Reregistration Eligibility Decision for Dicamba and Associated Salts

June 8, 2006

Reregistration Eligibility Decision

for

Dicamba and Associated Salts

List [B]

Case No. 0065

Reregistration Eligibility Decision (RED) Document for Dicamba and Associated Salts

Approved by: _____

Debra Edwards, Ph. D.
Director
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Date: _____

Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
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
GLN	Guideline Number
HAFT	Highest Average Field Trial
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.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
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
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
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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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 data submitted to the Environmental Protection 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 risks arising from the currently registered uses of dicamba, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. As a result of this review, the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has determined that all products containing the active ingredient dicamba are eligible for reregistration provided that the risk mitigation measures indicated in this document are adopted. The completion of the dicamba RED does not result in any additional tolerances being reassessed since all 60 existing tolerances were reassessed in 2000, when a new food use was established for dicamba [65 FR 33709, (May 24, 2000)].

Risks summarized in this document are those that result only from the use of dicamba. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to dicamba, and dicamba does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of reregistration, EPA has not assumed that dicamba shares a common mechanism of toxicity with other compounds. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism of toxicity on EPA’s website at http://www.epa.gov/pesticides/cumulative/.

II. Chemical Overview

- **Common Name**: Dicamba is an acid which forms salts in aqueous solutions. Various dicamba salts are formulated for herbicidal use and the following compounds are considered in this decision document: dimethylamine (DMA) salt, sodium (NA) salt, isopropylamine (IPA) salt, diglycolamine (DGA) salt, and potassium (K) salt.

- **Chemical Name**: 3,6-dichloro-2-methoxybenzoic acid or 2-methoxy-3,6-dichlorobenzoic acid

- **CAS Registry Numbers:**

Dicamba Acid: 1918-00-9
Dicamba DMA: 2300-66-5
Dicamba NA: 1982-69-0
Dicamba IPA: 555871-02-8
Dicamba DGA: 1040440-79-1
Dicamba K: 10007-85-9

- **OPP Chemical Numbers**:

Dicamba Acid: 029801
Dicamba DMA: 029802
Dicamba NA: 029806
Dicamba IPA: 128944
Dicamba DGA: 128931
Dicamba K: 129043

- **Common Trade Names**: Banvel; Trimec

- **Basic Manufacturer**: BASF

Dicamba (2-methoxy-3,6-dichlorobenzoic acid) is a selective benzoic acid herbicide registered for the post emergent control of certain broadleaf weeds and woody plants. It was first registered in the United States in 1967 and is widely used in agricultural, industrial, and residential settings. According to the EPA Pesticide Sales and Usage Report for 2000/2001, dicamba is the seventh most commonly used conventional pesticide in the home and garden market sector. The residential products are typically formulated as dry weed-and-feed products or as liquids in concentrates or ready-to-use sprays. Many of these formulations include other herbicides to provide a broader spectrum of weed control.

Use Sites:

- Dicamba salts have registered uses on right-of-way areas, asparagus, barley, corn, grasses grown in pasture and rangeland, oats, proso millet, rye, sorghum, soybeans, sugarcane, and wheat. Golf courses and residential lawns are also registered.

Mode of Action:

- Dicamba is an auxin agonist and causes rapid and uncontrolled growth of the stems, petioles, and leaves of sensitive plants. This uncontrolled cell division and growth in turn results in the destruction of vascular tissue, leading to plant death. Weed control is generally achieved in 5 to 7 days.

Formulations:

- There are 434 dicamba products formulated as liquids, wettable powders, standard granules, and water dispersible granules. Residential products are typically formulated as granular weed-and-feed formulations or as liquids in concentrates or ready-to-use sprays.

Methods and Timing of Application:

- Application methods include groundboom, rights-of-way sprayer, turfgun, backpack sprayer, tractor-drawn broadcast spreader, push-type broadcast spreader, and by fixed-wing aircraft. Typically one application is made per growing season.

Use Rates:

- Rates for all salts and formulations are normalized to dicamba acid equivalents per acre (ae/A). Application rates range from 0.5 to 2.8 lb ae/A.

III. Summary of Dicamba Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for dicamba, as presented fully in the documents: "Dicamba: HED Chapter of the Reregistration Eligibility Decision Document," written by C. Olinger, Y.Yang, T. Dole, and M. Hawkins (9/13/2005), and "Environmental Fate and Ecological Risk Assessment for the Reregistration of Dicamba and Dicamba Sodium, Potassium, Diglycoamine, Dimethylamine, and Isopropylamine Salts," written by W. Erickson, I. Abdel-Saheb, and S. Borges (11/15/05). There were no public comments which required revisions to the risk assessments.

The purpose of this section is to summarize the key features and findings of the risk assessments in order to help the reader better understand the risk management decision reached by the Agency. While the full risk assessments and related supporting documents are not included in this document, they are available in the public docket at www.regulations.gov (docket # EPA-HQ-OPP-2005-0479) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for dicamba for the purpose of making a reregistration eligibility decision. The Agency evaluated the toxicology, product and residue chemistry, and occupational and residential exposure studies submitted for dicamba and determined that the data are adequate to support a reregistration decision. A summary of the human health risk assessment findings and conclusions are below.

1. Toxicology

The available toxicity data on dicamba are adequate to assess dicamba's hazard potential. Table 1 below presents the acute toxicity profile for dicamba:

Table 1. Acute Toxicity Profile on Dicamba Acid

Guideline	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral toxicity / rat	00078444	LD_{50} => 2740 mg/kg	III
870.1200	Acute dermal toxicity / rat	00241584	LD_{50} => 2000 mg/kg	III
870.1300	Acute inhalation toxicity / rat	00263861	LC_{50} => 5.3 mg/L	IV
870.2400	Primary eye irritation / rabbit	00241584	Irritant	II
870.2500	Primary dermal irritation / rabbit	00237955	Irritant	II
870.2600	Dermal sensitization / guinea pig	00263861	Non-Sensitizer	--

See Table 2 for a summary of the toxicological endpoints used in the human health risk assessment for dicamba.

FQPA Considerations

Developmental studies were conducted on both rats and rabbits, following *in utero* and/or pre-/post-natal exposure to dicamba. No evidence of increased susceptibility was observed. In addition, no evidence of developmental anomalies of the fetal nervous system were observed in the prenatal developmental toxicity studies in either rats or rabbits at maternally toxic doses of up to 300 or 400 mg/kg/day. Also, no evidence of behavioral or neurological effects on the offspring was observed in the two-generation reproduction study in rats. Based on the weight of evidence, a developmental neurotoxicity study (DNT) is not required. Additionally, because the dicamba dietary and residential risk assessments are not expected to underestimate exposure, the special FQPA safety factor has been removed (reduced to 1X) for the dicamba risk assessment.

Table 2. Summary of Toxicological Endpoints Dicamba		
Exposure Scenario	**Factor Used in Risk Assessment**	**Study and Endpoint of Risk Assessment**
Dietary Risk Assessment		
Dietary (Acute)- all populations	UF= 300x aRfD= 1.0 mg/kg/day aPAD= 1.0 mg/kg/day	**MRID no: 42774104** **Acute Neurotoxicity Study in Rats** The aRfd was determined based on a LOAEL of 300 mg/kg/day in the rat acute neurotoxicity study and an UF of 300x (10x for interspecies extrapolation, a 10x for intraspecies variation, and a 3x for using a LOAEL, instead of a NOAEL) LOAEL = 300 mg/kg/day Neurotoxicity signs such as impaired gaits and righting reflex were seen in both male and females at the lowest dose tested, 300 mg/kg/day
Dietary (Chronic)- all populations	UF= 100x cRfD= 0.45 mg/kg/day cPAD= 0.45 mg/kg/day	**MRID no: 43137101** **Multi-Generation Reproduction Study in Rats** The cRfD was established based on the NOAEL of 45 mg/kg/day in the multi-generation reproduction study and an uncertainty factor of 100x (10x for interspecies extrapolation, 10x for intraspecies variation). NOAEL = 45 mg/kg/day LOAEL = 136 mg/kg/day Decreased pup weight was seen at the LOAEL of 136 mg/kg/day
Residential Risk Assessment (Adults and Toddlers)		
Acute Oral Exposure (Toddlers)	Level of Concern MOE= 300	**MRID no: 42774104** **Acute Neurotoxicity Study in Rats** LOAEL = 300 mk/kg
Dermal and Inhalation Short, Intermediate & Long-term	Level of Concern MOE= 100 15% dermal absorption factor 100% inhalation absorption	**MRID no: 43137101** **Multi-Generation Reproduction Study in Rats** NOAEL = 45 mg/kg/day LOAEL = 136 mg/kg/day
(Occupational) Non- Dietary Risk Assessment		
Dermal- Short & Intermediate Term (1-30 days)	Level of Concern= 100 15% dermal absorption factor	**MRID no: 43137101** NOAEL = 45 mg/kg/day LOAEL = 136 mg/kg/day
Inhalation- Short & Intermediate Term (1-30 days)	Level of Concern MOE= 100 100% inhalation absorption	**MRID no: 43137101** NOAEL = 45 mg/kg/day LOAEL = 136 mg/kg/day
Cancer	Not likely to be carcinogenic to humans	**MRID no: 00146150** **MRID no: 40872401**

UF = uncertainty factor
aRfD = acute reference dose
LOAEL=lowest observed adverse effect level
MOE = margin of exposure
cRfD = chronic reference dose
NOAEL = no observed adverse effect level

2. Dietary Exposure and Risk from Food and Drinking Water

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. Dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose predicted to result in no unreasonable adverse health effects to any human population subgroup, including sensitive members of such population subgroups. This level of concern is referred to as the population adjusted does (PAD), which reflects the reference dose (RfD), either acute or chronic, adjusted to account for the FQPA safety factor.

Estimated risks that are less than 100% of the PAD are below the EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on any given day with no adverse health effect expected. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no adverse health effects expected.

a. Acute Dietary (Food and Drinking Water)

Acute dietary risk is based on the quantity of food and water consumed in one day and the estimated maximum residue values in food and water. EPA evaluated the acute dietary risks using the Dietary Exposure Evaluation Model (DEEM- FCID™, Version 2.03), which incorporates food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

EPA conducted an unrefined, Tier 1 acute dietary food exposure/risk analysis for dicamba using tolerance level residue values, default processing factors, and the assumption of 100% crop treated for all commodities. For Tier 1 analysis, which are based on upper-bound pesticide residue value inputs (e.g., assuming 100% of registered crops are treated with the pesticide, or that residues are present at tolerance level), EPA presents acute dietary results at the 95^{th} percentile of exposure which provides a high-end estimate of risk and is protective of the general U.S. population and all population subgroups.

The residues of concern for tolerance enforcement and risk assessment are dicamba, the 3,6-dichloro-5-hydroxybenzoic acid (5-OH dicamba) metabolite, and the 3,6-dichlorosalicylic acid (DCSA) metabolite. The Agency assessed dietary risk from drinking water using the full distribution of estimated residues in surface water, generated by PRZM-EXAMS models from use of dicamba on sugarcane, which is the worst-case risk scenario. Residues of dicamba acid and it's degradate, DCSA, were combined for the risk assessment. The acute dietary estimates are below the Agency's level of concern at the 95^{th} exposure percentile for all population sub-groups. When considering food alone, the most highly exposed subgroup for acute exposure is children, aged 1-2, with 5.4% of the aPAD consumed. When considering both food and water, the most highly exposed subgroup was infants with 11% of the aPAD consumed at the 95^{th} percentile. See Table 3 for a summary of dietary exposure and risk for dicamba.

b. Chronic Dietary (Food and Drinking Water)

EPA conducted an unrefined Tier 1 chronic dietary food risk analysis using the average consumption values for food and the average tolerance levels of those foods. Estimated exposure to dicamba and its residues of concern for all population subgroups is well below the level of concern. When considering food alone, or food and water, the most highly exposed subgroup is children, aged 1-2, at 6.5% and 6.6% of the cPAD, respectively.

Actual exposures to dicamba are likely to be considerably lower than these estimates. These assessments assume all commodities have tolerance level residues; however, residues sampled in most field trials were lower. The assessments also assume 100% of all crops are treated, but a screening level usage analysis indicates that the percent crop treated for most commodities is less than 20%. Only drinking water from surface water sources are considered, but the model estimates for ground water are much lower than surface water estimates; therefore the use of surface water is protective. A summary of the dietary exposure and risk for dicamba is presented in Table 3 below.

Table 3. Summary of Dietary Exposure and Risk for Dicamba: Food and Water

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary exposure mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.0435	4.4	0.0118	2.6
All Infants (< 1 year old)	0.108	11	0.0199	4.4
Children 1-2 years old	0.0756	7.6	0.0297	6.6

For additional information, please see Section 5.2 of the HED risk assessment.

3. Residential Exposure and Risk

Both spot and broadcast treatments are permitted by product labels. Exposures from lawn treatment are expected to be short-term in duration because the label allows only two broadcast treatments per year and use directions for spot treatments recommend repeat applications after two to three weeks for hard-to-kill weeds.

Non-cancer risk estimates (such as residential estimates) are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100x, which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences within a species of laboratory animal). Additional uncertainty or safety factors may also be applied. In the case of dicamba, EPA's level of concern for residential exposure is an MOE of 100 for short-, intermediate-, and long-term residential risk assessments for both dermal and inhalation routes of exposure. EPA's level of concern for acute exposures is an MOE of 300, which incorporates the standard uncertainty

factors and a 3X for using a LOAEL rather than a NOAEL as the endpoint. EPA determined that the available data support the removal of the default 10X FQPA safety factor. Thus, scenarios that yield MOEs that are less than 300 for acute exposure and less than 100 for all other exposures may trigger concern. No scenarios resulted in exceedances of the levels of concern.

a. Residential Handler Exposure and Risk

The handler exposure data were taken from the Pesticide Handler Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (ORETF) data. The residential handler risks were calculated using standard assumptions, the highest quality unit exposure data available, and the maximum label application rates. All the MOEs for residential handler exposure are greater than the level of concern MOEs of 300 for acute exposures and 100 for short-term exposures, and therefore the risks are below the EPA's level of concern. Seven scenarios for residential handling and application of dicamba were assessed resulting in MOEs ranging from 3,800 to 62,000.

b. Residential Postapplication Exposure and Risk

Residential postapplication exposure data were taken from four turf transferable residue studies. All of the studies were reviewed by the Agency and were found to meet the guidelines for postapplication exposure monitoring. Acute MOEs for toddlers ingesting granules resulted in acute MOEs $\geq$ 1500. Please see the HED risk assessment for more details on granular ingestion. The acute MOEs for toddlers playing on turf are greater than the MOE of 300 for dermal and incidental ingestion risk, and are below EPA's level of concern. Typically, the Agency does not assess inhalation risk for postapplication exposures since inhalation is not considered to be an important postapplication route of exposure for most active ingredients. All short-term MOEs for both adults and toddlers are greater than 100 and are below the EPA's level of concern. A summary of the MOE estimates is included in Tables 5 and 6.

Table 5. Acute Dicamba MOEs for Turf Exposures (Application Rate = 1.0 lb ae/acre)

Scenario	TTR (ug/cm^2)	TC (cm^2/hr)	Dermal MOE	Hand-to-Mouth MOE	Object-to-Mouth MOE	Soil Ingestion MOE	Total MOE
Toddlers							
Playing	0.29	5,200	9,900	20,000	80,000	5,900,000	6,100
Target MOE is 300							

Table 6. Short Term Dicamba MOEs for Turf Exposures (Application Rate = 1.0 lb ae/acre)

Scenario	TTR (ug/cm^2)	TC (cm^2/hr)	Dermal MOE	Hand-to-Mouth MOE	Object to Mouth MOE	Soil Ingestion MOE	Total MOE
Toddlers							
Playing	0.060	5,200	7,200	7,200	29,000	2,100,000	3,200
Adult							
Yard work	0.060	14,500	12,000	N/A			
Golf	0.060	500	170,000				
Target MOE is 100							

TTR = turf transferable residues TC = transfer coefficient

For more residential exposure information, please see the HED risk assessment.

4. Aggregate Exposure and Risk

The FQPA amendments to the Federal Food, Drug and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposure and other exposures for which there is reliable information."

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways) as well as exposure from non-occupational sources (e.g., residential uses). Acute aggregate exposures (less than one day) may result from consuming treated food or drinking water. Acute aggregate exposures may also result from residential exposures such as adults doing yard work or playing golf on treated turf, or from children playing on treated turf. Typically the Agency does not aggregate acute dietary exposures with acute residential exposures, because it is very unlikely that high-end food and water exposures will occur on the same day as the maximum residential exposures. Therefore, acute aggregate risks for dicamba are equal to the acute dietary risks. As noted above, the acute dietary risk estimates for the U.S. population and all subgroups are well below the Agency's level of concern. The most highly exposed subgroup is infants at 11% of the aPAD.

The short-term aggregate assessment considered exposures from food, drinking water, residential handler, and residential postapplication activities. Average food and water exposure estimates were used in the assessment. The residential handler scenario that resulted in the highest exposures, adults who mix/load/apply with a (mix-your-own) hose-end sprayer, was used in the adult aggregate assessment. The exposure from the yard work postapplication scenario was used for the adult assessment, and the exposure from the toddler playing on turf scenario was used in the child assessment. The MOEs for all scenarios for the short-term aggregate assessment range from 1,030 to 2,720. Since the MOEs are greater than 100, the risks are below the EPA's level of concern.

There are no residential scenarios that would result in intermediate- or long-term residential exposures. Therefore no intermediate-term aggregate assessment was necessary, and chronic aggregate risks are equal to chronic dietary risks. As discussed above, the chronic dietary aggregate risk estimates for the U.S. population and all subgroups are well below the Agency's level of concern. The most highly exposed population subgroup is children, aged 1-2 years, at 6.6% of the cPAD.

5. Occupational Exposure and Risk

Workers can be exposed by mixing, loading, or applying dicamba or by entering a previously treated site. Like residential risk, worker risk is also measured by MOEs. For handlers, the Agency initially assesses risk at "baseline" which considers an individual's normal work clothing (e.g., long sleeve shirt and long pants), no gloves, and no respirator. If there is a concern at baseline, the Agency considers the use of protective measures (e.g., personal protective equipment and engineering controls) to lower the risk. Personal protective equipment (PPE) can include an additional layer of clothing, chemical-resistant gloves, or a respirator.

Common examples of engineering controls include enclosed tractor cabs, closed loading systems, and water-soluble packaging.

a. Occupational Handler Risk

The handler exposure data were taken from the Pesticide Handler Exposure Database (PHED), the Outdoor Residential Exposure Task Force (ORETF) and the California Department of Pesticide Regulations (CA DPR). The PHED data were used primarily to assess the large scale agricultural and forestry scenarios and the ORETF data were used for evaluating lawn care scenarios. The CA DPR data were used to assess the backpack applicator scenario for the forest site preparation use, which includes multiple applicators that are supplied by a nurse tank.

Several handler exposure scenarios were assessed, and can be found in the human health risk assessment. The MOEs for the baseline exposure scenarios that are below the Agency's level of concern are shown in Table 7 below. With the addition of chemical resistant gloves, all of the occupational handler scenarios listed below have MOEs above 100, and are not of risk concern. All other mixer, loader, or applicator scenarios had an MOE greater than 100 for workers at wearing single layer of clothing and no chemical resistant gloves (baseline).

Table 7. Dicamba Handler Combined MOEs					
Exposure Scenario	**Crop or Site**	**Application Rate (lb ae/acre)**	**Acres/ Day**	**Margins of Exposure**	
				Baseline	**Baseline + Gloves**
Mixer/Loader (M/L)					
M/L WP for turfgun application	Turf	1	100	53	>1000
M/L Liquids for Aerial	Sugar Cane	2.8	1200	2	200
M/L Liquids for Aerial	Soybeans, RPF	2	1200	3	280
M/L Liquids for Aerial	Small Grains,	0.5	1200	12	>1000
M/L Liquids for Groundboom	Sugar Cane	2.8	200	13	>1000
M/L Liquids for Groundboom	Soybean, RPF	2	200	18	>1000
M/L Liquids for Groundboom	Small Grains, Corn	0.5	200	72	>1000
M/L Liquids for Groundboom	Sod Farms	1	80	90	>1000
M/L Liquids for ROW Sprayer	ROW	2	50	72	>1000
M/L Liquids for Turf Gun	Turf	1	100	72	>1000
M/L Liquids for Backpack Application	Forest Site Prep	2	40	90	>1000
Backpack Application	Turf	1	4	ND	410
Turfgun Application	Turf	1	5	ND	>1000
M/L/A Wettable Powder with Turfgun	Turf	1	5	ND	>1000
M/L/A WDG with Turfgun	Turf	1	5	ND	>1000
M/L/A Liquid Flowables with Turfgun	ROW, RPF	1	5	ND	>1000
M/L/A Liquids with Backpack Sprayer	Turf	2	4	ND	970
Load/Apply Granules with a Push Cyclone		1	5	ND	>1000

RPF= Rangeland, Pastures, and Fallow Land ND= Not Determined
ROW= Right of Way

b. Occupational Postapplication Risk

Postapplication dicamba exposures can occur in the agricultural environment when workers enter fields recently treated with dicamba to conduct tasks such as scouting and irrigation. Because dicamba is typically applied once per season and the relevant agricultural scenarios occur for only a few weeks per year, it is anticipated that dicamba exposures would be primarily short-term, and, more rarely, intermediate-term.

Occupational postapplication exposure data were taken from the three turf transferable residue studies submitted. All of the short- and intermediate-term MOEs are above 100 on day of treatment, and therefore risks are not of concern. The current Worker Protection Standard (WPS) Restricted Entry Interval (REI) for dicamba is 24 hours.

6. Incidents reports

The incident analysis was prepared under a separate memo by Monica Spann, M.P.H., and Jerome Blondell, PhD., of the Office of Pesticide Programs. Only those incidents involving products with dicamba as the sole active ingredient in a product were considered. There was only a single report in the Incident Data System of minor eye irritation resulting from dicamba flaked dust falling into a person's eye.

Poison Control Center data for the years 1993 through 2003 indicate that there were 24 occupational exposures to dicamba. Of these 24 cases, three had a moderate medical outcome and one was considered a major medical outcome. The major outcome case was a 15 year old who was exposed in the eye and experienced blurred vision, irritation, non-reactive pupils, and a visual defect.

The Poison Control Center data indicated that there were 146 non-occupational (i.e., residential) exposure cases and 13 of these cases were classified as a moderate medical outcome with primary symptoms of eye irritation, corneal abrasion, coughing, and difficulty breathing. One case with major medical outcome was a 16 year-old with chest pain, dysrhythmia, tachycardia (fast pulse), multiple seizures, and coma after inhalation. However, there were no other cases with such serious symptoms among the 146 exposures.

No incidents of dicamba poisoning were reported in California from 1982 through 2003.

B. Environmental Risk Assessment

The Agency has conducted an environmental assessment for dicamba for the purpose of making a reregistration decision. The Agency evaluated environmental fate and ecological studies submitted for dicamba and determined that the data are adequate to support a reregistration decision. More in-depth details of the studies used to develop the risk assessments and to support the guideline studies are provided in "Environmental Fate and Ecological Risk Assessment for the Reregistration of Dicamba and Dicamba Sodium, Potassium, Diglycoamine, Dimethylamine, and Isopropylamine Salts," written by W. Erickson, I. Abdel Saheb, and S. Borges (11/15/05), which is found in the electronic docket. A summary of the environmental risk assessment findings and conclusions is provided below.

1. Environmental Fate and Transport

The Agency bridged the environmental fate data requirements for the dicamba sodium and potassium salts, dimethylamine salt (DMA), isopropylamine salt, and diglycoamine salt (DGA) to the dicamba acid since the dicamba salts rapidly convert to the free acid of dicamba. Dicamba acid is very soluble and very mobile in laboratory soil studies.

Aerobic soil metabolism is the main degradative process for dicamba acid. The observed half-life for dicamba acid was six days with formation of the non-persistent degradate DCSA. DCSA degraded at approximately the same rate as dicamba with the final metabolites being

carbon dioxide and microbial biomass. Dicamba is stable to abiotic hydrolysis at all pH levels and photodegrades slowly in water and in soil.

Under anaerobic soil conditions, dicamba has a half-life of 141 days. The major degradate under anaerobic conditions was DCSA, which is persistent in anaerobic systems. There are no data for the aerobic aquatic metabolism in dicamba; however, supplemental information indicates that dicamba degrades more rapidly in aquatic systems when sediment is present.

Based on fate characteristics, dicamba and DCSA would be somewhat persistent in aerobic and anaerobic conditions and would be expected to be persistent in groundwater.

2. Environmental Effects

a. Ecological Risk Estimation

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of dicamba products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs), indicating whether a pesticide, when used as labeled, has the potential to cause adverse effects on non-target organisms (see Table 8 below). When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category. These risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 8. EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	LOC terrestrial animals	LOC aquatic animals	LOC Plants
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Listed Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	Not Assessed

b. Aquatic Organism Risk

The Agency used modeling to derive estimated environmental concentrations (EECs) for dicamba in surface water to represent a variety of aquatic habitats, such as ponds adjacent to treated fields, which are relevant to risk assessment for aquatic animals.

Available acute toxicity data for aquatic species indicate that dicamba is slightly toxic to fish and invertebrates with LC_{50} and the median effect concentration (EC_{50}) values for fish and invertebrates of 28 mg/L and 34.6 mg/L respectively. There were no exceedances of the aquatic acute risk, endangered species, and chronic risk LOCs for fish and invertebrates with all RQs $\leq$ 0.01, indicating that freshwater fish and invertebrates inhabiting surface waters adjacent to a treated field would not be at risk of adverse acute effects from use of dicamba. However, since there are no chronic studies for fish and invertebrates which measure effects such as survival, growth, and reproduction of fish and invertebrates, chronic risk to aquatic organisms is an uncertainty. Likewise, due to insufficient invertebrate toxicity data, risk to sediment-dwelling benthic organisms remains an uncertainty.

Toxicity studies indicate that dicamba is not toxic to aquatic vascular plants with the EC_{50} for the freshwater vascular plant of 3.25 mg/L. There were no exceedances of the acute risk LOC for freshwater vascular plants. However, the LOCs for non-vascular plants were exceeded for the application rates 2.8 lbs ae/acre and 2.0 lbs ae/acre. Consequently, aquatic non-vascular plants would potentially be at risk for adverse effects to growth and development from use of dicamba at these labeled rates.

Table 9. Summarized Acute Aquatic Plant Risk Quotients for Dicamba Acid

Scenario	Listed freshwater vascular	Non-listed	
		Freshwater vascular	Freshwater non-vascular
Michigan asparagus (0.5 lbs ae/A)	Ground app. <1 Aerial app . <1	<1 <1	<1 <1
Texas pasture (2.0 lbs ae/A)	Ground app. <1 Aerial app. <1	<1 <1	1.39 1.38
Florida sugarcane (2.8 lbs ae/A)	Ground app. <1 Aerial app. <1	<1 <1	2.79 2.72

All aquatic plant RQs from other dicamba uses at rates of less than 2 lb ae/A were less than 1 and are below EPA's level of concern.

c. Terrestrial Organism Risk

Birds

Dicamba salts are categorized as practically non-toxic to avian species based on dietary studies. However, oral gavage studies indicate dicamba acid was moderately toxic to bobwhite quail and slightly toxic to mallard ducks.

The acute risk LOC was exceeded for small birds consuming mean residues of dicamba on short grass, tall grass, broadleaf forage, and small insects, and for large birds consuming short grass. See Table 10 for a listing of RQs calculated based on predicted mean residues from application of dicamba at various rates. Levels of concern are set at 0.5 for acute risk and 0.1 for acute endangered species risk.

Table 10. Avian Acute Risk Quotient Summary from Predicted Mean Residues					
Food type	**Weight class (g)**	**RQs**			
		2.8 lbs ae/acre	**2.0 lbs ae/acre**	**1.0 lbs ae/acre**	**0.75 lb ae/acre**
short grass	20	2.04	1.46	0.72	0.54
	100	0.91	0.65	0.32	0.24
	1000	0.29	0.21	0.10	0.08
tall grass	20	0.86	0.62	0.30	0.23
	100	0.39	0.28	0.14	0.10
	1000	0.12	0.09	0.04	0.03
broadleaf forage, small insects	20	1.08	0.77	0.38	0.28
	100	0.48	0.35	0.17	0.13
	1000	0.15	0.11	0.05	0.04
fruit, pods, seeds, large insects	20	0.17	0.12	0.06	0.04
	100	0.08	0.05	0.03	0.02
	1000	0.02	0.02	0.01	0.01

The Agency assesses acute avian risks from granular formulations differently than for liquid formulations with granular RQ's based on a ratio of the LD_{50} and the amount of active ingredient applied to one square foot of ground. Dicamba has several products which are formulated with fertilizers and the avian and mammalian risks from these products were assessed after the risk assessment document was completed. For products that are applied at 0.29 lb ae/A or greater, acute risk LOCs are exceeded for 20 gram birds with RQs ranging up to 7.5 for a 2.0 lb ae/A application. Please see the EFED's Response to Comments document for the complete granular assessment.

The Chronic Risk LOC was not exceeded for any use with the maximum RQ of 1.0. Consequently, birds are not expected to be at risk from chronic developmental/reproductive effects when exposed to dicamba as a result of the labeled uses of the pesticide.

Mammals

Dicamba acid is classified as practically non-toxic to small mammals on an acute oral basis. There were no exceedances of any acute LOC from predicted mean residues.

The Agency assesses acute mammalian risks from use of granular formulations differently than the use of liquid formulations. Granular RQ's are based on the ratio of the LD_{50} and the amount of active ingredient applied to one square foot of ground. Dicamba has several products which are formulated with fertilizers. Avian and mammalian risks from these products were assessed after the risk assessment document was posted in EPA's public docket. For products that are applied at 1.0 and 2.0 lb ae/A, mammalian endangered species LOCs are exceeded for 15 gram mammals with RQs of 0.1 and 0.2, respectively. This is solely based on EPA's screening-level assessment. The assessment for larger mammals and lower application rates resulted in no exceedances. See EFED's Response to Comments document for the complete granular assessment.

The Chronic Risk LOC of 1.0 was exceeded for mammals consuming maximum and mean predicted dicamba residues on short grass for application rates greater than or equal to 0.75

lb ae/A. For a listing of RQs for mean foliar residues on different food items, please see Table 11. For tall grass, broadleaf forage, and small insects, the chronic risk LOC was exceeded as well. There were no exceedances of the chronic risk LOC for mammals consuming the maximum residues on fruit, seeds, and large insects. As a result, mammals could potentially be at risk for developmental/reproductive effects or for direct effects on foraging behavior when chronically exposed to dicamba as a result of the labeled uses of the herbicide.

Table 11. Mammalian Chronic Risk Quotient Summary from Predicted Mean Residues

Food type	Weight class (g)	RQs			
		2.8 lb ae/acre	2.0 lb ae/acre	1.0 lb ae/acre	0.75 lb ae/acre
short grass	15	2.29	1.63	0.82	0.61
	35	1.96	1.40	0.70	0.53
	1000	1.03	0.74	0.37	0.28
tall grass	15	0.97	0.69	0.35	0.26
	35	0.83	0.59	0.30	0.22
	1000	0.44	0.31	0.16	0.12
broadleaf forage, small insects	15	1.21	0.86	0.43	0.32
	35	1.04	0.74	0.37	0.28
	1000	0.55	0.39	0.20	0.15
fruit, pods, seeds, large insects	15	0.19	0.13	0.07	0.05
	35	0.16	0.12	0.06	0.04
	1000	0.08	0.06	0.003	0.02

Dicamba is an herbicide; as expected, terrestrial non-target plants are potentially at risk from its use. Seedling emergence and vegetative vigor are impacted by exposure to dicamba acid; adverse effects include stunting, chlorosis, and plant death. Plant LOCs are 1.0 for both non-listed and listed plants. Dicots are much more sensitive to dicamba than monocots. See Table 12 for a listing of RQs.

Table 12. Summarized Terrestrial Plant Acute Risk Quotients

Scenario	Acute Non-listed RQs			Acute Listed RQs		
	Adjacent to treated sites	Semi-aquatic areas	Drift	Adjacent to treated sites	Semi-aquatic areas	Drift
Sugarcane (2.8 lbs ae/A)						
Ground spray application						
Monocot	3.96	33.68	0.19	5.25	44.63	0.22
Dicot	62.22	528.89	4.12	76.36	649.09	7.00
Aerial spray application						
Monocot	5.28	23.11	0.93	7.00	30.63	1.08
Dicot	82.96	362.96	20.59	101.82	445.45	35.00
Hay, pasture/rangeland, soybean and agricultural fallowland (2.0 lbs ae/A)						
Ground spray application						
Monocot	1.42	12.03	0.07	1.88	15.94	0.08
Dicot	22.22	188.89	1.40	27.27	231.82	2.50
Aerial spray application						
Monocot	1.89	8.25	0.33	2.50	10.94	0.38
Dicot	29.63	129.63	7.35	36.36	159.09	12.50

Table 12. Summarized Terrestrial Plant Acute Risk Quotients						
Scenario	**Acute Non-listed RQs**			**Acute Listed RQs**		
	Adjacent to treated sites	**Semi-aquatic areas**	**Drift**	**Adjacent to treated sites**	**Semi-aquatic areas**	**Drift**
Corn (0.75lbs as/A)						
Ground spray application						
Monocot	1.06	9.02	0.05	1.41	11.95	0.06
Dicot	16.67	141.67	1.10	20.45	173.86	1.88
Aerial spray application						
Monocot	1.42	6.19	0.25	1.88	8.20	0.29
Dicot	22.22	97.22	5.50	27.27	119.32	9.38

3. Ecological Incidents

Dicamba acid: Thirty-five ecological incidents attributed to dicamba use have been recorded in the Ecological Incident Information System (EIIS) as of June 1, 2005. Incidents reported include terrestrial, plant, and aquatic impacts. Although the database lists a terrestrial mammalian incident in Utah where dicamba was applied, the database states that dicamba is "unlikely" to have caused the incident. Impacts to plants included a wide range of crops (soybeans, corn, wheat) as well as non-agricultural application. The specific impacts varied from browning and plant damage to mortality of all plants within the treated area. Aquatic impacts consist of two fish kill incidents associated with agricultural and residential turf application.

Dicamba Sodium Salt: Fifteen incidents attributed to dicamba sodium salt use have been recorded in the EIIS as of June 1, 2005. All reported incidents were associated with plant damage to crops including sorghum, soybean, corn, and sugar beets.

Dicamba Dimethylamine Salt: Forty-six incidents attributed to dicamba dimethylamine salt use have been recorded in the EIIS as of June 1, 2005. Incidents reported include plant and aquatic impacts. The majority of incidents to plants (40 of 45) were associated with residential turf application and ranged from browning to mortality. Agricultural application resulted in plant damage to cotton, corn and soybeans. The single reported aquatic incident was a fish kill of unknown magnitude resulting from turf application.

Dicamba Potassium Salt: Three incidents attributed to dicamba, potassium salt use have been recorded in the EIIS as of June 1, 2005. There were 2 incidents reported of impacts to plants, both associated with application on corn resulting in plant damage. The sole aquatic impact was associated with agricultural application which resulted in the mortality of 2,000 perch.

Dicamba Diglycoamine Salt: Two incidents attributed to dicamba, diglycoamine salt use have been recorded in the EIIS as of June 1, 2005. Both incidents were associated with impacts to plants (soybeans) which resulted in plant damage.

4. Risk to Endangered Species

The Agency's screening level ecological risk assessment for endangered species results in the determination that dicamba will have no direct acute effects on threatened and endangered freshwater fish, estuarine fish, and aquatic invertebrates. However, the assessment indicates that dicamba has the potential for causing risk to endangered birds, mammals, and non-target plants. Further, potential indirect effect to any species dependent upon a species that experiences effects cannot be precluded from use of dicamba. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Chronic RQs exceeded LOCs for endangered mammals at all application rates modeled. Acute LOCs were exceeded for endangered birds at all application rates. LOCs were exceeded for terrestrial plants adjacent to treated areas and in semi-aquatic areas at all application rates.

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 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 dicamba as an active ingredient. The Agency has reviewed these generic data, and has determined that the data are sufficient to support reregistration of all products containing dicamba.

The Agency has completed its review of submitted data and its assessment of the dietary, residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient dicamba. Based on these data, the Agency has sufficient information on the human health and ecological effects of dicamba to make its decision as part of the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing dicamba will be eligible for reregistration provided that (i) required product specific data are submitted, (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. Needed label changes and language are listed in Section V. Appendix A is a detailed table listing all dicamba uses that are eligible for reregistration. Appendix B identifies generic data requirements that the Agency reviewed as part of its determination of the reregistration eligibility of dicamba, and lists the submitted studies the Agency found acceptable. Data gaps are identified as either outstanding generic data requirements that have not been satisfied with acceptable data or additional data necessary to confirm the decision presented here.

Based on its evaluation of dicamba, the Agency has determined that dicamba products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FFDCA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of dicamba. If all changes outlined in this document are incorporated into the product labels, then all current risks for dicamba will be adequately

mitigated for the purposes of this interim determination under FIFRA. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section IV.D.5.a of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for dicamba. During the public comment period on the risk assessments, which closed on February 27, 2006, the Agency received five comments from five sources: BASF, the University of Hawaii at Manoa, Department of the Environment San Francisco, The Thurston County, Washington, Public Health and Social Services Department, and a citizen. BASF's comments pertained to ecological and water risks in the dicamba science chapters. The City of San Francisco and Thurston County both emphasized the importance of risk reduction measures for dicamba through alternative pesticides. The University of Hawaii's comment was in support of benefits of use of dicamba on golf courses, seed corn, sugarcane, and asparagus. The citizen comment pertained to adverse effects from using dicamba. The comments in their entirety are available in the public docket (EPA-HQ-OPP-0479) at http://www.regulations.gov. A detailed Response to Comments document is available in the public docket as well.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

Dicamba tolerances were reassessed in 2000 when a new food use was added. However, as part of the FIFRA reregistration, EPA assessed the risks associated with this pesticide. EPA has determined that aggregate risk from food, drinking water, and residential exposures to dicamba is within is own "risk cup" and that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for dicamba meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, drinking water, and residential uses. The FQPA Safety Factor has not been retained for dicamba because acceptable developmental and reproduction studies have been submitted and reviewed, there is a low concern and no residual uncertainties for pre- and postnatal toxicity, and the dietary and the residential assessments are not expected to underestimate exposure.

2. 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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee

(EDSTAC), EPA determined that there was a scientific basis 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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 for additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on dicamba, there was no evidence of endocrine disruption effects. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, dicamba may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption

3. Cumulative Risks

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to dicamba and any other substances. For the purposes of this reregistration decision, therefore, EPA has not assumed that dicamba has a common mechanism of toxicity with other substances.

4. Tolerance Reassessment Summary

The completion of the dicamba RED does not result in any additional tolerances being reassessed. All 60 existing tolerances were reassessed at the time a new food use was established for dicamba. Please see Federal Register Notice 65 FR 33709 (May 24, 2000), for further reference.

D. Regulatory Rationale

1. Human Health Risk Assessment

a. Aggregate Risk

As discussed in Chapter 3, aggregate risk refers to the combined risk from food, drinking water, and residential exposures. In addition, aggregate risk can result from one-time (acute), short-term and/or chronic exposures. For dicamba, aggregate risk for food, drinking water, and residential exposures are below the Agency's level of concern for acute, short term, and chronic exposure. No mitigation is necessary for dietary, drinking water, or residential exposure to dicamba.

b. Occupational Risk

(i) Handlers

Due to risk exceedances for scenarios such as mixing/loading/applying, dicamba labels must be amended to add chemical resistant gloves to all mixers, loaders, applicators, and any

other handlers. The addition of gloves to the assessment resulted in MOEs $\geq$ 280 for all exposure scenarios.

(ii) Postapplication

There are no short/intermediate re-entry risks for dicamba on the day of application. However, due to a toxicity category II for acute eye irritation, the current REI of 24 hours will remain unchanged.

2. Environmental Risk Mitigation

Because of the potential non-target animal and plant risks, the Agency is requiring that the maximum application rate be reduced to 1.0 lb ae/acre for a single application and reduced to 2.0 lb ae/acre per year for all use patterns. This will result in lowering the potential risks of concern to aquatic plants. This rate reduction will also lower acute risks to all animals (except small herbivorous birds), as well as chronic risk to mammals. Assessed risks to terrestrial plants will be lowered, but not eliminated.

a. Spray Drift

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 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 airblast 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.

From its assessment of dicamba, as summarized in this document, the Agency concludes that no specific additional drift mitigation measures are needed at this time. In the future, dicamba product labels may need to be revised to include additional or different drift label statements. The Agency encourages the inclusion of best management practices on labels to reduce spray drift.

b. Endangered Species Considerations

The Agency's screening level ecological risk assessment for endangered species results in the determination that dicamba will have no direct acute effects on threatened and endangered freshwater fish, estuarine fish, and aquatic invertebrates. However, the Agency's level of concern was exceeded for endangered birds, mammals, and non-target plants. Further, potential indirect effect to any species dependent upon a species that experiences effect cannot be precluded from use of dicamba. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Chronic RQs exceeded LOCs for endangered mammals at all application rates modeled. Acute

LOCs were exceeded for endangered birds at all application rates. LOCs were exceeded for terrestrial plants adjacent to treated areas and in semi-aquatic areas at all application rates.

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 address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of dicamba, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines use of dicamba "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to dicamba at levels of concern. EPA is not requiring specific dicamba label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

V. What Registrants Need to Do

The Agency has determined that dicamba is eligible for reregistration; however, additional data are required to confirm this decision. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data and generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data that the Agency intends to require for dicamba to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of dicamba for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Guideline	Study Description
Residue Chemistry	
860.1340	Residue Analytical method for barley grain and straw, wheat straw, and soybean seeds.
860.1360	Multiresidue methods data for the dicamba metabolites of concern (5-OH dicamba and DCSA).
860.1380	Storage stability data for sugarcane molasses and animal commodities.
860.1500	Crop Field Trials for soybean forage and hay (if no feeding restrictions appear on the label).
860.1500	Crop Field Trials for sugarcane
Ecological Exposure	
850.4225	Seedling emergence for end use products.
850.4250	Vegetative vigor studies for end use products

2. Labeling for Manufacturing-Use Products

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant 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. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in the Risk Mitigation Summary section. The following table describes how language on the labels should be amended.

Conclusions

The Agency is issuing this Reregistration Eligibility Decision (RED) document for dicamba, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing dicamba. The Agency has determined that all currently registered uses of dicamba are eligible for reregistration provided that the mitigation measures are adopted on product labels.

The risk assessments for dicamba are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making.

VI. Appendices

Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 13: Summary of Labeling Changes for Dicamba

Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into an herbicide for the following use(s) [small grains, corn, sorghum, sugar cane, golf course and residential lawns, sod farms, pastures, rangeland and rights of ways]."	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)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"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 Pollution 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
End Use Products Intended for Occupational Use (WPS and Non WPS uses)		

PPE Requirements Established by the RED[1] For Liquid, Wettable Powder, Granulars and Water Dispersible Granular Formulations	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-resistant material*). If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H*] on an EPA chemical-resistance category selection chart." All mixers, loaders, and applicators and other handlers must wear : < Long-sleeved shirt and long pants < Shoes plus socks, and < Chemical-resistant gloves (except for applicators using groundboom equipment, pilots and flaggers) "See engineering controls for additional requirements and exceptions."	Immediately following/below 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."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for Liquid, Wettable Powder, Granulars and Water Dispersible Granular Formulations	Pilots must use cockpits in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6).	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
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.	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

	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."	
Environmental Hazards	"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."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, Under Agricultural Use Requirements Box

Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	For minimum early entry PPE use the following: "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 worn over short-sleeve shirt and short pants, * chemical resistant footwear plus socks * chemical-resistant gloves made of any waterproof material * chemical-resistant headgear for overhead exposure. * protective eyewear "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated area."	Direction for Use Agricultural Use Requirements box
Entry Restrictions for products having occupational uses on the label not subject to the WPS	For products applied as sprays "Do not enter or allow others to enter until sprays have dried." For products applied dry "Do not enter or allow others to enter until dusts have settled."	If no WPS use on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
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."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk	Labels must be amended to reflect the following maximum application	Directions for Use

Mitigation)	rates and the maximum number of treatments per year: Maximum single application rate: 1.0 lb ai/acre and no more than 2 applications per year.	
Spray Drift	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift."	Directions for Use
End Use Products Intended for Residential Use		
Environmental Hazards	"Do not apply to water. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements Immediately Following the User Safety Recommendations
Application Restrictions	"Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	For products applied as sprays: "Do not allow people or pets to enter the treated area until sprays have dried." For products applied dried "Do not allow people or pets to enter the treated area until dusts have settled."	Directions for use under General Precautions and Restrictions

[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.