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Agency

Prevention, Pesticides
And Toxic Substances
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Reregistration Eligibility Decision (RED) Diclofop-Methyl

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and comments received related to the preliminary and revised risk assessments for the herbicide diclofop-methyl. Based on comments received during the registrant error correction period, the Agency revised the human health and environmental effects risk assessments and made them available to the public on August 28, 2000. During this comment phase, all interested parties were invited to participate and provide comments and suggestions on ways the Agency might mitigate the estimated risks presented in the revised risk assessments. The Agency is now publishing its reregistration eligibility, risk management, and tolerance reassessment decision for the current uses of diclofop-methyl and its associated human health and environmental risks.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of diclofop-methyl. The EPA is now publishing its decision on the reregistration eligibility of and risk management decision for the current uses of diclofop-methyl and its associated human health and environmental risks. The Agency's decision on the chemical diclofop-methyl can be found in the attached document entitled, "Reregistration Eligibility Decision for Diclofop-Methyl" which was approved on September 29, 2000.

A Notice of Availability for this Reregistration Eligibility Decision for diclofop-methyl is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the website: http:www.epa.gov/pesticides/reregistration/diclofop-methyl.

The RED is based on the updated technical information found in the diclofop-methyl public docket. The docket not only includes background information and comments on the Agency's preliminary risk assessments, it also now includes the Agency's revised risk assessments for diclofop-methyl (revised as of August 10, 2000), and documents summarizing the Agency's Response to

Comments. The Response to Comments documents address corrections to the preliminary risk assessments submitted by chemical registrants.

This document and the process used to develop it are the result of a pilot process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions on pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA)**,** the Agency is undertaking a special effort to maintain open public dockets on pesticides and to engage the public in the reregistration and tolerance reassessment processes for these chemicals. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA.

This document contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. Note that registrants of diclofop-methyl must respond to DCIs issued by the Agency within 90 days of receipt of this letter.

In this RED, the Agency has determined that diclofop-methyl will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. The Agency believes that current uses of diclofop-methyl may pose unreasonable adverse effects to human health and the environment, and that such effects can be mitigated with the risk mitigation measures identified in this RED. Accordingly, the Agency recommends that registrants implement these risk mitigation measures immediately. Section IV of this RED describes labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by diclofop-methyl. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Anne Overstreet at (703)308-8068. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Veronica Dutch at (703) 308-8585.

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision
for
Diclofop-Methyl
Case No. 2160

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Diclofop Methyl Team

Office of Pesticide Programs:

Health Effects Risk Assessment

Christina Jarvis
Bob Fricke
Al Nielsen
Seyed Tadayon
Sheila Piper
Richard Griffin

Environmental Fate Risk Assessment

Subijoy Dutta
Nicholas Mastrota

Use and Usage Analysis

Arnold Aspelin
Virginia Dietrich
Alan Halvorson

Registration Support

Eugene Wilson

Risk Management

Anne Overstreet
Michael McDavit

Glossary of Terms and Abbreviations

AE	Acid Equivalent
a.i.	Active Ingredient
AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
ARC	Anticipated Residue Contribution
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CFR	Code of Federal Regulations
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
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, noncarcinogenic health effects are not anticipated to occur.
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLC	Gas Liquid Chromatography
GLN	Guideline Number
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA

Glossary of Terms and Abbreviations

HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HAFT	Highest Average Field Trial
HDT	Highest Dose Tested
IR	Index Reservoir
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.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse 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.
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
NA	Not Applicable
N/A	Not Applicable
NAWQA	USGS National Water Quality Assessment
NOEC	No Observable Effect Concentration
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances

Glossary of Terms and Abbreviations

Pa	pascal, the pressure exerted by a force of one newton acting on an area of one square meter.
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RS	Registration Standard
RUP	Restricted Use Pesticide
SAP	Science Advisory Panel
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	STOrage and RETrieval (USEPA repository of water quality data)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution

Glossary of Terms and Abbreviations

torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
TRR	Total Radioactive Residue
UF	Uncertainty Factor
Fg/g	Micrograms Per Gram
Fg/L	Micrograms Per Liter
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UV	Ultraviolet
WHO	World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for diclofop-methyl. This document also presents the Agency's tolerance reassessment for diclofop-methyl, which includes the consideration of risk to infants and children for any potential dietary, drinking water, dermal, inhalation, or oral exposures. The Agency made its reregistration eligibility determination and tolerance reassessment decisions based on the data required for reregistration, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of diclofop-methyl are eligible for reregistration, provided specific changes are made to the label.

The revised risk assessments are based on review of the required target database supporting the use patterns of currently registered products. To strengthen stakeholder involvement and help ensure decisions made under Food Quality Protection Act (FQPA) are transparent and based on the best available information, the Agency opened a public docket during the development of this Reregistration Eligibility Decision (RED) and invited stakeholders to provide comments on the Agency's risk assessments before issuing its risk mitigation decision on diclofop-methyl. After considering the revised risks and comments from Aventis Crop Science, the technical registrant of diclofop-methyl, EPA developed its risk management decision for uses of diclofop-methyl that pose risks of concern. This decision is discussed fully in this document. In this document, existing tolerances have been reassessed and new tolerances established for the combined residues of diclofop-methyl and diclofop-acid (free and conjugated), determined as diclofop-methyl, in milk and livestock (cattle, goats, horses, and sheep) commodities.

Diclofop-methyl is a restricted use herbicide used on wheat, barley, and golf courses (turf). Diclofop-methyl, first registered in 1982, controls or suppresses various grass weed species. The total annual domestic usage of diclofop-methyl is approximately 750,000 pounds of active ingredient (a.i.).

Overall Risk Summary

EPA's human health risk assessment for diclofop-methyl indicates few risk concerns. Food risks, as measured by both an acute and chronic Population Adjusted Doses (PAD), are well below the Agency's level of concern. However, when considering the carcinogenic potential of diclofop-methyl, the dietary (food) risk appears to be over the level of concern (1.2×10^{-6}). Even though the dietary (food) cancer risk is slightly over the level of concern (10^{-6}), the Agency believes this may be an overestimate of actual carcinogenic exposure to diclofop-methyl in the food supply. Drinking water risk estimates based on surface and goundwater screening models (after considering limited monitoring data and a small scale prospective ground water (PGW) study) are less than the level of concern for all populations.

The Agency estimates that golfers who regularly play on treated courses over a lifetime may face a cancer risk of concern (2.2×10^{-6}). Furthermore, when golfer exposure is aggregated with dietary exposure, a higher cancer risk for such golfers would result. These risk estimates, however, are believed to overstate the actual risk to golfers who play on treated courses. Therefore, the Agency finds that mitigation is unnecessary for post-application exposure to golfers.

The most significant human risk concern relates to cancer risk for handlers who mix, load, and apply diclofop-methyl to agricultural sites. To a large extent, this concern can be mitigated by handlers using appropriate engineering controls, such as closed systems and enclosed application equipment.

In addition, EPA has identified a potential acute risk to small herbivorous mammals when repeated spot applications of diclofop-methyl are applied to turf. The Agency has also identified a risk to non-target terrestrial plants.

To mitigate the few risks of concern associated with diclofop-methyl as part of making the decision to reregister this pesticide, EPA finds a number of label amendments are necessary. Results of the risk assessments, and required label amendments to mitigate those risks, are presented in this RED.

The Agency has concluded that the tolerances for diclofop-methyl meet the Food Quality Protection Act (FQPA) safety standards. Existing tolerances on plant commodities have been reassessed and new tolerances on plants and animals will be established.

Dietary Risk (Food and Water)

The **acute and chronic dietary** exposure assessments for diclofop-methyl are analyses that incorporate percent crop treated information and anticipated residues. The acute dietary risk estimate for females (13-50 years old) is less than 8% of the acute population adjusted dose at the 99.9th percentile. The chronic dietary analysis indicates no risk of concern for any population subgroup, with an estimate of less than 1% of the chronic population adjusted dose for the highest exposed population subgroup (children 1-6 years old). Using modeling estimates, acute and chronic drinking water levels of comparison (DWLOC's) find that food and drinking water exposures do not exceed the Agency's level of concern; therefore, no specific mitigation is warranted.

The **carcinogenic dietary risk** for diclofop-methyl is estimated to be 1.2×10^{-6}, which is nearly equivalent to the level (10^{-6}) generally considered negligible by the Agency. This estimate is based on the estimated average dietary exposure of the general U.S. population, multiplied by the upper-bound potency factor (Q_1*) of 2.3×10^{-1} $(mg/kg/day)^{-1}$. Diclofop-methyl is classified as a likely human carcinogen based on laboratory studies in the rate and the mouse. The dietary carcinogenic risk estimate appears above the level of concern because various input parameters to the assessment, such as the estimate for the percentage (15%) of dairy cattle grazing in diclofop-methyl treated wheat fields,

express protective assumptions. A DWLOC for cancer was not calculated. Based on the Agency's knowledge of environmental fate properties and limited monitoring data on diclofop-methyl, there is no concern for carcinogenic exposure in food and water.

Non-Occupational Post-Application Risk (Golfers)

The **non-cancer risk** estimate is not of concern for post-application exposure to golfers who play on a course treated with diclofop-methyl. Non-cancer risk estimates indicate that entry by golfers to a treated golf course results in a margin of exposure (MOE) well over 100 on the day of application, as soon as the spray has dried.

Cancer risk for golfers is 2.2×10^{-6} based on exposure on the day of application at the typical application rate of 1 lb active ingredient/acre (ai/A). The Agency believes that the cancer risks associated with golfers on diclofop treated turf is an upper-bound estimate since the post-application risk assessment is based on protective assumptions related to golfer behavior and diclofop-methyl use practices. The risk is overestimated because the Agency assumes the golfer is exposed continuously during a round of golf (four hours, assuming the entire course is treated), two days per year, for 50 years. But because diclofop-methyl is usually applied as a spot treatment covering less than the entire course, the golfer would be exposed for a much shorter duration (probably ½ hour rather than four hours). The odds of a golfer encountering diclofop-methyl treatment twice a year for a lifetime is also a remote probability. The Agency is therefore not concerned with cancer risks to golfers exposed to residues of diclofop-methyl on treated turf.

Aggregate Risk

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically food, drinking water, and non-occupational sources (e.g., golfers on treated courses). Four aggregate risk assessments were calculated for diclofop-methyl.

The **acute aggregate risk** estimate for diclofop-methyl addresses exposure from food and drinking water on a single day. Acute dietary food risks for females 13-50 years old are below the Agency's level of concern (<100% aPAD). The modeled concentrations of diclofop-methyl in groundwater and surface water are also below the Agency's level of concern for exposure to diclofop-methyl in drinking water. Based on the available information, the Agency concludes that residues of diclofop-methyl in drinking water (when considered along with exposures from food uses) would not result in an acute aggregate human health risk of concern.

The **short-term aggregate risk** assessment considers exposure from food, water, and non-occupational sources of exposure to a pesticide. Non-occupational, dermal short-term exposure (one to seven days) is likely to occur on golf courses, where diclofop-methyl may be applied within a few hours prior to golfer play. Calculated short-term DWLOC's do not exceed the Agency's level of

concern as a contribution to short-term aggregate exposure. Based on available information, the Agency concludes that aggregate residues of diclofop-methyl in food and drinking water, combined with golfer exposure do not result in a short-term risk estimate of concern.

Chronic (non-cancer) aggregate risk estimates for diclofop-methyl addresses long-term exposure from food, drinking water, and non-occupational sources of exposure. No chronic non-occupational sources of exposure were identified for diclofop-methyl. Therefore, the chronic aggregate exposure assessment addresses exposure from food and drinking water only. Chronic dietary food risks are below the Agency's level of concern (<100% cPAD) for all population subgroups. The modeled concentration of diclofop-methyl in groundwater and surface water is also below the Agency's level of concern for exposure to diclofop-methyl in drinking water as a contribution to chronic aggregate risk.

The **cancer aggregate risk** estimate to diclofop-methyl addresses the combined carcinogenic exposure from food, drinking water, and non-occupational sources of exposure (in this case, exposure to golfers). The Agency does not believe that exposure to residues of diclofop-methyl in food and drinking water contribute to an aggregate risk of concern for the general population. The food cancer risk is based on certain protective exposure assumptions and the water cancer risk is based on screening level modeling estimates. When considering the existing environmental fate data, the Agency also concludes that diclofop-methyl is unlikely to reach surface and groundwater.

As part of the cancer aggregate risk, the carcinogenic risk to golfers is 2.2×10^{-6}. Any aggregation of carcinogenic exposure to golfers with carcinogenic exposure from food and drinking water would ordinarily increase the risk further above the level of concern. In this case, golfer exposure to diclofop-methyl is probably much less than the assessment indicates. Because the cancer risk estimate to golfers is based on high-end assumptions and may possibly overestimate risk, aggregation with food and drinking water estimates does not result in a meaningful estimate of aggregate carcinogenic exposure. The Agency concludes that there is neither an aggregate carcinogenic concern for the general population nor for golfers who play on diclofop-methyl treated courses.

Occupational Risk - and Risk Management

The Agency evaluated seven potential exposure scenarios for mixers, loaders, applicators, and other handlers associated with diclofop-methyl use patterns. The assessment includes handlers involved in mixing/loading and applying liquids for hand gun sprayer, groundboom and aerial applications.

Non-cancer handler risk is based on combined dermal and inhalation exposures for short- and intermediate term exposure durations. The assessment indicates that MOEs are generally not of concern, except for handlers involved in aerial application. Assuming handlers only wear personal protective equipment (PPE), the handlers supporting aerial application have MOEs of concern (MOE

of 60 for the mixer/loader). However, when assuming the use of engineering controls, the MOEs are greater than 100 for all handlers.

Cancer handler risk for dermal and inhalation exposure range from $1.4x10^{-2}$ to $5.1x10^{-6}$ at the baseline level, $8.4x10^{-5}$ to $6.0x10^{-7}$ with personal protective equipment (PPE), and $5.8x10^{-5}$ to $1.4x10^{-6}$ at the engineering controls level. The Agency is generally concerned when cancer risk estimates are greater than 1×10^{-6}. The Agency found that exposure to wheat and barley handlers could be substantially reduced by employing appropriate engineering controls, such as closed mixing/loading systems and enclosed application equipment. To minimize the occupational cancer risk to such handlers, the registrant has agreed to implement engineering controls to reduce exposure to all handlers.

Occupational Post-Application Risks

Several occupational post-application exposure scenarios were evaluated by the Agency. Post-application risk scenarios include workers who mow and maintain golf course turf grass and workers who scout in wheat and barley fields.

Non-cancer post-application risk estimates for workers indicate that entry by golf course workers to mow/maintain turf grass is not of concern on the day of application as soon as the sprays have dried. Similarly, the MOE for reentry by workers into wheat or barley fields for scouting is also not of concern on the day of application.

Cancer risk for post-application exposure to workers mowing/maintaining golf course turf is $6.1x10^{-6}$ on the day of application at a rate of 1.0 lbs. ai/A. Because the label discourages mowing for 36 hours for efficacy reasons, the actual risk to mowers is less than the Agency's risk estimate. The calculation of cancer risk for workers scouting wheat and barley is $2.3x10^{-5}$ on the day of application. The Agency does not anticipate the need for wheat and barley scouts to reenter a treated field prior to the end of the REI. For these reasons, the Agency is not concerned about the post-application cancer risk to workers associated with diclofop-methyl use. The restricted entry interval (REI) for wheat and barley, 24 hours, should be maintained based on the carcinogenicity of the active ingredient.

Ecological Risk

Most risk quotient estimates show low risk to various non-target organisms. The Agency has, however, identified certain ecological risks of potential concern. Although there are remaining uncertainties, diclofop-methyl poses a risk of reproductive toxicity to mammals on an acute basis and may also pose a chronic risk to mammals. Runoff and spray drift from diclofop-methyl poses a high risk to nontarget grasses and sedges, and in the absence of appropriate toxicity data on nontarget aquatic plants, may pose high risk for these species. Revised label language on reducing spray drift will

help to reduce exposure to non-target organisms. Additional information will also be provided by the registrant to confirm that there is no chronic risk to mammalian species.

The Agency is issuing this RED for diclofop-methyl, as announced in a Notice of Availability published in the *Federal Register*. A sixty day public comment period will be provided. This RED document includes guidance and time frames for complying with any required label changes for products containing diclofop-methyl.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database 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" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- Whether and How to Use Data Derived from Human Studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices lists Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page at www.epa.gov/pesticides/diclofop-methyl and in the Public Docket.

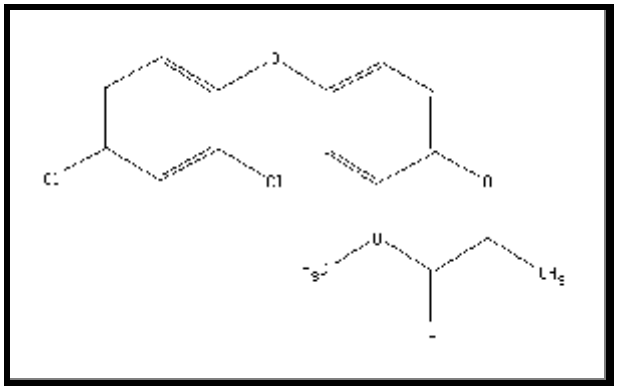
II. Chemical Overview

A. Regulatory History

Diclofop-methyl was first registered in the United States in 1982 for the control or suppression of wild oats and annual grasses in wheat and barley. It is currently also registered for weed control on established bermuda grass on golf courses. The use of diclofop-methyl on golf courses is authorized under Section 24(c) of FIFRA in the states of AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, and TX.

B. Chemical Identification

- **Chemical Name:** Methyl 2-(4-(2,4-dichlorophenoxy)phenoxy)-propanoate



- **Common Name:** Diclofop-methyl
- **Chemical Family:** Aryloxyphenoxy propionate
- **Case Number:** 2160
- **CAS Registry Number:** 51338-27-3
- **OPP Chemical Code:** 110902
- **Empirical Formula:** $C_{16}H_{14}Cl_2O_4$
- **Molecular Weight:** 341.2

- **Trade & Other Names:** Hoelon® and Illoxan®

- **Basic Manufacturer:** Aventis Crop Science

Diclofop-methyl is a colorless, crystalline solid with a melting point of 39-41^0 C; density of 1.30±0.05 g/cm^3 at 40^{0}C; octanol/water partition coefficient (P_{ow}) of 37,800; and vapor pressure of 1.9 x 10^{-6} mm Hg at 20^0 C. Diclofop-methyl is practically insoluble in water (0.3 mg/100 mL), and is soluble in xylene (253 g/100 mL), acetone (249 g/100 mL), and ethanol (11 g/100 mL).

- **Use Profile**

The following information is based on the currently registered uses of diclofop-methyl:

Type of Pesticide: Herbicide

Summary of Use Sites:

Food: Wheat and Barley

Residential: None

Public Health: None.

Other Nonfood: Golf Course (Turf). (Of the existing turf-related uses on current Special Local Need or Section 24(c) product registrations, the registrant is only supporting the turf use on golf courses.)

Target Pests: Controls wild oats and annual grassy weeds in wheat and barley, as well as goosegrass in established bermudagrass turfs on golf courses. Specifically, diclofop-methyl is used for the control of annual rye grass, broadleaf signal grass, crab grass, fall panicum, barnyard grass, water grass, foxtail grasses, goose grass, wild oats, itch grass, raoul grass, persian darnel, volunteer corn, witch grass (suppression), smallseed canary grass, and spring millet grass.

Formulation Types Registered: Formulated as a manufacturing product (93% active ingredient (ai)) and as an emulsifiable concentrate (34.7% ai)

Method and Rates of Application:

Equipment - Applied by fixed-wing aircraft, tractor-drawn equipment, and hand held equipment

Method and Rate - Broadcast; soil incorporated treatment; spray. The current maximum label rate is 1.0 lb ai/A for use on wheat and barley. In addition, the registrant is supporting the golf course turf use at a maximum rate of 1 1b ai/A (per treatment) and a seasonal maximum of 1.5 1b ai/A (per year). There is a maximum of one application per growing season on wheat and barley and a maximum of two applications on golf course turf (not to exceed the golf course turf seasonal maximum of 1.5 1b ai/A/year).

Timing - May be applied pre-plant, pre-emergent, or post-emergent (over 90% of diclofop-methyl usage is post-emergent)

Use Classification: Restricted Use Pesticide (due to carcinogenicity in mice)

C. Estimated Usage of Pesticide

This section summarizes the best usage estimates available for diclofop-methyl. A full listing of all uses of diclofop-methyl, with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" document, which is available in the public docket. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as variability in using data from various information sources. Approximately 750,000 lbs a.i. of diclofop-methyl are used annually, according to Agency and registrant estimates. The use of diclofop-methyl has been decreasing due to the introduction of other herbicides.

Table 1. Diclofop-Methyl Estimated Usage for Representative Sites

Crop/Site	Lbs. Active Ingredient Applied (Wt. Avg.)[1]	Percent Crop Treated (Likely Maximum)	Percent Crop Treated (Wt. Avg.)
Wheat	610,000	2%	1%
Barley	130,000	4%	1%
Golf Course	16,000	2%	1%

[1]Weighted Average is based on data for 1987 -1996; the most recent years and more reliable data are weighted more heavily.

III. Summary of Diclofop-Methyl Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for diclofop-methyl, as fully presented in the documents, "The HED Chapter of the Reregistration Eligibility Decision Document (RED)," dated August 10, 2000, and "EFED RED Chapter for Diclofop-Methyl," dated July 26, 2000. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

A. Human Health Risk Assessment

EPA provided a copy of the preliminary risk assessment for diclofop-methyl to the registrant in May of 2000 for identifying any errors in the Agency's analysis. In response to registrant comments, the risk assessments were updated and refined. Revisions to the human health risk assessment are listed below:

- Revised the short-term inhalation endpoint from a chronic feeding study in the rat to the more appropriate 90-day feeding study in the rat.

- Updated the dietary risk assessment to incorporate the percentage that cattle forage in diclofop-methyl treated fields.

- Revised the conclusion on endocrine disruptor effects of diclofop-methyl, clarifying that the mammalian toxicity data does not provide evidence that diclofop-methyl causes effects related to disruption of the endocrine system.

1. Dietary Risk from Food

a. Toxicity

The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete. The reregistration eligibility determination is therefore supported for all currently registered uses.

b. FQPA Safety Factor

The FQPA Safety Factor is intended to provide up to an additional 10-fold safety factor (10X), to safeguard against a special sensitivity in infants and children to specific pesticide residues in food or to compensate for an incomplete database. The Agency reduced the FQPA Safety Factor to 1X after evaluating the hazard and exposure data for diclofop-methyl. The FQPA Safety Factor was reduced to 1X for the following reasons:

1. The toxicology database is complete for the assessment of the effects following *in utero* and/or postnatal exposure to diclofop-methyl;

2. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to diclofop-methyl in the available toxicity data;

3. The Agency determined that a developmental neurotoxicity study is not required for diclofop-methyl;

4. Adequate monitoring data, surrogate data, and/or modeling outputs are available to satisfactorily assess dietary and non-occupational sources of exposure and to provide a screening level drinking water exposure assessment. The assumptions and models used in the assessments do not underestimate the potential risk for infants and children.

c. Population Adjusted Dose (PAD)

The PAD is a term that characterizes the dietary risk of a chemical, and reflects the Reference Dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA safety factor (i.e., RfD/FQPA safety factor). In the case of diclofop-methyl, the FQPA safety factor is 1; therefore, the acute or chronic RfD equals the acute or chronic PAD. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

d. Summary of Toxicological Endpoints

Three toxicological endpoints from animal studies were selected for evaluating the dietary risk to diclofop-methyl, corresponding to the acute dietary risk, chronic dietary risk (non-cancer), and chronic dietary risk (carcinogenicity) assessments. In addition to considering the FQPA Safety Factor discussed above, the Agency applied the conventional uncertainty factor (UF) of 100 to account for both for interspecies extrapolation (10X) and for intraspecies variability (10X).

The acute RfD of 0.1 mg/kg/day for females (13-50 years old) is derived from the developmental toxicity study in the rat. The acute endpoint was based on significant decreases in fetal body weight and crown-rump length, distended ureters, and skeletal abnormalities at the Lowest-Observed-Adverse-Effect-Level (LOAEL) of 32 mg/kg/day. The no-observed-adeverse-effect-level (NOAEL) for the pups was established at 10 mg/kg/day. The study and endpoint selected are considered appropriate since it is assumed that the fetal effects could have resulted from a single exposure *in utero*. The LOAEL for maternal systemic toxicity was established at 10 mg/kg/day. A NOAEL for maternal toxicity was not established. No appropriate endpoint was identified for the U.S. general population, including infants and children. There were no effects observed in oral toxicology studies (including maternal toxicity in the developmental toxicity studies in rats and rabbits) that are

attributable to a single exposure (dose) and applicable to the general population and other sub-populations.

The chronic RfD of 0.0023 mg/kg/day is derived from a combined chronic feeding/carcinogenicity study in the rat, and was calculated as the NOAEL (0.23 mg/kg/day) divided by an UF of 100X (10X for interspecies extrapolation and 10X for intraspecies variability). The chronic endpoint was based on increased absolute and relative liver and kidney weights, increased ALT (alanine aminotransferase), AST (aspartate aminotransferase), and AlkP (alkaline phosphatase) activities, impaired lipid and protein metabolism, and histopathology (hypertrophy, lipofuscin storage) in males and females at the LOAEL of 2.3 mg/kg/day.

For the cancer risk assessment, the Agency used a positive carcinogenicity study in mice which found a NOAEL of 0.24 mg/kg/day in males and 0.25 mg/kg/day in females. The LOAEL for systemic toxicity was established at 0.76 mg/kg/day and was based on clinical chemistry findings of relative organ weights in males and females. Electron-micrographs revealed peroxisome proliferation in the livers of high-dose animals. Based on the results of the mouse study, as well as a carcinogencity study in the rat (MRID 43927302) which also exhibited adenomas and carcinomas, diclofop-methyl was classified as a likely human carcinogen with a Q_1* of $2.3 \times 10^{-1}(mg/kg/day)^{-1}$.

Diclofop-methyl is classified as a likely human carcinogen based on laboratory studies in the rat and the mouse. However, the registrant believes that a linear low dose approach based on liver tumors in mice should not be used for the cancer risk assessments. The Agency has discussed the mode of action of liver carcinogenicity of diclofop-methyl and determined that data demonstrating peroxizome proliferation were very limited and consisted of high-dose animals from a mouse oncogenicity study and a 90-day feeding study in the rat. Control or intermediate dose animals were not examined, which makes evaluation of possible dose-response relationships impossible to determine. Also, peroxizome measurements did not substantiate what the Agency believes is the most sensitive indicator of peroxizome proliferation, catalase activity in the mouse. Therefore, the Agency is using a linear low-dose approach (Q^*) to assess chronic cancer risk to diclofop-methyl. The Agency's detailed analysis on the toxicity of diclofop-methyl can be found in the August 10, 2000 Human Health Risk Assessment as well as the "HED Response To Comments" document. A brief overview of the studies used for the dietary risk assessment is outlined in Table 2 in this document.

Table 2: Human Dietary Risk Assessment of Diclofop-Methyl

Assessment	Dose (mg/kg/day)	Endpoint	Study	UF	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary (females 13-50)	NOAEL=10	Decreased fetal body weights, extended ureters, skeletal abnormalities. Effects attributed to a single dose	Developmental Toxicity Study in the Rat (MRID 92036042)	100	1	0.1
Acute Dietary (General Population, including infants and children)	None	No endpoint selected	None	-	-	-
Chronic Dietary (Non-cancer)	NOAEL=0.23	Increased relative liver and kidney weights, liver histopathology (hypertrophy lipofuscin storage).	Chronic Toxicity Study in the Rat (MRID 43927302)	100	1	0.0023
Chronic Dietary (Carcinogenic)	Q_1*=2.3 x 10^{-1} $(mg/kg/day)^{-1}$	Liver Adenomas and Carcinomas with significant pair-wise comparisons.	Carcinogenicity Study in the Mouse (MRID 92036058)	N/A	-	-

e. Exposure Assumptions (Food)

Dietary risk assessment for diclofop-methyl is based on estimates of diclofop-methyl and/or its metabolites that may occur in barley grain and wheat grain. The assessment also includes the possible occurrence of diclofop-methyl residues in milk or animal tissues due to the feeding of treated grain, hay, or forage to dairy and beef cattle.

Submitted Data: Dietary risk assessment for diclofop-methyl is based, in part, on magnitude of the residue (field trial data) and processing studies submitted by the registrant in support of the reregistration of diclofop-methyl on wheat and barley grain, hay, and forage. The dietary risk assessment for diclofop-methyl is also based on submitted ruminant and poultry feeding studies that established the level of residue transfer to animal tissue, milk, and eggs.

Monitoring Data: Under the Pesticide Data Program (PDP), the USDA sampled wheat grain for diclofop-methyl in 1995 (600 samples), 1996 (340 samples), and 1997 (623 samples). Of these samples, there are two detections reported at 0.009 ppm and 0.01 ppm. The Limit of Detection (LOD) was described as 0.006 ppm for all samples.

FDA domestic surveillance data (years 1992-1998) is also available for diclofop-methyl residue in whole grain barley, whole grain wheat, processed wheat commodities, whole milk, and milk

products including cream and cheese. There are no reported detections of diclofop-methyl in any samples. Data indicate the Limit of Quantitation (LOQ) for FDA milk samples does not exceed 0.01 ppm. In addition, the analytical method employed by FDA may not include all of the pertinent metabolites of diclofop-methyl and as a result, the FDA data are not fully usable for risk assessment purposes. There are also no FDA surveillance data for diclofop-methyl residues in animal tissue.

Metabolites of Diclofop-Methyl: Diclofop-methyl metabolizes in plants and animals, and degrades in the environment to form various chemical species. For the tolerance expression of diclofop-methyl, the Agency has determined the residues of concern for plants are diclofop-methyl and its metabolites, 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoic acid (hereafter referred to as "diclofop acid") and 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy] - propanoic acid (hereafter referred to as "hydroxy diclofop") and hydroxy conjugates. For animals, the residues of concern are diclofop-methyl and its metabolite, diclofop acid.

Usage Data: Annual usage of diclofop-methyl has been estimated by the EPA using information from USDA's National Agricultural Statistics Service, The National Center for Agricultural Food and Policy, and other data sources. Estimates have been made, per commodity, of the weighted average yearly use and the estimated maximum yearly use.

Diclofop-methyl is estimated to be currently used on less than 1% of the total U.S. barley crop. Diclofop-methyl usage on wheat varies somewhat according to variety, with an estimated use of 1.2% used on winter wheat (winter wheat accounts for approximately 50% of total wheat produced), 0.4% use on spring wheat, and an estimated 12% use on durum wheat (durum wheat accounts for <4% of total wheat production). Total usage on wheat is estimated to be less than 2% of all wheat grown in the U.S.

Most diclofop-methyl usage is post-emergence (>90%), which suggests the potential importance of livestock exposure via foraging of treated wheat. The chronic risk assessment assumes, at most, 15% of dairy cattle consume wheat forage, a practice resulting in possible residues in milk. Data indicate that barley is not a significant forage item.

i. Residue Estimates for Acute Dietary (food) Risk:

The Dietary Exposure Evaluation Model (DEEM™) program for acute dietary exposure is based on each individual record of consumption from USDA's Continuing Survey of Food Intake by Individuals (CSFII). The program produces a distribution (from the 10th to the 99.9th exposure percentile) of daily exposures for individuals comprising the U.S. population and/or population subgroups (for this assessment, females 13-50 years of age). Acute dietary exposure (as calculated through DEEM™) is compared to the acute population adjusted dose (aPAD), which is the dose at which an individual could be exposed on any given day and no adverse health effects would be

expected, accounting for the FQPA safety factor. Acute dietary exposure that is less than 100% of the aPAD is not of concern.

Wheat/Barley Grain: The combined residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop were non-detectable (< 0.10 ppm) in field trial studies in/on wheat and barley grain. Wheat and barley processing data demonstrate that residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop, do not concentrate in bran, flour, or other processed fractions following post-emergence foliar application at five times the label rate.

Because wheat and barley grain are blended commodities, the residue estimate for risk assessment is based on a number of key assumptions, including ½ the LOQ (0.05 ppm in field trial studies), a (reduction) factor of 0.2 based on processing data at five times the label rate, and the percent of total crop treated (2% for wheat and 4% for barley). On this basis, the residue estimates for acute risk assessment are 0.2 ppb for wheat and 0.4 ppb for barley.

The extrapolated values are considered to be of higher confidence than the PDP/FDA monitoring samples taken from the whole grain. As mentioned previously, the analytical methyl employed by FDA may not have included all of the pertinent metabolites of diclofop-methyl and as a result, the FDA data are not fully useable for risk assessment purposes. Thus, the extrapolated values were selected for the risk assessment and the monitoring data helps to confirm the estimates used.

Animal Tissues: Metabolism studies have demonstrated a transfer of diclofop-methyl and diclofop acid to animal tissue (meats/fat/internal organs). Lacking monitoring data for these commodities, this aspect of the acute dietary risk assessment relies solely on extrapolated residue levels, based on an estimate of the possible exposure, or burden, to livestock from treated items, and transfer factors derived from ruminant and poultry feeding studies. Data from the poultry feeding study and an estimate of a low dietary residue burden for poultry led to a decision that a tolerance is not required for eggs or other poultry products. On the same basis, poultry products were not a factor in the dietary risk assessment.

A dietary burden reflecting a theoretical maximum exposure to diclofop-methyl for beef cattle (extrapolated to goats and sheep) and swine, is based on the feed items of wheat grain, wheat forage, and barley hay (and for acute assessment assumes 100% treatment of each item). Residue estimates for wheat forage (the most significant contribution to the diclofop-methyl dietary burden) are based on field trial measurements at day 26 following postemergence treatment. Although residue measurements for forage at day 10 following application were used to establish tolerances, the 26-day interval from application to foraging is considered a better estimate of actual agricultural practices and more suitable for risk assessment (the registrant has agreed to modify the current restriction on the diclofop-methyl label to preclude grazing for 28 days). From these data, a dietary burden of 1.86 ppm was established for beef cattle and a dietary burden of 45 ppm established for swine, based on wheat grain only.

Ruminant feeding data were used to derive estimates of residue transfer from plant feed items to liver, kidney, fat, and muscle of beef cattle, and swine tissue. Since the assessment is for acute, or maximum exposure, the highest measured residue from the feeding study dose level most closely corresponding to the estimated dietary burden (1.86 ppm) was used to calculate the final transfer factor for each of the above tissues.

Based on the data outlined above (residue burden x transfer factor), the residue estimates for acute dietary risk from ruminant tissues are: 46 ppb in meat/byproducts, 130 ppb in fat, 840 ppb in kidneys, and 220 ppb in liver. Swine tissue residue estimates, which are based on wheat grain only, are assessed at: 1 ppb in meat/byproducts, 3 ppb in fat, 20 ppb in kidney, and 5.4 ppb in liver.

Milk: Although extensive FDA surveillance monitoring data is listed for diclofop-methyl in milk and milk products (with no detections of diclofop-methyl or metabolites), the Agency decided not to use the FDA data in the risk assessment. This decision was made because it could not be determined if the FDA multi-residue method (The Pesticide Analytical Manual (PAM)- Volume II) identified the diclofop-methyl metabolites expected in milk.

The dietary burden for dairy cattle was estimated as above, except averaged residues from field trial studies were used instead of maximum residues to account for the blending that occurs in milk processing. Transfer factors were based on residues measured from the feeding study dose level most closely corresponding to the estimated dietary burden of 3.04 ppm.

Based on the data outlined above (residue burden x transfer factor), the residue estimates for acute dietary risk from dairy products are: 0.31 ppm in whole milk, 0.015 ppm in skim milk, and 0.79 ppm in cream (milk fat).

ii. Residue Estimates for Chronic and Carcinogenic Dietary (Food) Risks:

Chronic dietary exposure estimates are based on averaged consumption data for the entire U.S. population, and within population subgroups such as "all infants." For this assessment, the averaged consumption estimate of each population group is multiplied by residue estimates for wheat/barley grain, livestock tissue, and milk. Chronic dietary exposure estimates are calculated by the DEEM^{TM} program, and chronic dietary risk is calculated as a percent of the cPAD.

No appropriate endpoint was identified for the U.S. general population, including infants and children. There were no effects observed in oral toxicology studies (including maternal toxicity in the developmental toxicity studies in rats and rabbits) that are attributable to a single exposure (dose).

Wheat/Barley Grain: The combined residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop were non-detectable (<0.10 ppm) in/on wheat and barley grain in field trial

studies. Wheat and barley processing data demonstrate that residues of diclofop-methyl and its metabolites, diclofop acid and hydroxy diclofop, do not concentrate in bran, flour, etc. following post-emergence foliar application at 5x the label rate. Because wheat and barley grain are blended commodities, the residue estimate for risk assessment is based on ½ the LOD (0.05 ppm in field trial studies), a reduction factor of 0.2 based on processing data at 5x label rate, and factored for the percent of total crop treated (2% for wheat and 0.5% for barley). On this basis, the residue estimates for chronic risk assessment are 0.05 ppb for barley grain (and processed commodities) and 0.2 ppb for wheat grain (and processed commodities).

Animal Tissues: Residue estimates for chronic risk assessment for ruminant meats (and pork) were derived from the estimates summarized above for acute risk assessment. However, each chronic residue estimate has been factored for percent crop treated data, with the intent to more accurately reflect the variations of exposure expected over the long-term (cancer risk is based on the assumed lifetime exposure).

Based on the data outlined above (residue burden x transfer factor x percent crop treated) the residue estimates for chronic dietary risk from residues in ruminant tissues are: 0.9 ppb in meat/byproducts, 2.5 ppb in fat, 17 ppb in kidney, and 4 ppb in liver. Swine tissues are estimated at: 0.02 ppb in meat/meat byproducts, 0.04 ppb in fat, 0.4 ppb in kidney, and 0.09 ppb in liver.

Milk: Residue estimates for the chronic risk assessment for milk (and milk products) were derived from the residue estimates summarized above for the acute assessment. However, estimates for chronic risk assessment were adjusted for percent crop treated (1.6% for wheat forage) and for the estimated percent of total dairy cattle that may forage spring or winter wheat. The estimate for dairy cattle foraging, believed to be an upper-bound estimate, is 15% of total dairy cattle.

Based on the data outlined above (average residue burden x average transfer factor x percent crop treated x percent forage), the residue estimate for chronic dietary risk from milk and milk products is: 0.5 ppb (0.5 ppb is entered for each milk category in the DEEM program: non-fat solids, fat solids, sugar, and water).

2. Food Risk Characterization

a. Acute Dietary (food) Risk:

Generally, a dietary risk estimate that is less than 100% of the acute or chronic Population Adjusted Dose is not of concern. The diclofop-methyl acute dietary risk from food is well below the Agency's level of concern; that is, less than 100% of the acute PAD is utilized for females 13-50 years old. The results indicate that females (ages 13-50) are acutely exposed to diclofop-methyl at 8% of the aPAD (at the 99.9th exposure percentile). Table 3 below presents a summary of acute dietary risk to diclofop-methyl.

b. Chronic Dietary (food) Risk:

As previously mentioned, the DEEM^{TM} model was used to calculate chronic dietary exposure estimates based on average consumption data for the U.S. population and U.S. population subgroups including infants and children. Based on the residue and percent crop treated data outlined above, the DEEM^{TM} model estimates that all population subgroups, including infants and children, are chronically exposed to diclofop-methyl at a level less than, or equal to, 1% of the respective cPAD. Table 3 below presents a summary of chronic dietary risks to diclofop-methyl.

Table 3: Refined Acute and Chronic Dietary Risk Estimates

Population	Acute Dietary (99.9th percentile)		Chronic Dietary	
	Exposure (mg/kg/d)	% aPAD	Exposure (mg/kg/d)	% cPAD
U.S. General Population	n/a	n/a	0.000005	<1%
Children (1-6 years)	n/a	n/a	0.000016	<1%
All infants (< 1 year)	n/a	n/a	0.000007	<1%
Females (13-50)	0.007558	<8%	0.000003	<1%

c. Carcinogenic Dietary (food) Risk

As previously discussed, a carcinogenic risk for diclofop-methyl is quantified, based on the estimated average dietary exposure of the general U.S. population (0.000005 mg/kg bw/day) multiplied by the upper-bound potency factor (Q_1*) of 2.3 x10^{-1} (mg/kg/day)$^{-1}$. On this basis, the upper-bound carcinogenic risk estimate for diclofop-methyl is calculated to be 1.2 x 10^{-6}, which is the level generally considered negligible by the Agency (10^{-6}).

3. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground water and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. Modeling is considered to be an unrefined assessment and provides a high-end estimate of exposure.

Limited domestic surface and ground water monitoring data were available in the STORET data base (from 1989-1992) for diclofop-methyl and diclofop acid. All of the data were from ambient waters in Minnesota, Idaho, and Colorado. Reported concentrations in the monitoring data ranged from 0 to 0.1 ppb; the reported data represent values for the limits of detection in most cases.

The risk of contaminating surface or ground water by diclofop-methyl was evaluated by assessing the estimated environmental concentrations (EEC) for both surface and ground water for

parent diclofop-methyl (and its acid degradate) and the potential maximum population exposed through drinking water. The Agency considered the existing STORET monitoring data and a small scale prospective groundwater study (MRID 44532501) to characterize the potential for diclofop-methyl to contaminate ground water sources of drinking water. EEC's of diclofop-methyl in drinking water were calculated using PRZM/EXAMS (Tier 2 surface water) and SCI-GROW2 (Tier 1 groundwater). Because of the lack of adequate monitoring data from across the country, the Agency has conducted a surface water analysis and a Tier 1 groundwater analysis for diclofop-methyl using computer modeling.

Diclofop-methyl is not expected to reach ground or surface water in significant quantities under most conditions. If it were to reach surface water, it is expected to degrade rapidly by microbial metabolism. If diclofop-methyl were to reach ground water, it could possibly persist due to potentially low microbial activity. Biodegradation is the only apparent means of diclofop-methyl dissipation. Parent diclofop-methyl degrades rapidly in aerobic soil ($T_{1/2}$ # 1 day) to its acid metabolite, diclofop acid. Diclofop-methyl and its acid metabolite degraded with an estimated half life of 21 to 51.3 days in four aerobically incubated soils. Under anaerobic conditions, diclofop-methyl also degrades rapidly to diclofop acid. Diclofop acid was persistent under anaerobic conditions with a half life of greater than 60 days. Under almost all conditions, degradation is expected to be so rapid that diclofop-methyl will not have time to move in soil. Its low solubility in water (3 mg/L) also causes it to be less mobile in soil.

The residues of concern for drinking water are diclofop-methyl and its degradate, diclofop acid. PRZM/EXAMS and SCI-GROW modeling estimates, as well as monitoring data from the prospective groundwater study, include both the parent diclofop-methyl and its acid degradate. For the purposes of this risk assessment, the Agency assumes that the degradate is as toxic as the parent. The models were run assuming the parameters (i.e., application rate, frequency of application, etc.) associated with diclofop-methyl use on wheat and barley.

a. Surface Water

The Agency considered the existing STORET surface water monitoring data but decided the data were not suitable for predicting a drinking water estimate. Because the data values were all below the limit of detection (<0.1 ppb), the Agency decided that surface water modeling would provide more appropriate values for drinking water risk calculations.

For drinking water derived from surface water bodies, an **acute** concentration of 1.47 ppb was used to evaluate the risk to human health. This value is based on the maximum (upper 90th) percentile concentration calculated using PRZM-EXAMS. A **chronic** value of 0.097 ppb was used to evaluate the chronic and cancer risk to human health. This value is based on the 10 year annual mean concentration calculated using PRZM-EXAMS.

b. Ground Water

For drinking water derived from groundwater, a value of 0.067 ppb was used to evaluate acute, chronic, and cancer risks to human health. This value is based on the SCI-GROW2 model and assumes one application per season of 1 lb ai/acre.

A small scale prospective groundwater study found that diclofop-methyl does not leach to groundwater. In this study at 48 days after treatment, researchers detected bromide tracers in the shallow groundwater wells, indicating recharge of aquifer, yet neither diclofop-methyl nor its acid metabolites were detected in groundwater or soil water samples.

Because the predicted concentration (0.067 ppb) of diclofop-methyl in groundwater is below the limit of quantitation (1 ppb) from the prospective groundwater study, the Agency cannot predict with certainty whether diclofop-methyl will or will not reach groundwater at some level between 0 and 1 ppb. However, when taking all available information into consideration, particularly the environmental fate properties, the results of the prospective groundwater study, and the limited STORET ground water monitoring data, the Agency concludes that neither diclofop-methyl nor its acid metabolite are expected to reach groundwater. Nonetheless, the Agency used the modeled estimates to quantify exposure to potential diclofop-methyl residues in drinking water.

c. Drinking Water Levels of Comparison (DWLOC's)

To determine the maximum allowable contribution of pesticide residues from drinking water in the diet, EPA first looks at how much of the overall risk is contributed by food (and if appropriate, residential uses or other non-occupational sources of exposures), and then calculates a "drinking water level of comparison" (DWLOC) to determine whether modeled values exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary (food) exposure, does not exceed a level of concern. Acute exposure to residues of diclofop-methyl is considered to be exposure in a one-day time period via the oral route of exposure (i.e, through food and/or drinking water only).

The results of the Agency's drinking water analysis for acute (one-day), short-term, and chronic (lifetime) exposure are summarized below. Details of this analysis, which used screening models, actual monitoring data, and a small scale prospective ground water study are found in the HED Revised Human Health Risk Assessment, dated August 10, 2000.

i. DWLOC's for Acute Exposure

For acute risk, the potential drinking water exposure derived from either ground or surface water is not of concern. The DWLOC for the sub-population of females aged 13 to 50 is 3000 ppb.

Because the EEC is less than the DWLOC, the Agency has no concern for acute exposure to diclofop residues in water. The table below presents the values for the acute drinking water assessment.

Table 4. Summary of DWLOC Values for Acute Dietary Risk

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb) (SCI-GROW)	Surface Water (ppb) (PRZM-EXAMS)	DWLOC (ppb)
Females 13-50	0.1	0.007558	0.092442	0.067	1.47	3000

ii. DWLOC's for Short-Term Exposure

For short-term risk, the potential drinking water exposure derived from either ground or surface water is not of concern. Since the EECs are less than the DWLOC's for short-term exposure for all population subgroups (refer to Table 5), the Agency has no concern for short-term exposure to residues of diclofop-methyl in drinking water. Short-term risk applies only to a golfer who receives a combined exposure from dietary and non-occupational (i.e., golfing on a treated course) sources.

Table 5. Summary of DWLOC Values for Short-Term Dietary Risk

Population Subgroup	Surface Water (ppb) (PRZM-EXAMS)	Ground Water (ppb) (SCI-GROW)	Dermal Exposure (mg/kg/d)	Chronic Food Exposure (mg/kg/d)	Allowable Short-Term Water Exposure (mg/kg/d)	DWLOC (ppb)
U.S. Population	0.097	0.067	0.0036	0.000005	0.014842	500
Children (1-6)	0.097	0.067	0.0036	0.000016	0.014833	100
Females (13-50)	0.097	0.067	0.0036	0.000003	0.014845	400

iii. DWLOC's for Chronic Exposure

For chronic risk, potential exposure to drinking water residues from diclofop-methyl derived from ground and surface water is not of concern for all populations. There are no chronic non-occupational sources of exposure of diclofop methyl to consider in the DWLOC calculation. Since the EEC is less than the DWLOC for chronic exposure for the most highly exposed population of children 1-6, (DWLOC= 20), the Agency has no concern for chronic exposure to residues of diclofop-methyl in drinking water.

Table 6. Summary of DWLOC Values for Chronic (Non-Cancer) Risk

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Allowable Water Exposure (mg/kg/day)	Ground Water (ppb)	Surface Water (ppb) (PRZM-EXAMS)	DWLOC (ppb)
U.S. Population	0.0023	0.000005	0.002295	0.067	0.097	80
Children 1-6	0.0023	0.000016	0.002284	0.067	0.097	20
Females 13-50	0.0023	0.000003	0.002297	0.067	0.097	70

iv. DWLOC's for Cancer

The Agency typically calculates a cancer DWLOC for a pesticide that poses a potential dietary (food) risk. The cancer DWLOC is the concentration of a pesticide in drinking water as a part of the aggregate chronic exposure that results in a negligible cancer risk (10^{-6}).

The carcinogenic risk estimate for diclofop-methyl in the food supply (for the general U.S. population) is estimated to be 1.2×10^{-6}. Since this risk estimate is at the level (10^{-6}) generally considered negligible, the Agency was unable to calculate a $DWLOC_{cancer}$ because the DWLOC represents availability in the "risk cup." Since the $1.2x10^{-6}$ slightly exceeds the Agency's level of concern, there is no room in the "risk cup" for a DWLOC calculation.

4. Residential Handler and Non-Occupational Risk

a. Residential Handler Risk

There are no residential handler exposure scenarios expected because diclofop-methyl is a restricted use pesticide. A residential handler exposure assessment was not conducted.

b. Non-Occupational Post-Application Risk

The Agency has determined that there are potential non-occupational, post-application exposure scenarios that may occur to golfers and children over six years old who accompany adults to a golf course that has been treated with diclofop-methyl. MOEs do not exceed the Agency's level of concern for adults playing golf on diclofop-methyl treated golf courses. An MOE greater than 100 is not of concern to the Agency. It should also be noted that the Agency is developing a policy to standardize its golf course risk assessment procedures and that this policy will address children of various ages who play golf. The current risk assessment for adult golfers is thought to be protective of children who are 12 years of age and older because their surface area to body weight ratio is relatively constant from that age through adulthood and the predominant exposures are thought to be from the dermal route. The Agency is also concerned about children who are younger and is currently developing a policy to calculate and characterize exposures to this population. At this time, the Agency

has not completed this policy so the quantitative risk values for diclofop-methyl have not been calculated for younger children.

The following assumptions were used in estimating non-occupational post-application exposure to golfers on the day of application:

1) Dislodgeable foliar residue (DFR) values are assumed to be five percent (5%) of the application rate at day zero for turf-grass application, and transfer coefficients are assumed to be 500 cm^2/hour;

2) Continuous exposure is assumed to occur for 4 hours per day (assuming the entire 18-hole course is treated);

3) Average adult body weight is 70 kg;

4) Estimated exposure frequency to the highest residue level is 2 days/year (based on the assumption that a golfer would play up to four times on a course where diclofop-methyl is used, two times of which were on the day of treatment), and

5) Exposure duration is 50 years; and lifetime is assumed to be 70 years.

i. Non-Cancer Risk

Non-cancer risk estimates (a short-term scenario) for diclofop-methyl indicate that entry by golfers is not of concern on the day of application, as soon as the spray is dry. The Agency evaluated the non-occupational post application (golfer) non-cancer risk at both the 1 lb ai/A and at the 1.5 lb ai/A rate even though the registrant is not supporting use at this higher rate. The resulting MOE for this scenario is 310 at the typical application rate of 1.0 lbs. ai/A. This MOE is therefore not of concern to the Agency.

ii. Cancer Risk

The cancer risk for non-occupational exposure on a treated golf course (on the day of application) is 2.2×10^{-6}. Such long-term exposure assessments are conventionally based on the typical rate, which in this case is 1.0 lbs ai/A. The Agency is relying upon the supported, typical rate of 1 lb ai/A as the appropriate rate for assessing the post application non-occupational (golfer) cancer risk. For non-occupational exposure to a pesticide, the Agency considers a cancer risk probability of 10^{-6} or less to be negligible.

As mentioned above, the assumptions used in the cancer assessment for golfers are based on surrogate data and factors related to the behavior and environmental fate of the chemical in the

environment (e.g., dissipation of transferable residues). Due to a lack of chemical specific exposure data, and better information on actual use practices and golfer behavior, assumptions used to calculate post-application risks (e.g., hours exposure per day) are based on the professional judgement of Agency scientists and tend to be conservative.

5. Aggregate Risk

An aggregate risk assessment considers the combined risk from dietary exposure (food and drinking water) and residential risk or other non-occupational exposures, when appropriate. In this case, the Agency evaluated four types of aggregate exposures. Results of the aggregate risk assessment are summarized here, and are discussed extensively in the "Revised HED Chapter of the Reregistration Eligibility Decision Document." This document is available on the Agency's web page at www.epa.gov/pesticides/ diclofop-methyl and in the Public Docket.

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require that for establishing a pesticide tolerance "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, and residential uses of a pesticide, and other non-occupational sources of exposure. When appropriate, aggregate risk assessments are conducted for acute (one day), short-term (one to seven days), intermediate-term (seven days to several months), and chronic (lifetime) exposure. Occupational exposure is not considered in any aggregate exposure assessment.

a. Acute Aggregate Risk

The acute aggregate risk estimate for diclofop-methyl addresses exposure from food and drinking water. Acute exposure is considered to occur in a one-day time frame via the oral route of exposure (i.e. through food and drinking water). Acute dietary food risk for females 13-50 is below the Agency's level of concern (<100% aPAD). The estimated concentrations of diclofop-methyl in groundwater and surface water are below the Agency's level of concern for exposure to diclofop-methyl in drinking water as a contribution to acute aggregate risk.

Based on the available information, the Agency concludes that residues of diclofop-methyl in drinking water (when considered along with exposures from food uses) would not result in an acute aggregate human health risk of concern.

b. Short-Term Aggregate Risk

A short-term aggregate risk assessment considers exposure from food, water, and non-occupational sources of exposure to a pesticide for a period of 1 to 7 days. For diclofop-methyl,

dermal short-term exposure is likely to golfers who play on a course that has been treated within a few hours of use. At the registrant supported rate for use on golf courses, 1 lb ai/A, the MOE is 310 for non-occupational exposure.

Calculated short-term DWLOCs do not exceed the Agency's level of concern as a contribution to short-term aggregate exposure. The DWLOC for the most highly exposed sub-population, children 1-6 years old, is 100 ppb and the EEC is 0.097 ppb. Based on these estimates, the Agency concludes that residues of diclofop-methyl in drinking water when considered along with exposures from food uses and the short-term non-occupational exposure to golfers, would not result in a short-term aggregate human health risk of concern.

c. Chronic (Non-Cancer) Aggregate Risk

The chronic (non-cancer) aggregate risk estimate for diclofop-methyl addresses exposure from food, drinking water, and non-occupational sources of exposure. No chronic residential scenarios were identified for diclofop-methyl. Risk to golfers is a non-occupational source of potential exposure, however, golfers are only assumed to be exposed to the highest residues of diclofop for two days per year. Golfers were, therefore, included only in the short-term assessment (1-7 days). For this reason, the chronic aggregate exposure assessment addresses exposure from food and drinking water only.

Chronic dietary food risks are below the Agency's level of concern (<100% cPAD) for all population subgroups. The estimated concentration of diclofop-methyl in groundwater and surface water is below the Agency's level of concern for exposure to diclofop-methyl in drinking water as a contribution to chronic aggregate risk. Based on available information, the Agency concludes that residues of diclofop-methyl in drinking water (when considered along with exposures from food uses) would not result in a chronic aggregate human health risk estimate of concern.

d. Cancer Aggregate Risk

The cancer aggregate risk estimate to diclofop-methyl addresses carcinogenic (lifetime) exposure from food, drinking water, and residential sources of exposure (in the case of diclofop-methyl, long-term exposure to golfers). For the general population, the Agency does not believe that exposure to residues of diclofop-methyl in food and drinking water will significantly contribute to aggregate cancer risk.

The carcinogenic exposure to golfers (2.2×10^{-6}) is of concern; therefore, any aggregation of carcinogenic exposure to golfers with carcinogenic exposure from food and drinking water will only increase the risk further above the Agency's level of concern. However, as previously mentioned, the Agency believes that the cancer risk estimate for golfers is based on conservative assumptions and overestimates risk.

4. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or application, or re-entering treated sites. Occupational handlers of diclofop-methyl include: individual farmers or growers who mix, load, and/or apply pesticides, professional or custom agricultural applicators, and golf course management professionals. Risk for all of these potentially exposed populations is measured by a MOE, which determines how close the occupational exposure comes to a NOAEL. Generally, MOEs greater than 100 are not of concern. In certain cases, the Agency also calculated a lifetime cancer risk

a. Toxicity

By the oral route of exposure, diclofop-methyl is a toxicity category II and by the dermal route, it is placed in acute Toxicity Category III. Diclofop-methyl is placed in toxicity category IV via the inhalation route. Regarding the eye irritation potential of diclofop-methyl, test results place it in Toxicity Category III. In primary irritation studies, diclofop-methyl produced moderate eye irritation (toxicity category III) and slight dermal irritation (toxicity category IV). Refer to Table 7b below for a summary of the acute toxicity of diclofop-methyl.

Table 7b. Acute Toxicity Profile

Study Type	Animal	Results - Category Basis	Toxicity Cat	MRID No.
81-1 (870.1100): Acute Oral (LD_{50})	Rat	Combined LD_{50}=512 (428-636) mg/kg	II	41476001 92036052
81-2 (870.1200): Acute Dermal (LD_{50})	Rat	Male and Female LD_{50} > 2000 mg/kg	III	00071522 92036013
81-3 (870.1300): Acute Inhalation (LC_{50})	Rat	Male and female LC_{50}> 3.83 mg/L	IV	00032595
81-4 (870.2400): Primary Eye Irritation	Rabbit	Slight ocular irritant, Conjunctival redness and discharge at 24 hr, cleared by 72hr	III	42428601
81-5 (870.2500): Primary Dermal Irritation	Rabbit	Slight irritant, PII = 0.8 (0 to 72 hr)	IV	40213506
81-6 (870.2600): Dermal Sensitization	Guinea Pig	Buehler: Negative	NA	41476003 92036047
		Maximization: Moderate to severe sensitizer	NA	41476002 41476003 92036046

All occupational risk calculations are based on the most current toxicity information available for diclofop-methyl, including a 21-day dermal toxicity study in the rat. The uncertainty factor (UF) of 100 was applied to the risk assessment: 10X to account for interspecies extrapolation and 10X to account for intraspecies variability.

The short- and intermediate-term dermal NOAEL of 5 mg/kg/day is derived from a 21-day dermal toxicity study in the rat, and is based on increased liver enzymes, proteins, and absolute and relative liver weights at the LOAEL of 25 mg/kg/day. Diclofop-methyl is not expected to be used on a continuous long-term basis (i.e., greater than six months per year) resulting in chronic exposure to workers or handlers. Therefore, the Agency only conducted short-, intermediate-term, and cancer occupational risk assessments.

A dermal absorption factor (after 10 hours of exposure) of 15% is used to convert the dermal dose to an equivalent oral dose for the cancer risk assessment only. This factor is based on the results from the dermal absorption study, which measured two formulations of diclofop-methyl (Hoelon 3EW and 3EC).

The subchronic feeding study in the rat is appropriate for short- and intermediate-term inhalation risk assessment since the effect (liver toxicity) is consistent with the other studies in both rats and mice. The current use pattern for diclofop-methyl does not indicate a concern for long-term inhalation or dermal exposure. The toxicological endpoints, and other factors used in the occupational and residential risk assessments for diclofop-methyl are listed below.

Table 7a. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Risk Assessments for Diclofop-Methyl

Assessment	Dose	Endpoint	Study	UF*
Short-Term and Intermediate-Dermal	NOAEL=5mg/kg/day	Increased liver enzymes, proteins, and absolute and relative liver weights	21-Day Dermal Toxicity Study in the Rat (MRID 41476004)	100
Inhalation (Short- and Intermediate-Term)	Oral NOAEL=1.6 mg/kg/day	Based on increased liver enzymes, proteins, and absolute and relative liver weights. 100% inhalation is assumed	Sub-Chronic Oral Toxicity Study in the Rat (MRID 42573301)	100
Long-term Non-cancer(Dermal and Inhalation)	Based on the use pattern, this risk assessment was not conducted			N/A
Cancer (Dermal and Inhalation)	Q_1* of 2.3×10^{-1} $(mg/kg/day)^{-1}$	Based on Liver adenomas and carcinomas with significant trend and pair-wise comparisons.	Mouse Carcinogenicity Study (MRID 92036058)	100

* UF includes a 10X for interspecies variability and a 10X for intraspecies variability.

b. Occupational Risk Assessment Exposure Assumptions

i. Occupational Handler Risks

Anticipated use patterns, application methods, and application rates were derived from current end use product labeling. Application rates specified on diclofop-methyl labels range from 1 lb ai/A in

agricultural settings to 1.5 lb ai/A on golf course turf. The registrant is only supporting the 1.0 lb ai/A for golf course turf. However, the risk assessment considered the higher rate on golf courses for some assessments.

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protective. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an MOE or cancer risk (i.e., going from minimal to maximum levels of protection) that is no longer of concern to the Agency. The lowest level of personal protective equipment (PPE) is baseline PPE. If required (i.e., MOEs are less than 100), increasing levels of risk mitigation PPE are applied. If MOEs are still less than 100, engineering controls (EC) are applied. In some cases, EPA will conduct an assessment using PPE or ECs taken from a current label. The levels of protection that formed the basis for calculations of exposure from diclofop-methyl activities include:

- **Baseline:** Long-sleeved shirt and long pants, shoes and socks.
- **Minimum PPE:** Baseline + chemical resistant gloves and a respirator.
- **Maximum PPE:** Coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation.
- **Engineering controls:** Engineering controls such as a closed cab tractor for application scenarios, or a closed mixing/loading system, such as a closed mechanical transfer system for liquids or a packaged based system (e.g., Lock-N-Load for granulars or water soluble packaging for wettable powders).

The Agency has determined that occupational exposure to diclofop-methyl residues via the dermal and inhalation routes of exposure may occur during mixing, loading, applying, and other handler-use activities. Based on registered use patterns, seven major exposure scenarios have been identified for diclofop-methyl:

(1) mixing/loading liquids for groundboom application;
(2) mixing/loading liquids for aerial application;
(3) mixing/loading liquids for hand gun sprayer application;
(4) applying liquids with a groundboom sprayer;
(5) applying liquids with a fixed-wing aircraft;
(6) applying liquids with a hand gun sprayer; and
(7) flagging for liquid applications.

The exposure scenarios are of short-term (1-7 days) and intermediate-term (one week to several months) duration only. No chronic occupational handler exposure scenarios have been identified for diclofop-methyl. However, the Agency also evaluated the cancer risk for handlers of diclofop-

methyl. The estimated exposures consider baseline protection (long pants; long sleeved shirt; no gloves; open mixing/loading; and open cab tractor), additional PPE (double layer of clothing; chemical resistant gloves; and a dust mist respirator), and engineering controls (closed mixing/loading; enclosed cab, cockpit, and truck; and water soluble packaging).

Chemical-specific exposure data for assessing human exposures during pesticide handling activities were not submitted to the Agency in the support of the reregistration of diclofop-methyl. It is Agency policy to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical specific monitoring data are not available. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.

General assumptions used in the occupational handler exposure assessment include an average body weight of an adult handler as 70 kg and an average work day interval of eight hours. Each exposure scenario includes the allowable maximum application rate that was identified on available product labels. In addition, a range of application rates was used for golf courses. The daily acres treated are Agency standard values; deviations from Agency standard values include the use of 40 acres per day for groundboom application to golf courses. The Agency believes that most users of diclofop-methyl on golf courses are handlers employed by the golf course rather than professional or custom applicators. Such users typically only spot treat about 5 acres at a time, rarely treating the whole golf course. Nonetheless, the Agency assumed handlers would treat the entire course because the label does not limit the user from treating an entire golf course (which is assumed to be 40 acres). Also, the Agency typically uses a value of 1,200 acres for aerial treatment to wheat and barley. In the case of diclofop-methyl, the Agency has determined that 350 acres is more representative of current diclofop use practices. Therefore, risk to workers who handle diclofop-methyl supporting aerial applications was assessed at 350 acres per day.

Several issues should be considered when interpreting the occupational exposure risk assessment. These include: the quality of the PHED data set; the use of several generic protection factors for calculating handler exposures (e.g., 80 percent protection factor over baseline for inhalation unit exposure to account for the use of a dust/mist respirator); and the use of standard assumptions (e.g., acres treated per day, square feet applied, and gallons of liquid applied) that are based on the Agency's best professional judgement. Estimates of acres treated per day were provided by the registrant and, while the registrant's estimates are generally lower than Agency estimates, the magnitude of the differences are not considered sufficient to significantly impact the results of the assessment.

The PHED task force has evaluated all data within the system and developed a set of grading criteria to characterize the quality of the original study. Mixing/loading/applying liquids by groundboom scenario has a high quality grade; mixing/loading liquid for a hand gun sprayer has a high quality grade; applying liquid with a hand gun sprayer has a low quality grade; mixing/loading liquid for fixed-wing aircraft has a high quality grade; applying with a fixed wing aircraft has a low quality grade; and flagging for liquid application has a high quality grade.

ii. Non-Cancer Handler Risk

Dermal and inhalation NOAELs for diclofop-methyl were based on a common endpoint; therefore, the dermal and inhalation MOEs were combined to determine a total short-term MOE and a total intermediate-term MOE. Short-term MOEs represent exposure scenarios that are one to seven days in duration. Intermediate-term MOEs represent exposure scenarios that are one week to several months in duration. A MOE greater than or equal to 100 is not of concern.

iii. Cancer Handler Risk

General assumptions used in the occupational cancer risk assessment include an average body weight of 70 kg, a career duration of 35 years which represents a typical working lifetime, a lifetime of 70 years, 15% dermal absorption and 100% inhalation absorption, a Q_1* of 2.3×10^{-1} $(mg/kg/day)^{-1}$, and PPE (baseline plus coveralls and a dust/mist respirator). Two exposure frequency scenarios were used for wheat and barley in the calculations: the first represents the maximum number of applications per site per year for private use (10 days), and the second represents commercial handlers making multiple applications per site per year (20 days). For golf courses, an exposure frequency of 10 days per year is assumed.

The cancer risk assessment for handlers uses a baseline exposure scenario and, as needed, increasing levels of risk mitigation (PPE and engineering controls) to achieve cancer risks that are not of concern. The Agency's goal is to mitigate occupational cancer risk estimates to 1×10^{-6} or less. For diclofop-methyl, cancer risk for occupational dermal and inhalation exposure range from 1.4×10^{-2} to 5.1×10^{-6} at the baseline level, 8.4×10^{-5} to 6.0×10^{-7} with PPE, and 5.8×10^{-5} to 1.4×10^{-6} at the engineering control level.

Table 8: Summary of Exposure Variables, MOEs, and Cancer Risks for Handlers of Diclofop-Methyl

Exposure Scenario (Scenario #)	Application Rates (lb ai/A)	Acres Treated per Day	Total Short-term MOE			Total Intermediate-term MOE			Cancer		
			Baseline[1]	PPE[2]	Eng. Control[3]	Baseline[1]	PPE[2]	Eng. Control[3]	Baseline[1]	PPE[4]	Eng. Control[3]
Mixer/Loader Risk											
Mixing/loading liquids for groundboom application (1)	1.0	80	2	165	NA	2	165	NA	1.60e-03/ 3.20e-03	9.61e-06/ 1.92e-05	4.90e-06/ 9.80e-06
	1.0	40	3	325	NA	3	325	NA	7.90e-04	4.80e-06	2.50e-06
	1.5		2	220	NA	2	220	NA	NA	NA	NA
Mixing/loading liquids for aerial application (2)	1.0	350	<1	60	110	<1	60	110	6.90e-03/ 1.40e-02	4.20e-05/ 8.40e-05	2.20e-05/ 4.40e-05
Mixing/loading liquids for hand gun sprayer (3)	1.0	5	25	2615	NA	25	2615	NA	9.80e-05	6.00e-07	NA
	1.5		15	1745	NA	15	1745	NA	NA	NA	NA
Applicator											
Applying liquids with a groundboom sprayer (4)	1.0	80	270	NA	NA	270	NA	NA	1.0e-05/ 2.0e-05	6.50e-06/ 1.30e-05	2.90e-06/ 5.80e-05
	1.0	40	535	NA	NA	535	NA	NA	5.10e-06	3.10e-06	1.40e-06
	1.5		360	NA	NA	380	NA	NA	NA	NA	NA
Applying liquids with a fixed-wing aircraft (5)	1.0	350	See Eng. .Control	See Eng. Control	165	See Eng. Control	See Eng. Control	165	See Eng. Control	See Eng. Control	1.30e-05/ 2.60e-05
Applying liquids with a hand gun sprayer (6)	1.0	5	See PPE	205	NA	See PPE	205	NA	See PPE	1.90e-05	NF
	1.5		See PPE	135	NA	See PPE	135	NA	NA	NA	NA
Flagger											
Flagging for liquid application (7)	1.0	350	85	100	760	85	100	760	9.50e-05/ 1.90e-04	7.3e-05/ 1.5e-04	1.90e-06/ 3.80e-06

* Target MOEs for all the above scenarios are 100.

1. Baseline dermal exposure scenarios includes long pants, long shirts and no gloves. Baseline inhalation exposure represents no respirator
2. Additional dermal PPE for scenarios 1, 3 and 6 includes long pants, long shirts and gloves and for scenario 2 includes long pants, long shirts, gloves and coverall. Additional inhalation PPE for scenario 2 includes organic vapor respirator (10-fold PF).
3. Engineering Controls dermal exposure value represents scenario 2 enclosed mixing and loading, scenario 5 enclosed cockpits and scenario 7 enclosed cab with single layer clothes, no gloves.
4. Maximum PPE (coveralls and organic vapor respirator) were used for cancer assessment. (All scenarios except scenario 5.)

5. Occupational Post-Application

The post-application occupational risk assessment considered exposures to workers entering treated sites in agriculture as well as exposures that can occur as a result of turf management activities on golf courses. The Agency has determined that there are potential post-application exposures to occupational workers in the following scenarios: mowing/maintaining golf course turfgrass; and scouting of wheat and barley fields. Because harvesting wheat and barley is fully mechanized, there is low potential for post-application exposure. Therefore, a quantitative risk assessment was not conducted for this scenario. Fully mechanized is defined as activities that eliminate the potential for pesticide exposure by physically separating the worker from anything that has been treated with the pesticide to which the restricted-entry interval applies. This includes, but is not limited to, soil, water, air, or surfaces of plants. These mechanized processes must meet the criteria described in the Worker Protection Standard for entry during a restricted entry interval (REI) for activities with "no contact." The current REI for diclofop-methyl is 24 hours.

No chemical specific post-application exposure studies were conducted by the registrant. Therefore, post-application exposures to occupational workers were estimated using assumptions for a surrogate post-application assessment presented in the Standard Operating Procedures (SOPs) for Residential Exposure Assessments (12/18/97). These data were used in conjunction with Agency standard values for transfer coefficients to assess potential exposures to workers reentering treated sites.

The following assumptions were used in the calculations of occupational post-application risk: dislodgeable foliar residue (DFR) values are assumed to be five percent of the application rate at day zero for turfgrass application; transfer coefficients are assumed to be 500 cm^2/hour for mowing and maintaining golf course turf and 1000 cm^2/hour for scouting of wheat and barley; daily exposure is assumed to occur for eight hours per day for mowing and maintaining golf course turf and scouting wheat and barley; the average adult body weight is assumed to be 70 kg; exposure frequency is assumed to be four days/year for golf course mowing and 10 days/year for wheat and barley scouting (based on best professional judgement); exposure duration is assumed to be 35 years (a typical working lifetime); and lifetime is assumed to be 70 years.

a. Occupational Non-Cancer Post-Application Risk

Entry by golf course workers to mow and maintain golf course turf is acceptable on the day of application, as soon as the spray is dry. MOEs are based on a dermal NOAEL of 5 mg/kg/day. The MOEs for this scenario are 155 for workers who mow and/or maintain golf course turf at the 1.0 lbs ai/A rate and 105 for these workers at the higher, spot application rate of 1.5 lbs ai/A (this latter rate is not supported by the registrant). The MOE for the scout who reenters a wheat or

barley field is 195 at the typical application rate of 1.0 lb ai/A. A MOE greater than100 is not of concern.

b. Occupational Cancer Post-Application Risk

The calculation of cancer risk for workers scouting in treated wheat and barley fields is $2.3x10^{-5}$ on the day of application. The Agency estimated the cancer risk for workers who mow and maintain golf courses to be $6.1x10^{-6}$, at the typical rate of 1.0 lbs ai/A. The Agency is relying upon the supported, typical rate of 1 lb ai/A as the appropriate use rate for assessing the occupational post application cancer risk on golf courses.

D. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects Division chapter, dated July 26, 2000 available in the public docket or at www.epa.gov/pesticides/reregistration/diclofop-methyl.

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics, pesticide use, and/or monitoring data. To evaluate the potential risk to nontarget organisms from the use of diclofop-methyl products, EPA calculates a Risk Quotient (RQ), which is the ratio of the estimated exposure concentration to the toxicity endpoint values, such as LD50 (the median lethal dose at which 50% of the test animals die) or LC50 (the median concentration of a substance which causes death to 50% of the test animals). The RQ, a non-probabilistic expression of risk, is simply a means of integrating the results of ecological exposure and ecological toxicity. These RQ values are compared to levels of concern (LOCs), which provide an indication of the risk that a particular pesticide and/or use may pose for nontarget organisms. If the RQ does not exceed the LOC, it is unlikely that the pesticide will pose a significant risk. Similarly, when RQs are equal to or greater than the LOC, additional refinements or mitigation are usually undertaken. Use, toxicity, fate, and exposure are considered to characterize the risk as well as the level of certainty and uncertainty in the assessment.

Terrestrial and aquatic risks were assessed for a single broadcast application of diclofop-methyl at the rate of 1 lb ai/A. Risk to terrestrial organisms were also assessed for multiple spot-treatment applications. For spot treatments, the maximum application rate for spot treatments is 1.0 fl oz per 1000 ft^2, or approximately 1.0 lb ai/A, the same as for broadcast applications. The maximum per season or annual rate for spot treatment is 1.5 fl oz per 1000 ft^2, or 1.53 lb ai/A. Therefore, to assess the worst case use pattern, the assessment was based on a single application at 1.0 lb ai/A followed by a second application of 0.53 lb ai/A. The application interval was assumed to be 7 days. Risk to aquatic organisms was not assessed for repeated spot-treatment applications because there were no risks identified for a single broadcast application. For aquatic exposure, the single broadcast

application represents the worst-case use pattern because of significantly higher quantity of application and the area treated as compared to spot treatments.

1. Environmental Fate and Transport

Biodegradation is the predominant means of dissipation of diclofop-methyl. Parent diclofop-methyl rapidly degrades in aerobic soil ($T_{1/2}$ # 1 day) to its acid metabolite, diclofop acid. Diclofop-methyl and its acid metabolite degraded with an estimated half life of 21 to 51.3 days in four aerobically incubated soils. Under anaerobic conditions diclofop-methyl degraded rapidly to diclofop acid. The diclofop-acid was extremely persistent under anaerobic conditions with a half life of greater than 60 days. Under almost all uses, the degradation is expected to be so rapid that diclofop-methyl will not have time to move in soil. Its low solubility in water (0.8 mg/L at pH 7.0) also causes it to be immobile.

Diclofop-methyl is stable to hydrolysis at pH 5 with a reported half-life of 363 days. Under alkaline conditions diclofop-methyl is unstable with a half-life of 12.5 hours at pH 9. In pH 7 buffer solution, diclofop-methyl is moderately stable with a half-life of approximately 32 days. Diclofop acid was the only degradate detected in any of the solutions, and it did not undergo any further hydrolytic degradation at any pH in a study performed at 25EC. (MRID 41573309)

In another hydrolysis study (Acc. No. 244-465) performed at 21EC, it was demonstrated that diclofop-methyl hydrolyzed rapidly at pH 9 with a half-life of 1.85 days, slowly at pH 7 with a half-life of 21.4 days, and at pH 5 the half-life was 2650 days. Diclofop acid was the only degradate detected in any of the solutions, and it did not undergo any further hydrolytic degradation at any pH.

Diclofop-methyl plus diclofop acid, the primary degradate, degraded with estimated half-lives of 21 to 51.3 days in four aerobically incubated soils. Parent diclofop-methyl was rapidly degraded to diclofop acid. Except for the sterilized soils, all the parent had been degraded by the 4th day of sampling to mainly diclofop acid. The concentration of the primary degradate reached it highest concentration at 1 or 2 days (77.7% of applied radioactivity, 1.17 ppm) and then decreased to an average 13.1% (0.2 ppm) of the applied radioactivity after 100 days of incubation. Diclofop acid degraded to diclofop phenol (4-(2,4-dichloro phenoxy)-phenol, but never was greater than 4% of applied radioactivity (0.06 ppm). Extractable residues accounted for 14-40% of the applied radioactivity by the termination of the study; while bound residues were 25-42% of applied radioactivity. (MRID 41573311).

To better understand the environmental fate and transport of diclofop-methyl and its free acid metabolite in soil, soil water, and groundwater, a small scale prospective groundwater (PGW) study was undertaken by the registrant in Minnesota (MRID 44532501). The study site selected represented wheat production in a cold climate where diclofop-methyl usage is relatively high. Study results up to 2 years after the initial application of diclofop-methyl show that no residues leached into ground water.

Based upon the modeling, monitoring, and the PGW study, diclofop-methyl is not expected to reach either ground water or surface water in significant quantities.

Diclofop-methyl is not persistent in soil under aerobic conditions ($T \leq 1$ day) and has very low persistence in anaerobic soil or water. The residues that do reach surface waters will likely be rapidly degraded by microbial metabolism. The results of the PGW study indicated that neither diclofop-methyl or its acid degradate migrated to the ground water during the two- plus- year study in a worst case scenario application.

2. Risk to Bird and Mammal Species

a. Acute Risk To Birds

Results of acute oral toxicity testing with an upland game bird, using technical grade diclofop-methyl, found LD_{50} values greater than 2000 mg/kg. Diclofop-methyl is practically nontoxic to avian species on an acute oral basis. In addition, the results of subacute dietary testing with an upland game bird (the northern bobwhite) and a waterfowl (the mallard) using technical grade diclofop-methyl yielded LC_{50}'s which exceeded 5000 ppm. Therefore, diclofop-methyl is practically nontoxic to birds on an acute and a subacute dietary basis. (MRID's 40072901 and 40072902).

For all use sites and application methods of diclofop-methyl, acute risk quotients for birds are less than the Agency's level of concern. The RQs range from 0.01 to 0.03. Because all acute RQs are less than the LOC for acute high risk (0.5) and risk to endangered species (0.1), all uses of diclofop-methyl are predicted to pose no risk to birds on an acute basis. The Agency, therefore, has no concern for acute and subacute risks to birds.

b. Chronic Risks To Birds

Results of avian reproductive studies with technical grade diclofop-methyl found no significant effect of reproduction or parental toxicity at dietary concentrations up to 200 ppm. The studies are supplemental because the test levels were not high enough to determine the NOAEL and LOAEL, and the highest test concentration was less than the maximum expected environmental concentration (EEC). With a maximum application rate of 1 lb ai/A, the maximum EEC is 240 ppm. Because the available data is sufficient to conclude a low risk of chronic effects to birds, the registrant's request to waiver new avian reproduction studies to fulfill this guideline has been approved by the Agency.

For single broadcast applications to wheat, barley, and turf, chronic avian risk quotients for reproductive effects range from 0.08 (seeds) to 1.2 (short grass). Because the short grass RQ slightly exceeds the chronic risk LOC of 1, chronic risk is not ruled out. However, avian reproduction studies have shown that diclofop-methyl caused no reproductive effects at 200 ppm, the highest concentration tested. Therefore, chronic risks to bird species are probably not high, even for birds eating short grass

(chronic RQ of 1.66). The Agency therefore, has little concern for chronic risks to both endangered as well as non-endangered birds.

c. Acute Risks to Mammals

Wild mammal testing is not required for diclofop-methyl because a rat toxicity test submitted to the Agency provided adequate information on toxicity to mammals. The geometric mean of the LD_{50} for male and female rats is 568 mg/kg. This indicates that diclofop-methyl is moderately toxic to small mammals on an acute oral basis.

A limited amount of information on the subchronic toxicity of diclofop acid, the primary degradation product of diclofop-methyl, is provided by a subchronic study with the rat. This study found that a dietary concentration of 500 ppm of diclofop acid caused increased kidney weight in males. The NOAEL was 100 ppm. For comparison, a 30-day feeding study with the rat testing diclofop-methyl found increased organ weights in males at a dietary concentration of 80 ppm. This study did not determine the NOAEL. These results indicate that diclofop acid is less toxic to mammals than the parent compound, diclofop-methyl.

For use of diclofop-methyl on wheat, barley, and turf, acute risk quotients for mammals are below the LOC for high risk and thus do not pose a high risk to non-endangered species. For small herbivorous mammals feeding on short grass, the RQ (0.55) slightly exceeds the high acute risk LOC (0.5). This indicates that repeated spot applications of diclofop-methyl on turf may pose an acute risk to small herbivorous mammals. Risk Quotients for other types of mammals are below the LOC for high risk. Therefore, with the exception of the border-line risk finding for small herbivorous mammals, the Agency does not have a concern for acute risks to both endangered and non-endangered mammals.

d. Chronic Risks To Mammals

Based on the results of some chronic and sub-chronic mammalian studies, the NOAEL and LOAEL for ecologically significant effects in mammals are established at 30 ppm and 100 ppm, respectively, based on pup mortality observed in the 3-generation reproduction test. It is noteworthy that a short-term (15-week) developmental study showed fetotoxic effects with an oral dose of 32 mg/kg body weight, which is approximately equivalent to an dietary dose of 640 ppm. This indicates that short-term exposure to diclofop-methyl can impair reproduction of mammals, although somewhat higher doses are required than for long-term exposures.

Chronic risk quotients for mammals range from 0.50 to 8.0. Because RQs for all food types (with the exception of seeds) exceeds the chronic LOC (1.0), all uses of diclofop-methyl may pose chronic risk to mammals, and may pose a risk to threatened as well as endangered mammalian species.

Since the Agency's risk assessment screen indicates that there may be a chronic risk, risk could be further evaluated and refined if additional existing fate data were provided by the registrant. The registrant has agreed to provide additional data which may support a conclusion that diclofop-methyl has a shorter half life on foliage that is shorter than that assumed by the Agency in the risk assessment. If the Agency confirms the shorter half-life, then the chronic risk to mammals would not be of concern.

3. Risk to Aquatic Animal Species

Results of acute toxicity testing with freshwater fish using technical grade diclofop-methyl and a formulated product indicate that LC_{50} values for both a cold water test species (the rainbow trout) and a warm water test species (the bluegill sunfish) falls in the range of 0.1 to 1 ppm. (MRIDs 41573302, 41606301, and 00098297) for the technical grade; and MRIDs 41606302 and 41606303 for formulated product).

A study with the rainbow trout provides information on the free acid metabolite of diclofop-methyl. The 96-hr LC_{50} was determined to be 21.9 ppm. This indicates that the acid metabolite of diclofop-methyl is less toxic to fish than the parent by almost two orders of magnitude (MRID 00098297).

Acute and chronic RQs for fish and aquatic invertebrates range from less than 0.01 to .02. No RQ exceeds the LOC for high risk or risk to threatened or endangered species. For both the broadcast applications to turf and spot treatments on golf courses, the Agency is not concerned with acute or chronic risks to freshwater or marine fish and invertebrates.

4. Risk To Terrestrial and Aquatic Plant Species

a. Acute and Chronic Risks Non-target Terrestrial Plants

Tier 2 terrestrial plant testing was required and submitted for diclofop-methyl because it is an herbicide that has terrestrial non-residential outdoor use patterns, could move off the application site via runoff and spray drift (for aerial applications), and might affect endangered or threatened plant species associated with the application sites. The required testing consists of seedling emergence and vegetative vigor tests with ten crop species.

Results of tier 2 seedling emergence testing show ryegrass is the most sensitive monocotyledon and the most sensitive species overall, with an EC_{25} of 0.012 lb ai/A and an NOAEC of 0.0063 lb ai/A. Lettuce was the most sensitive dicotyledon. These data indicate that monocotyledons are much more sensitive to diclofop-methyl than are dicotyledons. (MRID 41606306).

Results of tier 2 vegetative vigor were similar to the seedling emergence test in showing that monocotyledons are much more sensitive to diclofop-methyl than are dicotyledons. Ryegrass is the

most sensitive monocotyledon and the most sensitive species overall, with an EC_{25} of 0.10 lb ai/A and an NOAEC of 0.0625 lb ai/A. Lettuce was the most sensitive dicotyledon. (MRID 41606306).

RQ values for the acute and chronic risks to non-target terrestrial plants range from 0.10 to 17.46. Because these RQs exceed the LOC of 1, use of diclofop-methyl on wheat, barley, and turf is predicted to pose high risk to non-target terrestrial plants. Threatened and endangered species would also be at risk if exposed to runoff and/or spray drift. Risks generally stem from effects on seedling emergence and growth from soil exposure. Effects on vegetative vigor from spray drift alone are predicted to be minimal.

b. Acute and Chronic Risks to Aquatic Plants

Exposure to non target aquatic plants may occur through runoff and spray drift from treated sites. No aquatic plant testing has been submitted for diclofop-methyl or diclofop acid. The test guideline requirements (850.4400 and 850.5400) have not been fulfilled.

In section V of this document, additional data will be required to allow the Agency to determine risk to aquatic plants. Because the Agency does not have data to adequately assess risk to aquatic plants, high risk to aquatic plants is assumed.

IV. Risk Management, Reregistration and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient diclofop-methyl 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 diclofop-methyl 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 diclofop-methyl. Appendix A lists the uses eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of diclofop-methyl.

These data were sufficient to allow the Agency to determine that diclofop-methyl can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency, therefore, finds that all products containing diclofop-methyl as the active ingredient are eligible for reregistration, provided specified changes are made to the label. Actions needed to reregister particular products are addressed in Section V of this document The Agency believes that these label changes

address the current risk estimates and reflect the use of all acceptable data available at this time together with uncertainty factors and where data gaps exist.

The Agency may take appropriate regulatory action if new information comes to the Agency's attention regarding the reregistration of diclofop-methyl. The Agency may also require the submission of additional data (1) to support the registration of products containing diclofop-methyl, (2) if the data requirements for registration change, or (3) if the guidelines for generating such data change.

B. Summary of Comments and Responses

When making this reregistration decision, the Agency took into account comments received during the registrant error correction and public docket phases of the RED development process. The registrant was given 30 days to review the preliminary risk assessments for errors and the public was also provided an opportunity to comment on the revised risk assessments. The registrant provided general comments and technical correction type comments, most of which have been incorporated into the revised assessments. The comments and Agency responses are available in their entirety in the OPP public docket.

Among the comments provided by the registrant several are noteworthy. The registrant commented that the endpoint based on a chronic feeding/carcinogenicity study in rats is inappropriate to assess single exposures or intermittent exposures of less than one week to several months, when toxicity studies of more relevant dosing duration are available. The registrant felt that the 90-day feeding study in rats was more appropriate for the short-term inhalation risk assessment endpoint than the chronic feeding/carcinogenicity study in rats. The Agency concurs with the registrant's basic position and has changed the endpoint for acute and chronic intermediate-term inhalation exposure. These endpoints are now established using a NOAEL of 1.6 mg/kg/day from a sub-chronic feeding study in the rat.

In addition, the registrant believes that the default turf transferable residue (TTR) value of 5% of the application rate used in the Agency's post application risk assessment should be replaced with a TTR value of 0.30% of the application rate (Day 0) based on some of the newly submitted Outdoor Residential Exposure Task Force (ORETF) data. In the registrant's view, the use of ORETF data in place of the default assumptions used by the Agency would refine the golfer cancer risk to a level that is traditionally acceptable to the Agency.

The Agency does not believe that the 0.30% value is adequately supported by the ORETF data in the case of diclofop-methyl, nor did ORETF develop chemical specific data for diclofop-methyl use on golf courses to replace default values. In the past few months, the Agency has in fact updated the assumptions used in such risk assessments and adjusted parts of the Residential Exposure SOPs, such as using a Turf Transferrable Residue (TTR) based on 5% of application rate on the day of application. The former default TTR value was 20%.

C. Tolerance Reassessment

Based on the review of the generic data for diclofop-methyl, the Agency has sufficient information to reassess tolerances for diclofop-methyl. Specific findings are discussed in the following section.

D. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from exposure to diclofop-methyl is within its own "risk cup." In other words, because at this time diclofop-methyl has not been found to share a common mechanism of toxicity with other chemicals, EPA is able to conclude that the tolerances for diclofop-methyl meet the FQPA safety standards. In reaching this determination EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. An aggregate assessment was conducted for exposures through food, drinking water, and non-occupational (golfers) sources of exposure. Results of this aggregate assessment indicate that the human health risks from these combined exposures are considered to be within acceptable levels; that is, combined risks from all exposures to diclofop-methyl "fit" within the risk cup. Although the aggregate assessment suggests that the combined exposure slightly exceeds the Agency's level of concern for carcinogenic risk, the Agency concludes that such variance is within an acceptable range, given the upper bound assumptions and variables involved in calculating exposure.

b. Enforcement Method

The current FDA enforcement method for diclofop-methyl is the Pesticide Analytical Manual (PAM)-Volume II. This method, however, fails to detect a metabolite of concern, diclofop acid, which is part of the tolerance expression. In support of tolerance reassessment, the registrant developed a new enforcement method. The new method, HRAV-14 (GLC/ECD), has been independently validated by the registrant which successfully subjected a ruminant metabolism study to independent laboratory validation. Based on detailed discussions with the registrant and technical supporting evidence, the Agency expects that the HRAV-14 method will be fully validated. The reassessed tolerances reflect this more sensitive enforcement method.

2. Tolerance Summary

Tolerances for residues of diclofop-methyl are established under 40 CFR §180.385(a). Only tolerances for plant commodities are presently established, and none have been established for animal

commodities. Plant commodity tolerances are expressed in terms of the combined residues of the herbicide diclofop-methyl [methyl-2-(4-(2,4-dichlorophenoxy)phenoxy) propanoate] and its metabolites 2-[4-(2,4-dichlorophenoxy)phenoxy] propanoic acid and 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy] propanoic acid and its conjugates.

The nature of the residue in plants is based on an acceptable wheat metabolism study. The Agency reviews of the submitted study concluded that the plant residues of concern requiring regulation should remain the parent, diclofop acid, and hydroxy diclofop and its conjugates, provided that food/feed uses of diclofop-methyl are limited to barley and wheat.

The nature of the residue in animals is based on an acceptable ruminant and poultry metabolism studies. The residues of concern for both ruminants and poultry are diclofop-methyl and diclofop acid, free and conjugated. Regulation of hydroxy diclofop in animal matrices is not necessary since its concentration in animal tissues is relatively low.

a. Tolerances To Be Listed Under 40 CFR §180.385(a)(1)

Sufficient field residue data were submitted to reassess the established tolerances for barley grain, barley straw, wheat grain, and wheat straw. There are no registered uses on lentils and peas, and no registrants have committed to support diclofop-methyl uses on these crops; therefore, the established tolerances for these crop commodities will be revoked.

The available barley and wheat processing studies indicate that diclofop-methyl residues of concern do not concentrate in the crop's respective processed fractions. Therefore, tolerances are not required for the processed fractions of barley and wheat. The Agency will further divide 40 CFR §180.385(a) into 40 CFR §180.385(a)(1) and 40 CFR §180.385(a)(2) for separate designations of diclofop residues of concern in plants and animals, respectively.

b. Tolerances Needed Under 40 CFR §180.385(a)(1)

Tolerances are required and must be proposed for barley hay, wheat forage, and wheat hay. Based on the maximum combined residues from the field trials, the Agency will establish tolerance levels of 6.0 ppm for barley hay, 12.0 ppm for wheat forage, and 1.0 ppm for wheat hay. Adequate aspirated wheat grain fractions (grain dust) are available; however, based on the use pattern and submitted residue data, a tolerance is not necessary.

c. Tolerances Needed Under 40 CFR §180.385(a)(2)

The available ruminant feeding study suggests that tolerances should be established for the combined residues of diclofop-methyl and diclofop acid (free and conjugated), determined as diclofop-methyl, in milk and livestock (cattle, goats, horses, and sheep) commodities. The Agency notes that the

submitted ruminant feeding study (MRID 44178001) did not consider the reasssessed tolerances for barley hay and wheat forage when calculating ruminant dietary burdens, as such, the test animals were dosed at levels significantly lower than the 1x, 3x, and 10x levels recommended by Agency's guidelines (860.1480). However, since the submitted study clearly demonstrates transfer of residue to livestock commodities at all fortification levels (0.11 ppm, 0.33 ppm, and 1.1 ppm) and the highest dose (25 ppm) approximates the 1x dietary burden (29.5 ppm), the Agency used this study and determined that livestock tolerances be determined by extrapolation to the 1x dietary burden. Based on the maximum combined residues observed in milk and tissues of dairy cattle orally administered with the test substance at 25.0 ppm (0.85x maximum dietary burden) and extrapolating to 1x, the Agency recommends tolerance levels of 4.0 ppm in milk, 7.0 ppm in meat-by-products (excluding kidney), 25.0 ppm in kidney, and 1.0 ppm in meat and fat of cattle, goat, horses, and sheep.

A feeding study on swine is not available. However, translating the residue data from the ruminant feeding study and using the 0.09 ppm maximum theoretical dietary burden for swine, the Agency concludes that tolerances should be established for diclofop-methyl residues in fat and meat-by-products (mbyp) of hogs. Tolerances at the LOQ (0.05 ppm) should be established for residues in hog fat and mbyp (excluding kidney), and a separate tolerance should be established at 0.1 ppm for residues in hog kidney. Tolerances are not required for the meat of hogs as residues were <LOQ in meat of cattle dosed at a level (1.1 ppm) equivalent to 12x the maximum dietary burden for hogs.

The Agency will commence proceedings to modify or revoke the existing tolerances, and to correct commodity definitions. Table 10 below summarizes the tolerances for diclofop-methyl.

Table 10. Tolerance Summary for Diclofop-Methyl.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances To Be Listed under 40 CFR §180.385(a)(1):			
Barley, grain	0.1	0.1	
Barley, straw	0.1	0.1	
Lentils	0.1	Revoke	Uses on lentils and dry peas have been deleted from the registrant's label.
Pea seeds, dry	0.1	Revoke	
Wheat, grain	0.1	0.1	
Wheat, straw	0.1	0.1	
Tolerances Needed Under 40 CFR §180.385(a)(1):			
Barley, hay	None	6.0	
Wheat, forage	None	12.0	
Wheat, hay	None	1.0	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances Needed Under 40 CFR §180.385(a)(2):			
Cattle, fat	None	1.0	
Cattle, meat		1.0	
Cattle, mbyp (excluding kidney)		7.0	
Cattle, kidney		25.0	
Goat, fat	None	1.0	
Goat, meat		1.0	
Goat, mbyp (excluding kidney)		7.0	
Goat, kidney		25.0	
Hog, fat	None	0.05	
Hog, mbyp (excluding kidney)		0.05	
Hog, kidney		0.1	
Horse, fat	None	1.0	
Horse, meat		1.0	
Horse, mbyp (excluding kidney)		7.0	
Horse, kidney		25.0	
Milk	None	4.0	
Sheep, fat	None	1.0	
Sheep, meat		1.0	
Sheep, mbyp (excluding kidney)		7.0	
Sheep, kidney		25.0	

3. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have

an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, diclofop-methyl may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

E. Human Health Risk Mitigation

1. Dietary Mitigation

The following discussion addresses risk mitigation measures pertaining to dietary exposure to residues of diclofop-methyl in food and water. Among the specific mitigation measures discussed below, the Agency has also determined that a number of general restrictions were needed or reaffirmed.

To address rotational crop concerns, a suitable plant-back interval (PBI) has been established for crops commonly rotated into fields treated with diclofop-methyl. The registrant has agreed to establish a 30-day PBI for barley forage, lettuce, root and tuber vegetables, leafy vegetables, and small grains rotated into diclofop-methyl treated soils.

In addition, the existing database supports different pre-harvest intervals (PHI) for both wheat and barley. For barley, the PHI is 66 days. For wheat, the PHI is 77 days.

The Agency is also maintaining a grazing restriction on wheat and barley. This will provide a mechanism to minimize the potential transfer of diclofop-methyl residues to meat and milk commodities (discussed more fully in the carcinogenic dietary risk section below). The label will specify the need for a time dependent (28 day) grazing restriction.

a. Acute Dietary (Food)

Acute dietary exposure that is less than 100% of the aPAD does not exceed the Agency's risk concern. The results indicate that the population subgroup of U.S. females (ages 13-50) are acutely exposed to diclofop-methyl at 8% of the aPAD. The acute dietary risk (food) of diclofop-methyl is below the Agency's level of concern at the 99.9th percentile. Because no appropriate endpoint was identified for the U.S. general population, including infants and children, diclofop-methyl does not pose an acute dietary (food) risk to other sub-populations. No mitigation is necessary.

b. Chronic Dietary (Food)

The chronic dietary risk for diclofop-methyl does not exceed the Agency's level of concern (i.e., is less than 100% of the cPAD) for all sub-populations. The most exposed subgroup is children (1-6 years), whose dietary exposure is less than 1% of the cPAD. Therefore, no mitigation is necessary.

c. Carcinogenic Dietary (Food)

The upper-bound carcinogenic risk estimate for diclofop-methyl is calculated to be 1.2×10^{-6}, slightly exceeding the Agency's level of concern (10^{-6}). Although the Agency has some concern for a dietary (food) cancer risk in this range, the Agency believes the actual exposure to residues of diclofop-methyl and the concomitant risk is less than the quantified estimate suggests for the following reasons:

1) The dietary cancer risk is based on the assumption that an individual would be exposed to a constant carcinogenic level of diclofop-methyl residues over a lifetime, a condition that is not likely in this case because of declining use. Although a relatively small percentage of national wheat and barley crop is currently treated (estimated to be less than 2% of U.S. wheat and less than 1% of U.S. barley crops), the level of exposure in future years will probably be even lower. Overall use of diclofop-methyl is decreasing due to the introduction of other herbicides; the downward trend is expected to continue.

2) The greatest potential contributor to dietary risk is milk from cows as a result of foraging on treated wheat. Lactating cows may graze diclofop-treated wheat fields, transferring residues into their milk. The extent of this potential exposure is difficult to measure. In the preliminary assessment, sixty percent of lactating dairy cattle were assumed to be grazing on diclofop-methyl treated forage. However, after reviewing information about dairy and wheat cultural practices, the Agency has revised this estimate to 15%, based on an estimate of producing dairy cattle that may be feeding on wheat forage, nationwide (whether or not the grower used diclofop-methyl). In addition, less than two percent of the U.S. wheat is treated with diclofop-methyl. For these reasons, the Agency has reduced its estimates of the dietary burden from milk containing diclofop-methyl. It is not common practice among cattle farmers who use diclofop-methyl to allow cattle to forage in wheat and barley fields. According to expert opinion within as well as outside of the Agency, farmers inclined to allow cattle to graze in treated fields would not be expected to go the expense of treating a field with diclofop-methyl for grassy weeds which the cattle would otherwise find palatable.

In addition, there are remaining uncertainties on the carcinogenic potential of diclofop-methyl which influence the Agency's position on managing the carcinogenic dietary risk. As a peroxisome proliferator in certain laboratory animals, diclofop-methyl's cancer classification and the appropriate method for quantifying the cancer risk are more indefinite than the Agency would prefer. The scientific community remains uncertain whether such a mechanism of cancer in test species is predictive of cancer in humans. At a minimum, the Agency is mindful that absent other evidence of carcinogenicity, the uncertainty associated with pesticides that exhibit only peroxisome proliferation in tested species, like diclofop-methyl, bears on how the Agency chooses to regulate such pesticides.

The Agency is, therefore, not generally concerned with the current cancer dietary risk estimate resulting from exposure to diclofop-methyl residues in food. However, the Agency still recognizes the sensitivity of the dietary analysis and the enduring need for a grazing restriction in this particular case. The Agency's diclofop-methyl findings are highly dependent upon the relatively low percentage of crop treated and the assumption that the national trend for diclofop-methyl use is declining. If the percent of crop treated were to increase on wheat and barley, then the dietary (food) risk would be higher and the Agency would have a much greater concern.

The dietary risk assessment found that the main component of the dietary exposure estimate is diclofop-methyl residues in milk, as a result of livestock foraging and grazing in treated fields. Diclofop-methyl shows a high ability to transfer residues to livestock animals. To minimize the potential for livestock feeding on treated crops when residues are still present, it is necessary to maintain a grazing restriction on the label. The registrant has agreed to modify the current restriction on diclofop-methyl labels to preclude grazing for 28-days post treatment. While this measure to reduce the occurrence of residues in milk is difficult to enforce, the establishment of tolerances on meat and milk commodities is enforceable.

d. Drinking Water

Diclofop-methyl is not expected to reach ground or surface water under most conditions. Degradation is expected to be so rapid that diclofop-methyl will not have time to move in soil. Its low solubility also causes it to be immobile in soil. In a controlled field experiment, diclofop-methyl was shown not to leach into groundwater in any appreciable quantity.

i. DWLOC's for Acute Risks

The acute DWLOC for females ages 13-50 is 3000 ppb. Because the DWLOC exceeds the EECs (1.47 for surface water concerns, and 0.067 for ground water concerns), acute risks for both surface and ground water are not of concern to the Agency and therefore do not require mitigation.

ii. DWLOC's for Chronic Risks

The chronic DWLOCs for the U.S. population (80 ppb), children 1 to 6 years of age (20 ppb), and females 13 to 50 years of age (70 ppb), are all greater than the chronic EECs (0.097 for surface water and 0.067 for ground water) and therefore are not of concern to the Agency. No mitigation is required.

iii. DWLOC's for Cancer Risks

As discussed previously, the Agency was unable to calculate a $DWLOC_{cancer}$ because the DWLOC represents availability in the "risk cup." Nonetheless, based on environmental fate properties and limited monitoring data, diclofop-methyl is not expected to reach surface and ground water in significant quantities. The water exposure estimates are based on ecological models, which may not reflect actual residue concentrations in drinking water. Taken together, these considerations lead the Agency to conclude that there is not a cancer risk resulting from exposure to diclofop-methyl residues in either surface or ground water.

2. Non-Occupational Risk Mitigation

a. Non-Occupational Non-Cancer Risk Mitigation

Non-cancer risk estimates for diclofop-methyl indicate that entry by golfers is not of concern on the day of application as soon as the spray is dry. The MOE for this scenario is 310. This risk is therefore not of concern to the Agency and does not warrant mitigation.

b. Non-Occupational Cancer Risk Mitigation

The Agency has determined that the non-occupational cancer risk to golfers is $2.2x10^{-6}$, yet has also concluded that some of the assumptions in the assessment are conservative. For example, diclofop-methyl is applied to less than 1% of all golf courses nationally. However, the Agency assumed that an individual may come into contact with diclofop-methyl residues for four hours per day, two days per year. The golfer would need to be on the course during both of those treatment days. Also, the analysis assumes that an individual is exposed to the highest residues for four hours per episode. Diclofop is not usually applied to an entire golf course and is more commonly applied to five acres or less at any given time. As a result, approximately 1/8th of the course would have residues rather than the whole course.

As illustrated above, the Agency believes that a golfer is more likely to be exposed for much less than 4 hours. A more realistic assumption for exposure duration is 1/2 hour per round of golf. The resulting cancer risk is $2.7x10^{-7}$. The Agency believes that this is a more realistic exposure scenario in

accordance with current use practices. Thus, the Agency is not requiring any mitigation measures for non-occupational cancer risks.

3. Aggregate Risk Mitigation

a. Acute Aggregate Risk Mitigation

Based on the available information, the Agency concludes that residues of diclofop-methyl in drinking water (when considered along with exposures from food uses) would not result in an acute aggregate human health risk of concern. No mitigation measures are required.

b. Short-Term Aggregate Risk Mitigation

Calculated short-term DWLOCs do not exceed the Agency's level of concern as a contribution to short-term aggregate exposure. Based on available information, the Agency concludes that residues of diclofop-methyl in drinking water (when considered along with exposures from food uses and short-term non-occupational exposure) would not result in a short-term aggregate human health risk estimate of concern. No mitigation is required.

c. Chronic (Non-Cancer) Aggregate Risk Mitigation

Chronic dietary food risks are below the Agency's level of concern (<100% cPAD) for all population subgroups. The estimated concentration of diclofop-methyl in groundwater and surface water is below the Agency's level of concern for exposure to diclofop-methyl in drinking water as a contribution to chronic aggregate risk.

Based on the available information, the Agency concludes that residues of diclofop-methyl in drinking water (when considered along with exposures from food uses) would not result in a chronic aggregate human health risk estimate of concern. No mitigation is required.

d. Chronic (Cancer) Aggregate Risk Mitigation

The carcinogenic exposure to golfers (2.2×10^{-6}) is of concern; therefore, any aggregation of carcinogenic exposure to golfers with carcinogenic exposure from food and drinking water would only increase the risk further above the Agency's level of concern. However, for reasons mentioned earlier, the Agency has determined that the three components of the aggregate cancer risk provide marginal concern. The food exposure is predicated on constant diclofop-methyl use (which the Agency believes is declining) and a theoretical assumption on the number of diclofop-methyl growers who allow cattle to graze in treated fields. This assumption may not reflect actual grazing practices on diclofop-methyl fields.

Moreover, the golfer exposure component is based on high end assumptions which may overestimate risk. The circumstances required for an individual golfer to receive such regular, lifetime exposures to diclofop-methyl are unlikely. The drinking water exposure component is based on modeling estimates, despite the Agency's conclusion that diclofop-methyl is not likely to be found in drinking water. Coupling the uncertainty of golfer exposure with the combined dietary exposure from residues in food and water in this case represents an even more unlikely event. Thus, the Agency does not believe mitigation measures are warranted to address the aggregate cancer risk.

4. Occupational Risk Mitigation

a. Agricultural Handler Risk Mitigation

i. Handler Non-Cancer Risk Mitigation

Total short- and intermediate-term MOEs for non-cancer handler risk are not of concern (MOE $100) at the highest level of risk mitigation (PPE or engineering controls) for all scenarios. MOEs range from <1 to 535 at baseline; 60 to 2615 at PPE; and 110-760 at the engineering control level. The value used for daily acres treated (350 acres) for scenarios (2) and (5) is based on the Agency's estimate of acreage that would be reasonably expected to be treated in a single day. Current agronomic practices are believed to exclude whole field treatments. If farmers were treating their entire crop with diclofop-methyl, the Agency would have used a larger acreage estimate (e.g., 1,200 acres) except for the handler risks associated with aerial applications. The Agency is generally not concerned with non-cancer handler risks of diclofop-methyl. To address the aerial handler risk, the Agency finds the use of engineering controls necessary. The registrant has agreed to implement engineering controls to mitigate the handler risks associated with the use of diclofop-methyl.

ii. Handler Cancer Risk Mitigation

The Agency's goal is to reduce worker cancer risks to 10^{-6} or less, although risks somewhat higher than 10^{-6} may be considered acceptable if measures to mitigate these risks are not available and benefits of continuing use are demonstrated. Thus, for risks that are greater than 10^{-6} and less than 10^{-4}, the Agency carefully examines risks in this range including the benefits of use, availability of alternatives, number of workers at risk, and will seek ways to further mitigate these risks. Because all of the worker scenarios described in Section III have cancer risk estimates in the range of 10^{-6} to 10^{-4}, the Agency considered whether additional worker mitigation measures were available.

The Agency is concerned with cancer handler risks associated with the use of diclofop-methyl on wheat and barley. Even though the cancer handler risks associated with diclofop-methyl which incorporate engineering controls, range from 2.6×10^{-5} (applying liquids by air) to 4.9×10^{-6} (mixing and loading for groundboom application), the risks are higher with the use of PPE only. To minimize handler exposure to diclofop-methyl, the registrant has agreed to modify diclofop-methyl labels for

wheat and barley uses to include the use of engineering controls. Although the registrant has not specified how this is to be accomplished, the Agency has been assured by the registrant that they will provide an equivalent protection to closed mixing/loading systems and enclosed application equipment. For the purposes of reregistration, the Agency assumes the adoption of closed mixing/loading systems and the use of enclosed cabs/cockpits for diclofop-methyl use on barley and wheat. Based on current agronomic practices, the Agency anticipates that wheat and barley growers will not have significant difficulty converting to the use of engineering controls.

b. Post-Application Worker Risk Mitigation

i. Workers Who Mow and Maintain Golf Courses

The acute reentry risk for workers who mow and maintain golf courses is not of concern to the Agency on the day of treatment after the spray is dry. Application rates specified on diclofop-methyl labels range from 1.0 lb ai/A in agricultural settings to 1.5 lb ai/A on golf course turf even though the registrant is only supporting the 1.0 lb ai/A for golf course turf. The MOE is 155 at the maximum supported application rate of 1.0 lbs ai/A. To ensure such workers do not reenter before the spray is dry, the Agency will maintain the current restriction stating, "Do not enter or allow workers entry into treated areas until spray is dry."

The post-application chronic (cancer) risk estimate for mowers, however, is estimated to be $6.1x10^{-6}$, which exceeds the Agency's level of concern for such workers. However this estimate may overestimate the risk, considering current use directions. A use practice associated with diclofop-methyl use on golf course turf effectively mitigates this cancer risk concern. Current diclofop-methyl products labeled for golf course turf use prescribe, for efficacy reasons, that the course not be mowed within 36 hours of treatment. Because diclofop-methyl is a contact herbicide, users must be careful not to mow or otherwise disturb the action of the herbicide on the target grass weeds within the first few days of application. As a result, mowers who follow label instructions are not likely to receive the level of exposure that the post-application cancer risk assessment predicts. To ensure protection of workers who mow treated golf courses, diclofop-methyl labels need to retain language that precludes mowing within 36 hours of treatment.

ii. Workers Who Scout Wheat and Barley Fields

For scouts entering a treated wheat or barley field (at the 1.0 lb ai/A rate), the MOE is 195 and the cancer risk is $2.3x10^{-5}$ for lifetime exposure. While the former risk is not of concern, the latter cancer risk is of concern to the Agency. Because the exposures are assumed to occur on the day of treatment, maintaining the current REI of 24 hours will mitigate some of the potential cancer risk. Moreover, as a practical matter, scouts are not expected to regularly reenter treated fields as early as the REI, and when they do reenter a treated field, it is expected to be many days post treatment. In addition, the Agency will maintain the early entry PPE currently on the label, for the reasons stated

above. As a consequence, wheat and barley scouts are probably at little cancer risk with the existing mitigation measures in place. Diclofop-methyl labels do not need further mitigation for this concern.

5. Environmental Risk Mitigation

For all use sites and application methods of diclofop-methyl, acute and chronic risk quotients for birds and aquatic animals are generally not of concern. The Agency, therefore, finds little basis for risk mitigation.

In regards to acute risks to both endangered and non-endangered mammals, with the exception of small herbivorous mammals, the Agency does not have a concern. Since the Agency's risk assessment screen indicates that there may be a chronic risk to mammals, risk could further be evaluated and refined if additional information were provided on an existing study. The Agency is aware of a study that may show that diclofop-methyl has a foliar half life that is shorter than that assumed by the Agency. The registrant has agreed to submit this information to the Agency for further consideration. If this shorter half life is confirmed, the chronic risk to mammals would be of no concern to the Agency.

The use of diclofop-methyl on wheat, barley, and golf course turf is predicted to pose high risk to non-target terrestrial plants. Threatened and endangered plant species would also be at risk if exposed to runoff and/or spray drift. Risks generally stem from effects on seedling emergence and growth from soil exposure. The Agency is, therefore, concerned with risk to non-target terrestrial plants. However, diclofop-methyl is relatively less toxic than many other commonly used herbicides on wheat, barley, and golf courses. Furthermore, the current spray drift language, as set forth by this document, will reduce the potential exposure to non-target terrestrial plant species.

The Agency does not have data to adequately assess risk to aquatic plants. In section V of this document, additional data will be required to allow the Agency to determine risk to aquatic plants. The Agency only recently determined that such testing would be required. Notwithstanding the conclusions of this RED, the Agency may revisit the need for risk mitigation after reviewing the required data on the toxicity to aquatic plants.

F. Other Labeling Modifications

Label amendments are necessary such as use and safety information which needs to be placed on the labeling of all end-use products containing diclofop-methyl. For the specific labeling statements, refer to Section V of this document

Provided the following risk mitigation measures are incorporated in their entirety into labels for diclofop-methyl-containing products, the Agency finds that all currently registered uses of diclofop-methyl would be eligible for reregistration.

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989), and is providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to required limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. A final program, which may be altered from the interim program, will be described in a future Federal Register notice. The Agency 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.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling as specified in section V of this document. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard air-blast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, labels should be amended to include the following spray drift related language.

For products that are applied outdoors in liquid sprays, regardless of application method, the following must be added to the labels:

"Do not allow this product to drift"

For outdoor liquid or granular products that are applied aerially, further label language is necessary for spray drift management. Specific label language is outlined in Table 11, “Summary of Labeling Changes for diclofop-methyl” of this document.

V. What Registrants Need To Do

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of diclofop-methyl for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

- pH (§ 830.7000) - an aqueous suspension must be tested
- UV/Visible Absorption (§ 830.7050) - product properties
- Dermal Exposure (§ 875.2400)
- Foliar Dislodgeable Residue Dissipation (§ 875.2100)
- Bioaccumulation Study in Fish (§ 850.1730)
- Aquatic Plant Toxicity (§ 850.4400 and 850.5400) - see below

To fulfill the aquatic/algal plant toxicity guidelines, the following species must be tested at Tier I: *Pseudokirchneria subcapitata* and *Lemna gibba*. Aquatic Tier II studies are required for all low dose herbicides (those with the maximum use rate of 0.5 lbs ai/A or less) and any pesticide showing a negative response equal to or greater than 50% in Tier I tests. The following species must be tested at Tier II: *Pseudokirchneria subcapitata, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae*, and a freshwater diatom.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies.

All registrants must submit applications for amended registration. This application should include the following items: completed EPA application form 8570-1, five copies of the draft label with all required label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to The Reregistration Eligibility Decision" document. All amended labels must be submitted within 8 months of signature of this document. The Reregistration Division contact is Veronica Dutch at (703) 308-8585.

B. End-Use Products

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

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to implement these changes is specified in the Table 11. Registrants must submit applications for amended registration. This application should include the following items: completed EPA application form 8570-1, five copies of the draft label with all required label amendments outlined in Table 11 of this document incorporated, and a description on the application, such as, "Responding to The Reregistration Eligibility Decision" document. All amended labels must be submitted within 8 months of signature of this document. The Reregistration Division contact is Veronica Dutch at (703) 308-8585.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 24 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 registrant may distribute and sell diclofop-methyl products bearing old labels/labeling for 12 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 24 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

D. Labeling Changes Summary Table

Table 11: Summary of RED Labeling for Diclofop-Methyl		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
Formulation Instructions required on all MUPs (or MP)	"Only for formulation into a herbicide for use on wheat, barley and golf courses."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"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 support of such use(s)." "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 support of such use(s)."	
Environmental Hazards Statements	"**Environmental Hazards**" "This chemical is toxic to terrestrial and aquatic plants. Do not discharge effluent containing this product into lakes, streams, ponds estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA."	Precautionary Statements under Environmental Hazards.
Restricted Use Pesticide	"Restricted Use Pesticide". "Due to carcinogenicity in the mouse. For retail sale and to be used only be certified applicators or persons under their direct supervision, and only for those uses covered by the certified applicator's certification."	Top of Front Panel

Description	Amended Labeling Language	Placement on Label
End Use Products		
RED PPE Requirements[1]	"**Personal Protective Equipment** "Some materials that are chemical resistant to this product are [Registrant Insert Correct Material]. If you want more options, follow the instructions for category [Registrant insert A, B, C, D, E, G, or H] on an EPA chemical-resistant category selection chart." "Mixers, loaders, applicators, flaggers, and other handlers using engineering controls must wear: - long-sleeve shirt and long pants, - shoes plus socks" "In addition, mixers and loaders must wear: - chemical resistant apron - chemical resistant gloves" "see engineering requirements below" "All other handlers performing tasks, such as spill clean-up, for which engineering controls are not feasible must wear: - coveralls over long-sleeve shirt and long pants, - chemical resistant gloves - chemical resistant footwear - a NIOSH approved respirator with an (OV) cartridge or a canister with any N,R,P or HE prefilter - Respirator with - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - chemical-resistant apron if exposed to the concentrate"	Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
PPE Requirements for 24C products used only on Golf Course Turf	"**Personal Protective Equipment** "Some materials that are chemical resistant to this product are [Registrant Insert Correct Material]. If you want more options, follow the instructions for category [Registrant insert A, B, C, D, E, G, or H] on an EPA chemical-resistant category selection chart." Mixers, loaders, applicators and other handlers must wear: - coveralls over long-sleeve shirt and long pants, - chemical resistant gloves - chemical resistant footwear plus socks, - Respirator with - an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or - a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or - a NIOSH approved respirator with an (OV) cartridge or a canister with any N,R,P or HE prefilter. In addition, mixers and loaders must wear a chemical resistant apron." Note: The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil.	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Amended Labeling Language	Placement on Label
Engineering Controls	**"Engineering Controls"** "Engineering Controls: "Mixers and loaders supporting applications by motorized equipment must use a closed system that transfers liquid pesticide in a manner that prevents the liquid and any vapor from contacting handlers or other people during the transfer and must: -- wear the personal protective equipment required above for mixers/loaders, -- wear protective eyewear if the system operates under pressure, and -- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: coveralls, chemical-resistant gloves, chemical-resistant footwear, and, a respirator of the type specified in the PPE section of this labeling, Applicators using motorized ground equipment and flaggers supporting aerial applications must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] for dermal protection. In addition, applicators must: -- wear the personal protective equipment required in the PPE section of this labeling for handlers using engineering controls, -- *either* wear the type of respirator specified in the PPE section of this labeling for handlers not using engineering controls *or* use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling, -- be provided and must have immediately available for use in an emergency when they must exit the cab in the treated area: coveralls, chemical-resistant gloves, chemical-resistant footwear, and, if using an enclosed cab that provides respiratory protection, a respirator of the type specified in the PPE section of this labeling, -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab." "Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)

Description	Amended Labeling Language	Placement on Label
User Safety Recommendations	**"User Safety Recommendations"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE 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."	Precautionary Statements: Hazards to Humans and Domestic Animals (Must be placed in a box.) (Immediately following Engineering Controls)
Environmental Hazards	**"Environmental Hazards:** "This pesticide is toxic to fish and aquatic invertebrates. 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 washwater or rinsate. Do not apply within 100 feet of any water body including impounded waters, rivers, streams, lakes, or oceans."	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval for wheat and barley	"Do not enter or allow workers entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, Agricultural Use Requirements Box
Restricted-Entry Interval for 24C products used on Golf Course Turf	"Do not enter or allow workers entry into treated areas until spray is dry."	Directions For Use

Description	Amended Labeling Language	Placement on Label
Personal protective equipment required for early entry	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is: - Coveralls over long sleeved-shirt and long pants - Chemical-resistant gloves. - Chemical resistant footwear plus socks - Protective eyewear	Precautionary Statements: Hazards to Humans and Domestic Animals
General 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."For any requirements specific to your State or tribe, consult the agency responsible for pesticide regulation. "Do not allow this product to drift." "Do not allow livestock to graze treated fields for 28 days after treatment." The maximum application rate is 1 lb ai/A per application per year. Do not apply within 100 feet of any water body including impounded waters, rivers, streams, lakes, or oceans.	Directions for Use
Application Restriction for 24(c) for Golf Course Turf Products	- All applications to turf other than golf course turf, must be removed from the label. - The label rate shall not exceed 1 lb ai/A per application. The maximum is 1.5 lb ai/A/yr - Maintain instructions to avoid mowing for at least 36 hours after treatment.	Directions for Use
Aerial Spray Drift Label Language	"Aerial Spray Drift Management" "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."	Directions for Use

Description	Amended Labeling Language	Placement on Label
Continued... Aerial Spray Drift Label Language	"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."	Directions for Use
Continued... Aerial Spray Drift Label Language	"Aerial Drift Reduction Advisory" "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)."	Directions for Use

Description	Amended Labeling Language	Placement on Label
Continued... Aerial Spray Drift Label Language	**"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."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"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."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"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."	Directions for Use

Description	Amended Labeling Language	Placement on Label
Continued... Aerial Spray Drift Label Language	**"SWATH ADJUSTMENT"** "When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator 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.)"	Directions for Use
Continued... Aerial Spray Drift Label Language	**"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."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"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."	Directions for Use
Continued... Aerial Spray Drift Label Language	**"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."	Directions for Use

Description	Amended Labeling Language	Placement on Label
Continued... Aerial Spray Drift Label Language	**"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)."	Directions for Use

[1]PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

VI. Related Documents and How to Access Them

This Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: "http://www.epa.gov/pesticides/op."

VII. Appendices

Appendix A: Use Patterns Eligible For Reregistration

DICLOFOP METHYL (CASE 2160): USE PATTERNS ELIGIBLE FOR REREGISTRATION

Application Type Equipment	Timing of Application	Formulation	Max. Single App. Rate (lb ai/A)	Seasonal Max. (lbs ai/A/Yr)	Restrictions/ Comments
Wheat					
Foliar Spray - Groundboom - Aerial	Pre-plant Pre-emergent Post-emergent	**34.7 % End Use Product** Emulsifiable Concentrate	**1**	**1**	***PBI - 30 Days for lettuce and barley forage, root and tuber vegetables, leafy vegetables, and small grains *PHI - 77 Days *REI - 24 hours ***Requires use of closed systems.
Barley					
Foliar Spray - Groundboom - Aerial	Pre-plant Pre-emergent Post-emergent	**34.7 % End Use Product** Emulsifiable Concentrate	**1**	**1**	***PBI - 30 Days for lettuce and barley forage, root and tuber vegetables, leafy vegetables, and small grains *PHI - 66 Days *REI - 24 hours ***Requires use of closed systems.
Golf Course Turf					
Foliar Spray - Groundboom - Hand-held Sprayer	None Specified	**34.7 % End Use Product** Emulsifiable Concentrate	**1**	**1.5**	*Wait at least 36 hours before mowing

Appendix B. Table Of Generic Data Requirements And Studies Used To Make The Reregistration Eligibility Decision

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #2160 (diclofop-methyl) covered by this RED. It contains generic data requirements that apply to diclofop-methyl in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

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 Guidance, 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 list the identify number of each study. This normally is the Master Record Identification (MIRD) 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 Diclofop-Methyl

REQUIREMENT **CITATION(S)**

PRODUCT CHEMISTRY

New OPPTS Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.1550	61-1	Product Identity and Composition	A,B,C	00068748
830.1600	61-2A	Start. Mat. & Mnfg. Process	A,B,C	40623104
830.1670	61-2B	Formation of Impurities	A,B,C	40623105
830.1700	62-1	Preliminary Analysis	A,B,C	42218801, 42156901, 42717001, 43492201
830.1750	62-2	Certification of limits	A,B,C	00068748
830.1800	62-3	Analytical Method	A,B,C	
830.6302	63-2	Color	A,B,C	41573301
830.6303	63-3	Physical State	A,B,C	41573301
830.6304	63-4	Odor	A,B,C	41573301
830.7050	None	UV/Visable Absorption	A,B,C	**Data Gap**
830.7200	63-5	Melting Point	A,B,C	41573301
830.7220	63-6	Boiling Point	A,B,C	NA
830.7300	63-7	Density	A,B,C	41573301
830.7840 830.7860	63-8	Solubility	A,B,C	42796401, 40806303

REQUIREMENT				CITATION(S)
New OPPTS Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7950	63-9	Vapor Pressure	A,B,C	40806304
830.7370	63-10	Dissociation Constant	A,B,C	42461501
830.7550	63-11	Octanol/Water Partition Coefficient	A,B,C	40806305
830.7000	63-12	pH	A,B,C	**Data Gap**
830.6313	63-13	Stability	A,B,C	42796401, 43396701
	ECOLOGICAL EFFECTS			
850.2100	71-1	Avian Acute Oral Toxicity	A,B,C	40072903
850.2200	71-2A	Avian Dietary Toxicity - Quail	A,B,C	40072901
850.2200	71-2B	Avian Dietary Toxicity - Duck	A,B,C	40072902
850.1075	72-1A	Fish Toxicity Bluegill	A,B,C	41606302
850.1075	72-1C	Fish Toxicity Rainbow Trout	A,B,C	41606303
850.1010	72-2A	Invertebrate Toxicity	A,B,C	41573303
850.1010	72-2B	Invertebrate Toxicity - TEP	A,B,C	41606304
850.1400	72-4A	Fish- Early Life Stage	A,B,C	00076867
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A,B,C	41737902
850.1500	72-5	Life Cycle Fish	A,B,C	43284601
850.4230	123-1	Non-target Terrestrial Plant Phytotoxicity	A,B,C	41606306

REQUIREMENT				CITATION(S)
New OPPTS Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
850.4400	123-2	Aquatic Plant Growth	A,B,C	**Data Gap**
	TOXICOLOGY			
870.1100	81-1	Acute Oral Toxicity-Rat	A,B,C	41476001, 92036052, 00123982, 00123983
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	A,B,C	00071522, 92036013, 00032595
870.1300	81-3	Acute Inhalation Toxicity-Rat	A,B,C	00032595, 00032595, 41573304
870.2400	81-4	Primary Eye Irritation-Rabbit	A,B,C	42428601
870.2500	81-5	Primary Skin Irritation	A,B,C	40213506
870.2600	81-6	Dermal Sensitization	A,B,C	41476002, 41476003, 92036047, 92036046
870.6100	81-7	Acute Delayed Neurotoxicity - Hen	A,B,C	Not Required
870.6200	81-8	Acute Neurotoxicity Screen	A,B,C	Not Required
870.3100	82-1A	90-Day Feeding - Rodent	A,B,C	42573301, 42593901
870.3200	82-2	21-Day Dermal - Rabbit/Rat	A,B,C	92036048, 41476004
870.4100	83-1A	Chronic Feeding Toxicity - Rodent	A,B,C	43927302, 92036057
870.4100	83-1B	Chronic Feeding Toxicity -Non-Rodent	A,B,C	92036057
870.4200	83-2A	Oncogenicity - Rat	A,B,C	432927302
870.4200	83-2B	Oncogenicity - Mouse	A,B,C	92036058
870.3700	83-3A	Developmental Toxicity - Rat	A,B,C	92036042
870.3700	83-3B	Developmental Toxicity - Rabbit	A,B,C	92036043

REQUIREMENT				CITATION(S)
New OPPTS Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.3800	83-4	2-Generation Reproduction - Rat	A,B,C	42543101, 42060501
870.4300	83-5	Combined Chronic Toxicity/ Carcinogenicity	A,B,C	43927302
870.5100	84-2A	Gene Mutation (Ames Test)	A,B,C	00071904
870.5375	84-2B	Structural Chromosomal Aberration	A,B,C	41476004, 41737901
None	84-4	Other Genotoxic Effects	A,B,C	00087816, 41996902, 42437801
870.7485	85-1	General Metabolism	A,B,C	41573306, 42364601
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2100	132-1A	Foliar Residue Dissipation	A,B,C	**Data Gap**
875.2400	133-3	Dermal Passive Dosimetry Exposure	A,B,C	**Data Gap**
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A,B,C	41573309
835.2240	161-2	Photodegradation - Water	A,B,C	41573307
835.2410	161-3	Photodegradation - Soil	A,B,C	41573308
835.4100	162-1	Aerobic Soil Metabolism	A,B,C	41573311
835.4400	162-3	Anaerobic Aquatic Metabolism	A,B,C	40806307
835.1240	163-1	Leaching/Adsorption/Desorption	A,B,C	40520301, 40806308, 42347801
835.6100	164-1	Terrestrial Field Dissipation	A,B,C	42252101
None	165-4	Bioaccumulation in Fish	A,B,C	**Data Gap**

REQUIREMENT				CITATION(S)
New OPPTS Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
835.7100	166-1	Prospective groundwater Study	A,B,C	44532501, 000441583, 000442748
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	A,B,C	00038848, 00038849, 00064486, 00068747, 00107467, 43476901, 43476902, 43476903, 43476905, 43995701
860.1300	171-4B	Nature of Residue - Livestock	A,B,C	42450101, 43437501, 43529601
860.1380	171-4E	Storage Stability	A,B,C	42442801-05, 42857501, 44915001
860.1500	171-4K	Crop Field Trials (Bulb Vegetables)	A,B,C	00149584, 00150890, 00155731, 42442802, 42442801, 44896102, 44896101
860.1500	171-4K	Crop Field Trials (Leafy Vegetables)	A,B,C	42442802
OTHER				
830.7050	None	UV/Visible Absorption	A,B,C	**Data Gap**
850.4400	122-2	Aquatic Plant Growth	A,B,C	**Data Gap**

Appendix C: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained the risk assessments and related documents as of August 28, 2000. The Agency considered comments on the revised risk assessments and added the formal "Response to Comments" documents to the docket.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/reregistration/diclofop-methyl

Appendix D. Citations Considered To Be Part Of The Database Supporting the Interim Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

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 (1999), 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.

DICLOFOP METHYL BIBLIOGRAPHY

MRID	CITATION
00003405	Schrader, J.W.; Haskins, W.F. (1974) Experiment: H-183--The Preliminary Evaluation of Herbicides for Use in Soybean Production: Project No. 3378. (Unpublished study received Oct 8, 1976 under 2224-50; prepared by [North Carolina State Univ.], Agricultural Experiment Station, Tidewater Research Station, submitted by Mobil Chemical Co., Industrial Chemicals, Richmond, Va.; CDL:
00032595	Thackara, J.W.; Rinehart, W.E. (1976) Acute Inhalation Study in Rats: Compound: HOE-23408: Project No. 76-1529. (Unpublished study received May 28, 1980 under 8340-12; prepared by Bio/dynamics, Inc., submitted by American Hoechst Corp., Somerville, N.J.; CDL:242741-A)
00070615	Hollander, H.; Weigand, W. (1978) Combined Chronic Toxicity and Tumorigenicity Study with HOE 23408 O H AT003 in Rats after Dietary Administration for Two Years: Report No. 449/78. (Unpublished study received Aug 17, 1978 under 8340-11; prepared by Hoechst AG, submitted by American Hoechst Corp., Somerville, N.J.; CDL:097282-A; 097281; 097283)
00071522	Mayer, Weigand, (1980) Acute Percutaneous Toxicity Study Conducted with HOE 23408--Active Ingredient on the Scarified Skin of Male and Female Rats in Compliance with EPA-guidelines: Report No. 502/80; A20365. (Translation of doc. no. A20304; unpublished study received Dec 19, 1980 under 8340-12; prepared by Hoechst AG, submitted by American Hoechst Corp., Somerville, N.J.; CDL:244056-A)
00071870	Hollander, H.; Weigand, W. (1978) Toxicity and Tumorigenicity of HOE 23408 O H AT003 in Mice during Administration for Two Years: Bericht Nr. 448/78; A14014. (Unpublished study received Aug 17, 1978 under 8340-11; prepared by Hoechst AG, West Germany, submitted by American Hoechst Corp., Somerville, N.J.; CDL: 097284-A; 097285)
00071904	Gericke, D., Wagner, W.H. (1977) Test for Mutagenicity in Bacteria Strains in the Absence and Presence of a Liver Preparation: A09834. (Unpublished study received May 26, 1978 under 8340-11; prepared by Hoechst AG, West Germany, submitted by American Hoechst Corp., Somerville, N.J.; CDL:097111-B)

DICLOFOP METHYL BIBLIOGRAPHY

MRID	CITATION
00071908	Baeder,Weigand; Kramer, (1975) Test Report on the Embryotoxic Effect of HOE 23 408 O H on Wistar-rats after Oral Administration: A03604. (Translation; unpublished study received May 26, 1978 under 8340-11; prepared by Hoechst AG, West Germany, submitted by American Hoechst Corp., Somerville, N.J.; CDL: 097109-A)
00071913	Brunk, Weigand, Kramer, et al. (1977) Report on a Repeated-dose (15 Months) Oral Toxicity Study of HOE 23408 O H AT003 in Beagle Dogs: Report No. 809/77; Al1202. (Translation; unpublished study received May 26, 1978 under 8340-11; prepared by Hoechst AG, West Germany, submitted by American Hoechst Corp., Somerville, N.J.; CDL:097109-F)
00076867	LeBlanc, G.A.; Mastone, J.D.; Wilson, B.F. (1981) The Toxicity of Hoelon to Fathead Minnow (Pimephales promelas) Embryos and Larvae: Report #BW-81-4-853. (Unpublished study received May 21, 1981 under 8340-11; prepared by EG & G Bionomics, submitted by American Hoechst Corp., Somerville, N.J.; CDL: 245123-G)
00087816	Myhr, B.C.; McKeon, M. (1981) Evaluation of Hoe 23408 O H AS204 in the Primary Rat Hepatocyte Unscheduled DNA Synthesis Assay: Genetics Assay No. 5590; A21734. Final rept. (Unpublished study, including letters dated Jul 14, 1980 from H. Kelker to Dr. Rochling and Dec 17, 1981 from B.I. Doerr to D.J. Lawatsch, received Dec 30, 1981 under 8340-11; prepared by Litton Bionetics, Inc., submitted by American Hoechst Corp., Somerville, N.J.; CDL: 246512-B
00087820	Fumero, S.; Mondino, A.; Peano, S.; et al. (1980) Study of the Mutagenic Activity of the Compound Hoe 23408 with~Saccharomyces~µ~cerevisiae~µ: [Submitter] A19671. (Translation; unpublished study, including letters dated Nov 29, 1979 from H. Kelker to Dr. Rochling and Dec 17, 1981 from B.J. Doerr to D.J. Lawatsch, received Dec 30, 1981 under 8340-11; prepared by Istituto di Ricerche Biomediche, Antoine Marxer, S.p.A., Italy, submitted by American Hoechst Corp., Somerville, N.J.; CDL:246512-F)
00098297	Petrocci, A. (1980) Letter sent to D. Greene dated Sep 12, 1980: Confirmatory testing of customer's products similar to Onyx NP 9.0 prototype: LC 58288. (Unpublished study received Feb 12, 1981 under 4170-30; prepared by Onyx Chemical Co., submitted by Betco Corp., Toledo, Ohio; CDL:244740-A)

DICLOFOP METHYL BIBLIOGRAPHY

MRID	CITATION
00123982	Scholz; Weigand (1973) HOE 23408 O H: 2-(4-(2,4-Dichlorophenoxy)-phenoxy)-methyl-propionate: Acute Oral Toxicity Determined with Male SPF Wistar Rats: A02158. (Translation; unpublished study received Aug 22, 1975 under 6G1664; prepared by Hoechst Aktiengesellschaft, W. Ger., submitted by American Hoechst Corp., Somerville, NJ; CDL:094678-B)
00123983	Scholz; Weigand (1974) Acute Oral Toxicity of 2-(4-(2.4-Dichloro-phenoxy)-phenoxy)-methyl-propionate (HOE 23408 O H) in Female SPF-wistar-rats (Carrier Substance: Sesame Oil): A02062. (Translation; unpublished study received Aug 22, 1975 under 6G1664; prepared by Hoechst Aktiengesellschaft, W. Ger., submitted by American Hoechst Corp., Somerville, NJ; CDL:094678-C)
00139613	Baeder; Horstmann; Weigand; et al. (1978) Effect of Hoe 23408 O H AT003 on Pregnancy of the Rabbit--Strain Hoe:HIMK (SPFWiga)--after Oral Administration: Bericht-Nr. 296/78; A17691. (Translation; unpublished study received Jan 18, 1984 under 8340-11, prepared by Hoechst AG, W. Ger., submitted by American Hoechst Corp., Somerville, NJ; CDL:072294-A)
40072901	Hinken, C.; Grimes, J.; Jaber, M. (1986) Diclofop-Methyl Technical: (Code: HOE 023408 OH ZD95 0003): A Dietary LC50 Study with the Bobwhite: Laboratory Project ID No. 125-138. Unpublished study prepared by Wildlife International Ltd. in cooperation with Analytical Development Corp. 38 p.
40072902	Hinken, C.; Grimes, J.; Jaber, M. (1986) Diclofop-Methyl Technical: (Code: HOE 023408 OH ZD95 0003): A Dietary LC50 Study with the Mallard: Laboratory Project ID No. 125-139. Unpublished study prepared by Wildlife International Ltd. in cooperation with Analytical Development Corp. 36 p.
40072903	Hinken, C.; Grimes, J.; Jaber, M. (1986) Diclofop-Methyl Technical: (Code: HOE 023408 OH ZD95 0003): An Acute Oral Toxicity Study with the Bobwhite: Laboratory Project ID No. 125-140. Unpublished study prepared by Wildlife International Ltd. 27 p.

DICLOFOP METHYL BIBLIOGRAPHY

MRID	CITATION
40213506	Diehl, K-H.; Leist, K-H. (1986) Diclofop-Methyl--Oil in Water Emulsion 369 (g/L)...Testing for Primary Dermal Irritation in Rabbits: Lab Project No.: 86.0404. Unpublished study prepared by Hoechst AG. 16 p.
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Appendix E: Generic Data Call-In

See attached table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrant under separate cover.

Appendix F: Product Specific Data Call-In

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrant under separate cover.

Insert PDCI–Page 2 of 4

Insert PDCI–Page 4 of 4

Appendix G: List of Registrants Sent this Data Call-In

Registrant Name and Address

Appendix H: List of Available Related Documents and Electronically Available Forms

- Pesticide Registration Forms are available at the following EPA internet site:

  http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

   DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.

8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
   b. EPA Form No. 8570-4, Confidential Statement of Formula
   c. EPA Form No. 8570-27, Formulator's Exemption Statement
   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List
   B. Biopesticides and Pollution Prevention Division (BPPD) Contacts
   C. Antimicrobials Division Organizational Structure/Contact List
   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
   f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)
   g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States," PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

A. Health and Environmental Effects Science Chapters.
B. Detailed Label Usage Information System (LUIS) Report.