The tests for gene mutation were the Salmonella assay and an L5178/$TK^{+/-}$ mouse lymphoma test (Accession Number 262712 and 262713). The tests for structural chromosome aberration were an *in vivo* micronucleus assay in Chinese hamsters (Accession Numbers 26712 and 26713) and a dominant lethal assay in mice (MRID 00015630). Tests for other genotoxic activity included DNA damage/repair assays in rat hepatocytes and in human fibroblasts and an *in vivo/in vitro* unscheduled DNA synthesis assay (MRID 43244003).

However, metolachlor was positive in a test for induction of cell proliferation for hepatocytes from male rats at one dose level (MRID 43244004).

h. Metabolism

In a dermal penetration study, doses of 0.01, 0.1, and 1.0 mg/cm^2 of metolachlor applied to rat skin were found to be absorbed in relatively large amounts with significant bioaccumulation observed in the carcass. The absorption at 24 hours was up to 62.8% of the administered dose, with up to 30.1% of the dose remaining in the carcass (MRID 418331-02). Dermal absorption is assumed to be 62.8% in the human, based on this study.

Several metabolism studies have been performed with metolachlor and the available data indicate the compound is readily absorbed after oral dosing and excreted in approximately equal amounts in urine and feces over 3 days (MRID 401144-01; Accession Number 262713). A variety of metabolites were located in urine and feces and the proposed metabolic pathway involves cleavage of metolachlor's ether bond and subsequent oxidation to carboxylic acid, as well as hydrolytic removal of the chlorine atom. No conjugation was observed. (MRID Nos. 00015655, 00039193, 00015425).

i. Reference Dose (RfD) for Chronic Oral Exposure

The RfD for metolachlor was determined to be 0.10 mg/kg/day based upon the results of the one-year toxicity study in dogs. The NOEL was 300 ppm, or 9.7 mg/kg/day, based on decreased body weight gain at 1000 ppm (33 mg/kg/day). An uncertainty factor of 100 was used to derive the RfD for metolachlor.

There is no acceptable daily intake (ADI) set by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).

j. Toxiocology Data Gaps

There are no toxicological data gaps.

2. Exposure Assessment

a. Dietary Exposure

(1) Residue Information and Background

Tolerances for residues of metolachlor in or on food/feed commodities are currently expressed in terms of the combined residues (free and bound) of the herbicide metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound. Adequate enforcement methods are available for the determination of these residues.

The qualitative nature of the residue in plants is adequately understood. The Metolachlor Registration Standard dated March, 1980, concluded that the qualitative nature of the residue was adequately understood in corn and soybeans. Metabolism of metolachlor involves conjugation with glutathione, breakage of this bond to form the mercaptan, conjugation of the mercaptan with glucuronic acid, hydrolysis of the methyl ether, and conjugation of the resultant alcohol with a neutral sugar. A minor pathway may involve sugar conjugation of metolachlor directly to the corresponding oxo-compounds. Residues of concern in corn and soybeans are metolachlor and its metabolites, determined as the derivatives CGA-37913 and CGA-49751.

The Metolachlor Registration Standard dated March, 1980, concluded that the qualitative nature of the residue in animals was adequately understood. Metolachlor is rapidly metabolized and almost totally eliminated in the urine and feces of ruminants (goats), non-ruminants (rats), and poultry. Metolachlor per se was not detected in any of the excreta or tissues.

Adequate methods for purposes of data collection and enforcement of tolerances for metolachlor residues are available. Methods for determining the combined residues of metolachlor and its metabolites, as the derivatives CGA-37913 and CGA-49751, are described in PAM, Vol. II, as Method I (plants; GC-NPD) and Method II (animals; GC-MS).

Storage stability studies have been conducted using fortified samples of beef muscle, beef liver, milk, eggs, peanut nutmeats, potatoes, corn forage, corn grain, and corn oil. Residues of CGA-37913 are stable in frozen storage (# -10 EC) in beef muscle for up to 52 days, in corn oil for up to 102 days, and in or on the remaining animal and plant commodities for up to 1 year. Residues of CGA-49751 are stable in frozen storage (# -10 EC) in the animal commodities for up to 1 year, and in or on the plant commodities for up to 2 years. The registrant has reported the storage intervals for a sufficient number of the treated samples from existing studies used to support proposed and established tolerances. The outstanding plant and animal magnitude of residue studies must report the storage conditions and intervals for all samples; samples should be stored under the conditions and analyzed within the intervals of demonstrated residue stability.

Residue data are needed to support post-emergence uses of the new DF formulations.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.368(a) for: almonds, hulls; cabbage; corn, field, forage; corn, field, fodder; corn, field, grain; peppers, bell; potatoes; sorghum, fodder (milo); sorghum, forage (milo); sorghum, grain (milo); stone fruits group; peas and associated vine and hay commodities; beans and associated forage and hay commodities; soybeans; soybeans, forage; and soybeans, hay; tree nuts group, eggs; milk; the fat, kidney, liver, meat, and meat byproducts of cattle, goats, hogs, horses, sheep; and the fat, liver, meat, and meat byproducts of poultry. The dietary burden has been recalculated and the residues reported in the livestock feeding studies adjusted for losses in frozen storage.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.368(b) for: the straw, forage, and grain of barley, buckwheat, oats, rice, rye, and wheat.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR §180.368(c) for: peppers, chili; peppers, Cubanelle; and peppers, tabasco.

Food/feed additive tolerances are needed for the following processed commodities: "potatoes, dry peel" (4.0 ppm); "potatoes, wet peel" (0.5 ppm); "potatoes, granules" (0.5 ppm); and "potatoes, waste from processing" (4.0 ppm), soybean hulls (0.4 ppm) and "peanuts, meal" (level cannot be determined). However, Delaney issues may prevent the establishment of these tolerances.

Additional data are required to reassess other established tolerances (see tolerance reassessment section, for details).

The confined rotational crop data indicate that [^{14}C]Metolachlor residues accumulated in lettuce, beets, and wheat planted 115 days after ring-labeled [^{14}C]metolachlor (radiochemical purity 99.1%) was applied at approximately 3.0 lb ai/A to loamy sand soil subsequently planted to potatoes. At mature harvest, total [^{14}C]residues were 0.3 ppm in lettuce; 0.66 ppm and 0.86 ppm in beet tops and roots; and 2.86, 0.14, an 1.17 ppm in wheat stalks, grain, and hulls, respectively. In immature and mature crops, organosoluble residues ranged from 4.09 to 19.66% of the recovered radioactivity, water soluble residues ranged from 55.44 to 92.74%, and unextractable residues ranged from 1.82 to 28.52% Radioactive residues were inadequately characterized. Additional data are required.

Because metolachlor is assessed as a Group C carcinogen, it is subject to the Delaney clause of the FFDCA. See Section IV.B.1 "Tolerance Reassessment."

Feeding studies are available for ruminants and poultry. These studies indicate that finite residues will occur in milk, meat, poultry, and eggs. The tolerance reassessment summary for these commodities is included in the Risk Managament Decision Section of this Reregistration Eligibility Document.

(2) Anticipated Residue Data

In order to more accurately estimate dietary exposure to metolachlor, anticipated residues for commodities which are major contributors to the dietary risk were determined using available field trial data. Portions of the metolachlor residue database consist of Craven data. Ciba-Geigy is in the process of generating replacement data for the Craven data. For this anticipated residue assessment, Craven data were not used to generate average residues. Tolerances previously established using Craven data were used provided sufficient other data were available to support those tolerances on an interim basis.

	Anticipated residues were:	Tolerances:
Cabbage	0.055 ppm	1.0 ppm
Potatoes		
whole or pulp	0.09 ppm	0.2 ppm
granules	0.18 ppm	
flakes	0.18 ppm	
peel	0.14 ppm	
chips	0.09 ppm	
Peanuts	0.27 ppm	0.5 ppm
peanut oil	0.054 ppm	
Milk	0.0005 ppm	0.02 ppm
local		
milksheds	0.0021 ppm	
Meat	0.0018 ppm beef, goat, sheep, & pork MEAT	0.02 ppm
	0.0013 ppm beef, goat, sheep, & pork FAT	0.02 ppm
	0.0044 ppm beef, goat, sheep, & pork LIVER	0.05 ppm
	0.007 ppm beef, goat, sheep, & pork KIDNEY	0.2 ppm
Eggs	0.006 ppm	0.02 ppm
Poultry	0.006 ppm for poultry liver (giblets)	0.05 ppm
	0.0108 ppm poultry meat, meat by-products	0.02 ppm

poultry fat	0.006 ppm	
Field, corn grain	0.04 ppm	Not established
Corn Processed Products	0.04 ppm	Not established
Soybean		
seed	0.10 ppm	0.2 ppm for grain
meal	0.10 ppm	Not established, 0.4 ppm tolerance needed
hulls	0.14 ppm	Not established, 0.4 ppm tolerance needed
oil	0.03 ppm	Not established, 0.4 ppm tolerance needed

b. Occupational and Residential

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

(1) Use Summary

The emulsifiable concentrate formulation is the most commonly used formulation on all sites. Ground application is the method of choice for all sites. Aerial applications are allowed for some use sites.

Metolachlor is applied by chemigation, air or is broadcast. Rates of application vary from 0.75 lb ai/A to 4.0 lb ai/A. Maximum use rates on the major crops are: 4 lb ai/A (nursery turf), and 3 lb ai/A (corn, soybeans, peanuts, potatoes, pod crops, sorghum and safflower). Metolachlor is applied either immediately at or after planting (soybeans) or at a 14 to 45 day pre-plant or post-emergent interval (dry beans and grapefruit). In the case of Tabasco or chili peppers, directed post-emergent sprays can be made at mid-season.

At this time some products containing metolachlor are intended primarily for homeowner use and some are intended primarily for occupational use.

(2) Summary of Toxicity Concerns Impacting Occupational and Residential Exposure

Metolachlor technical is in Toxicity Category III for acute dermal, oral, and inhalation effects and is in Toxicity Category IV for dermal and eye irritation. These toxicity categories do not trigger any requirement for evaluation of or reduction in, worker exposure. Consequently, no worker exposure data were required by the Registration Standard (1980). However, since the Standard was issued additional toxicological endpoints for worker exposure have been identified. A 21-day dermal toxicity study was performed on New Zealand white rabbits with 0, 10, 100 or 1000 mg/kg/day of metolachlor. The systemic NOELS were 100 mg/kg/day for both sexes. The systemic LOEL was 1000 mg/kg/day based on increased bilirubin in both sexes, absolute and relative liver weights for males, and in relative kidney weights for females. In addition, metolachlor is classified as a Group C non-quantified carcinogen. Quantification of risk is based on a NOEL of 15 mg/kg/day derived from the chronic rat study.

(3) Summary of Potential Occupational and Residential Exposures

Handler (Mixers, Loaders, Applicators, etc.) Exposures: EPA has determined that there is an exposure potential for mixers, loaders, applicators, or other handlers during normal use associated with metolachlor. Exposures to loaders, applicators, and loader-applicators is likely when granular formulations are used. Exposures to mixer-loaders, applicators, flaggers, and mixer-loader-applicators is likely when liquid formulations are used.

Post-Application Exposures: EPA has determined that there is an exposure potential for persons entering treated sites after application is complete. For many uses of metolachlor, the potential for post-application exposure is diminished since the herbicide is incorporated into the soil following application. If metolachlor is appropriately incorporated, post-application exposures should be limited to those situations where the task being performed disturbs the soil sub-surface. There is more risk of exposure to metolachlor following post-emergent applications, especially applications to turf.

(4) Handler (Mixers, Loaders, Applicators, Etc.) Exposures & Assumptions

Mixer/loader/applicator (M/L/A) exposure data for metolachlor were not required during the Registration Standard or Phase IV of the reregistration process, since no toxicological criteria had been triggered at that time. However, handler exposure data for the emulsifiable concentrate (EC) are available. A mixer/loader (MRID #40279809) was submitted. Data from this study, combined with the Pesticide Handlers Exposure Database (PHED, ver 1.01) were used to estimate worker exposure. The daily exposure estimates for the mixer/loader (M/L), applicator (A), flagger (F), and combined job functions, mixer/loader/applicator

(M/L/A) are shown in the attached tables. Surrogate exposure data for the granular formulation are available using PHED. However, these data are deficient, since the surrogate exposure data for exposure to granular formulations are based on an insufficient number of data measurements (fewer than 15 replicates) that are of unacceptable quality. In addition, there is no information on exposure when coveralls and gloves are used.

Based on the use patterns and potential exposures described above, four major exposure scenarios were identified for metolachlor: (1) mixing/loading the liquid formulation to support ground application, (2) applying the liquid formulation with a ground equipment, (3) mixing/loading the liquid formulation to support aerial application, (4) applying the liquid with aerial equipment, (5) flagging for aerial applications, (6) loading the dry (granular) formulation, and (7) applying the dry formulation with ground equipment. The exposure scenarios are presented in the attached Tables along with the corresponding exposure/risk assessment. Footnotes to the tables list the actual clothing and equipment worn by persons being monitored in the exposure studies.

Daily exposure (mg ai/kg bw/day)

$$= \frac{\text{unit exposure(mg ai/lb ai) x use(lb ai/A) x Daily Acres Treated (A/day)}}{\text{body wt (kg)}}$$

The following assumptions are made for the EC and granular use patterns:

- mixing/loading by ground application is done 1 day/year (Typical Private Rate)
- ground application is done 1 day/year (Typical Private Rate)
- aerial application is done 1 day/year (Typical Private Rate)
- M/L/A exposure is 10 days/year via ground equipment (Typical Commercial Rate)
- Aerial exposure is 10 days/year for turf uses (conservative estimate)
- Applications to rights of way, pastures, rangeland, very large farms are expected to be a maximum of 10 d/yr (conservative estimate).

Mixer/loaders diluting large batches of metolachlor on a regular basis will be exposed to a greater extent than those who prepare the pesticide for one application per year. Furthermore, the label instructions specify a maximum use rate of 4.0 lb ai/A for use on sod farms.

These calculations of daily exposure to metolachlor by handlers are used to assess the risk to those handlers.

(5) Post Application Exposure to Workers

Post-application exposure data were not required during the Registration Standard or Phase IV of the reregistration process, since, at that time, no toxicological criteria had been triggered for metolachlor. A foliar dislodgeable residue study (MRID#410539-01) was submitted in support of a registration for the use of metolachlor to control weeds on ornamental turf grass.

A rough estimate of the exposure to postapplication workers was made using foliar dislodgeable residues from that study together with the Poppendorf transfer coefficient of 10,000 to estimate transfer of residues to the entire body surface. These calculations of daily exposure to metolachlor by post-application workers are used to assess the risk to those workers.

(6) Additional Occupational/Residential Exposure Studies

Two exposure studies are required as confirmatory data. A foliar residue dissipation (132-1a) and dermal passive dosimetry study (133-3) are required to better refine the risk for residential turf.

3. Risk Assessment

a. Dietary

There was no evidence, based on the available data, that metolachlor is associated with significant reproductive or developmental toxicity under the testing conditions. The data available for review to address or characterize the hazard of a one-time or one-day exposure, did not indicate that a one-day exposure to the chemical would be of such concern as to warrant the need for an acute dietary risk assessment.

The DRES chronic exposure analysis used a Reference Dose (RfD) of 0.10 mg/kilogram body weight/day, based on a No Observed Effect Level (NOEL) of 9.7 mg/kg bwt/day and an uncertainty factor of 100. The NOEL was from a one year feeding study in dogs which demonstrated decreased body weight gain as the effect of concern.

Metolachlor has been classified as a Group C (possible human) carcinogen by the HED Carcinogenicity Peer Review Committee. As discussed under the Toxicology Assessment (B)(1)(d) cancer risk assessments are based on a MOE approach. The MOE was calculated from a NOEL of 15 mg/kg/day derived from the chronic rat study. However, because the RfD is set on a NOEL of 9.7 mg/kg/day, dietary cancer concerns are adequately addressed by the DRES chronic exposure analysis using the RfD.

Anticipated Residue/Dietary Risk Estimates

A DRES analysis using anticipated residue (AR) estimations and percent crop treated data was performed to estimate dietary risk.

The ARC for the overall U.S. population from food uses of metolachlor being supported through reregistration is 0.000199 mg/kg bwt/day, which represents less than 0.2% of the RfD. If the pending use on celery is included, the ARC is raised to 0.000205 mg/kg bwt/day, still less than 0.2% of the RfD. The subgroup most highly exposed through the diet, non-nursing infants less than one year of age, has an ARC from recommended uses of 0.00641

mg/kg bwt/day, or less than 0.6% of the RfD. If the pending use is included, the exposure is raised to 0.000644 mg/kg bwt/day (less than 0.6% of the RfD). This low fraction of allowable RfD is considered to be an acceptable dietary exposure risk. Tolerance reassessments due to replacement of Craven data are not expected to significantly affect the RED.

b. Occupational and Residential

The toxicological endpoints of concern for occupational and residential exposure are Group C carcinogen classification and systemic toxicity resulting from exposure of one week to several months (intermediate exposure). A NOEL of 100 mg/kg/day was used to estimate MOEs, based on systemic toxicity from a 21-day dermal toxicity study in New Zealand white rabbits. Because the effects discussed above are from a dermal study, a dermal absorption of 100% is assumed.

Intermediate Length Exposure MOE =

$$\frac{\text{NOEL}}{\text{Dose}} = \frac{\text{100 mg/kg/day}}{\text{Maximum Daily Exposure}}$$

Risk to Handlers (Mixers, Loaders, Applicators, etc.)

Margins of exposure (MOEs) for occupational exposure were calculated for handlers using the NOEL (100 mg/kg/day) based on a risk concern for intermediate (one week to several months) exposure. The calculated MOE's for subchronic toxicity are given presented in the following Tables. The primary risk concern is for commercial handlers. Non-commercial handlers are likely to be exposed only once per year.

The calculations indicate that MOEs for subchronic systemic effects are unacceptable (less than 100) for mixer/loaders supporting aerial applications of metolachlor. The MOEs for mixers/loaders supporting ground applications of liquid metolachlor formulations and for applicators applying liquid metolachlor formulations using ground equipment are acceptable only when certain personal protective equipment (gloves and coveralls) are worn by those handlers.

The following risk mitigation measures for handlers, combined with generic worker protection labeling, should mitigate these risks:

- **mandatory use of a closed mixing and loading system by mixer/loaders who are supporting aerial applications of metolachlor when using liquid formulations.**

- **requirement of chemical-resistant gloves and coveralls worn over short-sleeve shirt and short pants for mixers/loaders supporting ground use applications of liquid metolachlor formulations and for applicators applying liquid metolachlor**

formulations using ground equipment.

Risk From Post Application Exposures

Based on the rough post-application exposure estimates, the risk posed by post-application exposure to metolachlor was estimated. Results of a turf dislodgeable residue study indicate significant residue levels at 0 days post-application (at 16 micrograms/cm^2). However, residues rapidly decline by one day post application (0.269 micrograms/cm^2). EPA has determined that post-application exposures do not appear to pose an unreasonable risk to individuals entering treated areas, provided entry is not permitted immediately following application. Therefore, for all uses within the scope of the worker protection standards (WPS), EPA is requiring a restricted-entry interval (REI) of 24 hours and personal protective equipment for workers who enter the treated area before the REI is expired.

The 24-hour post-application entry restriction for metolachlor does not apply to uses outside the scope of the Worker Protection Standard for Agricultural Chemicals, including out-of-scope commercial uses and homeowner uses. The predicted frequency, duration, and degree of exposure by such uses do not warrant the same risk mitigation measures required for users covered by the WPS who are engaged in agriculture for commercial or research purposes. For nonWPS occupational uses and homeowner uses, EPA is requiring:

- for liquid applications: a prohibition on entry until sprays have dried;
- for granular applications: a prohibition on entry until dusts have settled or, if the granules must be watered-in, a prohibition on entry until the treated area is dry, following the watering-in.

The calculated MOE's for subchronic toxicity are given in the following Tables 2 and 3.

TABLE 2: ESTIMATED MOE'S FOR MIXER/LOADERS, APPLICATORS, MIXER/LOADER/APPLICATORS, AND FLAGGERS FOR LIQUID FORMULATION OF METOLACHLOR

SITE	INDIVIDUAL EXPOSED	GROUND OPEN POUR	GROUND CLOSED SYSTEM	AERIAL OPEN POUR	AERIAL CLOSED SYSTEM
VEGETABLE Corn, Soybeans, Sorghum, Peanuts, Potatoes, Pod Crops, Safflower (Maximum Rate, 3.0 lb ai/A)	M/L:	170	1670	40	380
	A:	3890	3890	950	950
	M/L/A:	170	1170	--	--
	F:			260	260
TURF Nursery and Sod (Maximum Rate, 4.0 lb ai/A)	M/L :	130	1250	30	290
	A:	2920	2920	710	710
	M/L/A:	130	880	--	--
	F:			200	200

M/L, A, and M/L/A wears Gloves and Coveralls
Aerial Applicator (pilot) wears No Gloves and Short Sleeves
Flaggers wear No Gloves, No Coveralls, Long pants and Long Sleeves
M/L = Mixer/Loader; A = Applicator; M/L/A = Mixer/Loader/Applicator;
F = Flagger

TABLE 3: ESTIMATED MOE'S FOR MIXER/LOADERS, APPLICATORS AND MIXER/LOADER/APPLICATORS FOR THE GRANULAR FORMULATION OF METOLACHLOR

SITE	INDIVIDUAL EXPOSED	GROUND OPEN POUR
VEGETABLE **Corn, Soybean, Sorghum, Peanut, Potatoes, Pod Crops, Safflower** (Maximum Rate, 3.0 lb ai/A)	M/L: A: M/L/A:	4200 25000 3600
TURF **Nursery and Sod** (Maximum Rate, 4.0 lb ai/A)	M/L: A: M/L/A	3100 19000 2700

M/L, A, and M/L/A wears Gloves and Coveralls
M/L = Mixer/Loader
A = Applicator
M/L/A = Mixer/Loader/Applicator

C. Environmental Assessment

1. Environmental Fate

a. Environmental Chemistry, Fate and Transport

Metolachlor appears to be stable to hydrolysis at pH's of 5, 7, 9 without significant degradation of parent material after 30 days.

The aqueous photolysis half-life was 70 days when exposed to natural sunlight and 0.17 day when exposed to artificial sunlight (450 watt mercury arc lamp with light intensity of 4500-4800 uW/cm^2). After 30 days exposure to natural sunlight the degradation products were CGA-41638 (3.63% of applied radiocarbon), CGA-51202 (3.54%), CGA-46129 (3.42%), CGA-50720

(3.20%), and parent metolachlor remaining was 62.92%.

The soil photolysis half-life of metolachlor when exposed to natural sunlight was 8 days, and when exposed to artificial light conditions (mercury arc lamp with intensity of 1600-2400 uW/cm^2) the half-life was 37 days. The major degradates reported after 21 days exposure to natural sunlight were CGA-51202 (maximum of 3.4% of applied radiocarbon), CGA-37735 (9.0%), CGA-41638 (5.7%), CGA-40172 (6.2%), and CGA-37913 (maximum of 7.3% of applied radiocarbon).

Under aerobic soil conditions metolachlor degraded with a half-life of 67 days in a sandy loam soil. The major metabolite was CGA-51202 (maximum of 28.09% of applied radioactivity at 90 days posttreatment). Other identified metabolites were CGA-37735 (maximum of 14.85% at 272 days), CGA-41638 (maximum of 2.06% at 90 days), and CGA-13656 (maximum of 1.02% immediately posttreatment). Other metabolites that were detected but not quantified were CGA-40172, CGA-41507, CGA-40919, and CGA-37913.

The aerobic aquatic metabolism half-life of metolachlor was 47 days. The major metabolites in the sediment were CGA-41507 (3.34% of applied radiocarbon at 29 days), CGA-50720 (1.17%), CGA-40172 (1.13%), CGA-46127 (1.54%) and parent metolachlor was 34.56%. In the water fraction after 29 days incubation parent metolachlor was 30.90% and the metabolite CGA-41507 was 1.21% and CGA-51202 was 1.99%.

Under anaerobic soil conditions metolachlor degraded with a half-life of 81 days in a sandy loam soil that was incubated under anaerobic conditions for 60 days at 25^{0}C following 30 days of aerobic incubation. The major degradate in both the soil and flood water was CGA-51202 (maximum of 23.33% of applied radiocarbon at 29 days after anaerobic conditions were established); and other reported degradates were CGA-37735 (1.25% at 29 days), CGA-41638 (8.30% at 60 days), CGA-13656 (1.46% at 29 days), and CGA-50720 (maximum of 7.34% at 60 days).

The anaerobic aquatic metabolism half-life for metolachlor was 78 days. In the anaerobic waters the major degradates were CGA-40172 (maximum of 5.64% at 12 months), CGA-37913 (maximum of 4.28% at 6 months), CGA-46127 (maximum of 4.69% at 12 months) and CGA-41507 (maximum of 4.85% at 6 months). The major degradates in the sediment were CGA-41507 (maximum of 15.88% of applied radiocarbon at 12 months), CGA-40172 (maximum of 3.18% at 12 months), CGA-46127 (maximum of 13.02% at 12 months), CGA-50720 (maximum of 1.67% at 29 days), and CGA-37913 (maximum of 2.33% at 6 months), and after 12 months the sediment contained 1.47% parent metolachlor.

In the unaged portion of the leaching and adsorption and desorption study metolachlor was shown to range from being highly mobile in a sand soil (K_d value of 0.08) to being moderately mobile (K_d value of 4.81 in a sandy loam soil) from column leaching studies using four soils. The leachate contained from 15.03% to 82.91% (comprised of 75.5% parent metolachlor, 1.14% of CGA-51202, 3.69% of CGA-37735, and 2.26% CGA-41638) of the applied radioactivity. In batch equilibrium studies employing the same four soils, the Freundlich adsorption (K_{ad}) values ranged from 0.108 to 2.157. These data indicate that metolachlor has the potential to range from being a moderately mobile material (clay soil and sandy loam soil) to being a highly mobile material (loam soil and sand soil).

In the aged leaching portion of the leaching and adsorption and desorption study the reported cumulative K_d for aged metolachlor and its degradates in columns of an Iowa sandy loam soil was 2.01. This indicates that metolachlor and its identified degradates (CGA-51202, CGA-37735, and CGA-41638) have the potential to be mobile since in other studies it was shown that metolachlor and its CGA-51202 degradate leached the slowest in the Iowa sandy loam soil compared to their leaching rate in the other three soils tested. Batch equilibrium studies showed that CGA-51202 has the potential to be extremely mobile with reported Freundlich adsorption (K_{ad}) values ranging from 0.04 in the Maryland sand to 0.171 in the Iowa sandy loam soil.

Laboratory volatility studies indicated that volatility is not a significant mode of dissipation for metolachlor from the soil. The maximum dissipation was 0.05% of the metolachlor dose volatilizing per day.

In numerous terrestrial field dissipation studies using metolachlor (Dual 8E and Dual 25G) both applied at 4 and 6 lb ai/A the half-life of metolachlor in the 6-12 inch soil layer ranged from 7 days (Iowa) to 292 days (California) with a range of the total water applied ranging from 16.97 inches to > 40 inches during the study period. Detections of metolachlor were made as far as the 36-48 inch soil layer in some of the tests. The degradate CGA-40172 (0.07 ppm) and CGA-40919 (0.21 ppm) were detected in the 36-48 inch soil layers in one Iowa site. CGA-50720 was not detected (< 0.07 ppm) in any soil sampled at any interval.

Metolachlor appears to have a low potential to bioaccumulate in fish with a reported whole body bioconcentration factor of 69X and a whole body elimination of 93% after 14 days depuration.

Substantial amounts of metolachlor could be available for runoff to surface water for several months post-application. The low soil/water partitioning of metolachlor indicates that most of the metolachlor runoff from soil will be in

the form of dissolution in runoff water. A substantial amount of data on metolachlor in the surface water of the mid-western corn belt are available. Based upon these data along with a literature review submitted by Ciba-Geigy (Tierney and Newby 1993), the Agency has reached and/or concurs with the following conclusions with respect to metolachlor concentrations in surface waters.

Metolachlor is among the top five pesticides in terms of frequency of detection and greatest concentrations in samples of both raw and finished surface water in the mid-western corn belt. It is detected in a high percentage of surface water samples collected from numerous locations within the corn belt for several months post-application. Detection percentages in early spring, before application, and in late fall and winter, many months after application, are lower than the first few months post-application, but are still relatively high due presumably to its persistence.

Metolachlor concentrations typically increase rapidly from pre-application concentrations of below one ppb to post-application peak concentrations of typically several ppb. Peak concentrations sometimes exceed 10 ppb and occasionally exceed 20 ppb. Peak concentrations exceeding 50 ppb appear to be rare, but peak concentrations of metolachlor exceeding 50 ppb (up to 154 ppb) have been reported. In areas where tile drainage and/or groundwater inflow contribute substantially to the loading to surface waters, secondary peaks may occur substantially after peak flow. Peak concentrations of metolachlor are generally greater in surface waters draining small watersheds than in those draining large watersheds.

Most of the available metolachlor data are for streams and rivers. Goolsby et al (1993) reported detection percentages for metolachlor in 76 midwestern reservoirs that were comparable to those for streams and rivers. The small amount of metolachlor data for 10 lakes and reservoirs summarized by Tierney and Newby (1993) indicate that elevated metolachlor concentrations sometimes occur later and/or remain longer in some lakes and reservoirs than in streams or rivers. However, the maximum metolachlor concentration reported for the 10 lakes and reservoirs listed in the Tierney and Newby review was only 6.8 ppb.

The study by Smith et al (1987) was the only study available in which finished drinking water was sampled. However, metolachlor concentrations in raw and finished water should generally be comparable because the primary treatment processes employed by most surface water supply systems are not effective in removing pesticides with low soil/water partitioning such as metolachlor.

The Agency computed annual and multiple year Time Weighted Mean Concentrations (TWMCs) using the available data. All were less than 10 ppb,

and most were less than 5 ppb. The computed annual TWMCs are probably somewhat larger than the actual time integrated means, but are more accurate approximations of the time integrated means than arithmetic means. Maximum and seasonal-annual time weighted mean concentrations of metolachlor in surface water at the same sampling location often vary substantially, sometimes by greater than ten times, from year to year depending in part upon the intensity, duration, and timing of post-application runoff events.

Metolachlor is not yet formally regulated under the Safe Drinking Water Act (SDWA). Therefore, no enforcement MCL has been established for it. However, it has relatively high drinking water health advisories (1-10 day HAs of 2000 ppb and lifetime HA of 100 ppb). When pesticides become regulated, their lifetime HA usually becomes their MCL.

Based upon the available results it appears highly unlikely that maximum or short term average metolachlor concentrations will exceed the 1-10 day HAs of 2000 ppb or that annual average metolachlor concentrations will exceed the lifetime HA (potentially the MCL) of 100 ppb anywhere. Although metolachlor is not yet formally regulated by the SDWA, water supply systems are required to sample and analyze for it. The Agency will review such data when they become available.

b. Environmental Fate Assessment

Although the environmental fate data base is not complete, the information from all acceptable and upgradeable environmental fate data from the 1980 Registration Standard to present indicate that parent metolachlor appears to be moderately persistent to persistent. It also ranges from mobile to highly mobile in different soils and it has been detected in ground water. Metolachlor is stable to hydrolysis under normal environmental conditions of pH 5.0, 7.0, and 9.0. Metolachlor degradation appears to be dependent on microbially mediated (aerobic soil metabolism $t_{1/2} = 67$ days, anaerobic soil metabolism $t_{1/2} = 81$ days) and abiotic processes (photodegradation in water $t_{1/2} = 70$ days under natural sunlight and photodegradation on soil $t_{1/2} = 8$ days under natural sunlight). The major degradates were identified as CGA-51202, CGA-50720, CGA-41638, CGA-37735, and CGA-13656.

Depending on the soil characteristics metolachlor has the potential to range from a moderately mobile to a highly mobile material (K_d values ranging from 0.08 to 4.81). Upgradeable field dissipation studies indicate that metolachlor is persistent in the surface soil ($t_{1/2}$ ranging from 7 days to 292 days the upper 6 inch soil layer). Metolachlor was reportedly detected as far as the 36 to 48 inch soil layer in some of the studies. The degradate CGA-51202 was detected (0.11 ppm) as far as the 30-36 inch soil depth; CGA-40172 was detected as far as the

36-48 inch depth; CGA-40919 was detected in the 36-48 inch depth (0.21 ppm), and CGA-50720 was not detected (0.07 ppm) in any soil segment at any interval (MRID 41335701 and 41309802).

Metolachlor appears to have a low potential to bioaccumulate in fish with a reported whole body bioconcentration factor of 69 and a whole body elimination of 93% after 14 days depuration.

The "Pesticides in Ground Water Data Base 1992" indicates that residues of metolachlor have been detected in wells in 20 states. The lifetime Health Advisory for metolachlor has been established at 100 ppb. Levels exceeded the Health Advisory in a total of 3 wells located in Wisconsin, New York, and Montana. In five other states concentrations in well water exceeded 10% of the HAL. A recent 6(a)(2) report submitted by the registrant indicates metolachlor residues in one well that also exceeds the 100 ppb HAL. Because of these detections the Agency is concerned about the degradation of water quality that occurs in metolachlor use areas.

Metolachlor is among the top five pesticides in terms of frequency of detection and greatest concentrations in samples of both raw and finished surface water in the mid-western corn belt. It is detected in a high percentage of surface water samples collected from numerous locations within the corn belt for several months post-application. In streams and rivers of the corn belt, metolachlor concentrations typically increase rapidly from pre-application concentrations of below one ppb to post-application peak concentrations of typically several ppb.

Most of the available metolachlor data are for streams and rivers. However, available detection percentages for metolachlor in 76 midwestern reservoirs were comparable to those for streams and rivers. The data indicates that elevated metolachlor concentrations sometimes occur later and/or remain longer in some lakes and reservoirs than in streams or rivers.

Only one of the available studies involved finished drinking water. However, metolachlor concentrations in raw and finished water should generally be comparable because the primary treatment processes employed by most surface water supply systems are not effective in removing pesticides with low soil/water partitioning such as metolachlor.

Based upon the available results, it appears highly unlikely that maximum or short term average metolachlor concentrations will exceed the 1-10 day HAs of 2000 ppb or that annual average metolachlor concentrations will exceed the lifetime HA (potentially the MCL) of 100 ppb anywhere. Although metolachlor is not yet formally regulated by the Safe Drinking Water Act, water supply systems are required to sample and analyze for it. The Agency will review

such data when they become available.

2. Ecological Effects

a. Ecological Hazard

(1) Non-Target Birds

Avian Acute

In order to establish the toxicity of metolachlor to birds, the minimum data required on the technical material are: an avian single-dose LD50 test with either one species of waterfowl, preferably the mallard, or one species of upland game bird, preferably bobwhite; and two avian dietary LC50 tests, one with a species of waterfowl, preferably the mallard, and one with a species of upland game bird, preferably the bobwhite. The acceptable data are described below.

Based on acute toxicity data, metolachlor is practically non-toxic to birds. An avian acute oral study performed on the mallard duck resulted in an LD_{50} value of 4640 mg/kg (MRID 00015547).

On a subacute dietary basis, metolachlor is practically non-toxic to birds. Two studies one on the mallard duck and one on the bobwhite quail, produced LC_{50} values greater than 10,000 ppm (MRIDs 00016425, 00016426).

Avian Chronic

Avian reproduction studies are required because of repeat application to peanuts, corn, and potatoes and because this is a persistent chemical (half life ranging from 7 to 292 days). In order to establish the chronic toxicity of metolachlor to birds, the data required on the technical material are: two avian reproduction studies, one with a species of waterfowl, preferably the mallard; and one with a species of upland game bird, preferably the bobwhite quail. The available data are described below.

One supplemental avian reproduction study for the mallard duck shows that the LOEL is 1000 ppm. A risk assessment was performed using this supplemental study, but new avian reproduction studies are required to confirm the chronic risk assessment. (MRID 00162292) The new avian reproduction studies have been required in a Data Call-In Notice dated May 10, 1994.

(2) Non-Target Freshwater Fish

Acute

The minimum data required for establishing the acute toxicity of metolachlor to fish are two 96-hour studies with the technical product: one with cold water species, preferably rainbow trout; the other with a warm water species, preferably bluegill sunfish. The acceptable data are described below.

The test results show that technical metolachlor is moderately toxic to freshwater fish in acute exposures. The LC_{50}'s ranged from 3.9 to 10 ppm (MRID's 00018722, 00018723, 00015534).

Chronic

Chronic toxicity to fish is a concern because of repeat application to peanuts, corn, and potatoes and because this is a persistent chemical (half life ranging from 7 to 292 days). In order to establish the chronic toxicity of metolachlor to fish, the data required on the technical material is a fish early life stage study with one of the recommended species. The available study is described below.

The supplemental fish early life stage study gives an NOEC of 0.78 ppm and an LOEC of 1.6 ppm. The geometric mean is 1.17 ppm.

(3) Non-Target Freshwater Invertebrates

Acute

The minimum data required for establishing the acute toxicity of metolachlor to aquatic invertebrates is one 48-hour acute toxicity test with the technical product. The acceptable study is described below.

The test results show that metolachlor is slightly toxic to aquatic invertebrates in acute exposures. The EC_{50} is equal to 25.1 ppm (MRID 43044603).

Chronic

Chronic toxicity to invertebrates is a concern because of repeat application to peanuts, corn, and potatoes and because this is a persistent chemical (half life ranging from 7 to 292 days). In order to establish the chronic toxicity to aquatic invertebrates the data required is an aquatic invertebrate reproduction study with the water flea, Daphnia magna. No acceptable aquatic invertebrate reproduction study is available.

However, based on the available data, the risk to freshwater invertebrates is not expected to be substantially different than the risk to fish. The aquatic

invertebrate reproduction study is required to confirm this assessment. This study has been required in a Data Call-In Notice dated May 10, 1994.

(4) Non-Target Estuarine and Marine Organisms

Acute

Metolachlor is registered for uses which may expose estuarine organisms to the pesticide. Such uses include cotton, corn, peanuts, turf, sorghum, soybeans, and right-of-way. To establish the toxicity of metolachlor to non-target estuarine/marine organisms, three studies are required: acute estuarine/marine toxicity for the fish, mollusk and shrimp. The available data are described below.

Technical metolachlor is slightly toxic to estuarine fish in acute exposures. The LC_{50} is 7.9 ppm (MRID 43044303). No studies were available for the shrimp and oyster. However, based on the available aquatic data, the toxicity to these organisms is not expected to be substantially different than the toxicity to fish. The shrimp and oyster studies have been recently required in a Data Call-In Notice (December 10, 1993) to confirm the estuarine assessment for metolachlor.

Chronic

To establish the chronic toxicity of metolachlor to estuarine fish, a chronic toxicity study was submitted. The study provides an NOEC of 1.0 ppm and LOEC of 2.2 ppm, based on length which was the most sensitive parameter (MRID 43044602).

(5) Non-Target Plants

Non-target plant studies are required for any herbicide used on terrestrial food and terrestrial non-food sites if, (1) ground application is used and the water solubility is greater than 10 ppm (metolachlor solubility is 530 ppm) or the vapor pressure is greater than 1.0×10^5 mmg Hg at 25 ^oC (metolachlor vapor pressure is 1.3×10^5 mmg Hg at 25 ^oC); or (2) the typical end product (TEP) is not thoroughly incorporated immediately after application (aerial application and chemigation). To establish the toxicity of metolachlor to non-target plants, the following studies are required: seed germination/seedling emergence; a vegetative vigor; and an aquatic plant growth study.

Since metolachlor is a herbicide, potential risk to non-target plants is likely. Non-target plant studies were recently required in a Data Call-In Notice (December 10, 1993). These studies are being required to confirm the risk to

non-target plants.

b. Ecological Effects Risk Assessment

The potential for ecological effects is presented in the following risk assessments, each covering a different combination of endpoint and exposure scenarios. Each risk assessment includes a risk quotient which combines the toxicity and exposure information. For each risk quotient there is an established value above which the risk is considered to be at a high level of concern (LOC). In addition to these high risk values, restricted use is considered when the risk quotient exceeds 0.1 for acute aquatic risk or 0.2 for acute avian risk. The generic risk quotients and their respective LOC's for each risk assessment are provided in the following table. Note that the same risk quotients are used for non-endangered and endangered species, but the acute LOC is lower for endangered species.

Established Levels of Concern (LOC's)

Endpoint/Scenario	Risk Quotient	Non-Endangered LOC	Endangered LOC
Mammalian acute	EEC/LC_{50}	0.5	0.1
Mammalian chronic	EEC/LEL	1.0	1.0
Avian acute	EEC/LC_{50}	0.5	0.1
Avian chronic	EEC/LEL	1.0	1.0
Aquatic acute	EEC/LC_{50}	0.5	0.05
Aquatic chronic	EEC/LEL	1.0	1.0
Non-target insects and plants	NOT QUANTIFIED	N/A	N/A

(1) Non-Endangered Species

Terrestrial Organisms (Avian)

Metolachlor is registered for numerous outdoor uses. Exposure to non-target organisms can result from direct applications, spray drift from treated areas, and runoff from treated areas. Such exposures can be both chronic as well as acute.

Acute Effects

Granular Products. The levels of concern for acute effects to avian species are not exceeded for any application rate (Table 1). The maximum application rate as a granular formulation is 4 lb ai/acre. For broadcast application with no incorporation the LD50/ft^2 = 0.007. The same LD50/ft^2 is assumed for banding.

Table 1. Comparison of LD50/ft^2 to the LOC for the highest granular application rate of metolachlor. (LD50 = 4640)

Maximum Application Rate	Method of Application	LD50/ft^2	LOC
4 lbs ai/acre	Broadcast (no incorporation)	0.007	High Risk $ 0.5 RU $ 0.2 ES $ 0.1

RU = Restricted Use ES = Endangered Species

Non-Granular Products. The levels of concern for acute effects to non-endangered avian species are not exceeded at any application rate (Table 2). The LOC for endangered birds is exceeded at an application rate of 6 lbs. ai/acre.

Table 2. Risk Quotient and LOC for the lowest and highest application rate of metolachlor. (LC50 > 10,000 ppm)

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/LC50)	LOC
Cabbage, Pepper Chili,Cotton, Seed Radish	2 lbs ai/acre	Short Grass (480)	0.048	High Risk $ 0.5 RU $ 0.2 ES $ 0.1
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai/acre	Short Grass (1440)	0.144	High Risk $ 0.5 RU $ 0.2 **ES $ 0.1**

RU = Restricted Use ES = Endangered Species

Chronic Effects

Preliminary chronic effects have been assessed based on a supplemental study for waterfowl. Preliminary evaluation of the study shows that the LOEL is 1000 ppm. Based on that LOEL, the risk quotients do not exceed the LOCs at the 2 lb. application rate (Table 3). The LOC is eceeded for the 6 lbs. application rate for short grass. Since this risk assessment was based on a supplementary study, the Agency has recently required two new avian reproduction studies in a Data Call-In Notice (May 10, 1994) to confirm the chronic risk assessment for birds.

Table 3. Chronic Risk Quotient and LOC for the lowest and highest application rate of metolachlor, based on a LOEL of 1000 ppm.

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/LOEL)	LOC
Cabbage, Pepper Chili, Cotton, Seed Radish	2 lb ai/acre	Short Grass(480)	0.48	**High Risk $ 1**
		Seeds (24)	0.024	
Corn, Peanuts	6 lbs ai/acre	Short Grass (1440)	1.4	
		Seeds (72)	0.072	

Terrestrial Organisms (Small Mammals)

The endangered species level of concern is exceeded, using the maximum EEC, for small mammals eating short grass at an application rate of 2 lbs./acre. The endangered species level of concern and restricted use level of concern are exceeded, using typical and maximum EEC's, for small mammals eating short grass, at application rates of 4 lbs./acre and higher. The risk quotients range from 0.1 to 0.3. (See table below) Small endangered grass eating mammals that can be associated with agriculture (based on habitat and food) are the following: in Utah the Utah prairie dog and in California the Giant Kangaroo rat, the Fresno Kangaroo rat, and the Stephen's Kangaroo rat.

An acute rat study indicated that the LD50 for the rat is 2780 mg ai/kg. The LC50 is estimated from the LD50, body weight of the organism in question, and food consumption. A representative of an herbivore (meadow vole LC50 = 4567 ppm), a granivore (deer mouse LC50 = 17,209 ppm) and an insectivore (least shrew LC50 = 2528) are used to estimate the risk to small mammals.

Table 4. Expected food items, typical and maximum estimated environmental concentrations and Acute LOC's for three small mammals representing different food preferences. T = Typical EEC, M = Maximum EEC

Use Sites	Application rate	Species (LC50)	Expected Food (EEC ppm)	Risk Quotient (EEC/LC50)	LOC
Cabbage, Pepper, Chili, Seed Radish	2 lbs ai/acre	Meadow Vole (4567 ppm)	Grasses T = 250 M = 480	T = 0.05 **M = 0.11**	HR $0.5 RU $0.2 **ES $0.1**
		Least Shrew (2528 ppm)	Insects T = 66 M = 116	T = 0.02 M = 0.04	
		Deer Mouse (17,209 ppm)	Seeds T = 6 M = 24	T = 0.0003 M = 0.001	
Soybeans, Corn, Citrus, Stone Fruits, Grapes	4 lbs ai/acre	Meadow Vole (4567 ppm)	Grasses T = 500 M = 960	**T = 0.1** **M = 0.21**	HR $0.5 **RU $0.2** **ES $0.1**
		Least Shrew (2528 ppm)	Insects T = 132 M = 232	T = 0.05 M = 0.09	
		Deer Mouse (17,209 ppm)	Seeds T = 12 M = 24	T = 0.0006 M = 0.0001	
Corn, Peanuts	6 lbs ai/acre	Meadow Vole (4567 ppm)	Grasses T = 750 M = 1440	**T = 0.16** **M = 0.32**	HR $0.5 **RU $0.2** **ES $0.1**
		Least Shrew (2528 ppm)	Insects T = 198 M = 348	T = 0.04 M = 0.07	
		Deer Mouse (17,209 ppm)	Seeds T = 18 M = 72	T = 0.001 M = 0.003	

Aquatic Organisms

Acute Effects

No acute effects to aquatic organisms (including freshwater invertebrates and fish and estuarine fish) are expected as a result of the use of metolachlor when a 6 or 1 foot deep water body scenario is employed. However, for the roadside use, a shallower scenario is considered to be more appropriate. The Agency considers the roadside and rights-of-way use to be the same. Using the LC_{50} of the most sensitive aquatic species, the freshwater fish, application of 1.25 lb ai/acre triggers the endangered species LOC for a water body of one foot deep or less (Table 5).

Table 5. Acute Risk Quotient and LOC for the lowest and highest application rate of metolachlor. (LC50 = 3.9 ppm)

Use Site	Application Rate	Depth (EEC ppm)	Risk Quotient (EEC/LC50)	LOC
Cabbage, Pepper Chili,Cotton, Seed Radish	2 lbs ai/acre	6 ft (0.061)	0.01	High Risk $ 0.5 RU $ 0.1 ES $ 0.05
Roadside	1.25 lbs ai/acre	6 ft (0.038)	0.009	High Risk $ 0.5 **RU $ 0.1** **ES $ 0.05**
		1 ft (0.229)	0.05	
		6 inches (0.458)	0.12	
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai/acre	6 ft (0.186)	0.04	High Risk $ 0.5 RU $ 0.1 ES $ 0.05

RU = Restricted Use ES = Endangered Species

No data are available on acute effects for estuarine/marine invertebrates; however, based on the available aquatic data, the risk to these organisms is not expected to be substantially different than the risk to the estuarine fish. The estuarine invertebrate data are being required to confirm the assessment for these organisms.

Chronic Effects

No chronic effects to freshwater or estuarine/marine fish are expected from the use of metolachlor (Table 6).

Table 6. Chronic Risk Quotient and LOC for the lowest and highest application rate of metolachlor. (Geometric Mean (GM)of NOEL and LOEL = 1.17 ppm)

Use Site	Application Rate	Depth (EEC ppm)	Risk Quotient (EEC/GM)	LOC
Cabbage, Pepper Chili,Cotton, Seed Radish	2 lbs ai/acre	6 ft (0.061)	0.05	High Risk $ 1
Roadside	1.25 lbs ai/acre	6 ft (0.38)	0.32	**High Risk $ 1**
		1 ft (0.229)	0.19	
		6 inches (0.458)	0.39	
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai/acre	6 ft (0.186)	0.15	High Risk $ 1

RU = Restricted Use ES = Endangered Species

No data are available on chronic effects for freshwater invertebrates. However, based on the available aquatic data, the risk to these organisms is not expected to be substantially different than the risk to freshwater fish. The invertebrate data have recently been required in a Data Call-In Notice (May 10, 1994) to confirm this assessment.

Non-Target Plants

There is no quantitative information available to conduct a risk assessment on non-target terrestrial plants. However, because metolachlor is a herbicide, risk to terrestrial non-target plants is expected. Non-target plant data are being required to confirm the risk to non-target plants.

(2) Endangered species

The level of concern for acute effects to avian species eating short grass is exceeded at an application rate of 6 lbs./acre for non-granular formulations using maximum EEC's (risk quotient = 0.1). Based on a supplemental study, the level of concern for chronic effects to avian species is exceeded at an application rate of 6 lbs./acre (risk quotient = 1.4). The level of concern is exceeded, using the maximum EEC, for small mammals eating short grass at an application rate of 2 lbs./acre (risk quotient = 0.1). The level of concern is exceeded, using typical and maximum EEC's, for small mammals eating short grass, at application rates of 4 lbs. ai and higher (risk quotients range from 0.1 to 0.3). The roadside use (application rate of 1.25 lbs. ai/acre) exceeds the level of concern for acute effects to endangered fish (risk quotient = 0.12).

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 ingredients 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 metolachlor as an active ingredient. 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 metolachlor except those containing the three crops specified below. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of metolachlor, 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 metolachlor except potatoes, soybeans and peanuts and to determine that all uses of metolachlor except potatoes, soybeans and peanuts can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products, except those registered for use on potatoes, soybeans and peanuts, containing metolachlor as the active ingredient are eligible for reregistration. EPA is unable to make an eligibility determination for the potato, soybean and peanut uses at this time because under current policies these uses need section 409 tolerances and such tolerances may be barred by the Delaney Clause. Additionally, EPA is in the process of evaluating legal challenges to its policies related to the coordination of actions under section 409's Delaney Clause and FFDCA section 408 and FIFRA. Refer to the discussion under "Tolerance Reassessment." 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 metolachlor except potatoes, soybeans, and peanuts, are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing metolachlor, 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 ingredient metolachlor, the Agency has sufficient information on the health effects of metolachlor and on its potential for causing adverse effects in aquatic organisms, wildlife and the environment. The Agency concludes that products containing metolachlor for all uses except potatoes,

soybeans and peanuts are eligible for reregistration.

The Agency has determined that metolachlor 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 metolachlor except potatoes, soybeans and peanuts are eligible for reregistration.

B. Regulatory Position

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

1. Tolerance Reassessment

Tolerances Listed Under 40 CFR section 180.368(a)

The tolerances listed in 40 CFR 180.368(a) are for the combined residues (free and bound) of the herbicide metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR 180.368(a) for: almonds, hulls; cabbage; corn, field, forage; corn, field, fodder; corn, field, grain; sunflower, seed; peppers, bell; potatoes; sorghum, fodder (milo); sorghum, forage (milo); sorghum, grain (milo); stone fruits group; peas and associated vine and hay commodities; beans and associated forage and hay commodities; soybeans; soybeans, forage; and soybeans, hay; and tree nuts group.

Certain analytical data submitted to support the established tolerances listed in 40 CFR 180.368(a) were generated by Craven laboratories. The Agency has evaluated the impact of these data and has determined that sufficient non-Craven data are available to support extensions of the existing tolerances on an interim basis until the Craven data are replaced. Craven replacement data are still needed for: corn, sweet (K + CWHR); cotton, seed (postemergence use only); peanuts; peanuts, hay; peanuts, vines; peanuts, hulls (EC formulation at layby); safflower, seed (processing data).

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR 180.368(a) for eggs; milk; the fat, kidney, liver, meat and meat byproducts of

cattle, goats, hogs, horses, sheep; and the fat, liver, meat and meat byproducts of poultry. The dietary burden to livestock has been recalculated based on the reassessed tolerances for metolachlor in livestock feeds and the residues reported in the livestock feeding studies adjusted for losses in frozen storage.

So that the commodity definitions listed in 40 CFR 180.368(a) will be in accordance with the definitions in the Commodity Index Report dated 10/28/92, the tolerances should be revoked for: "corn, forage and fodder; (8.0 ppm); "peanut, forage and hay" (30.0 ppm); "sorghum, forage and fodder" (2.0 ppm), and "soybeans, forage and hay" (8.0 ppm). Separate tolerances should be established in 40 CFR 180. 368(a) for: "corn, field, forage" (8.0 ppm); "corn, field, fodder" (8.0 ppm); "peanuts, hay" (30.0 ppm); "sorghum, fodder (milo)" (2.0 ppm); and "sorghum, forage (milo)" (2.0 ppm). The tolerances for "seed and pod vegetables (except soybeans)" (0.3 ppm) should be revoked, and separate tolerances should be established for "beans, dry" (0.1 ppm), "beans, succulent" (0.5 ppm); "peas, dry" (0.1 ppm) and "peas, succulent" (0.5 ppm). In addition, tolerances for legume vegetable group foliage (except soybean forage and soybean hay) should be replaced with tolerances of 3 ppm for beans, forage, and beans, hay; and with a tolerance of 15 ppm for peas, vines and 2 ppm for peas, hay.

Certain other commodity definitions listed in 40 CFR 180.368(a) are not in accordance with the definitions in the Commodity Index Report dated 10/28/92; see summary table below for additional modifications in commodity definitions.

Tolerances Listed Under 40 CFR 180.368(b)

The tolerances listed in 40 CFR 180.368(b) are for the combined residues (free and bound) of the herbicide metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, when present in the raw agricultural commodities listed in 40 CFR 180.368(b) as a result of the application of metolachlor to growing crops listed in 40 CFR 180.368(a). (Rotational crops)

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR 180.368(b) for: the straw, forage, and grain of barley, buckwheat, oats, rice, rye, and wheat.

Certain analytical data submitted to support the established tolerances listed in 40 CFR 180.368(b) were generated by Craven laboratories. The Agency has evaluated the impact of these data and has determined that sufficient non-Craven data are available to support extensions of the existing tolerances on an interim basis until the Craven data are replaced for non-grass animal feeds group. The non-Craven replacement data for alfalfa and clover (non-grass animal feeds group) have been received and screened. The screen indicates that current tolerances will not be exceeded.

So that the commodity definitions listed in 40 CFR 180.368(b) will be in accordance with the definitions in the Commodity Index Report dated 10/28/92, the tolerances should be revoked for: "millet, fodder" (0.5 ppm); "millet, forage" (0.5 ppm); "milo, fodder" (0.5 ppm); "milo, forage" (0.5 ppm); and "milo, grain" (0.1 ppm). The definitions for millet forage and fodder have been deleted from the Commodity Index Report, and do not appear in Table II of Subdivision O. The definitions for milo will be covered under 40 CFR 180.368(a) as: "sorghum, fodder (milo)" (2.0 ppm); "sorghum, forage (milo)" (2.0 ppm); and "sorghum, grain" (0.3 ppm).

Tolerances Listed Under 40 CFR 180.368(c):

The tolerances with regional registration as defined in section 180.1(n) listed in 40 CFR 180.368(c) are for the combined residues (free and bound) of the herbicide metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide] and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound.

Sufficient data are available to ascertain the adequacy of the established tolerances listed in 40 CFR 180.368(c) for peppers, chili; peppers, Cubanelle; and peppers, tabasco.

The established tolerance listed in 40 CFR 180.368(c) for "peppers, tabasco" (.5 ppm), should include a leading zero (0.5 ppm).

New Tolerances Needed:

Food/feed additive tolerances are needed for the following processed commodities: "potatoes, dry peel" (4.0 ppm); "potatoes, wet peel" (0.5 ppm); "potatoes, granules" (0.5 ppm); and "potatoes, waste from processing" (4.0 ppm), and soybean hulls (0.4 ppm). Peanuts will likely need a 409 tolerance once the Craven replacment data are submitted and the data are reviewed.

These tolerances may be barred by the requirement in FFDCA section 409's Delaney Clause barring the establishment of a tolerance for any substance found to induce cancer in man or animal. EPA policies concerning when section 409 tolerances are necessary are being reevaluated by the Agency in light of challenges questioning their legality. The Agency is unable to make a reregistration eligibility decision on the potato, soybean and peanut uses of metolachlor until a decision on these challenges has been reached.

TOLERANCE REASSESSMENT SUMMARY

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances listed under 180.368(a)			
Almond hulls	0.3	0.3	*Almonds, hulls*
Cabbage	1.0	1.0	
Cattle, fat	0.02	0.02	
Cattle, kidney	0.2	0.2	
Cattle, liver	0.05	0.05	
Cattle, meat	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Cattle, mbyp (except kidney and liver)	0.02	0.05	*Cattle, mbyp (exc. liver and kidney)* Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Corn, fresh (inc. sweet K + CWHR)	0.1	TBD To be determined	*Corn, sweet (K + CWHR)*
Corn, forage and fodder	8.0	Revoke and establish separate tolerances at 8.0 ppm	*Corn, field, forage* and *Corn, field, fodder*
Corn, grain	0.1	0.1	*Corn, field, grain*
Cottonseed	0.1	TBD	*Cotton, seed*
Eggs	0.02	0.02	
Goats, fat	0.02	0.02	
Goats, kidney	0.2	0.2	
Goats, liver	0.05	0.05	
Goats, meat	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Goats, mbyp (except kidney and liver)	0.02	0.05	*Goats, mbyp (exc. liver and kidney)* Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Hogs, fat	0.02	0.02	
Hogs, kidney	0.2	0.2	
Hogs, liver	0.05	0.05	
Hogs, meat	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Hogs, mbyp (except kidney and liver)	0.02	0.05	*Hogs, mbyp (exc. liver and kidney)* Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Horses, fat	0.02	0.02	
Horses, kidney	0.2	0.2	
Horses, liver	0.05	0.05	
Horses, meat	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Horses, mbyp (except kidney and liver)	0.02	0.05	*Horses, mbyp (exc. liver and kidney)* Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Legume vegetables group foliage (except soybean forage and soybean hay)	15.0	Revoke and establish separate tolerances at 3 ppm for beans, forage; 3 ppm beans, hay; 15 ppm for peas, vines; and 2 ppm for beans, hay	beans, forage beans, hay peas, vines peas, hay
Milk	0.02	0.02	
Peanuts	0.5	TBD[1]	
Peanut, forage and hay	30.0	TBD[1]	*Peanuts, hay* peanuts, vines and peanut forage are no longer regulated commodities
Peanut, hulls	6.0	TBD[1]	*Peanuts, hulls*
Peppers, bell	0.1	0.1	
Potatoes	0.2	0.2[1]	
Poultry, fat	0.02	0.02	
Poultry, liver	0.05	0.05	
Poultry, meat	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Poultry, mbyp (except liver)	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Safflower seed	0.1	0.1	*Safflower, seed*
Seed and pod vegetables (except soybeans)	0.3	Revoke and establish separate tolerances at 0.1 ppm beans, dry; 0.5 ppm for beans, succulent; 0.1 ppm for peas, dry; and 0.5 ppm for pea, succulent	*Beans, dry*; *Beans, succulent*; *Peas, dry*; and *Peas, succulent*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Sheep, fat	0.02	0.02	
Sheep, kidney	0.2	0.2	
Sheep, liver	0.05	0.05	
Sheep, meat	0.02	0.05	Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Sheep, mbyp (except kidney and liver)	0.02	0.05	*Sheep, mbyp (exc. liver and kidney)* Changes necessary to correct for losses in frozen storage and 50% radiovalidation in plants.
Sorghum, forage and fodder	2.0	Revoke and establish separate tolerances at 2.0 ppm	*Sorghum, fodder (milo)* and *Sorghum, forage (milo)*
Sorghum, grain	0.3	0.3	*Sorghum, grain (milo)*
Soybeans	0.2	0.2[1]	
Soybeans, forage and hay	8.0	8.0[1]	*Soybeans, forage* and *Soybeans, hay*
Stone fruits group	0.1	0.1	
Tree nuts group	0.1	0.1	

Tolerances listed under 180.368(b)			
Barley, fodder	0.5	0.5	*Barley, straw*
Barley, forage	0.5	0.5	
Barley, grain	0.1	0.1	
Buckwheat, fodder	0.5	0.5	*Buckwheat, straw*
Buckwheat, forage	0.5	0.5	
Buckwheat, grain	0.1	0.1	
Millet, fodder	0.5	Revoke	Commodity not listed in Subdivision O, Table II, and deleted from Commodity Index Report
Millet, forage	0.5	Revoke	Commodity not listed in Subdivision O, Table II, and deleted from Commodity Index Report
Millet, grain	0.1	0.1	
Milo, fodder	0.5	Revoke	Covered under "Sorghum, fodder (milo)"
Milo, forage	0.5	Revoke	Covered under "Sorghum, forage (milo)"

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Milo, grain	0.1	Revoke	Covered under "Sorghum, grain (milo)"
Nongrass animal feeds (forage, fodder, straw, and hay) group	3.0	TBD	*Non-grass animal feeds group*
Oats, fodder	0.5	0.5	*Oats, straw*
Oats, forage	0.5	0.5	
Oats, grain	0.1	0.1	
Rice, fodder	0.5	0.5	*Rice, straw*
Rice, forage	0.5	0.5	
Rice, grain	0.1	0.1	
Rye, fodder	0.5	0.5	*Rye, straw*
Rye, forage	0.5	0.5	
Rye, grain	0.1	0.1	
Wheat, fodder	0.5	0.5	*Wheat, straw*
Wheat, forage	0.5	0.5	
Wheat, grain	0.1	0.1	
Tolerances listed under 180.368(c)			
Peppers, chili	0.5	0.5	
Peppers, Cubanelle	0.1	0.1	
Peppers, tabasco	.5	0.5	
Food and Feed Additive Tolerances Needed[1]			
potatoes, dry peel		4.0	
potatoes, granules		0.5	
potatoes, waste from processing		4.0	
potatoes, wet peel		0.5	
peanuts, meal		cannot be determined, additional data are needed for peanuts, to replace Craven data	
soybeans, hulls		0.4	

[1] Delaney issues may prevent establishment of these tolerances.

Codex Harmonization

No maximum residue limits (MRLs) for metolachlor have been established by Codex for any agricultural commodity. Therefore, no questions of compatibility exist with respect to U.S. tolerances.

2. Rotational Crop Restriction

Metolachlor labels must prohibit planting any crop not specified on the label, unless all appropriate rotational crop tolerances are established.

3. Reference Dose

The reference dose for metolachlor was determined to be 0.1 mg/kg /day based on the chronic feeding study with dogs in which the NOEL was 9.7 mg/kg/day an uncertainty factor of 100 was used.

4. Cancer Risk Assessment

The 1991 HED Peer Review Committee recommended that metolachlor be classified as a Group C (possible human) carcinogen, with a Q_1* of 9.2×10^{-3} $(mg/kg/day)^{-1}$). The classification of Group C was based on increases in liver tumors in the female rat, by both pair-wise and trend analysis and the replication of the finding of tumors in the female rat in a second study. However, the Peer Review conducted July 27, 1994, recommended an MOE approach since there was no supportable mutagenicity concern and in light of new information on the relative metabolism of metolachlor, quinone imine is presumed to be the ultimate carcinogen for 2,6-dimethylaniline.

5. Endangered Species Statement

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

6. Environmental Hazard Statements

Certain environmental hazard statements are required for metolachlor products because of the potential risk to non-target plants. Specific language is found in Section V of this document.

7. Restricted Use Classification

Metolachlor is not currently classified as a restricted use pesticide. The Agency has determined that metolachlor products should not be classified as "restricted use" at this time. However, once the Restricted Use Rule for Ground Water is finalized, metolachlor will be considered a candidate for classification as restricted use for groundwater concerns. The eligibility determination made at this time is based upon a presumption that registrations will conform to all applicable regulatory conditions included in the final restricted use rule for groundwater.

8. State Management Plan Candidate

Since metolachlor has been detected in ground water as a result of normal agricultural use, the Agency will consider metolachlor as a candidate for state management plans when the State Management Plan rule is promulgated. EPA is proposing regulations that currently: 1) designate five pesticides, one of which is metolachlor, to be subject to EPA-approved State Management Plans (SMPs) as a condition of their legal sale and use; and 2) establish these SMPs as an "other regulatory restriction" by specifying procedures and criteria for SMP development, review and approval, as provided under the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA) Section 3(d). In proposing these individual pesticides to be subject to SMPs, EPA has determined that these pesticides may pose an unreasonable adverse effect to the environment by their ground-water contamination potential, in the absence of effective local management measures provided in a State plan. Any uses of metolachlor allowed pursuant to the final rule will be predicated on a finding that such uses will not pose unreasonable adverse effects on the environment when used pursuant to the conditions contained in the rule. Upon promulgation of this rule, the labels for pesticide products containing metolachlor may need to be changed to require use in accordance with an EPA-approved SMP, and to prohibit sale and use in those States without such an EPA-approved SMP, after a period (to be established in the rule) allowed for development and approval of these State plans. The eligibility determination made at this time is based upon a presumption that registrations will conform to all applicable requirements of the final regulation addressing this issue.

9. Groundwater Advisory

Current metolachlor labels have a ground water advisory statement. This statement must be modified to reflect current advisory language. Specific language is found in Section V of this document.

10. Surface Water Advisory

Since metolachlor can contaminate surface water through ground spray drift and run-off, a surface water advisory is required. Specific language is found in Section V of this document.

11. Spray Drift Advisory

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

12. Occupational/Residential Labeling Rationale/Risk Mitigation

a. Compliance with Worker Protection

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests. nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, 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 the plants are (or will be) grown in.

At this time some of the registered uses of metolachlor 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).
- in a manner not directly related to the production of agricultural plants,

including, for example, control of vegetation along rights-of-way, in hedgerows and fencerows and in other noncrop areas.

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.

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

Occupational-Use Products (WPS and NonWPS Uses)

At this time some of the registered uses of metolachlor are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. The PPE requirements will pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure to occupational handlers is similar for WPS and nonWPS uses.

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 regarding 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 EPA guidelines.

2. If the Agency has special concerns about an active ingredient due to very high acute toxicity or certain adverse effects, such as allergic effects or other effects (cancer, developmental toxicity, reproductive effects, etc):

- In the RED document 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 acute toxicity of each end-use product.

For granular metolachlor formulations, the MOE's were calculated as being acceptable for loaders and applicators without additional active-ingredient-based personal protective equipment.

For liquid (emulsifiable concentrate) there are special risk concerns (Group C carcinogen and systemic toxicity for intermediate exposure) that warrant the establishment of active-ingredient-based minimum PPE requirements for handlers of liquid (emulsifiable concentrate) metolachlor formulations. The MOE's were calculated as being acceptable for (1) occupational mixers/loaders of liquid formulations to support ground application and (2) occupational applicators and flaggers exposed during applications of the liquid formulation using the assumption that coveralls over a short-sleeved shirt and short pants and chemical-resistant gloves were worn. The use of PPE was not sufficient to reduce the MOE's to an acceptable level for mixers and loaders using open mixing systems to support aerial applications. Those MOE's were acceptable only with the use of closed mixing systems.

Handler PPE for Homeowner-Use Products

At this time some products containing metolachlor are intended primarily for homeowner use. EPA is not establishing minimum (baseline) handler PPE for metolachlor end-use products that are intended primarily for homeowner use, since the Agency anticipates that the frequency, duration, and degree of exposure by such users do not warrant the risk mitigation measures imposed for occupational handlers. Personal protective equipment, if appropriate, will be established based on the acute toxicity of the end-use product.

Postapplication/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval: Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS are established on the basis of 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: product-specific REI's established on the basis of adequate data and interim REI's that are longer than those that would be established under the WPS.

For occupational end-use products containing metolachlor as an active ingredient, EPA is establishing a 24-hour restricted-entry interval for each use of the product that is within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The basis for this recommendation is that metolachlor has a toxicological endpoint of concern for systemic toxicity for intermediate exposures and also is classified as a Group C carcinogen. EPA notes that the WPS places very specific restrictions on entry during restricted-entry intervals when that entry involves contact with treated surfaces. EPA believes that these existing WPS protections are sufficient to mitigate post-application exposures of workers who contact surfaces treated with metolachlor.

The WPS REI in effect until now was 12 hours. The WPS REI was established through labeling modifications specified in PR Notice 93-7, which implemented the labeling requirements of the 1992 Worker Protection Standard for Agricultural Pesticides.

For those uses of metolachlor that are incorporated into the soil, EPA notes that if metolachlor has been correctly incorporated, the WPS permits workers to enter the treated area during the restricted-entry interval without personal protective equipment or any other restriction if they are performing tasks that do not involve contact with the soil subsurface.

Early Entry PPE: The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry by workers if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and requirement that 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.

EC Formulations: There are special concerns about emulsifiable concentrate formulations of metolachlor (Group C carcinogen and systemic toxicity) and the MOE's for handlers were marginal. Therefore, for early entry following applications of the emulsifiable concentrate, EPA is establishing PPE for dermal protection that is more stringent than the PPE that would otherwise be established based on the acute toxicity of the active ingredient. Since metolachlor is classified as category IV for eye irritation potential, protective eyewear is not required.

Granular Formulations There are no special concerns about the granular formulation of metolachlor, since the MOE's for handlers were high. The PPE required for early entry following applications of granular formulation is the minimum early-entry PPE allowed by the Worker Protection Standard for Agricultural Pesticides. Since metolachlor is classified as category IV for eye irritation potential, protective eyewear is not required.

Occupational Use Products (nonWPS Uses)

At this time some registered uses of metolachlor are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency is establishing entry restrictions for all nonWPS occupational uses of metolachlor end-use products. For specific language refer to Section V of this document.

Homeowner Use Products (nonWPS Uses)

At this time some products containing metolachlor are intended primarily for homeowner use. EPA is concerned about post-application exposures to homeowners following application of metolachlor. For specific language, refer to Section V of this document.

Additional Labeling Requirements

The Agency is requiring additional labeling statements to be located on all end-use products containing metolachlor that are primarily for occupational use. For the specific labeling statements, refer to Section V of this document.

13. Ground-Water Protection Requirements

The "Pesticides in Ground Water Data Base 1992" indicates that residues of metolachlor have been detected in wells in 20 states. Levels exceeded the Health Advisory level of 100 ppb in a total of 3 wells located in Wisconsin, New York, and Montana. In five other states concentrations in well water exceeded 10% of the HAL. A recent 6(a)(2) report submitted by the registrant indicates metolachlor residues in one well that also exceed the HAL. Because of these detections, the Agency is concerned about the degradation of water quality that may occur in metolachlor use areas. Because of the widespread use of metolachlor and the detections in many states, the Agency is requiring two small scale prospective ground-water studies to determine metolachlor's impact on ground-water quality. In addition, metolachlor is part of a 19-state atrazine monitoring program. Data on metolachlor from this program have and are being made available to the Agency. The registrant will submit a full report of all metolachlor analyses from this program which is scheduled for completion in 1995.

The Agency is also requiring label statements to further reduce the risk of contamination posed by practices involved in the mixing and loading of metolachlor. These label statements are already found on some metolachlor labels. These statements are found in Section V.

V. ACTIONS REQUIRED BY REGISTRANTS

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

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of metolachlor for the above eligible uses has been reviewed and determined to be substantially complete for all uses. As noted, additional data have been recently required in Data Call-In Notices (12/10/93, 2/15/94 and 5/10/94). Also, additional confirmatory data are needed to fulfill requirements for the studies listed below:

Foliar Residue Dissipation (132-1a) - for use on residential turf
Dermal Passive Dosimetry Exposure (133-3) - for use on residential turf

2. Labeling Requirements for Manufacturing-Use Products

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

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

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

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

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

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. Occupational/Residential Labeling

(1) Personal Protective Equipment Requirements for Pesticide

Handlers (mixers, loaders, applicators, etc);

Sole-active-ingredient end-use products that contain metolachlor must be revised to adopt the handler personal protective equipment requirements set forth in this section. Any conflicting PPE requirements on their current labeling must be removed.

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

- **Handler PPE for Occupational-Use Products** (products NOT intended primarily for home use -- (see tests in PR Notice 93-7 and 93-11):

Minimum (Baseline) Personal Protective Equipment Requirements:

Some of the registered uses of metolachlor are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some are outside the scope of the WPS. The minimum (baseline) PPE requirements pertain to both the WPS and nonWPS uses by occupational handlers, since the potential exposure to occupational handlers is similar for WPS and nonWPS uses.

Granular Formulations: The Agency is establishing no minimum (baseline) PPE for WPS and nonWPS uses of metolachlor end-use products that are formulated as granules.

EC Formulations: The minimum (baseline) PPE for all WPS and nonWPS occupational uses of metolachlor end-use products formulated as a liquid is:

- **Products NOT Intended Primarily For Home Use:** The personal protective equipment (PPE) requirement for pesticide handlers on all end-use products, except products intended primarily for home use (see tests in PR Notice 93-7 and 93-11), is:

"Applicators and other handlers must wear:
--Coveralls over short-sleeved shirt and short pants
--Chemical-resistant gloves (see instructions * below)
--Chemical-resistant footwear plus socks
--Chemical-resistant headgear for overhead exposure
--Chemical-resistant apron when cleaning equipment, mixing, or loading" (see instructions ** below)

* The glove statement for metolachlor is the statement established through the instructions in Supplement Three of PR Notice 93-7.

** The words "mixing, or loading" may be removed if the product is formulated as "ready-to-use."

Actual End-Use Product Personal Protective Equipment Requirements: The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) personal protective equipment, if any, specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling: The personal protective equipment 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.

- **Products Intended Primarily for Homeowner Use**: EPA is not establishing minimum (baseline) handler PPE for metolachlor end-use products that are intended primarily for homeowner use. Personal protective equipment, if appropriate, will be established based on the acute toxicity of the end-use product.

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

(2) Entry Restrictions; Labeling

Sole-active-ingredient end-use products that contain metolachlor must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on their current labeling must be removed.

Multiple-active-ingredient end-use products that contain metolachlor must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

- **Occupational-Use Products (Products NOT Intended Primarily For Home Use):**

--Uses Within the Scope of the WPS:

Restricted-Entry Interval: A 24-hour restricted entry interval (REI) is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early-Entry Personal Protective Equipment (PPE):

EC Formulations: The PPE required for early entry following applications of the emulsifiable concentrate is:

--coveralls over short-sleeve shirt and short pants,
--chemical-/resistant gloves,
--chemical-resistant footwear plus socks,
--chemical-resistant headgear for overhead exposures.

Granular Formulations: The PPE required for early entry following applications of granular formulation is:
--coveralls,
--chemical-resistant gloves,
--shoes plus socks.

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.

--Uses Not Within the Scope of the WPS:

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 following 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 following the watering-in."

Placement in Labeling:

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

If no WPS uses are on label: Add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading: "Entry Restrictions:"

■ **Products Primarily Intended for Home Use**:

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 following 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 following the watering-in."

Placement in Labeling: Add the entry restriction to the labels of products primarily intended for homeowner use in a section in the Directions For Use with the heading: "Entry Restrictions:"

(3) Other Labeling Requirements

The Agency is requiring the following statements to be located on all metolachlor end-use product labeling 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:

"Mixers and loaders supporting aerial applications are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4). When using the closed system, the mixers' and loaders' PPE requirements may be reduced or modified as specified in the WPS."

"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:

"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:

In addition, because metolachlor is classified as a skin sensitizer, EPA is requiring the following statement in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements on the labeling of all end-use products containing metolachlor:

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

Soil Incorporation Statement:

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

"Exception: if the product is 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."

b. Environmental Hazards Statements

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

General information section of label:

"Do not apply under conditions which favor runoff or wind erosion of soil containing this product to non-target areas."

To prevent off-site movement due to run-off or wind erosion:

"Avoid treating powdery dry or light sand soils when conditions are favorable for wind erosion. Under these conditions, the soil surface should first be settled by rainfall or irrigation."

"Do not apply to impervious substrates such as paved or highly compacted surfaces."

"Do not use tailwater from the first flood or furrow irrigation of treated fields to treat non-target crops unless at least 1/2 inch of rainfall has occurred between application and the first irrigation."

c. Rotational Crops Restriction

Do not rotate to food or feed crops other than those listed on this label.

d. Ground Water Labeling/Mitigation; Mixing/Loading

The following label language regarding mixing/loading setbacks must appear in Precautionary Statements in the Environmental Hazards section of the label:

This product may not be mixed or loaded within 50 ft. of perennial or intermittent streams and rivers, natural or impounded lakes and reservoirs. This product may not be mixed/loaded or used within 50 ft. of all wells, including abandoned wells, drainage wells, and sink holes. Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 ft. of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or wash-water, and rain water that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self-contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above-specified minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site.

e. Ground Water Advisory

The following ground water advisory language must be placed on all

metolachlor labels:

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

f. Surface Water Advisory

The following surface water advisory language must be placed on all metolachlor labels:

> "Metolachlor can contaminate surface water through ground spray drift. Under some conditions, metolachlor may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."

g. 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).

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

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

Appendix A is 63 pages long and is not being included. Copies of Appendix A are available upon request per the instructions in Appendix D

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

GUIDE TO APPENDIX B

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

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	Chemical Identity	ALL	40276601
61-2A	Start. Mat. & Mnfg. Process	ALL	40276601
61-2B	Formation of Impurities	ALL	40276601
62-1	Preliminary Analysis	ALL	40276601
62-2	Certification of limits	ALL	40276601
62-3	Analytical Method	ALL	DATA GAP
63-2	Color	ALL	40276602
63-3	Physical State	ALL	40276602
63-4	Odor	ALL	40276602
63-5	Melting Point		N/A
63-6	Boiling Point	ALL	40276602
63-7	Density	ALL	40276602
63-8	Solubility	ALL	40276602
63-9	Vapor Pressure	ALL	40276602
63-10	Dissociation Constant	ALL	40276602
63-11	Octanol/Water Partition	ALL	40276602
63-12	pH	ALL	40276602
63-13	Stability	ALL	40276602
63-14	Oxidizing/Reducing Action	ALL	40276602

Data Supporting Guideline Requirements for the Reregistration of METOLACHLOR

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	Flammability	ALL	40276602
63-16	Explodability	ALL	40276602
63-17	Storage stability	ALL	40276602
63-18	Viscosity	ALL	40276602
63-19	Miscibility	ALL	40276602
63-20	Corrosion characteristics	ALL	40276602
63-21	Dielectric breakdown volt		N/A
64-1	Submittal of Samples		N/A
ECOLOGICAL EFFECTS			
71-1A	Acute Avian Oral - Quail/Duck	A,B,C	00062465
71-1B	Acute Avian Oral - Quail/Duck TEP		N/A
71-2A	Avian Dietary - Quail	A,B,C	00016425
71-2B	Avian Dietary - Duck	A,B,C	00016426
71-3	Wild Mammal Toxicity		N/A
71-4A	Avian Reproduction - Quail		DATA GAP
71-4B	Avian Reproduction - Duck		DATA GAP
71-5A	Simulated Field Study		N/A
71-5B	Actual Field Study		N/A
72-1A	Fish Toxicity Bluegill	A,B,C	00018722
72-1B	Fish Toxicity Bluegill - TEP		N/A

Data Supporting Guideline Requirements for the Reregistration of METOLACHLOR

REQUIREMENT		USE PATTERN	CITATION(S)
72-1C	Fish Toxicity Rainbow Trout	A,B,C	00018723
72-1D	Fish Toxicity Rainbow Trout- TEP		N/A
72-2A	Invertebrate Toxicity	A,B,C	00015546
72-2B	Invertebrate Toxicity - TEP		N/A
72-3A	Estuarine/Marine Toxicity - Fish	A,B,C	43044602
72-3B	Estuarine/Marine Toxicity - Mollusk		IN REVIEW
72-3C	Estuarine/Marine Toxicity - Shrimp		IN REVIEW
72-3D	Estuarine/Marine Toxicity Fish- TEP		N/A
72-3E	Estuarine/Marine Toxicity Mollusk - TEP		N/A
72-3F	Estuarine/Marine Toxicity Shrimp - TEP		N/A
72-4A	Early Life Stage Fish	A,B,C	47025723
72-4B	Life Cycle Invertebrate		DATA GAP
72-5	Life Cycle Fish		N/A
72-6	Aquatic Organism Accumulation		N/A
72-7A	Simulated Field - Aquatic Organisms		N/A
72-7B	Actual Field - Aquatic Organisms		N/A
122-1A	Seed Germination/Seedling Emergence		N/A

REQUIREMENT		USE PATTERN	CITATION(S)
122-1B	Vegetative Vigor		N/A
122-2	Aquatic Plant Growth		N/A
123-1A	Seed Germination/Seedling Emergence		IN REVIEW
123-1B	Vegetative Vigor		IN REVIEW
123-2	Aquatic Plant Growth		IN REVIEW
124-1	Terrestrial Field		N/A
124-2	Aquatic Field		N/A
141-1	Honey Bee Acute Contact		N/A
141-2	Honey Bee Residue on Foliage		N/A
141-5	Field Test for Pollinators		N/A
TOXICOLOGY			
81-1	Acute Oral Toxicity - Rat	ALL	00015523
81-2	Acute Dermal Toxicity - Rabbit/Rat	ALL	00015526
81-3	Acute Inhalation Toxicity - Rat	ALL	00015535
81-4	Primary Eye Irritation - Rabbit	ALL	00015528
81-5	Primary Dermal Irritation - Rabbit	ALL	00015530
81-6	Dermal Sensitization - Guinea Pig	ALL	00015631
81-7	Acute Delayed Neurotoxicity - Hen		N/A
82-1A	90-Day Feeding - Rodent		N/A
82-1B	90-Day Feeding - Non-rodent	A,B	00017690,00032174

Data Supporting Guideline Requirements for the Reregistration of METOLACHLOR

REQUIREMENT		USE PATTERN	CITATION(S)
82-2	21-Day Dermal - Rabbit/Rat		
82-3	90-Day Dermal - Rodent	A,B	41833101
82-4	90-Day Inhalation - Rat		N/A
82-5A	90-Day Neurotoxicity - Hen		N/A
82-5B	90-Day Neurotoxicity - Mammal		N/A
83-1A	Chronic Feeding Toxicity - Rodent	A,B	00001563,00042725,00084003,00117597
83-1B	Chronic Feeding Toxicity - Non-Rodent	A,B	40980701
83-2A	Oncogenicity - Rat	A,B	00129377,244166
83-2B	Oncogenicity - Mouse	A,B	000015634,00042725,00117597
83-3A	Developmental Toxicity - Rat	A,B	00151941
83-3B	Developmental Toxicity - Rabbit	A,B	00041283
83-4	2-Generation Reproduction - Rat	A,B	00080897
84-2A	Gene Mutation (Ames Test)	ALL	00026712,00026713
84-2B	Structural Chromosomal Aberration	ALL	00026712,00026713
84-4	Other Genotoxic Effects	ALL	43244003
85-1	General Metabolism	A,B	40114401
85-2	Dermal Penetration	ALL	41833102
86-1	Domestic Animal Safety		N/A
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	Foliar Residue Dissipation	ALL	41053901

REQUIREMENT		USE PATTERN	CITATION(S)
132-1B	Soil Residue Dissipation	N/A	
133-3	Dermal Passive Dosimetry Exposure		DATA GAP
133-4	Inhalation Passive Dosimetry Exposure		N/A
231	Estimation of Dermal Exposure at Outdoor Sites		N/A
232	Estimation of Inhalation Exposure at Outdoor Sites		N/A
233	Estimation of Dermal Exposure at Indoor Sites		N/A
234	Estimation of Inhalation Exposure at Indoor Sites		N/A
ENVIRONMENTAL FATE			
160-5	Chemical Identity		N/A
161-1	Hydrolysis	A,B,C	40430201
161-2	Photodegradation - Water	A,B,C	40430202
161-3	Photodegradation - Soil	A,B,C	40430203
161-4	Photodegradation - Air		N/A
162-1	Aerobic Soil Metabolism	A,B,C	41309801
162-2	Anaerobic Soil Metabolism	A,C	41309801
162-3	Anaerobic Aquatic Metabolism	A,B,C	41185701
162-4	Aerobic Aquatic Metabolism		N/A

Data Supporting Guideline Requirements for the Reregistration of METOLACHLOR

REQUIREMENT		USE PATTERN	CITATION(S)
163-1	Leaching/Adsorption/Desorption	A,B,C	40494602,40494603,40494604,40494605
163-2	Volatility - Lab	A,B,C	40494606
163-3	Volatility - Field		N/A
164-1	Terrestrial Field Dissipation	A,B,C	41309802,4148420106,413357016
164-2	Aquatic Field Dissipation		N/A
164-3	Forest Field Dissipation		N/A
164-5	Long Term Soil Dissipation		N/A
165-1	Confined Rotational Crop	A,B,C	41470601
165-2	Field Rotational Crop		N/A
165-3	Accumulation - Irrigated Crop		N/A
165-4	Bioaccumulation in Fish	A,B,C	41154201
165-5	Bioaccumulation - Aquatic NonTarget		N/A
166-1	Ground Water - Small Prospective		DATA GAP
166-2	Ground Water - Small Retrospective		
166-3	Ground Water - Irrigated Retrospective		N/A
201-1	Droplet Size Spectrum		RESERVED
202-1	Drift Field Evaluation		RESERVED
RESIDUE CHEMISTRY			
171-4A	Nature of Residue - Plants	A,B	42664302

Data Supporting Guideline Requirements for the Reregistration of METOLACHLOR

REQUIREMENT		USE PATTERN	CITATION(S)
171-4B	Nature of Residue - Livestock	B	00015423,00015424, 00015652,00015653, 00022872,00022873, 00022874,00022879, 00022880,00074898, 00074900,40766601 42644301,42652101
171-4C	Residue Analytical Method - Plants	A,B	00015432,00015466, 00015543,00015698, 00016306,00039176, 00111693,00125227
171-4D	Residue Analytical Method - Animal	A,B	00015432,00015466, 00015543,00015698, 00016306,00039176, 00111693,00125227
171-4E	Storage Stability	A,B	42810601,41506501,41506491,40980702,40980 703
171-4F	Magnitude of Residues - Potable H2O		N/A
171-4G	Magnitude of Residues in Fish		N/A
171-4H	Magnitude of Residues - Irrigated Crop		N/A
171-4I	Magnitude of Residues - Food Handling		N/A

Data Supporting Guideline Requirements for the Reregistration of METOLACHLOR

REQUIREMENT		USE PATTERN	CITATION(S)
171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		N/A
171-4K	Crop Field Trials		
	Root and Tuber Vegetables Group		
	- Potatoes	A	00105957, 00106191, 00109613
	- Radishes grown for seed		none
	Bulb Vegetables (*Allium* spp.) Group		
	- Onions	A	43000101
	Leafy Vegetables (except *Brassica* vegetables) Group		
	- Celery	A	41551201
	Brassica (cole) Leafy Vegetables Group		
	- Cabbage	A	40644901
	Legume Vegetables (succulent or dried) Group		
	- Beans (succulent and dried)	A	00064182, 00128731, 43295701
	- Peas (succulent and dried)	A	00064182, 00128731, 43295701

REQUIREMENT	USE PATTERN	CITATION(S)
- Soybeans		00015399, 00015400, 00015401, 00015402, 00015403, 00015404, 00015405, 00015406, 00015407, 00015408, 00015409, 00015410, 00015411, 00015540, 00015541, 00015542, 00015706, 00015719, 00015721, 00015722, 00015723, 00015725, 00015726, 00015727, 00015728, 00015729, 00015735, 00015736, 00015737, 00015760, 00015761, 00015762, 00015763, 00015764, 00015765, 00015766, 00015767, 00015768, 00015769, 00015770, 00015771, 00015772, 00015773, 00015774, 00015777, 00015778, 00015779, 00015780, 00016248, 00016427, 00016604, 00039174, 43178401
- Lupine	A	
Foliage of Legume Vegetables		
- Bean vines and hay	A	00128731, 43295701
- Pea vines and straw	A	00128731, 43295701
- Soybean forage and hay	A	00015399, 00015400, 00015401, 00015402, 00015403, 00015408, 00015540, 00015541, 00015542, 00015706, 00015719, 00015721, 00015722, 00015725, 00015726, 00015727, 00015728, 00015729, 00015731, 00015732, 00015733, 00015734, 00015736, 00015737, 00015760, 00015761, 00015762, 00015763, 00015764, 00015765, 00015766, 00015767, 00015768, 00015769, 00015770, 00015771, 00015772, 00015773, 00015774, 00015775, 00015777, 00039174, 43178403

REQUIREMENT	USE PATTERN	CITATION(S)
Fruiting Vegetables (except cucurbits) Group		
- Peppers	**A**	**00150180, 00156573, 40557301 40899301**
Stone Fruits Group		**00131376**
Tree Nuts Group		
- Almonds, hulls	**A**	
Cereal Grains Group		
- Barley	**A**	**00078297**
- Buckwheat	**A**	**00078297**

REQUIREMENT	USE PATTERN	CITATION(S)
- Corn, field and fresh	**A**	**00015428, 00015429, 00015430, 00015570, 00015571, 00015572, 00015586, 00015587, 00015588, 00015589, 00015590, 00015591, 00015592, 00015593, 00015594, 00015595, 00015597, 00015598, 00015599, 00015600, 00015601, 00015602, 00015676, 00015677, 00015678, 00015679, 00015680, 00015681, 00015682, 00015683, 00015684, 00015685, 00015686, 00015687, 00015688, 00015689, 00015690, 00015691, 00015692, 00015693, 00015694, 00015704, 00015705, 00015707, 00015708, 00015709, 00015710, 00015711, 00015712, 00015713, 00015714, 00015715, 00015716, 00015717, 00015718, 00015739, 00015740, 00015741, 00015742, 00015743, 00015744, 00015745, 00015746, 00015747,00015748, 00015749, 00015750, 00015751, 00015752, 00015753, 00015754, 00015755, 00015756, 00015757, 00015786, 00015787, 00015950, 00015954, 00015955, 00016392, 00016393, 00016394, 00016395, 00016396, 00016397, 00016398, 00016399, 00016435, 00016436, 00016437, 43178401**

REQUIREMENT	USE PATTERN	CITATION(S)
- Corn, field and fresh, continued	A	43178401
- Millet	A	00078297
- Milo	A	00078297
- Oats	A	00078297
- Rice	A	00078297
- Rye	A	00078297
- Sorghum	A	00015548, 00015549, 00015550, 00015551, 00015552, 00016607, 00016608, 00016609, 00016610, 00016990, 00016991, 00016992, 00111693
- Wheat	A	00078297
Forage, Fodder, and Straw of Cereal Grains Group		
- Barley, forage and straw	A	00078297
- Buckwheat, forage and straw	A	00078297
- Corn, forage and fodder	A	identical to corn grain
- Millet, forage and straw	A	00078297
- Milo, forage and straw	A	00078297
- Oats, forage and straw	A	00078297
- Rice, forage and straw	A	00078297
- Rye, forage and straw	A	00078297
- Sorghum, forage and fodder	A	identical to sorghum grain

REQUIREMENT		USE PATTERN	CITATION(S)
	- Wheat, forage and straw	A	00078297
	Grass forage, fodder, and hay Group	A	
	Non-grass Animal Feeds (forage, fodder, straw, and hay) Group		43367101
	Miscellaneous Commodities		
	- Cotton, seed	A	00065048, 00129058, 40980707, 43178402
	- Peanuts	A	00015553, 00015554, 00015555, 00015556, 00015557, 43263101
	- Peanuts, forage and hay	A	
	- Peanuts, hulls	A	
	- Safflower, seed	A	
171-4L	Magnitude of the Residue in Processed Food/Feed		
	- Beans (succulent and dried)	A	
	- Corn, field	A	40980705
	- Corn, fresh	A	40980705
	- Cotton	A	40980707
	- Peanuts	A	40980708
	- Potato	A	40980704
	- Safflower	A	
	- Sorghum, grain	A	
	- Sorghum, sweet	A	

REQUIREMENT	USE PATTERN	CITATION(S)
- Soybeans	A	40980706, 41506501

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

GUIDE TO APPENDIX C

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

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

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

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

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

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

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

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

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

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

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

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

BIBLIOGRAPHY

MRID	CITATION
00001563	Parks, W.L.; Miller, W. (1975) Final Report: Evaluation of a Urea Terrazole Fertilizer at Several Rates on Corn: Report No. 3068. (Unpublished study received Feb 4, 1977 under 1258-812; prepared by Univ. of Tennessee, Plant Science Dept., submitted by Olin Corp., Agricultural Div., Little Rock, Ark.; CDL:095799-I)
00001663	Iwan, G.R. (1976) Olin--14C Terrazole Channel Catfish, Ictalurus punctatus(Rafinesque), Static Bioaccumulation Study. (Unpublished study received Oct 20, 1976 under 1258-812; prepared by Union Carbide Corp., Aquatic Environmental Sciences, submitted by Olin Corp., Agricultural Div., Little Rock, Ark.; CDL:228143-AB)
00015399	Seim, V. (1975) Residue Report: Soybeans: AG-A No. 3268 I,II,III. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-A)
00015400	Peek, J.; Stahlberg, L. (1975) Residue Report: Soybeans: AG-A No. 3466 I,II. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-B)
00015401	Roper, J. (1975) Residue Report: Soybeans: AG-A No. 3523 I,II,III. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-C)
00015402	Juby, M. (1975) Residue Report: Soybeans: AG-A No. 3570 I,II,III. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-D)
00015403	Pruss, S.; Ross, R.H. (1976) Residue Report: Soybeans: AG-A No. 3650 III. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-E)
00015404	Peek, J.; Stahlberg, L. (1976) Residue Report: Soybeans: AG-A No. 3702 III. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-F)
00015405	Shriver, J.; Wendling, C. (1976) Residue Report: Soybeans: AG-A No. 3724 III. (Unpublished study including AG-A nos. 3742 II, 3743 II and 3747 II, received Jan 19, 1977 under 100-583; prepared in cooperation with Chemagro

BIBLIOGRAPHY

MRID	CITATION
	and E.I. du Pont de Nemours and Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-G)
00015406	Gaspard, J. (1976) Residue Report: Soybeans: AG-A No. 3758 II. (Unpublished study received Jan 19, 1977 under 100-583; prepared in cooperation with Chemagro, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-K)
00015407	Westmoreland, W.G. (1976) Residue Report: Soybeans: AG-A No. 3764 II. (Unpublished study received Jan 19, 1977 under 100-583; prepared in cooperation with Chemagro, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-L)
00015408	Pruss, S.W.; Schnappinger, M.G. (1976) Residue Report: Soybeans: AG-A No. 3775 II. (Unpublished study including AG-A no. 3776 II, received Jan 19, 1977 under 100-583; prepared in cooperation with E.I. du Pont de Nemours and Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-M)
00015409	Peek, J.; Stahlberg, L. (1976) Residue Report: Soybeans: AG-A No. 3778 II. (Unpublished study including AG-A nos. 3780 II and 3782 II, received Jan 19, 1977 under 100-583; prepared in cooperation with Chemagro and E.I. du Pont de Nemours and Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-O)
00015410	Thomas, J.; Herman, D. (1976) Residue Report: Soybeans: AG-A No. 3803 II. (Unpublished study including AG-A no. 3812 II, re- ceived Jan 19, 1977 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-R)
00015411	Pruss, S.W.; Luke, J.E. (1976) Residue Report: Soybeans: AG-A No. 3885. (Unpublished study received Jan 19, 1977 under 100- 583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 095747-T)
00015423	Sumner, D.D.; Thomas, R.D.; Cassidy, J.E. (1975) Structure Elucidation of the Metabolites of CGA-24705 in Corn: M4-68-2Y: Report No. GAAC-75012. (Unpublished study received Mar 26, 1975 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094378-F)

BIBLIOGRAPHY

MRID	CITATION
00015424	Gross, D. (1974) Uptake, Translocation annd Degradation of CGA 24 705 in Corn Grown Under Controlled Conditions: Project Report No. 13/74: Addendum to Project Report No. 8/74. (Unpublished study received Mar 26, 1975 under 5F1606; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094378-H)
00015428	Kincaid, L. (1975) Residue Report: Field Corn: AG-A No. 3383. (Unpublished study received Mar 26, 1975 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094379-O)
00015429	Thomas, J.; Herman, D. (1975) Residue Report: Field Corn: AG-A No. 3501 I,II. (Unpublished study received Mar 26, 1975 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094379-P)
00015430	Kincaid, L. (1975) Residue Report: Sweet Corn: AG-A No. 3446. (Unpublished study received Mar 26, 1975 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094379-T)
00015432	Ramsteiner, K.; Karlhuber, B. (1975) CGA 24705: Determination of Total Residue in Material of Animal Origin. Method no. REM 2/75 dated Feb 6, 1975. (Unpublished study received Mar 26, 1975 under 5F1606; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094379-AJ)
00015466	Aziz, S.A.; Ross, J.A. (1975) Analytical Method for the Determination of Residues of CGA-24705 Soybean Metabolites as CGA-37913 and CGA-49751 by Acid Hydrolysis. Method no. AG-286 dated Jun 10, 1975. (Unpublished study received Nov 25, 1975 under 6G1708; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094877-S)
00015523	Bathe, R. (1973) Acute Oral LD50 of Technical CGA-24705 in the Rat: Project No. Siss 2979. (Unpublished study received Mar 1, 1974 under 5G1553; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-B)
00015526	Bach, K.J. (1974) Acute Dermal LD50 Test in Rabbits: Contract No. 120-2255-34. (Unpublished study received on unknown date under 5G1553; prepared by Affiliated Medical Research, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-E)

BIBLIOGRAPHY

MRID	CITATION
00015528	Sachsse, K. (1973) Irritation of Technical CGA-24705 in the Rabbit Eye: Project No. Siss 2979. (Unpublished study received Mar 1, 1974 under 5G1553; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-G)
00015530	Sachsse, K. (1973) Skin Irritation in the Rabbit after Single Application of Technical CGA-24705: Project No. Siss 2979. (Unpublished study received Mar 1, 1974 under 5G1553; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-I)
00015535	Sachsse, K.; Ullmann, L. (1974) Acute Inhalation Toxicity of Technical CGA-24705 in the Rat: Project No. Siss 3516. (Unpublished study received on unknown date under 5G1553; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-N)
00015540	Ross, R.H. (1979) Metolachlor (Dual 8E); Chloramben (Amiben 2E): AG-A No. 5173 I,II. (Unpublished study including letter dated May 8, 1979 from S.L. Harrison to Warren A. Davis, received Jun 20, 1979 under 100-583; prepared in cooperation with AM-CHEM Products, Inc. and Union Carbide Agricultural Products Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:238677-B)
00015541	Kern, C.L. (1979) Metolachlor (Dual 8E); Chloramben (Amiben 2SL): AG-A No. 5218 I,II. (Unpublished study including letter dated May 8, 1979 from S.L. Harrison to Warren A. Davis, re- ceived Jun 20, 1979 under 100-583; prepared in cooperation with AM-CHEM Products, Inc. and Union Carbide Agricultural Products Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 238677-C)
00015542	Rose, W.; Clapp, T.; Clapp, G. (1979) Metolachlor (Dual 8E); Chloramben (Amiben 2E): AG-A No. 5341. (Unpublished study including letter dated May 8, 1979 from S.L. Harrison to Warren A. Davis, received Jun 20, 1979 under 100-583; prepared in cooperation with AM-CHEM Products, Inc. and Union Carbide Agricultural Products Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:238677-D)
00015543	Cargile, N.L.; Ross, J.A. (1979) Analytical Method for Residues of Metolachlor Plant Metabolites Determined as CGA-37913 and CGA- 49751 after Acid Hydrolysis. Method no. AG-338 dated Apr 23, 1979.

BIBLIOGRAPHY

MRID	CITATION
	(Unpublished study received Jun 20, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:238677-F)
00015546	Vilkas, A.G. (1976) Acute Toxicity of CGA-24705 Technical to the Water Flea,Daphnia magnaStraus. (Unpublished study received Nov 24, 1976 under 100-587; prepared by Union Carbide Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:226955-E)
00015548	Houseworth, L.D.; Rolla, H. (1977) Residues of Metolachlor in or on Sorghum Resulting from Preplant Incorporated and Preemergence Applications: Report No. ABR-77086. (Unpublished study received Nov 14, 1977 under 8G2019; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096625-A)
00015549	Ragsdale, D.; Peek, J. (1977) Residue Report: Sorghum: AG-A No. 4413 Third Report. (Unpublished study received Nov 14, 1977 under 8G2019; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096626-A)
00015550	Thomas, J.; Herman, D. (1977) Residue Report: Sorghum: AG-A No. 4418 Third Report. (Unpublished study received Nov 14, 1977 under 8G2019; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096626-B)
00015551	Turner, W.E. (1977) Residue Report: Sorghum: AG-A No. 4503 Third Report. (Unpublished study received Nov 14, 1977 under 8G2019; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096626-C)
00015552	Holt, B.E. (1977) Residue Report: AG-A No. 4753. (Unpublished study received Nov 14, 1977 under 8G2019; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096626-D)
00015553	Kahrs, R.A. (1979) Residues of Metolachlor in Peanuts Resulting from Preplant Incorporated or Preemergence Applications: Report No. ABR-79059. Summary of studies 098298-B, 098298-C, 098298-F, 098298-I and 098298-J. (Unpublished study received May 18, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:098298-A)

BIBLIOGRAPHY

MRID	CITATION
00015554	Rose, W.; Coble, H. (1979) Metolachlor (Dual 8E), Naptalam + DNBP (Dyanap 3E): AG-A No. 4715 I,II. (Unpublished study received May 18, 1979 under 100-583; prepared in cooperation with IRDC, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:098298-B)
00015555	Dill, R. (1979) Residue Report: Peanuts: AG-A No. 4742 II. (Unpublished study received May 18, 1979 under 100-583; prepared in cooperation with IRDC, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:098298-C)
00015556	McMahon, A. (1979) Residue Report: Peanuts: AG-A No. 4840 II. (Unpublished study received May 18, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:098298-F)
00015557	McMahon, A. (1979) Metolachlor (Dual 8E): AG-A No. 4841 I,II. (Unpublished study received May 18, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:098298-I)
00015570	Taylor, D.; Shriver, J.; Guthrie, C. (1976) Residue Report: Field Corn: AG-A No. 3372 II. (Unpublished study received Jun 20, 1977 under 100-590; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:230685-E)
00015571	Seim, V. (1976) Residue Report: Field Corn: AG-A No. 3674 II,III. (Unpublished study received Jun 20, 1977 under 100-590; submitted by Ciba-Geigy Coorp., Greensboro, N.C.; CDL:230685-G)
00015572	Chamberlain, E.; Shriver, J.; Wendling, C. (1976) Residue Report: Field Corn: AG-A N0. 3745 I,II,III. (Unpublished study received
00015572	Jun 20, 1977 under 100-590; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:230685-H)
00015586	Houseworth, L.D. (1978) Residues of Metolachlor and Atrazine in or on Corn Resulting from the Application of Metolachlor, Metola- chlor/Atrazine Tank Mixes or a Metolachlor/Atrazine Pre-pack through Center Pivot Irrigation Systems: Report No. ABR-78074. Summary of studies 235358-B through 235358-J. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:235358-A)

BIBLIOGRAPHY

MRID	CITATION
00015587	Stahlberg, L. (1978) Metolachlor (Dual 8E): AG-A No. 4870 I, II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235358-B)
00015588	Turner, W.E.; Wiese, A.F. (1978) Metolachlor (Dual 8E): AG-A No. 4908 I,II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 235358-C)
00015589	Threewitt, T. (1978) Metolachlor (Dual 8E): AG-A No. 4929 I, II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235358-D)
00015590	Stahlberg, L. (1978) Metolachlor + Atrazine; Dual 8E + Aa- trex 4L: AG-A No. 4871 I,II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235358-E)
00015591	Stahlberg, L. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4872 I,II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 235358-F)
00015592	Turner, W.E.; Wiese, A.F. (1978) Metolachlor + Atrazine, Dual 8E + Aatrex 4L: AG-A No. 4909 I,II. (Unpublished study re- ceived Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235358-G)
00015593	Turner, W.E.; Wiese, A.F. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4910 I,II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235358-H)
00015594	Threewitt, T. (1978) Metolachlor + Atrazine (Dual 8E + Aa- trex 80W): AG-A No. 4930 I,II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235358-I)
00015595	Threewitt, T. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4931 I,II. (Unpublished study received Oct 20, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 235358-J)

BIBLIOGRAPHY

MRID	CITATION
00015597	Buchholz, C. (1978) Metolachlor (Dual 8E); Cyanazine (Bladex 80W): AG-A No. 4752 I,II. (Unpublished study received Oct 20, 1978 under 100-583; prepared in cooperation with Shell Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235359-B)
00015598	Rose, W.; Monaco, T. (1978) Metolachlor (Dual 8E); Cyanazine (Bladex 4WDS): AG-A No. 4810. (Unpublished study received Oct 20, 1978 under 100-583; prepared in cooperation with Shell Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235359-C)
00015599	Turner, W. (1978) Metolachlor (Dual 8E); Cyanazine (Bladex 80W); Cyanazine (Bladex 4WDS): AG-A No. 4864 I,II. (Unpublished study received Oct 20, 1978 under 100-583; prepared in coopera- tion with Shell Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235359-D)
00015600	Stahlberg, L. (1978) Metolachlor (Dual 8E); Cyanazine (Bladex 80W): AG-A No. 4875 I,II. (Unpublished study received Oct 20, 1978 under 100-583; prepared in cooperation with Shell Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235359-E)
00015601	Clarkson, V. (1978) Metolachlor (Dual 8E); Cyanazine (Bladex 80W): AG-A No. 4972 I,II. (Unpublished study received Oct 20, 1978 under 100-583; prepared in cooperation with Shell Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235359-F)
00015602	Wustner, D.A. (1978) Metolachlor (Dual 8E); Cyanazine (Bladex 4L): AG-A No. 6013. (Unpublished study received Oct 20, 1978 under 100-583; prepared in cooperation with Shell Oil Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 235359-G)
00015631	Sachsse, K.; Ullmann, L. (1977) Skin Sensitizing (Contact Allergenic) Effect in Guinea Pigs of Technical CGA 24705: Project No. Siss 5726. (Unpublished study received Jan 18, 1978 under 100-583; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:096717-F)
00015652	Sumner, D.D.; Cassidy, J.E. (1974) The Metabolism of CGA-24705 in Corn: Report No. GAAC-74050. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094217-D)

BIBLIOGRAPHY

MRID	CITATION
00015653	Gross, D. (1974) Uptake, Translocation and Degradation of CGA 24 705 in Corn Grown under Controlled Conditions: Project Report No. 8/74. (Unpublished study received Sep 26, 1974 under 5G1553; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094217-F)
00015676	Tharrington, W.H. (1974) Residue Report: Field Corn: AG-A No. 2967. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-B)
00015677	Thetford, L.; Snow, J.G. (1974) Residue Report: Field Corn: AG-A No. 2972. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094216-C)
00015678	Roper, J. (1974) Residue Report: Field Corn: AG-A No. 2982. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-D)
00015679	Schnappinger, M.G. (1974) Residue Report: Sweet Corn: AG-A No. 3005. (Unpublished study received Sep 26, 1974 under
00015679	5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094216-E)
00015680	Anliker, W. (1974) Residue Report: Sweet Corn: AG-A No. 3083. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-G)
00015681	Davidson, W.E. (1974) Residue Report: Field Corn: AG-A No. 3103. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-H)
00015682	Shriver, J.; Conterio, W.A. (1974) Residue Report: Field Corn: AG-A No. 3132. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094216-I)
00015683	Shriver, J.; Guthrie, C.A. (1974) Residue Report: Field Corn: AG-A No. 3137. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094216-J)

BIBLIOGRAPHY

MRID	CITATION
00015684	Fickle, J. (1974) Residue Report: Field Corn: AG-A No. 3141. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-K)
00015685	Kincaid, L. (1974) Residue Report: Sweet Corn: AG-A No. 3153. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-L)
00015686	Ross, R.H. (1974) Residue Report: Field Corn: AG-A No. 3255. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-M)
00015687	Snow, J.G. (1974) Residue Report: Sweet Corn: AG-A No. 2974. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-N)
00015688	Westmoreland, W.G. (1974) Residue Report: Field Corn: AG-A No. 3070. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094216-P)
00015689	Snow, J.G. (1974) Residue Report: Field Corn: AG-A No. 3288. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-Q)
00015690	Stahlberg, L.; Peek, J. (1974) Residue Report: Field Corn: AG-A No. 3289. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094216-R)
00015691	Roper, J.; Thomas, J.; Herman, D. (1974) Residue Report: Field Corn: AG-A No. 3298. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-S)
00015692	Roper, J.; Thomas, J.; Herman, D. (1974) Residue Report: Field Corn: AG-A No. 3299. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-T)
00015693	Kern, C.L. (1974) Residue Report: Field Corn: AG-A No. 3325. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-U)

BIBLIOGRAPHY

MRID	CITATION
00015694	Juby, M. (1974) Residue Report: Field Corn: AG-A No. 3327. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-V)
00015698	Hormann, W.D.; Guth, J.A.; Formica, G.; et al. (1974) CGA 24705: Gas Chromatographic Determination of Total Residues in Material of Animal Origin (Provisional). Method no. REM 5/74 dated Jun 26, 1974. (Unpublished study received Sep 26, 1974 under 5G1553; prepared by Ciba-Geigy, Ltd., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-Z)
00015704	Juby, M. (1974) Residue Report: Field Corn: AG-A No. 3328. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-AK)
00015705	Kern, C.L. (1974) Residue Report: Field Corn: AG-A No. 3326. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-AL)
00015706	Kahrs, R.A. (1978) Summary: Residue Chemistry Data to Establish Tolerances for Residues of Metolachlor in Corn Forage and Fodder, Soybean Forage and Fodder, and Fresh Corn, including Sweet Corn (Kernels plus Cobs, Husks Removed): Report No. ABR- 78028. Summary of studies 094216-B, 094216-C, 094216-E through 094216-K, 094216-M, 094216-N, 094216-P through 094216-V, 094216-AK, 094216-AL, 094379-D, 094379-O, 094379-P, 094379-T, 094379-AB, 097134-Q, 097134-S, 097134-X, 097134-AE through 097134-AI, 097134-AO through 097134-AT, 228126-E through 228126-H, 228126-J, 230685-G, and 230685-H. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., greensboro, N.C.; CDL:097133-A)
00015707	Snow, J.G.; Tinklepaugh, ? (1976) Residue Report: Field Corn: AG-A No. 3799 II,III. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097134-S)
00015708	Ross, R.H. (1978) Metolachlor (Dual 8E): AG-A No. 4855 I,II, Second Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097134-AE)

BIBLIOGRAPHY

MRID	CITATION
00015709	Turner, W.E. (1978) Metolachlor (Dual 8E): AG-A No. 4860 I,II Second Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097134-AF)
00015710	Stahlberg, L. (1978) Metolachlor (Dual 8E): AG-A No. 4873 I, II, 2nd Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097134-AG)
00015711	Turner, W.E. (1978) Metolachlor + Atrazine (Dual 8E + AAtrex 4L): AG-A No. 4861 I,II Second Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:097134-AH)
00015712	Stahlberg, L. (1978) Metolachlor + Atrazine (Dual 8E + AAtrex 4L): AG-A No. 4874 I,II Second Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:097134-AI)
00015713	Buchholz, C. (1978) Metolachlor (Dual 8E): AG-A No. 4749 I, II. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097134-AO)
00015714	Rose, W.E.; Monaco, T. (1978) Metolachlor (Dual 8E): AG-A No. 4806. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097134-AP)
00015715	Clarkson, V. (1978) Metolachlor (Dual 8E): AG-A No. 4974. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097134-AQ)
00015716	Buchholz, C. (1978) Metolachlor + Atrazine (Dual 8E) + (AAtrex 80W): AG-A No. 4748 I, II. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097134-AR)
00015717	Rose, W.; Monaco, T. (1978) Metolachlor + Atrazine (Dual 8E) + (AAtrex 4L): AG-A No. 4807. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097134-AS)

BIBLIOGRAPHY

MRID	CITATION
00015718	Clarkson, V. (1978) Metolachlor, Atrazine (Dual 8E, AA- trey 80W): AG-A No. 4975. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:097134-AT)
00015719	Ross, R.H.; Pruss, S. (1976) Residue Report: Soybeans: AG-A No. 3650 I,II. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097135-A)
00015721	Shriver, J.; Wendling, C. (1976) Residue Report: Soybeans: AG-A No. 3747 II. 2nd Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-D)
00015722	Pruss, S.; Schnappinger, M.G. (1976) Residue Report: Soybeans: AG-A No. 3775 II. 2nd report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-E)
00015723	Peek, J.; Stahlberg, L. (1976) Residue Report: Soybeans: AG-A No. 3782. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-F)
00015725	Pruss, S.W.; Luke, J.E. (1976) Residue Report: Soybeans: AG-A No. 3885. 2nd Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-H)
00015726	Richards, R.F. (1976) Residue Report: Soybeans: AG-A No. 3948. 2nd Report. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-I)
00015727	Shriver, J.; Wendling, C. (1976) Residue Report: Soybeans: AG-A No. 3743. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-J)

BIBLIOGRAPHY

MRID	CITATION
00015728	Schnappinger, M.G.; Pruss, S.W. (1976) Residue Report: Soybeans: AG-A No. 3776. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-K)
00015729	Peek, J.; Stahlberg, L. (1976) Residue Report: Soybeans: AG-A No. 3780. (Unpublished study received May 11, 1978 under 100- 583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097135-L)
00015731	Shriver, J.; Wendling, C. (1977) Residue Report: Soybeans: AG-A No. 3742. (Unpublished study received May 11, 1978 under 100- 583; prepared in cooperation with Mobay Chemical Corp. and Analytical Biochemistry Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-O)
00015732	Gaspard, J.T. (1977) Residue Report: Soybeans: AG-A No. 3758. (Unpublished study received May 11, 1978 under 100-583; prepared in cooperation with Mobay Chemical Corp. and Analytical Biochemistry Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-P)
00015733	Westmoreland, W.G. (1977) Residue Report: Soybeans: AG-A No. 3764. (Unpublished study received May 11, 1978 under 100-583; prepared in cooperation with Mobay Chemical Corp. and Analytical Biochemistry Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-Q)
00015734	Peek, J.; Stahlberg, L. (1977) Residue Report: Soybeans: AG-A No. 3778. (Unpublished study received May 11, 1978 under 100- 583; prepared in cooperation with Mobay Chemical Corp. and Ana- lytical Biochemistry Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-R)
00015735	Luke, J. (1978) Metolachlor (Dual 8E): AG-A No. 4737 I,II. (Unpublished study received May 11, 1978 under 100-583; sub- mitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-T)
00015736	Kern, C. (1978) Metolachlor (Dual 8E): AG-A No. 4781 I,II. (Unpublished study received May 11, 1978 under 100-583; sub- mitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-U)

BIBLIOGRAPHY

MRID	CITATION
00015737	Herman, D. (1978) Metolachlor (Dual 8E): AG-A No. 4986 I,II. (Unpublished study received May 11, 1978 under 100-583; sub- mitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097135-V)
00015739	Chamberlain, E.; Stahlberg, L. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex 80W & 4L): AG-A No. 4790 I,II,III. (Unpublished study received Mar 16, 1979 under 100-583; prepared in coopera- tion with EN-CAS Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-B)
00015740	Luke, J.E. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex 80W +4L): AG-A No. 4811 I,II,III. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS An- alytical Laboratories, submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:237817-C)
00015741	Turner, W.E. (1978) Metolachlor (Dual8E); Atrazine (AAtrex 4L): AG-A No. 4862 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Texas Agricultural Experiment Station and EN-CAS Analytical Laborato- ries, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237817-D)
00015742	Dorr, J.; Buchholz, C. (1978) Metolachlor (Dual 6E); Atrazine (AAtrex 4L): AG-A No. 4750 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS An- alytical Laboratories, submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:237817-E)
00015743	Chamberlain, E.; Stahlberg, L. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex80W): AG-A No. 4791. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analytical Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-F)
00015744	Rose, W.; Monaco, T. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex 4L): AG-A No. 4808. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analyti- cal Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-G)
00015745	Chamberlain, E.; Stahlberg, L. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4792 I,II,III. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analytical Laboratories,

BIBLIOGRAPHY

MRID	CITATION

submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-H)

00015746 Luke, J.E. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4812 I,II,III. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analytical Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-I)

00015747 Turner, W.E. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4863 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Texas Agricultural Experiment Station and EN-CAS Analytical Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-J)

00015748 Dorr, J.; Buchholz, C. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4751 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analytical Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237817-K)

00015749 Chamberlain, E.; Stahlberg, L. (1979) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4793 A. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analytical Laboratories, submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:237817-L)

00015750 Rose, W.; Monaco, T. (1978) Metolachlor + Atrazine (Bicep 4.5L): AG-A No. 4809. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Analytical Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237817-M)

00015751 Rose, W.; Worsham, D.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex 80W); Paraquat (Paraquat CL): AG-A No. 4959 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Labora- tories and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237819-F)

00015752 Kern, C.L.; Staniforth, D.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex 80W or 4L); Paraquat (Paraquat CL): AG-A No. 5000 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Iowa State Univ., EN-CAS Laboratories and Chevron Chemical Co., sub- mitted by Ciba-Geigy Corp., Greensboro, N.C.;

BIBLIOGRAPHY

MRID	CITATION
	CDL:237819-H)
00015753	Schnappinger, M.G. (1979) Metolachlor (Dual 8E); Atrazine (AAtrex 80W); Glyphosate (Roundup 4E): AG-A No. 4888 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Laboratories and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237819-I)
00015754	Rose, W.; Worsham, D. (1979) Metolachlor (Dual 8E); Atrazine (AAtrex 80W); Glyphosate (Roundup 4E): AG-A No. 4960 I, II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Laboratories and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237819-J)
00015755	Searcy, S.; Herman, D. (1979) Metolachlor (Dual 8E); Atrazine (AAtrex 4L); Glyphosate (Roundup 4E): AG-A No. 4983 I, II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Laboratories and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237819-K)
00015756	Kern, C.L.; Staniforth, D. (1979) Metolachlor (Dual 8E); Atrazine (AAtrex 80W or 4L); Glyphosate (Roundup 4E): AG-A No. 4999 I, II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Iowa State Univ., EN-CAS Labora- tories and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237819-L)
00015757	Dorr, J.; Buchholz, C. (1979) Metolachlor (Dual 8E); Atrazine (AAtrex 4L); Glyphosate (Roundup 4E): AG-A No. 5004. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with EN-CAS Laboratories and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237819-M)
00015760	Kincaid, L. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4763 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-B)

BIBLIOGRAPHY

MRID	CITATION
00015761	Schnappinger, M.G. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4886 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.: CDL:237821-C)
00015762	Searcy, V.; Herman, D. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4893 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Rig- gleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and ADC Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-D)
00015763	Rose, W.; Worsham, D. (1979) Metolachlor + Glyphosate + Linuron; Dual 8E + Roundup 4E + Lorox 50W: AG-A No. 4956 I,II A. (Unpublished study including letter dated May 23, 1978 from J.D. Rig- gleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with Rocky Mount Experiment Station, ADC Laboratories and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-E)
00015764	Kincaid, L. (1979) Metolachlor (Dual 8E); Glyphosate (Roundup 4E); Metribuzin (Sencor 50W): AG-A No. 4765 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with ADC Laboratories and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-F)
00015765	Schnappinger, M.G. (1978) Metolachlor (Dual 8E); Glyphosate (Round- up 4E); Metribuzin (Sencor 50W): AG-A No. 4887 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with ADC Laboratories and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:237821-G)
00015766	Searcy, S.; Herman, D. (1979) Metolachlor (Dual 8E); Glyphosate (Roundup 4E); Metribuzin (Sencor 50W): AG-A No. 4895 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs,

BIBLIOGRAPHY

MRID	CITATION
	received Mar 16, 1979 under 100- 583; prepared in cooperation with ADC Laboratories and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-H)
00015767	Rose, W.; Worsham, D. (1979) Metolachlor (Dual 8E); Glyphosate (Roundup 4E); Metribuzin (Sencor 50W): AG-A No. 4958 I,II A. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100- 583; prepared in cooperation with ADC Laboratories and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-I)
00015768	Kincaid, L.; Slagowski, J.L. (1978) Metolachlor + Linuron + Para- quat; Dual 8E + Lorox 50W + Paraquat 2CL: AG-A No. 4762 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100- 583; prepared in cooperation with Chevron Chemical Co. and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-J)
00015769	Searcy, V.; Herman, D.; Slagowski, J.L. (1978) Metolachlor + Linuron + Paraquat: Dual 8E + Lorox 50W + Paraquat 2CL: AG-A No. 4892 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with Chevron Chemical Co. and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-L)
00015770	Schnappinger, M.G.; Slagowski, J.L. (1978) Metolachlor + Linuron + Paraquat (Dual 8E + Lorox 50W + Paraquat 2CL): AG-A No. 4915 I, II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with Chevron Chemical Co. and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-L)
00015771	Rose, W.; Worsham, D.; Slagowski, J.L. (1978) Metolachlor + Linuron + Paraquat: Dual 8E + Lorox 50W + Paraquat 2CL: AG-A No. 4955 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with Rocky Mount Experiment Station, Chevron Chemical Co. and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-M)

BIBLIOGRAPHY

MRID	CITATION
00015772	Kincaid, L.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Metribuzin (Sencor 50W); Paraquat (2Cl): AG-A No. 4764 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-M)
00015773	Searcy, S.; Herman, D.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Metribuzin (Sencor 50W); Paraquat (2Cl): AG-A No. 4894 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-O)
00015774	Schnappinger, M.G.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Metribuzin (Sencor 50W); Paraquat (2 Cl): AG-A No. 4916 I, II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-P)
00015775	Rose, W.; Worsham, D.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Metribuzin (Sencor 50W); Paraquat (Cl): AG-A No. 4957 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with E.I. du Pont de Nemours & Co., Inc. and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-Q)
00015777	Stahlberg, L. (1978) Metolachlor (Dual 8E); Naptalam + DNBP (Dya nap 3E): AG-A No. 4728 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Biospher- ics, Inc. for Uniroyal Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237822-B)
00015778	Herman, D. (1978) Metolachlor (Dual 8E); Naptalam + DNBP (Dyanap 3E): AG-A No. 4896 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Biospherics, Inc. for Uniroyal Chemical Co., submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:237822-C)

BIBLIOGRAPHY

MRID	CITATION
00015779	Schnappinger, M.G. (1978) Metolachlor (Dual 8E); Naptalam + DNBP (Dyanap 3E): AG-A No. 4934 I,II. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Biospherics, Inc. for Uniroyal Chemical Co., submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:237822-D)
00015780	Dill, R. (1978) Metolachlor (Dual 8E); Naptalam + DNBP (Dyanap 3E): AG-A No. 5053. (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Biospherics, Inc. for Uniroyal Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237822-E)
00015786	Chamberlain, E.; Taylor, T.D. (1978) Metolachlor, Dual 8E; Dicamba, Banvel: AG-A No. 4865 I, II. (Unpublished study received Mar 16, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237818-E)
00015787	Chamberlain, E.; Kern, C.L. (1978) Metolachlor, Dual 8E; Dicamba, Banvel: AG-A No. 4948 I,II. (Unpublished study received Mar 16, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237818-F)
00015950	Shriver, J.; Guthrie, C. (1975) Residue Report: Field Corn: AG-A No. 3406 II. (Unpublished study received Mar 26, 1975 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094379-AB)
00015954	Turner, W.E. (1974) Residue Report: Field Corn: AG-A No. 3057. (Unpublished study received Sep 26, 1974 under 5G1553; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094216-F)
00015955	Luke, J.E.; Slagowski, J.L. (1978) Metolachlor (Dual 8E); Atrazine (AAtrex 80W); Paraquat (Paraquat CL): AG-A No. 4964. (Unpublished study received Mar 16, 1979 under 100- 583; prepared in cooperation with EN-CAS Laboratories and Chev- ron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237819-G)
00016248	Richards, R.F. (1976) Residue Report: Soybeans: AG-A No. 3948. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095747-U)
00016306	Hermes, P. (1972) Biphasic Extraction of Radioactive Metabolites from

BIBLIOGRAPHY

MRID	CITATION
	Treated Biological Material. Method no. AG-214 dated Aug 15, 1972. (Unpublished study received Sep 26, 1974 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094385-Q)
00016392	Houseworth, L.D.; Rolla, H. (1977) Residues of Metolachlor and Atrazine in or on Corn Grain Resulting from Tank Mix Applications with and without Liquid Fertilizer--Preplant Incorporated and Preemergence Applications: Report No. ABR-77017. (Unpub- lished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-A)
00016393	Seim, V. (1976) Residue Report: Field Corn: AG-A No. 3672 II-III. (Unpublished study received Feb 18, 1977 under 100-583; sub- mitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-D)
00016394	Seim, V. (1976) Residue Report: Field Corn: AG-A No. 3673 I,II,III. (Unpublished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-E)
00016395	Ragsdale, D.; Stahlberg, L. (1976) Residue Report: Field Corn: AG-A No. 3704 I,II. (Unpublished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-F)
00016396	Taylor, T.D.; Shriver, J.; Wendling, C. (1976) Residue Report: Field Corn: AG-A No. 3734 I,II,III. (Unpublished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-G)
00016397	Shriver, J.; Wendling, C. (1976) Residue Report: Field Corn: AG-A No. 3735 I,II,III. (Unpublished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-H)
00016398	Snow, J.G.; Tinklepaugh, ? (1976) Residue Report: Field Corn: AG-A No. 3799 II,III. (Unpublished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 228126-I)
00016399	Thetford, L.; Snow, J.G.; Tinklepaugh, ? (1976) Residue Report: Sweet Corn: AG-A No. 3858. (Unpublished study received Feb 18, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:228126-J)
00016425	Fink, R. (1974) Final Report: Eight-Day Dietary LC50--Mallard Ducks:

BIBLIOGRAPHY

MRID	CITATION
	Project No. 108-111. (Unpublished study received on unknown date under 5G1553; prepared by Truslow Farms, Inc. in cooperation with Maryland, Dept. of Agriculture, Div. of Inspection and Regulation, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-O)
00016426	Fink, R. (1974) Final Report: Eight-Day Dietary LC50--Bobwhite Quail: Project No. 108-110. (Unpublished study received on unknown date under 5G1553; prepared by Truslow Farms, Inc. in cooperation with Maryland, Dept. of Agriculture, Div. of Inspection and Regulation, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094220-P)
00016427	Kahrs, R.A. (1979) Residues of Metolachlor and Chloramben in Soybeans Resulting from Preemergence or Preplant Incorporated Applications: Report No. ABR-79068. Summary of studies 238677-B through 238677-D. (Unpublished study received Jun 20, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:238677-A)
00016435	Houseworth, L.D. (1977) Residues of Metolachlor and Dicamba in or on Corn Grain Resulting from Preemergence Tank Mix Applications: Report No. ABR-77071. Summary of studies 232192-B through 232192-D. (Unpublished study received Nov 10, 1977 under 100- EX-59; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 232192-A)
00016436	Chamberlain, E.; Coan, R.M. (1977) Residue Report: Field Corn: AG-A No. 4253 II. (Unpublished study received Nov 10, 1977 under 100-EX-59; prepared in cooperation with Velsicol Chemical Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:232192-B)
00016437	Chamberlain, E.; Kern, C.L. (1977) Residue Report: Field Corn: AG-A No. 4264 II. (Unpublished study received Nov 10, 1977 under 100-EX-59; prepared in cooperation with Velsicol Chemical Corp. and Craven Laboratories, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:232192-C)
00016604	Shriver, J.; Wendling, C. (1976) Residue Report: Soybeans: AG-A No. 3724. (Unpublished study received May 11, 1978 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 097135-C)
00016607	Cheung, M.W.; Kahrs, R.A. (1979) Residues in Sorghum Resulting from

BIBLIOGRAPHY

MRID	CITATION
	Applications of Milocep 5L--Preplant Incorporated and Preemergence Applications: Report No. ABR-79015. Summary of studies 237815-B through 237815-F. (Unpublished study received Mar 16, 1979 under 100-604; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237815-A)
00016608	Davidson, W.E. (1979) Metolachlor-Propazine (Milocep 5L): AG-A No. 5159 I-II A. (Unpublished study received Mar 16, 1979 under 100-604; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237815-B)
00016609	Dill, R. (1978) Metolachlor + Propazine (Milocep 5L): AG-A No. 5176 A. (Unpublished study received Mar 16, 1979 under 100- 604; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237815-C)
00016610	Dill, R. (1978) Metolachlor-Propazine (Milocep 5L): AG-A No. 5176 II. (Unpublished study received Mar 16, 1979 under 100-604; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 237815-D)
00016990	Davidson, W.E. (1978) Metolachlor + Propazine; Dual 8E + Milo- gard 4L: Grain Sorghum: AG-A No. 4883 II A. (Unpublished study received Nov 24, 1978 under 100-EX-62; submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:235981-B)
00016991	Chamberlain, E.; Threewitt, T. (1978) Metolachlor + Propazine; Dual 8E + Milogard 80W: Grain Sorghum: AG-A No. 4926 II B. (Unpublished study received Nov 24, 1978 under 100-EX-62; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:235981-C)
00016992	Turner, W.E. (1978) Metolachlor + Propazine; Dual 8E + Milogard 80W: Grain Sorghum: AG-A No. 4995 A. (Unpublished study received Nov 24, 1978 under 100-EX-62; submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:235981-D)
00018722	Buccafusco, R.J.; Stiefel, C.; Sullivan, D.M.; et al. (1978) Acute Toxicity of CGA-24705 to Rainbow Trout (µSalmo gairdneri): Report #BW-78-6-186. (Unpublished study received Jul 13, 1978 under 100-597; prepared by EG&G, Bionomics, submitted by Ciba- Geigy Corp., Greensboro, N.C.; CDL:234396-B)
00018723	Buccafusco, R.J.; Stiefel, C.; Sullivan, D.M. (1978) Acute Toxicity of

BIBLIOGRAPHY

MRID	CITATION
	CGA-24705 to Bluegill (Lepomis macrochirus): Report #BW- 78-6-181. (Unpublished study received Jul 13, 1978 under 100-597; prepared by EG&G, Bionomics, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:234396-C)
00022872	Sumner, D.D.; Cassidy, J.E. (1975) The Uptake and Distribution of Phenyl-14C-CGA-24705 from Soil in Greenhouse Grown Soybeans: Report No. GAAC 75039. (Unpublished study received Jan 19, 1977 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:095750-F)
00022873	Sumner, D.; Cassidy, J. (1974) The Uptake and Distribution of Phenyl-14C-CGA-24705 from Soil in Greenhouse Grown Corn: Report No. GAAC-74015. (Unpublished study received Sep 26, 1974 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 094385-B)
00022874	Sumner, D.; Cassidy, J. (1974) The Uptake and Distribution of Phenyl-14C-CGA-24705 in Field Grown Corn: Report No. GAAC-74022. (Unpublished study received Sep 26, 1974 under 5F1606; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:093485-C)
00022879	Szolics, I.M.; Cassidy, J.E. (1978) The Uptake and Balance of Phenyl-14C-Metolachlor in Field Rotation Lettuce Planted in the Fall: Report No. ABR-78085. (Unpublished study received Aug 1, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:238899-C)
00022880	Szolics, I.M.; Cassidy, J.E. (1978) The Uptake and Balance of Phenyl 14C-Metolachlor in Field Rotation Lettuce Planted in the Spring: Report No. ABR-78086. (Unpublished study received Aug 1, 1979 under 100-583; submitted by Ciba-Geigy Corp., Greens- boro, N.C.; CDL:238899-D)
00026712	Bruhl, ? (1979) SN 66 752 Residues in Tobacco Plants, Cured Leaves, and Cigarette Smoke. (Unpublished study received Dec 13, 1979 under 2139-EX-24; prepared by Schering, AG, submitted by Nor-Am Agricultural Products, Inc., Naperville, Ill.; CDL:241517-D)
00026713	Pitblado, R.; Hawf, L.R.; Glaze, N.; et al. (1975) Analysis of Lima Beans for Possible Residues of Chloramben. (Unpublished study received May 23, 1975 under 264-266; prepared by Ridgetown Col- lege of Agriculture & Technology and others, submitted by Union Carbide Agricultural Products Co., Ambler,

BIBLIOGRAPHY

MRID	CITATION

Pa.; CDL:195120-B)

00032174 Jessup, D.C.; Arceo, R.J.; Estes, F.L.; et al. (1980) 6-Month Chronic Oral Toxicity Study in Beagle Dogs: IRDC No. 382-054. (Unpublished study received Jun 5, 1980 under 100-587; prepared by International Research and Development Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:242672-A)

00039174 Seim, V.; Peek, J.; Stahlberg, L.; et al. (1975) Residue Report: Soybeans: AG-A No. 3268 I,II,III. (Unpublished study including AG-A nos. 3466 I,II, 3523 I,II,III, 3570 I,II,III…, received Nov 25, 1975 under 6G1708; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094878-A)

00039176 Ciba-Geigy, Limited (19??) CGA 24 705 Feeding Study in Milk Cows: Methods. (Unpublished study received Nov 25, 1975 under 6G1708; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:094878-D)

00041283 Lightkep, G.E.; Christian, M.S.; Christian, G.D.; et al. (1980) Teratogenic Potential of CGA-24705 in New Zealand White Rabbits: Segment II Evaluation--Project 203-001. (Unpublished study received Sep 15, 1980 under 100-597; prepared by Argus Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:099630-A)

00042725 Marias, A.J.; Gesme, J.; Albanese, E.; et al. (1977) Report to Ciba-Geigy Corporation: Carcinogenicity Study with CGA-24705 Technical in Albino Mice: IBT No. 622-07925 (8532-07925). (Unpublished study including submitter summary, received Jan 18, 1978 under 100-583; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 096719-A; 096720)

00062465 Fink, R.; Beavers, J.B.; Brown, R.; et al. (1981) Final Report: Acute Oral LD50--Mallard Duck: Project No. 108-200. (Unpublished study received Mar 31, 1981 under 100-587; prepared by Wildlife International, Ltd. and Washington College, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:244691-B)

00064182 Ciba-Geigy Corporation (1980) [Residue of Dual 8E and Eptam 6E on Kidney Beans and Various Other Beans]. (Compilation; unpub- lished study received Mar 31, 1981 under 100-597; CDL:099988-B)

BIBLIOGRAPHY

MRID	CITATION
00065048	Ciba-Geigy Corporation (1981) [Residue Tests with Cotton]. (Compilation; unpublished study received Apr 28, 1981 under 100-597; CDL:070049-B)
00074898	Szolics, I.M.; Simoneaux, B.J.; Cassidy, J.E. (1981) The Uptake and Distribution of Phenyl-14C-metolachlor from Soil in Greenhouse Grown Potatoes: ABR-81023. (Unpublished study received Jul 15, 1981 under 100-597; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070182-B)
00074900	Szolics, I.M.; Simoneaux, B.J.; Cassidy, J.E. (1981) The Uptake and Distribution of Phenyl-14C-metolachlor from Soil in Greenhouse Grown Lettuce: ABR-81021. (Unpublished study received Jul 15, 1981 under 100-597; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:070182-D)
00078297	Ciba-Geigy Corporation (1981) [Tests for Residues in Various Crops and Soil]. (Compilation; unpublished study received Jul 23, 1981 under 100-587; CDL:245628-A)
00080897	Smith, S.H.; O'Loughlin, C.K.; Salamon, C.M.; et al. (1981) Two-generation Reproduction Study in Albino Rats with Metolachlor Technical: Study No. 450-0272. Final rept. (Unpublished study received Sep 30, 1981 under 100-597; prepared by Whittaker Corp., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:245959-A; 245960; 245961)
00084003	Marias, A.J.; Gesme, J.; Albanese, E.; et al. (1977) Revised Final Report to Ciba-Geigy Corporation: Carcinogenicity Study with CGA-24705 Technical in Albino Mice: IBT No. 622-07925 (8532- 07925). (Unpublished study received Jul 7, 1978 under 100-583; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:097169-A; 097170)
00105957	Ciba-Geigy Corp. (1982) Residues in or on Potato Tubers Resulting from 4.0 Lbs. AI/A Preemergence Applications of Dual 8E or Sequential Applications of Dual 8E + Sencor/Lexone Tank Mix Preemergence Followed by Dual 8E at Layby. (Compilation; unpublished study received Jun 25, 1982 under 100-597; CDL:247756-A)
00106191	Houseworth, L. (1979) Residues of Metolachlor and Metribuzin in Potato Tubers Resulting from the Use of Metolachlor and Metolachlor/Metribuzin Tank Mixes for Weed Control in Potato Cu ture: Report No.: ABR-79040. (Unpublished study received Apr 25, 1979 under 100-583; submitted by

BIBLIOGRAPHY

MRID	CITATION
	Ciba-Geigy Corp., Greens- boro, NC; CDL:098227-A)
00109613	Ciba-Geigy Corp. (1982) Metolachlor Residues Resulting from the Application of Dual 15G to Potatoes: Report # ABR-82036. (Compilation; unpublished study received Aug 12, 1982 under 100-638; CDL:248087-A)
00111693	Ciba-Geigy Corp. (1979) Summary of Metolachlor Residues in Sorghum Milling Fractions: Report No. ABR-79036. (Compilation; unpublished study received Mar 16, 1979 under 8F2098; CDL:098010-A)
00117597	Tisdel, M.; MacWilliams, P.; Dahlgren, R.; et al. (1982) Carcinogenicity Study with Metolachlor in Albino Mice: Study No. 79020. (Unpublished study received Nov 2, 1982 under 100-587; prepared by Hazleton Laboratories America, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:248722-A; 248723; 248724; 248725)
00125227	Ciba-Geigy Corp. (1975) Procyazine--Corn: Tank Mixes with CGA-24705 with and without Fertilizers: Preemergence and Preplant Incorporated Applications: Procyazine Plus CGA-24705--15% Granule: Summary of Residue Data. (Compilation; unpublished study received Nov 6, 1975 under 4G1469; CDL:095190-A)
00128731	Ciba-Geigy Corp. (1983) Residues in Forage and Fodder of Vegetable Pod Crops Resulting from Preplant Incorporated or Preemergence Applications of Dual 8E, Dual 8E + Premerge 3 or Dual 8E + Eptam 7E. (Compilation; unpublished study received Jun 16, 1983 under 100-597; CDL:071705-A)
00129058	Cargile, N. (1983) Letter sent to C. Brinkley dated Mar 7, 1983: Dual/cotton 24 (C) supportive data. (Unpublished study received Jun 24, 1983 under AZ 83/5; prepared by Ciba-Geigy Corp., submitted by State of Arizona, Phoenix, AZ; CDL:250597-A)
00129377	Tisdel, M.; Jackson, T.; MacWilliams, P.; et al. (1983) Two-year Chronic Oral Toxicity and Oncogenicity Study with Metolachlor in Albino Rats: Study No. 80030. Final rept. (Unpublished study received May 24, 1983 under 100-587; prepared by Hazleton Raltech, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL: 250369-A; 250370; 250371; 250372; 250373; 250374; 250375)

BIBLIOGRAPHY

MRID	CITATION
00131376	Ciba-Geigy Corp. (1983) Residues in or on Stone Fruit Resulting from Applications of Dual 8E Alone, or in Tank Mixture with Princep 80W or Princep Caliber 90. (Compilation; unpublished study received Sep 7, 1983 under 100-597; CDL:071927-A)
00150180	Interregional Research Project No. 4 (1984) The Results of Tests on the Amount of Metolachlor Residues Remaining in or on Chili Peppers. Unpublished compilation. 36 p.
00151941	Lochry, E. (1985) Embryo/Fetal Toxicity and Teratogenic Potential Study of CGA-24705 (…) Administered Orally Via Gavage to (…) Presumed Pregnant Rats: Final Report: Project No. 203-004. Unpublished study prepared by Argus Research Laboratories, Inc. 178 p.
00156573	Interregional Research Project No. 4 (1986) Petition Proposing a Tolerance for Metolachlor for Use in Tabasco Pepper Production in Louisiana. Unpublished study. 122 p. study. 122 p.
40114401	Orr, G. (1987) Disposition of Metolachlor in the Rat: (General Metabolism): Laboratory/Study No. ABR-86111. Unpublished study prepared by Ciba-Geigy Corp. 78 p.
40276601	Brown, R.; Lail, L. (1987) Technical Metolachlor: Product Chemistry Data: Study No. PC-87-019. Unpublished compilation prepared by Ciba-Geigy Corp. 80 p.
40276602	Brown, R.; Lail, L. (1987) Technical Metolachlor: Product Chemistry Data: Study No. PC-87-019. Unpublished compilation prepared by Ciba-Geigy Corp. 115 p.
40430201	Spare, W. (1987) Determination of the Hydrolysis Rate Constants of Metolachlor: Agrisearch Project No. 1263. Unpublished study prepared by Agrisearch Inc. 41 p.
40430202	Spare, W. (1987) Determination of the Solution Photolysis Rate Constants and Photodegradation Products of Metolachlor Under Natural and Artificial Light: Laboratory Study No. 1261. Unpublished study prepared by Agrisearch Inc. 63 p.

BIBLIOGRAPHY

MRID	CITATION
40430203	Spare, W. (1987) Soil Photolysis of Metolachlor Under Natural and Artifical Light: Laboratory Study No. 1262. Unpublished study prepared by Agrisearch Inc. 77 p.
40494602	Spare, W. (1987) Leaching Characteristics of Parent Metolachlor: Laboratory Study No. 1234. Unpubllshed study prepared by Agrisearch, Inc. 77 p.
40494603	Spare, W. (1987) Leaching Characteristics of Aged Metolachlor: Laboratory Study No. 1233. Unpublished study prepared by Agrisearch, Inc. 53 p.
40494604	Spare, W. (1987) Determination of Adsorption/Desorption Constants of Metolachlor: Agrisearch Project No. 1235. Unpublished study prepared by Agrisearch, Inc. 79 p.
40494605	Spare, W. (1988) Determinations of Adsorption/Desorption Constants of CGA-51202: Agrisearch Project No. 1266. Unpublished study prepared by Agrisearch, Inc. 66 p.
40494606	Spare, W. (1987) The Volatilization of Metolachlor from Soil (A Laboratory Study): Agrisearch Project No. 1260. Unpublished study prepared by Agrisearch, Inc. 60 p.
40557301	Baron, J. (1988) Metolachlor--Magnitude of Residue on Bell Pepper: Project ID: PR 1524. Unpublished study prepared by USDA Analytical Laboratories. 201 p.
40644901	Baron, J. (1988) Metolachlor--Magnitude of Residue on Cabbage: Project ID: IR-4 PR 1527. Unpublished study prepared by USDA Analytical Laboratory. 277 p.
40766601	Simoneaux, B. (1988) Uptake and Characterization of Metolachlor and its Metabolites in Field and Greenhouse Grown Potatoes: Laborat ory Study No. ABR-88110. Unpublished study prepared by Ciba-Geigy Corp. 104 p.
40899301	Baron, J. (1988?) Metolachlor--Magnitude of Residue on Cubanelle Peppers: Project ID: IR-4 Project 3829. Unpublished study prepared by USDA Environmental Chemistry Laboratory. 77 p.
40980701	Hazelette, J. (1989) Metolachlor Technical: Chronic Toxicity Study in Dogs:

BIBLIOGRAPHY

MRID	CITATION

Study No. 862253. Unpublished study prepared by Ciba-Geigy Corp. 758 p.

40980703 Cheung, M. (1989) Residue Stability Study of CGA-37913 and CGA- 49751 (Metolachlor Metabolites) in Beef Muscle, Beef Liver, Dairy Milk, and Poultry Eggs Under Freezer Storage Conditions (One-Year Interim Report): Project ID: ABR-88166. Unpublished study prepared by Ciba-Geigy Corp. 65 p.

40980704 Cheung, M. (1989) Residue Summary--Metolachlor Potato Processed Fractions: Project ID: ABR-88167. Unpublished study prepared by Ciba-Geigy Corp. 74 p.

40980705 Cheung, M. (1989) Residue Summary--Metolachlor Corn Processed Fractions (Dry and Wet Milling): Project ID: ABR-88168. Unpublished study prepared by Ciba-Geigy Corp. 87 p.

40980706 Cheung, M. (1989) Residue Summary--Metolachlor Soybean Processed Fractions: Project ID: ABR-88169. Unpublished study prepared by Ciba-Geigy Corp. 71 p.

40980707 Cheung, M. (1989) Residue Summary--Metolachlor Cotton Processed Fractions: Project ID: ABR-88170. Unpublished study prepared by Ciba-Geigy Corp. 73 p.

40980708 Cheung, M. (1989) Residue Summary--Metolachlor Peanut Processed Fractions: Project ID: ABR-88171. Unpublished study prepared by Ciba-Geigy Corp. 72 p.

41053901 Merricks, D. (1988) Pennant Dislodgeable Residue Study in Southern Turf Grass: Metolachlor: Final Report: Agrisearch Project No. 12102. Unpublished study prepared by Agrisearch, Inc. 82 p.

41154201 Fackler, P. (1989) Bioconcentration and Elimination of [Carbon 14] Residues by Bluegill (Lepomis macrochirus) Exposed to Metolachlor: Laboratory Report No. 87-9-2505. Unpublished study pre- pared by Springborn Life Sciences, Inc. 188 p.

41185701 Spare, W. (1989) Aerobic and Anaerobic Aquatic Metabolism of Meta-lachlor: Final Report: Study No. 1259. Unpublished study prepared by

BIBLIOGRAPHY

MRID	CITATION
	Agrisearch Inc. 140 p.
41309801	Spare, W. (1989) Soil Metabolism of Metolachlor under Aerobic, Aerobic/Anaerobic, and Sterile Conditions: Lab Project Number: 1258. Unpublished study prepared by Agrisearch Inc. in association with Ciba-Geigy Corp. 130 p.
41309802	Spare, W. (1989) Soil Metabolism of Metalochlor under Aerobic, Aerobic/Anaerobic, and Sterile Conditions: Lab Project Number: 1258. Unpublished study prepared by Agrisearch, Inc. 130 p.
41335701	Merricks, D. (1989) Metolachlor Field Dissipation Study in Iowa--Site B: Final Report: Lab Project Nos. 1264-B; 1264. Unpublished study prepared by Agrisearch Inc. 300 p.
41470601	Thede, B. (1990) Uptake of [Carbon 14]-Metolachlor in Rotational Crops grown in Soil which has been Previosly Used for Growing Potatoes: Lab Study No.: ABR-90037. Unpublished study prepared by Ciba-Geigy Corp. 74 p.
41484201	Merricks, D. (1989) Metolachlor Field Dissipation Study in Iowa-- Site A: Amendment to Final Report: Unpublished study prepared by Ciba-Geigy Corp. 6 p.
41506501	Cheung, M. (1990) Metolachlor: Response to EPA Deb Review of Residue Chemistry Data Submitted Under the Metolachlor Frstr: Lab Project Number: ABR-90045. Unpublished study prepared by Ciba-Geigy Corp. 20 p.
41551201	Baron, J. (1990) Metalochlor: Magnitude of Residue on Celery: Lab Project Number: IR-4 1337. Unpublished study prepared by USDA- ARS/Beltsville Agriculture Research Center. 162 p.
41833101	Mastrocco, F.; Huber, K.; Schiavo, D.; et al. (1987) Metolachlor Technical: 21-Day Dermal Toxicity Study in Rabbits: Lab Project Number: 862012. Unpublished study prepared by Ciba-Geigy Corp. 173 p.
41833102	Murphy, T. (1987) Dermal Absorption of Metolachlor in Rats: Lab Project Number: ABR-87051. Unpublished study prepared by Ciba- Geigy Corp. in coop. with WIL Research, Inc. 120 p.

BIBLIOGRAPHY

MRID	CITATION
42644301	Wurz, R. (1993) Metolachlor: Validation of Analytical Method AG-338, Analytical Method for the Residues of Metolachlor Plant Metabolites Determined as CGA-37913 and CGA-49751 after Acid Hydrolysis with Modifications for the Determination of Residues of Metolachlor in (carbon 14)-treated Corn and Potatoes from
42644301	Metabolism Studies: Lab Project Number: ABR-92088. Unpublished study prepared by CIBA-GEIGY Corp. 72 p.
42652101	Fleischmann, T. (1993) Uptake and Metabolism of (carbon 14)-Metolachlor in Greenhouse Grown Potatoes and Corn: Lab Project Number: ABR-92090: 93-90. Unpublished study prepared by Ciba-Geigy Corp. 170 p.
42810601	Cheung, M. (1993) Metolachlor: Response to EPA Review of Metolachlor Storage Stability Data Reported in ABR-88168 (Supplement) (MRID No. 42384401) and ABR-92042 (MRID No. 42502901): Lab Project Number: ABR-88168: ABR-92042. Unpublished study prepared by Ciba-Geigy Corp., Residue Chemistry Department. 97 p.
43000101	Kunkel, D. (1993) Metolachlor: Magnitude of Residue on Onion (Dry Bulb): Lab Project Number: 1520. Unpublished study prepared by USDA. 288 p.
43044000	Industry Task Force II on MCPA Research (1993) Submission of Summary Hazard Evaluation Data in Support of FIFRA 6(a)(2) for MCPA Acid, DMA Salt, and 2-EH Ester. Transmittal of 1 Study.
43178401	Grunenwald, M. (1994) Metolachlor: Magnitude of the Residues of Metolachlor as CGA-37913 and CGA-49751 in or on Field Corn Following Preplant Incorporated (PPI) and Layby Application of Dual 8E and Dual 25G: Lab Project Number: ABR/93065: 130377: 42-91. Unpublished study prepared by Ciba-Geigy Corp. 483 p.
43178402	Grunenwald, M. (1994) Metolachlor: Magnitude of the Residues of Metolachlor as CGA-37913 and CGA-49751 in Soybeans Following PPI Application of Dual 25G: Lab Project Number: ABR/93063: 130375: 38-91. Unpublished study prepared by Ciba-Geigy Corp. 212 p.
43178403	Grunenwald, M. (1994) Metolachlor: Magnitude of the Residues in Cottonseed Following PRE or PPI Application of Dual 8E to Cotton: Lab Project Number:

BIBLIOGRAPHY

MRID	CITATION
	ABR/93061: 130373: 36-91. Unpublished study prepared by Ciba-Geigy Corp. 258 p.
43244003	Ham, A. (1994) Metolachlor: Test for Other Genotoxic Effects in the in vivo/ in vitro Assay for Unscheduled DNA Synthesis in Rat Primary Hepatocytes with Two Timepoints: Final Report: Lab Project Number: 15881/0/494. Unpublished study prepared by Hazleton Washington, Inc. 46 p.
43263101	Grunenwald, M. (1994) Metolachlor--Magnitude of Residues in Peanuts Following Application of Dual 25G or 8E: (Data submitted as alternate to Craven Laboratories generated data): Lab Project Number: ABR-92076. Unpublished study prepared by Ciba-Geigy Co. 480 p.
43295701	Grunenwald, M. (1994) Metolachlor--Magnitude of the Residues of Metolachlor as CGA-37913 and CGA-49751 in Succulent and Dried
43295701	Legumes Following Preplant Incorporated (PPI) Application of Dual 8E: (Data Submitted as Alternate to Craven Laboratories Generated Data): Lab Project Number: ABR-93084: 39-91: 130376. Unpublished study prepared by Ciba-Geigy Corp. 355 p.
43367101	Grunenwald, M. (1994) Metolachlor: Magnitude of the Residues in Rotational Alfalfa and Clover Following PPI Application of Dual 8E to Field Corn: Lab Project Number: ABR/93-62. Unpublished study prepared by Ciba-Geigy Corp. 534 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to Metolachlor. 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 Metolachlor and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Appendix A

2. Health and Environmental Effects Science Chapters

3. Detailed Label Usage Information System (LUIS) Report

4. Metolachlor RED Fact Sheet

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

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

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

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

PR NOTICE 86-5

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

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

I. Purpose

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

II. Applicability

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

III. Effective Date

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

IV. Background

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

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

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

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

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

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

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

VI. Format Requirements

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

- INDEX-

A. Organization of Submittal Package

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

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

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

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

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

B. Transmittal Document

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

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

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,…. of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a

registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

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

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

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

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

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

C.1 Special Considerations for Identifying Studies

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

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

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

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

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

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third

would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

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

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

D. Organization of Each Study Volume

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

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

D.1. Title Page

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

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

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

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

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

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

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

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

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

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

D.3. Confidential Attachment

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

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

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

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

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

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

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

D.5. Good Laboratory Practice Compliance Statement

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

E. Reference to Previously Submitted Data

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

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for

microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

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

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

G. Special Requirements for Submitting Data to the Docket

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

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

V. For Further Information

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

/S/

James W. Akerman
Acting Director,
Registration Division

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

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

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

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

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

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

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

3. Transmittal date

4. List of submitted studies

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

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

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

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

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

Company Official: _____
Signature Name

Company Name _____

Company Contact: _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

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

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

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

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

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

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

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

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

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

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

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

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

DELETED WORDS OR PHRASE: Ethylene Glycol

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

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

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

DELETED PARAGRAPH(S):

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

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

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

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

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

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

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

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

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

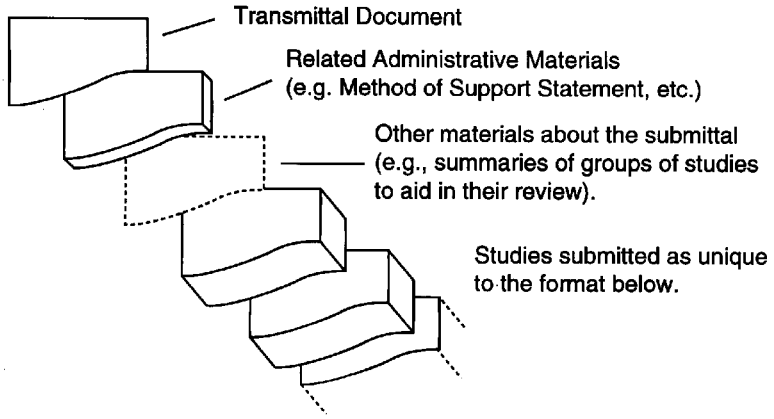
Example 3.

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

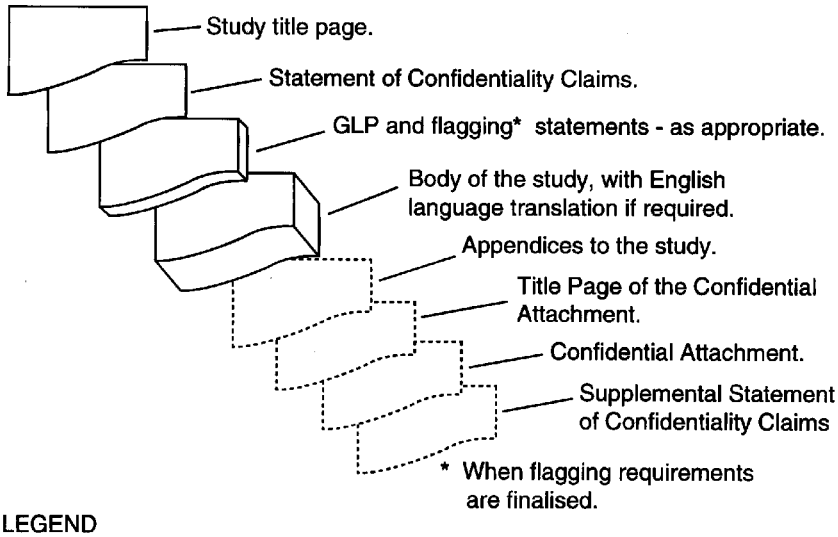
Submitter_____

ATTACHMENT 7.

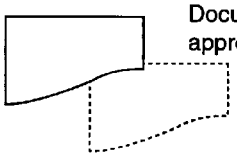
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



PR Notice 91-2

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

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

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients
Statement

I. PURPOSE:

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

II. BACKGROUND

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

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

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

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since

the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

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

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

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

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

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

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

V. COMPLIANCE SCHEDULE

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

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

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

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

VI. FOR FURTHER INFORMATION

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

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

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

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC
DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

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

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

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Reqistrant'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:

The Attachments to this Notice are:

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

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

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

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

II-B. SCHEDULE FOR SUBMISSION OF DATA

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

II-C. TESTING PROTOCOL

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

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

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

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

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

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

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

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

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

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

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

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

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

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

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

a. Voluntary Cancellation -

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

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

b. Use Deletion -

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

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

c. Generic Data Exemption -

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

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

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

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

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

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

d. Satisfying the Generic Data Requirements of this Notice

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

e. Request for Generic Data Waivers.

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

2. Product Specific Data Requirements

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

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

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

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

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

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

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

c. Request for Product Specific Data Waivers.

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

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

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

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

Option 1. Developing Data

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

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

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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

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

Option 2. Agreement to Share in Cost to Develop Data

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

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

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

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

Option 4. Submitting an Existing Study

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

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

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

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

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

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the

study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

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

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

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

Option 5. Upgrading a Study

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

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

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

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

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has

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

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

2. Product Specific Data

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

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

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

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

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.1., 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 A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

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

Attachment 1. Chemical Status Sheets

METOLACHLOR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 Metolachlor. 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 Metolachlor 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 Metolachlor are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional occupational and residential exposure data on Metolachlor are needed. These data are needed to fully complete the reregistration of all eligible Metolachlor 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 Jane Mitchell at (703) 308-8061.

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

Jane Mitchell, 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: Metolachlor

METOLACHLOR DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of Metolachlor, please contact Jane Mitchell at (703) 308-8061.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Veronica Dutch at (703) 308-8585.

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

Veronica Dutch
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: **Metolachlor**

Attachment 2. Combined Generic and Product Specific Data Call-In Response Forms Plus Instructions

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

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of data call-in (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form**. **BOTH** "Data Call-In Response" forms must be completed.

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.

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

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

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."
April 3, 1995
Item 7b.For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

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

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

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

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

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

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

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

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

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

Attachment 3. Generic and Product Specific Requirement Status and Registrant's Response Forms and Instructions

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

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.** Both "Requirements Status and Registrant's Response" forms must be completed.

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 Reqistrant'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

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

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

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

Using available information, batching has been accomplished by the process described in the preceding paragraph. 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.

The table below shows six batches of registrations.

BATCH NO.	EPA REG. NO. & SLN REG. No.	% OF METOLACHLOR & OTHER ACTIVE INGREDIENTS	FORMULATION TYPE
1	100-645	35.6% - Metolachlor 27.4% - Atrazine	Emulsifiable Concentrate
	100-710	34.8% - Metolachlor 27.4% - Atrazine	Soluble Concentrate
	NE 930003	35.6% - Metolachlor 27.4% - Atrazine	Emulsifiable Concentrate
2	3125-366	70.0% - Metolachlor 15.0% - Metribuzin	Emulsifiable Concentrate
	ID 900002	70.0% - Metolachlor 15.0% - Metribuzin	Emulsifiable Concentrate
3	62719-239	79.9% - Metolachlor 2.1% - Flumetsulam	Emulsifiable Concentrate
	62719-240	79.9% - Metolachlor 2.6% - Flumetsulam	Emulsifiable Concentrate
4	100-627	15.0% - Metolachlor	Granular
	100-638	25.0% - Metolachlor	Granular
	100-712	25.0% - Metolachlor	Granular
5	100-597	86.4% - Metolachlor	Emulsifiable Concentrate
	100-688	85.1% - Metolachlor	Emulsifiable Concentrate
	100-691	85.1% - Metolachlor	Emulsifiable Concentrate
	100-711	84.4% - Metolachlor	Emulsifiable Concentrate
	AZ 830005	86.4% - Metolachlor	Emulsifiable Concentrate
	FL 900002	85.1% - Metolachlor	Emulsifiable Concentrate

BATCH NO.	EPA REG. NO. & SLN REG. No.	% OF METOLACHLOR & OTHER ACTIVE INGREDIENTS	FORMULATION TYPE
5 (cont.)	FL 930001	86.4% - Metolachlor	Emulsifiable Concentrate
	LA 880005	86.4% - Metolachlor	Emulsifiable Concentrate
	NC 920005	86.4% - Metolachlor	Emulsifiable Concentrate
	NM 850004	86.4% - Metolachlor	Emulsifiable Concentrate
	NM 860004	86.4% - Metolachlor	Emulsifiable Concentrate
	NY 900001	86.4% - Metolachlor	Emulsifiable Concentrate
	OK 860003	86.4% - Metolachlor	Emulsifiable Concentrate

BATCH NO.	EPA REG. NO. & SLN REG. No.	% OF METOLACHLOR & OTHER ACTIVE INGREDIENTS	FORMULATION TYPE
	OR 910007	86.4% - Metolachlor	Emulsifiable Concentrate
	OR 930022	86.4% - Metolachlor	Emulsifiable Concentrate
	TX 830011	86.4% - Metolachlor	Emulsifiable Concentrate
	VA 920004	86.4% - Metolachlor	Emulsifiable Concentrate
	WI 890002	86.4% - Metolachlor	Emulsifiable Concentrate
	WI 940001	86.4% - Metolachlor	Emulsifiable Concentrate
6	100-673	86.4% - Metolachlor	Emulsifiable Concentrate
	NC 920004	86.4% - Metolachlor	Emulsifiable Concentrate
	VA 920005	86.4% - Metolachlor	Emulsifiable Concentrate
	WA 910004	86.4% - Metolachlor	Emulsifiable Concentrate

The following two tables show registrations which were not batched for various reasons such as additional active ingredients not found in any other registrations, significant differences in the inert ingredients, and significant differences in the concentrations of active and inert ingredients.

EPA REG. NO. & SLN REG. No.	% OF METOLACHLOR & OTHER ACTIVE INGREDIENTS	FORMULATION TYPE
100-587	95.0% - Metolachlor	Technical
100-590	27.5% - Metolachlor 20.8% - Atrazine	Emulsifiable Concentrate
100-665	0.5% - Metolachlor	Granular

EPA REG. NO. & SLN REG. No.	% OF METOLACHLOR & OTHER ACTIVE INGREDIENTS	FORMULATION TYPE
100-715	4.0% - Metolachlor 1.0% - Simazine	Granular
100-716	22.0% - Metolachlor 22.0% - Cyanazine	Emulsifiable Concentrate
100-731	36.6% - Metolachlor 17.4% - Atrazine	Emulsifiable Concentrate
100-747	55.0% - Metolachlor	Water Dispersible Granular
100-748	30.6% - Metolachlor 23.2% - Atrazine	Water Dispersible Granular

EPA REG. NO. & SLN REG. No.	% OF METOLACHLOR & OTHER ACTIVE INGREDIENTS	FORMULATION TYPE
241-328	68.5% - Metolachlor 2.74% - Imazethapyr	Soluble Concentrate
10182-134	22.70% - Metolachlor 7.84% - Paraquat Dichloride	Emulsifiable Concentrate

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

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

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

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

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

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

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

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

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

Does your study meet the following acceptance criteria?

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

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

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

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

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

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

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

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

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

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

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

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

SUBDIVISION F

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

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

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

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

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

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

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

Instructions for Completing the Confidential Statement of Formula

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
2070-0057
Approval Expires 3-31-96

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

Please fill in blanks below.

Company Name	Company Number
Product Name	**EPA Reg. No.**

I Certify that:

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

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-96

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-007 April 1995

R.E.D. FACTS

Metolachlor

Pesticide Reregistration

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

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

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0001, metolachlor.

Use Profile

Metolachlor is a broad spectrum herbicide used for general weed control in many agricultural food and feed crops (primarily corn, soybeans and sorghum), and on lawns and turf, ornamental plants, trees, shrubs and vines, rights of way, fencerows and hedgerows, and in forestry. The emulsifiable concentrate formulation is most commonly used, but granular formulations also are available. Ground application is the use method of choice for all sites, although aerial, irrigation, and chemigation application methods also are permitted.

Use practice limitations prohibit applying metolachlor in greenhouses or other enclosed structures, on muck or peat soils, on sweet potatoes or yams, to trees or vines transplanted less than 30 days (and only after depressions around the trees and vines have been filled in), on sand or loamy sand soils, to trees or vines that will bear harvestable fruit within 12 months, to Taloka Silt Loam, on English peas in Northeastern U.S., and on sorghum grown under dry-mulch tillage. They also prohibit grazing livestock in treated areas, feeding or grazing cover crops grown in treated orchards, and grazing or feeding peanut forage or fodder to livestock for 30 days following application.

Regulatory History

Metolachlor was first registered in the U.S. in 1976 for general weed control on turf. This pesticide was the subject of EPA's first Registration Standard, in March 1980. The Agency issued a second Registration Standard for metolachlor in January 1987, and Data Call-In notices in December 1993 and May 1994.

Human Health Assessment

Toxicity

Metolachlor displayed a low level of toxicity in acute tests. It is slightly toxic by the oral, dermal, and inhalation routes, and has been placed in Toxicity Category III (the second-lowest of four categories) for these effects. It is non-irritating to the eyes and skin (Toxicity Category IV), but is positive for skin sensitization in guinea pigs.

While a three-month subchronic feeding study in beagle dogs produced no effects, a six-month study resulted in reduced body weight gains and food consumption in the high dose dogs. A dermal toxicity study using New Zealand white rabbits resulted in increased bilirubin, increased liver weights in males, and increased kidney weights in females. In a chronic feeding study using beagle dogs, metolachlor caused decreased body weight gain.

Metolachlor has been evaluated for carcinogenic activity in both rats and mice. No treatment-related cancer effects were observed in two studies using mice. In studies using rats, metolachlor caused a significant increase in liver nodules and carcinomas in high dose females. In 1991, the Agency's HED Peer Review Committee recommended that metolachlor be classified as a Group C possible human carcinogen, based on increases in liver tumors in the female rat. However, a Peer Review conducted in July 1994 recommended a margin of exposure (MOE) approach to assessing chronic risk since there was no supportable mutagenicity concern, and in light of new information on the relative metabolism of metolachlor indicating that formation of the derivative presumed to be the ultimate carcinogen actually is very low.

Metolachlor shows some evidence of causing developmental toxicity effects in rats but none in rabbits. It was not mutagenic in several tests.

Dietary Exposure

People may be exposed to residues of metolachlor through the diet. Tolerances or maximum residue limits have been established for residues in/on a variety of food and feed commodities including corn, cotton, peanuts, pod crops, potatoes, safflower, sorghum, soybeans, stone fruits, tree nuts, nonbearing citrus and grapes, and cabbage; straw, forage and grain of barley, buckwheat, oats, rice, rye, and wheat; several types of peppers; and eggs, milk, and the fat, meat and meat byproducts of poultry, cattle, goats, hogs, horses, and sheep (please see 40 CFR 180.368(a),(b) and (c)).

Sufficient data are available to determine the adequacy of most established tolerances. (Certain studies generated by Craven Laboratories are being replaced.) However, some tolerances need to be revoked, some need to be replaced, and some separate ones need to be established to bring them up to date with current commodity definitions.

New food/feed additive tolerances are needed for processed potatoes (dry peel, wet peel, granules, and waste from processing) and soybean hulls, and, based on some replacement studies, will likely be needed for peanuts. Under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), however, food and feed additive tolerances may not be established for pesticides that induce cancer in man or animals. Although its cancer-causing potential in humans is weak, EPA still considers metolachlor to be a chemical that "induces cancer" within the meaning of the Delaney clause. Therefore, under current policy EPA would not issue these food and feed additive tolerances, and would not continue in effect tolerances for the associated raw agricultural commodities potatoes, soybeans, and peanuts.

EPA currently is evaluating its policies regarding pesticide tolerances, registrations, and the Delaney clause in light of ongoing legal challenges. Because of these issues, the Agency is unable to make a reregistration eligibility decision at this time regarding the potato, soybean, and peanut uses of metolachlor.

EPA has assessed the dietary risk posed by metolachlor. The Anticipated Residue Concentration (ARC) for the overall U.S. population represents less than 0.2% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly exposed subgroup, non-nursing infants less than one year old, has an ARC which represents less than 0.6% of the RfD. This low fraction of the allowable RfD is considered to be an acceptable dietary exposure risk.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders and applicators) may be exposed to metolachlor during normal use of both granular and liquid formulations. The potential for post-application exposure also exists for people entering treated sites. For many uses of metolachlor, however, this potential is diminished since the herbicide is incorporated into the soil following application. For post-emergent applications, especially applications to turf, there is more of a risk of post-application exposure.

Because metolachlor is a possible human carcinogen and systemic toxicity may result from intermediate exposure (one week to several months), EPA assessed exposure and risk to workers using several major exposure scenarios. Margins of Exposure (MOEs) for subchronic systemic effects are unacceptable (less than 100) for mixers/loaders during aerial applications of liquid metolachlor. In addition, MOEs for

mixers/loaders/applicators during ground applications of liquid metolachlor are acceptable only when certain personal protective equipment (PPE) (gloves and coveralls) is worn by those handlers.

To mitigate these risks to metolachlor handlers, EPA is requiring use of a closed mixing and loading system by mixers/loaders supporting aerial applications of liquid formulations. In addition, mixers/loader/applicators must wear appropriate PPE--chemical-resistant gloves and coveralls over short-sleeved shirts and short pants--during/supporting ground applications of liquid metolachlor formulations.

Post-application exposures do not appear to pose an unreasonable risk to people entering treated areas, as long as they do not reenter immediately after application. Therefore, for all uses within the scope of the Worker Protection Standard (WPS), EPA is requiring a 24-hour restricted entry interval (REI), strengthening the interim 12-hour REI in place until now, as well as PPE for workers who enter treated areas before the REI has expired.

For uses outside the scope of the WPS, EPA is requiring, for liquid applications, a prohibition on entry until sprays have dried, and for granular applications, a prohibition on entry until dusts have settled or the treated area is dry following watering-in.

Human Risk Assessment

Metolachlor is of low acute toxicity but can cause dermal sensitization. It is classified as a "Group C," possible human carcinogen based on increases in liver tumors in the female rat. Metolachlor also shows some evidence of causing developmental toxicity in rats.

Although people may be exposed to residues of metolachlor through the diet, dietary risks appear to be minimal. Systemic toxicity risks to certain handlers (mixers/loaders/applicators) are of concern from intermediate exposure to metolachlor, but will be mitigated by requiring use of closed mixing and loading systems for aerial applications of liquid formulations, and use of certain minimum, baseline PPE (gloves and coveralls) for all handlers during ground use of liquid formulations. To reduce post-application exposure and risk, a more stringent 24-hour REI is being imposed, as is early entry PPE.

Environmental Assessment

Environmental Fate

Parent metolachlor appears to be moderately persistent to persistent. It ranges from mobile to highly mobile in different soils, and has been detected in ground water. Metolachlor is stable to hydrolysis under normal environmental conditions. Degradation is dependent on microbially mediated and abiotic processes. Five major degradates have been identified.

Metolachlor has the potential to range from a moderately mobile to a highly mobile material in different types of soil. It is persistent in surface soil with a half-life in the 6-12 inch soil layer ranging from 7 to 292 days.

Detections were made as far as the 36-48 inch soil layer in some tests. Metolachlor has a low potential to bioaccumulate in fish.

Residues of metolachlor have been detected in ground water in 20 states. Detections in three states have been found to contain residues that exceed the lifetime Health Advisory of 100 ppb for metolachlor. In five other states, concentrations in well water exceed 10% of the Health Advisory Level (HAL). Because of these detections, EPA is concerned about the degradation of water quality that occurs in metolachlor use areas.

Metolachlor is among the top five pesticides found in surface water in the mid-western corn belt. It is detected in a high percentage of surface water samples collected from numerous locations within the corn belt for several months post-application. Comparable levels are found in streams, rivers, and reservoirs.

It appears unlikely that metolachlor concentrations will exceed the 1-10 day or lifetime Health Advisory levels. Although metolachlor is not yet formally regulated by the Safe Drinking Water Act, water supply systems are required to sample and analyze for it. EPA will review these data when they become available.

Ecological Effects

Metolachlor is practically nontoxic to birds on both an acute and a subacute dietary basis. New avian reproduction studies are required to determine its chronic toxicity to birds. Metolachlor is moderately toxic to freshwater fish on an acute basis. It is slightly toxic to aquatic invertebrates on an acute basis. A reproduction study is required to confirm that chronic risks to aquatic invertebrates are similar to risks to fish. Metolachlor is slightly toxic to estuarine fish in acute exposures. Since metolachlor is a herbicide, potential risk to nontarget plants is likely.

Ecological Effects Risk Assessment

Metolachlor is registered for many outdoor uses. Acute as well as chronic exposures to nontarget organisms can result from direct applications, spray drift, and runoff from treated areas.

The level of concern (LOC) for endangered birds is exceeded at an application rate of 6 lbs active ingredient (ai) per acre. In addition, the LOC is exceeded for waterfowl at 6 lbs. ai/acre in short grass.

In addition, the endangered species LOC is exceeded for small mammals eating short grass at an application rate of 2 lbs/acre. The endangered species and restricted use LOCs are exceeded for small mammals eating short grass at an application rate of 4 lbs./acre and higher.

Although no acute effects to aquatic organisms are expected as a result of exposure to metolachlor in deeper water, freshwater fish (the most sensitive aquatic species) trigger the endangered species LOC in a shallow water body one foot deep or less. Risk to non-target plants also is expected.

In summary, endangered species levels of concern are exceeded in some circumstances for birds, small mammals, and endangered fish.

Limitations may be imposed on the use of metolachlor in the future to protect threatened and endangered species when EPA implements the Endangered Species Protection Program.

Risk Mitigation

EPA is requiring the following risk mitigation measures for metolachlor, as discussed earlier:

- An environmental hazard statement is required on product labeling to protect endangered plants.
- Metolachlor will be considered a candidate for classification as a restricted use pesticide for groundwater concerns when the Restricted Use Rule for Ground Water goes into effect.
- Since metolachlor has been detected in ground water as a result of normal agricultural use, EPA will consider metolachlor as a candidate for state management plans when the State Management Plan rule is promulgated.
- The ground water advisory on existing product labels must be modified to reflect current advisory language.
- A surface water advisory also is required since metolachlor can contaminate surface water through ground spray drift and run-off.
- Interim spray drift advisory language must be placed on product labels.
- Metolachlor products applied as liquids that have uses within the scope of the WPS warrant the establishment of minimum PPE requirements for handlers. In addition, mixers and loaders must use closed mixing systems to support aerial applications (see discussion above).
- EPA also is requiring a strengthened 24-hour REI for uses that are within the scope of the WPS.
- Early entry PPE for dermal protection also is required for emulsifiable concentrate formulations.
- Certain entry restrictions also are required for uses outside the scope of the WPS and for homeowner use products.
- To protect ground water, EPA is requiring two small-scale prospective ground water studies on metolachlor, as well as a report on the results of a 19-state monitoring program.

Label statements also are required to reduce mixing and loading risks.

Additional Data Required

EPA is requiring the following generic studies for metolachlor to confirm its regulatory assessments and conclusions: a Foliar Residue Dissipation study and a Dermal Passive Dosimetry Exposure study for use on residential turf. The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling

All metolachlor end-use products must comply with EPA's current

Changes Required

pesticide product labeling requirements, and with the following (for detailed labeling instructions, please see the metolachlor RED):

Personal Protective Equipment (PPE) Requirements for Pesticide Handlers

Sole-active-ingredient products must be revised to adopt the PPE requirements set forth in this section. Any conflicting PPE requirements on current labeling must be removed. Multiple-active-ingredient products must compare these handler PPE requirements to those on current labeling and retain the more protective.

Handler PPE for Occupational-Use Products (products NOT intended primarily for home use):

Minimum (Baseline) Personal Protective Equipment Requirements: Some uses of metolachlor are within the scope of the Worker Protection Standard (WPS) and some are outside its scope. The minimum (baseline) PPE requirements pertain to both the WPS and nonWPS uses by occupational handlers, since potential exposure is similar.

Granular Formulations: The Agency is establishing no minimum (baseline) PPE for WPS and nonWPS uses of metolachlor products formulated as granules.

EC Formulations: The minimum (baseline) PPE for all WPS and nonWPS occupational uses of metolachlor products formulated as liquids is:

"Applicators and other handlers must wear:

--Coveralls over short-sleeved shirt and short pants

--Chemical-resistant gloves (see instructions * below)

--Chemical-resistant footwear plus socks

--Chemical-resistant headgear for overhead exposure

--Chemical-resistant apron when cleaning equipment, mixing, or loading" (see instructions ** below)

* The glove statement for metolachlor is the statement established through instructions in Supplement Three of PR Notice 93-7.

** The words "mixing, or loading" may be removed if the product is formulated as "ready-to-use."

Actual End-Use Product Personal Protective Equipment Requirements: The PPE that would otherwise be established based on the acute toxicity of each end-use product must be compared to the minimum (baseline) PPE specified above, and the more protective must be placed on product labeling.

Placement in Labeling: The PPE must be placed on 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 specified there.

Products Intended Primarily for Homeowner Use:

EPA is not establishing minimum (baseline) handler PPE for metolachlor end-use products intended primarily for homeowner use. Any necessary PPE will be established based on the acute toxicity of the end-use product.

Placement in Labeling: PPE requirements, if any, must be placed on end-use product labeling immediately following the precautionary statements in "Hazards to Humans (and domestic animals)."

Entry Restrictions

Sole-active-ingredient products must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on current labeling must be removed. Multiple-active-ingredient products must compare the entry restrictions set forth in this section to those on current labeling and retain the more protective. A specific time-period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Occupational-Use Products (products NOT intended primarily for home use):

--Uses Within the Scope of the WPS:

Restricted-Entry Interval: A 24-hour restricted entry interval (REI) is required for uses within the scope of the WPS on all end-use products.
Early-Entry Personal Protective Equipment (PPE):

EC Formulations: The PPE required for early entry following applications of the emulsifiable concentrate is:

--coveralls over short-sleeve shirt and short pants,

--chemical-/resistant gloves,

--chemical-resistant footwear plus socks,

--chemical-resistant headgear for overhead exposures.

Granular Formulations: The PPE required for early entry following applications of granular formulation is:

--coveralls,

--chemical-resistant gloves,

--shoes plus socks.

Placement in Labeling: The REI must be inserted into the standardized REI statement and 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.

--Uses Not Within the Scope of the WPS:

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 following 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 following the watering-in."

Placement in Labeling:

If WPS uses also are on label: Follow instructions in PR Notice 93-7 for establishing Non-Agricultural Use Requirements box and place appropriate nonWPS entry restriction in that box.

If no WPS uses are on label: Add appropriate nonWPS entry restriction to labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading: "Entry Restrictions:"

Products Primarily Intended for Home Use:

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 following 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 following the watering-in."

Placement in Labeling: Add entry restriction to labels of products primarily intended for homeowner use in section in Directions For Use with the heading: "Entry Restrictions:"

Other Labeling Requirements

The Agency is requiring the following labeling statements on all metolachlor end-use products 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:

"Mixers and loaders supporting aerial applications are required to use closed systems. The closed system must be used in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4). When

using the closed system, the mixers' and loaders' PPE requirements may be reduced or modified as specified in the WPS."

"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:

"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:

Because metolachlor is classified as a skin sensitizer, EPA is requiring the following statement in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements on the labeling of all end-use products:

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

Soil Incorporation Statement:

Registrants may add the following statement to their labeling in the Agricultural Use Requirements box immediately following the restricted entry interval:

"Exception: if the product is 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."

Environmental Hazard Statement

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

Rotational Crops Restriction

"Do not rotate to food or feed crops other than those listed on this label."

Ground Water Labeling/Mitigation; Mixing/Loading

The following language regarding mixing/loading setbacks must appear in Precautionary Statements in the Environmental Hazards section of the label:

> "This product may not be mixed or loaded within 50 ft. of perennial or intermittent streams and rivers, natural or impounded lakes and reservoirs. This product may not be mixed/loaded or used within 50 ft. of all wells, including abandoned wells, drainage wells, and sink holes. Operations that involve mixing, loading, rinsing, or washing of this product into or from pesticide handling or application equipment or containers within 50 ft. of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or wash-water, and rain water that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self-contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to completely exclude precipitation from contact with the pad shall have a minimum containment capacity of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above-specified minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site."

Ground Water Advisory

The following ground water advisory language must be placed on all metolachlor labels:

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

Surface Water Advisory

The following surface water advisory language must be placed on all metolachlor labels:

> "Metolachlor can contaminate surface water through ground spray drift. Under some conditions, metolachlor may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several months post-application. These include poorly draining or wet soils with readily visible slopes toward adjacent

surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas over-laying tile drainage systems that drain to surface water."

Endangered Plants Labeling

The following is required in the general information section of label:

"Do not apply under conditions which favor runoff or wind erosion of soil containing this product to non-target areas."

To prevent off-site movement due to run-off or wind erosion:

"Avoid treating powdery dry or light sand soils when conditions are favorable for wind erosion. Under these conditions, the soil surface should first be settled by rainfall or irrigation."

"Do not apply to impervious substrates such as paved or highly compacted surfaces."

"Do not use tailwater from the first flood or furrow irrigation of treated fields to treat non-target crops unless at least 1/2 inch of rainfall has occurred between application and the first irrigation."

Spray Drift Labeling

The following language must be placed on the label of each product 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."

Aerial drift reduction advisory information must be contained in product labeling. See the metolachlor RED document for this additional required labeling.

Regulatory Conclusion

The use of currently registered products containing metolachlor, in accordance with labeling amended to reflect the risk mitigation measures imposed by this RED, generally will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products, except on potatoes, soybeans, and peanuts, are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision regarding the potato, soybean, and peanut uses because, under current policy, the food and feed additive tolerances needed to support these uses appear to be barred by the Delaney clause in the FFDCA.

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

For More Information

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

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

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

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

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

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-

free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.