Docket Number: EPA-HQ-EPA- OPP-2007-1135
www.regulations.gov

Quinclorac Summary Document
Registration Review: Initial Docket
December 2007

Case # 7222

Docket Number: EPA-HQ-EPA- OPP-2007-1135
www.regulations.gov

Quinclorac Summary Document
Registration Review: Initial Docket
December 2007

Approved By:

_____

Steven Bradbury, Ph.D.
Director, Special Review and
Reregistration Division

Docket Number: EPA-HQ-EPA- OPP-2007-1135
www.regulations.gov

TABLE OF CONTENTS

Docket Number: EPA-HQ-EPA- OPP-2007-1135
www.regulations.gov

I. Preliminary Work Plan - Quinclorac

Introduction:

The Food Quality Protection Act of 1996 mandated a new program: registration review. All pesticides distributed or sold in the United States generally must be registered by the U.S. Environmental Protection Agency (USEPA; EPA; The Agency), based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency has begun to implement the new registration review program, and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of quinclorac.

Quinclorac is a systemic pre- and post- emergent herbicide to control broadleaf and grass weeds. It is registered for use on agricultural crops as well as on turf in residential and commercial areas.

Anticipated Risk Assessment and Data Needs:

The Agency will conduct a comprehensive ecological risk assessment, including an endangered species assessment for quinclorac. The Agency will also perform an occupational risk assessment, a drinking water assessment, a residential handler assessment, and an aggregate assessment.

Ecological Risk:

- The most recent comprehensive ecological risk assessment for registered uses was conducted on wheat and sorghum in 1999. The Agency has not conducted a risk assessment that supports a complete endangered species determination. Please refer to Section IV, Ecological Risk Assessment Problem Formulation, for a detailed discussion of the anticipated risk assessment needs.

- The Agency anticipates needing the following data in order to conduct a complete ecological risk assessment, including an endangered species assessment, for all uses:

    - (GLN 850.1010) Aquatic invertebrate acute toxicity test, freshwater daphnids
    - (GLN 850.1300) Daphnid chronic toxicity test
    - (GLN 835.7100) Ground water monitoring

- The planned ecological risk assessment will allow the Agency to determine if quinclorac's use has "no effect" on federally listed threatened or endangered species (listed species) or their designated critical habitat. If the screening level assessment indicates that quinclorac "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of quinclorac is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (Services), as appropriate.

Human Health Risk:

- The toxicological endpoint selections are adequate; however, the toxicology database for quinclorac is incomplete at this time. A 90-day inhalation toxicity study in the rat is required to assess inhalation exposure from spray uses (GLN 870.3465).

- The residue chemistry database is complete. However, newly submitted aspirated grain fraction studies on wheat and sorghum will have to be reviewed, and livestock tolerances may need to be revised based on this review.

- The dietary (food alone) assessment is adequate. However, a new drinking water assessment will be conducted; therefore, an aggregate assessment will be needed.

- The residential post application exposure assessment is adequate, therefore no residential post application assessment is needed. However, no residential handler risks were assessed; therefore, a new residential handler assessment is needed.

- No occupational risk assessments have been conducted. Occupational risk assessments will be needed for all scenarios.

- Please refer to Section V of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health.

Timeline:
EPA has created the following estimated timeline for the completion of the quinclorac registration review. The Agency may conduct the occupational assessment much earlier in the process, allowing mitigation (if necessary) to occur well before completion of the final decision.

Registration Review for quinclorac – Projected Registration Review Timeline	
Activities	**Estimated Month/Year**
Phase 1: Opening the docket	
Open Public Comment Period for Quinclorac Docket	2007 – Dec.
Close Public Comment Period	2008 – Mar.
Phase 2: Case Development	
Develop Final Work Plan (FWP)	2008 – Apr.- Jun.
Issue DCI	2009 – Jan - Mar.
Data Submission	2013 – Jan - Mar.
Open Public Comment Period for Preliminary Risk Assessments	2014 – Jul. – Sept.
Close Public Comment Period	2014 - Oct. – Dec.
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	2015 – Jan. – Mar.
Close Public Comment Period	2015 – Apr. – Jun.
Final Decision and Begin Post-Decision Follow-up	2015 – Jul. Sept.
Total (years)	8

Guidance for Commenters:
The public is invited to comment on EPA's preliminary registration review work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided prior to issuing a final work plan for the quinclorac case.

- Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. Please see section V of this document, Quinclorac, Human Risk Problem Formulation Document in Support of Registration Review, for a listing of the differences among the U.S., Canada, Codex, and Mexico tolerances.

- Quinclorac is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the "OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process" (see: http://www.epa.gov/oppfead1/cb/ppdc/2006/november06/session1-sop.pdf), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

- EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to quinclorac compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Stakeholders are also specifically asked to provide information and data in the following areas.

- There is specific information that will assist the Agency in refining the ecological risk assessment, including any species-specific effects determinations. The Agency is interested in obtaining the following information regarding the use of quinclorac:

    1. confirmation on the following label information
        a. sites of application
        b. formulations
        c. application methods and equipment
        d. maximum application rates
        e. frequency of application, application intervals, and maximum number of applications per season
        f. geographic limitations on use
    2. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops)
    3. use history
    4. median and 90th percentile reported use rates (lbs ai/acre) from usage data – national, state, and county
    5. application timing (date of first application and application intervals) by crop – national, state, and county
    6. sub-county crop location data

7. usage/use information for non-agricultural uses (e.g., forestry, residential, rights-of-way)
8. directly acquired county-level usage data (not derived from state level data)
    a. maximum reported use rate (lbs ai/acre) from usage data – county
    b. percent crop treated – county
    c. median and 90th percentile number of applications – county
    d. total pounds per year – county
    e. the year the pesticide was last used in the county/sub-county area
    f. the years in which the pesticide was applied in the county/sub-county area
9. typical interval (days)
10. state or local use restrictions
11. ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
12. monitoring data

Next Steps:

After the comment period closes, the Agency will prepare a Final Work Plan for this pesticide.

Docket Number: EPA-HQ-EPA- OPP-2007-1135
www.regulations.gov

II. FACT SHEET

Background Information:

- Quinclorac Registration Review case number: 7222
- Quinclorac is a systemic pre- and post- emergent herbicide to control broadleaf and grass weeds on rice, sorghum, wheat, residential lawns, ornamentals and turf grass.
- Quinclorac PC code: 128974; CAS #: 84087-01-4
- Technical Registrant: Albaugh Inc.
- First approved for use in 1992, therefore not subject to reregistration.
- Tolerance Reassessment was released on March 26, 1999 through publication in the Federal Register (64 FR 14626).
- Special Review and Reregistration Division (SRRD), Chemical Review Manager (CRM): Joy Schnackenbeck: schnackenbeck.joy@epa.gov
- Registration Division (RD) Contacts:
  Jim Tompkins: tompkins.jim@epa.gov; Hope Johnson: johnson.hope@epa.gov
- 34 total active products are registered; 1 technical product, 3 manufacturing use products, 26 end use products, and 4 special local needs permits (SLN; 24c).
- Quinclorac is sold in several different formulations including water dispersible granules, emulsifiable concentrate and wettable powder.
- Quinclorac can be applied through aerial equipment, tank spray, boom sprayer, hand held sprayer, and backpack sprayer.

Use & Usage Information: (For additional details, please refer to the BEAD Appendix A document in the quinclorac docket.)

- Quinclorac is a quinoline carboxylic acid, whose mechanism of herbicidal action is generally mimicry of the plant growth hormone, auxin.
- Quinclorac is used on less than 2.5 % of the total crop treated for corn, summer fallow, sorghum and wheat. On average, it is used on 30% of the total crop treated for rice.
- Approximately 313,000 pounds of quinclorac are used annually.

Recent Actions:

- A Rule for quinclorac was issued on 10/28/2007 (72 FR 55068) which established tolerances for residues in or on imported barley grain. BASF Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).
- A Rule for quinclorac was issued on 3/26/1999 (64 FR 14626), which established FQPA tolerances for residues on wheat and sorghum. This Rule also included the tolerance reassessment for rice, sorghum, wheat, residential lawns, ornamentals and turf grass.

Docket Number: EPA-HQ-EPA- OPP-2007-1135
www.regulations.gov

Ecological Risk Assessment Status:
Please refer to Section IV of this document, Ecological Risk Assessment Problem Formulation for quinclorac registration review, for a detailed discussion of the anticipated ecological risk assessment needs. Below is a summary of the findings:

- The Agency will need to conduct new assessments for all registered uses because some uses and application type scenarios were not assessed for ecological risk and did not include current terrestrial and aquatic models.
- The Agency has some freshwater invertebrate data which indicates low risk for aquatic animals, however there are some unusual results with these studies, which were completed with a formulated product. Therefore, the Agency is requiring freshwater invertebrate tests with the technical, and will use these tests to estimate risks to estuarine animals.
- No acute or chronic risk exceedences of the Agency's level of concern are anticipated for aquatic fish or invertebrates. However, uncertainty exists for acute and chronic risks to estuarine marine invertebrates until further data is submitted. Chronic risks to estuarine marine fish will be estimated from acute to chronic ratios.
- Before the risk assessments are developed for public comment, the Agency will ensure that all currently registered uses of quinclorac have an endangered species assessment completed. The ecological risk assessment will allow the Agency to determine whether quinclorac use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (Services), as appropriate.

Human Health Risk Assessment Status:
Please refer to Section V of this document, Human Health Effects Scoping Document, for a detailed discussion of the anticipated risk assessment needs for human health. A summary follows:

Dietary (Food and Water):

- The residue chemistry database is complete with the newly submitted aspirated grain fraction (AGF) studies. A review of the AGF studies are needed, and livestock tolerances may need to be revised based on this review.
- The dietary exposure assessment is up-to-date, and no further dietary assessments are needed. There are no risks of concern even with a very conservative assessment.
- A drinking water assessment is needed.

Residential:

- The post application exposure assessments are adequate.
- No residential handler assessment has been conducted; therefore, a residential handler assessment is needed for the registration review of quinclorac.

Occupational:

- No occupational assessments have been conducted for quinclorac. A new occupational assessment is required for the registration review once the inhalation endpoint is selected.

Aggregate:

- Once the drinking water assessment is completed, the Agency will conduct an aggregate assessment.

Incident Reports:

- The search of the National Poison Control Center System (NPCS) showed only a total of five incidents related to quinclorac in the 13-year span of data collected and only two cases were reported in OPP's Incident Data System (IDS) from 1999 to the present. In addition, there were no cases reported in the National Institute of Occupational Safety and Health Sentinel Event Notification System for Occupational Risks (NIOSH/SENSOR) database involving quinclorac. *A more detailed summary is provided in a separate document in this docket.*

Tolerances:

- US tolerances are listed under 40 CFR 180.463. A table listing the differences between current US tolerances as compared to Codex, Canada, and Mexico appears in section V of this document, Human Health Effects Scoping Document.

Data Call-In Status:

- There are no current data call-ins.

Labels:

- A list of registration numbers may be found in the quinclorac docket and the labels can then be obtained from the Pesticide Product Label System (PPLS) website: http://oaspub.epa.gov/pestlabl/ppls.home.

Registration #	Product Name	Company Name	Percent Active Ingredient
228-423	DQD SELECTIVE HERBICIDE	NUFARM AMERICAS INC.	7.91

Registration #	Product Name	Company Name	Percent Active Ingredient
228-531	NUP 12D02 HERBICIDE	NUFARM AMERICAS INC.	8.25
239-2689	LAWN CRABGRASS AND WEED KILLER	THE ORTHO BUSINESS GROUP	0.1
538-296	TURF BUILDER WITH WEED CONTROL III	SCOTTS COMPANY, THE	0.52
1381-209	QUINCLORAC 75 DF	WINFIELD SOLUTIONS, LLC	75
2217-885	EH-1426 HERBICIDE	PBI/GORDON CORP	3.49
2217-886	EH-1427 HERBICIDE	PBI/GORDON CORP	5.69
2217-887	EH-1428 HERBICIDE	PBI/GORDON CORP	0.121
2217-888	EH-1425 HERBICIDE	PBI/GORDON CORP	8.38
2217-894	EH-1432 HERBICIDE	PBI/GORDON CORP	1.61
2217-896	EH-1437 HERBICIDE	PBI/GORDON CORP	2.13
2217-901	EH-1434 HERBICIDE	PBI/GORDON CORP	5.65
2217-906	EH-1449 HERBICIDE	PBI/GORDON CORP	0.104
7969-93	FACET 50 WP	BASF CORPORATION	50
7969-109	QUINCLORAC MANUFACTURING USE PRODUCT	BASF CORPORATION	98
7969-113	FACET 75 DF HERBICIDE	BASF CORPORATION	75
7969-130	DRIVE 75 DF HERBICIDE	BASF CORPORATION	75

Registration #	Product Name	Company Name	Percent Active Ingredient
7969-152	PARAMOUNT BW HERBICIDE	BASF CORPORATION	15
7969-158	FACET GR HERBICIDE 46	BASF CORPORATION	1.5
7969-172	DRIVE 75 MANUFACTURERS CONCENTRATE	BASF CORPORATION	75
7969-222	CLEARPATH HERBICIDE	BASF CORPORATION	61.98
34704-920	QUINCLORAC 75DF HERBICIDE	LOVELAND PRODUCTS, INC.	75
42750-85	QUINCLORAC TECHNICAL	ALBAUGH INC	99
42750-88	QUINCLORAC 75DF AG	ALBAUGH INC	75
42750-90	QUINCLORAC 75DF SP	ALBAUGH INC	75
42750-131	QUINCLORAC 75 SWF	ALBAUGH INC	75
71085-26	RICEPRO	RICECO LLC	2
73220-15	QUALI-PRO QUINCLORAC 75	FARMSAVER.COM, LLC	75
79676-22	QUINCLORAC G-PRO 75 DF	GRO-PRO, LLC	75
81927-21	ALLIGARE QUINCLORAC 75 WDG	ALLIGARE, LLC	75
AR070006	RICEPRO	RICECO LLC	2
UT990003	FACET 75 DF HERBICIDE	BASF CORPORATION	75
98ND20		ND Dept. of Agriculture	
98NE07		NE Department of Agriculture	

III. GLOSSARY of TERMS and ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
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
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
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
GENEEC	Tier I Surface Water Computer Model
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
LOAEL	Lowest Observed Adverse Effect Level
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 submitted studies.

MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
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
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

IV. Ecological Risk Assessment Problem Formulation

U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: November 27, 2007

MEMORANDUM

Subject: EFED Problem Formulation for Quinclorac Registration Review
PC: Code: 128974 D344485

To: Joy Schnackenbeck, Chemical Review Manager
Special Review and Reregistration Division (7508P)

From: Marie Janson, Environmental Scientist, ERBI
Thuy Nguyen, RAPL, ERBI
Nancy Andrews Ph.D., Branch Chief, ERBI
Environmental Fate and Effects Division (7507P)

Attached is the EFED's problem formulation document in support of the Quinclorac registration review docket opening. This memorandum outlines (1) the methods that will likely be used in the ecological risk assessment of Quinclorac (2) data gaps, and (3) additional data needs.

EXECUTIVE SUMMARY

Quinclorac is systemic pre- and post-emergent herbicide to control broadleaf and grass weeds on residential/commercial turf grasses and on other turf grasses (picnic grounds, athletic field, golf, and sod farms), agricultural fallow/ idleland, agricultural rights of way/ fence rows/ hedge rows, grasses grown for seed, rice, sorghum and wheat. In addition to the above registered uses, Emergency Use Permits (EUPs) on impounded waters were also issued.

The most recent comprehensive risk assessment for registered uses was conducted on wheat and sorghum (Feb 17, 1999). The most recent EUP was conducted on aquatic weed control to non-flowing water bodies (May 17,2007). The drinking water assessment was conducted on turf grass application (September 13, 2007).

Based on the results of the above risk assessments the following risk concerns were noted from registered uses:

- risks to listed and non-listed terrestrial plants wheat and sorghum applications
- (listed and non-listed) acute risk to birds from wheat and sorghum applications*

Based on the results of the above EUP for aquatic weed control the following risk concerns were noted:

- risks to listed and non-listed terrestrial plants (spray drift exceedences only)
- risks to non listed* and listed unicellular and vascular plants
- (listed and non-listed) acute and chronic risk to mammals*
- (listed and non-listed) acute and chronic risk to birds*

There is insufficient evidence to completely refute these exceedences, however there is sufficient evidence to refine the concerns.

Based on available laboratory studies, EFED has identified two major (BH 514-1 and BH 514 2-OH; >10% applied)) and one minor (BH 514-HMe-ester; <10% applied) quinclorac metabolites. In most of the acceptable terrestrial field dissipation studies (1988/1989, 1989/1990, and 1996/1997 studies), leaching from these degradates. An acceptable guideline adsorption/desorption study for BH-514-1 indicates that this metabolite is mobile to very mobile in sand, sandy loam, loam, clay loam, and silty clay soils. Two guideline leaching and adsorption/desorption studies (MRID 45598701 and 45598702) for BH 514 2-OH and BH 514-HMe-ester were submitted to the Agency, in 2002, however not yet reviewed. These studies will undergo reviews and until they are deemed acceptable by the Agency, the above mentioned metabolites are considered potential contaminants of groundwater resources, based on the "Acceptable" field studies. EFED believes that since quinclorac is persistent and mobile and its metabolites have the ability to leach through soil profiles, the potential for groundwater impacts to non-target crops via contaminated groundwater is likely. Therefore, a small scale prospective groundwater contamination study for quinclorac (and possibly its metabolites) under the expected conditions of use of all currently registered crops is requested.

EFED anticipates revisions to the risk assessments based on new application scenarios and additional toxicity data requested. Previous assessments were based on lower application scenarios or higher intervals between applications.

PROBLEM FORMULATION

Problem formulation is used to establish the direction and scope of an ecological risk assessment. According to the Guidelines for Ecological Risk Assessment (USEPA, 1998), problem formulation consists of defining the problem and purpose for the assessment, and developing a plan for analyzing and characterizing risk. The critical components of the problem formulation are selection of the assessment endpoints, formulation of risk hypotheses and the conceptual model, and development of an analysis plan. The analysis plan and supporting rationale are aimed at determining whether the uses of Quinclorac on residential/commercial turf grasses and on other turf grasses (picnic grounds, athletic field, golf, and sod farms), agricultural fallow/ idleland, agricultural rights of way/ fence rows/ hedge rows, grasses grown for seed, rice, sorghum and wheat could result in exposures that cause unreasonable adverse effects (risk) to non-target organisms including those federally listed as threatened or endangered (hereafter referred to as "listed"). Emergency Use Permits also will also be characterized in the assessment on aquatic weed control on impounded waters.

1. INTEGRATION OF AVAILABLE INFORMATION

The risk assessments available in the docket, and which serve as the basis for this problem formulation, include the following:

- Feb 17, 1999, Quinclorac Herbicide Environmental Fate and Ecological Effects Assessment and Characterization for a Section 3 for Use on Wheat and Sorghum

- May 17, 2007, Ecological Risk Assessment for Experimental Use Permit for Quinclorac for Aquatic Weed Control for the application of quinclorac to non- flowing water bodies such as retention ponds and lakes to evaluate the control and selectivity of submerged and emergent aquatic weed species DPBarcode: D334717.

- September 13, 2007, Estimated Drinking Water Assessment for Quinclorac (3,7-dichloro-8-quinolinecarboxylic acid, CAS# 84087-01-4) Use on Turfgrasses DPBarcode: 341487

Based on the results of the above risk assessments the following risk concerns were noted from registered uses:

- risks to listed and non-listed terrestrial plants from wheat and sorghum applications
- (listed and non-listed) acute risk to birds from wheat and sorghum applications*

Based on the results of the above EUP for aquatic weed control the following risk concerns were noted:

- risks to listed and non-listed terrestrial plants (spray drift exceedences only)
- risks to non listed* and listed unicellular and vascular plants
- (listed and non-listed) acute and chronic risk to mammals*
- (listed and non-listed) acute and chronic risk to birds*

There is insufficient evidence to completely refute these exceedences, however there is sufficient evidence to refine the concerns.

The following maximum use rates were used in previous assessments:

Feb 17, 1999, Section 3 Assessment for Use in Wheat and Sorghum: The maximum annual application rate is 0.75 lb a.i./acre at 0.125 - 0.245 lb ai/acre for ground and aerial applications.

September 13, 2007, Estimated Drinking Water Assessment for Quinclorac Use on Turfgrasses: The maximum annual application rate is 1.5 lb a.i./acre at 0.25 – 0.75 lb ai/A/ appl at 21-day interval for ground spray or spot spray application.

May 17, 2007, Ecological Risk Assessment for Experimental Use Permit for Quinclorac for Aquatic Weed Control: For submerged vegetation control quinclorac is applied in sufficient quanity to reach a water concentration of 0.5 mg/L with up to 2 applications per year.

All assessments did not provide the highest labeled application rates (2 applications @0.75 lb ai/A) and current minimum intervals (14 days). In addition, current labels have ground, aerial and granular applications which were not incorporated in all assessments. Therefore, a new drinking water assessment and ecological risk assessment is required with the above maximum application rates, minimum intervals and application scenarios.

There are two reported incidents for quinclorac. Both incidents ref# I012162-001 and ref# I015496-001 indicated plant damage to tomatoes in Arkansas from drift exposure. There are additional data that suggest the effects of primary drift may occur at considerable distances downwind from the target site and effect commercial yields of sensitive crops. Additional information is summarized in the 1999 EFED risk assessment in the Risk Characterization Section on Non-Target Plant Effects (Drift Implications for Risks to Non-Target Crops and Wild Plants).

2. DATA GAPS AND ANTICIPATED DATA NEED

Acute and chronic freshwater invertebrate toxicity tests- The acute freshwater invertebrate toxicity test was based on a formulated product (quinclorac with surfactant BAS 864 01 S). The *Daphnia magna* 21-day NOAEC of 110 mg/L is used as the freshwater invertebrate toxicity endpoint for chronic exposure. It should be noted that the 21-day NOAEC unexpectedly exceeds the 48-hour EC_{50} for the same species. This observation is likely the result of differences in test water conditions, or as the result of surfactant use in the acute toxicity test. As quinclorac is an acid subject to dissociation in water, differences in water hardness may influence the toxicity of the compound. The available data suggest that quinclorac is more toxic to freshwater invertebrates in soft water (48-hour LC_{50}= 28.9 mg/l in water 40-48 mg $CaCO_3$/L) compared to harder water (21-day NOAEC 110 mg/l in water >150 mg $CaCO_3$/L). An alternative explanation for the disparate toxicity results may be the presence of surfactant in the acute test, whereas no surfactant is evident for the chronic test. The use of the available 21-day chronic data as the toxicity endpoint for all freshwater systems represents an uncertainty.

Decision: Acute and chronic freshwater invertebrate studies conducted on TGAI and current guideline requirements are requested. This data will then be used to estimate values for estuarine marine invertebrate chronic toxicity.

Estuarine marine fish and estuarine marine invertebrate Early Life-Stage toxicity tests- No early life-stage or full life-cycle studies were submitted for estuarine marine fish or invertebrates.
Decision: Early life-stage chronic estuarine marine fish and invertebrate toxicity tests for quinclorac are not requested. Estimated values derived from ACRs will be sufficient pending acute and chronic freshwater invertebrate study based on TGAI.

Ground water contamination study for quinclorac (and possibly its metabolites):
Based on available laboratory studies, EFED has identified two major (BH 514-1 and BH 514 2-OH; >10% applied)) and one minor (BH514-HMe-ester; <10 % applied) quinclorac metabolites. In the field (1988/1989, 1989/1990, and 1996/1997 studies), leaching from these degradates into the soil profiles were observed. An acceptable guideline adsorption/desorption study for BH-514-1 indicated that this metabolite is mobile to very mobile in sand, sandy loam, loam, clay loam, and silty clay soils. Two guideline leaching and adsorption/desorption studies (MRID 45598701 and 45598702) for BH 514 2-OH and BH 514-HMe-ester were submitted to the Agency, in 2002, however not yet reviewed. These studies will undergo reviews and until they are deemed acceptable by the Agency, the above mentioned metabolites are considered potential contaminants of groundwater resources, as suggested by data from the "Acceptable" terrestrial field dissipation studies.

Decision: Based on the environmental persistence of quinclorac, its potential to enter groundwater (as modeled by SCI-GROW and indicated in terrestrial field studies), and the potential for groundwater impacts to non-target crops via contaminated groundwater, a small scale prospective groundwater contamination study for quinclorac (and possibly its metabolites) under the expected conditions of use of all currently registered crops is requested. Specifically, since both parent quinclorac and BH 514-1 are carboxylic acids, they are expected to be anions under the normal environmental pH range (5.5 – 8.5), therefore possess high potential to be mobile in mineral soils.

3. PESTICIDE TYPE, CLASS, AND MODE OF ACTION

Quinclorac is a quinoline carboxylic acid. The mechanism of herbicidal action is generally similar to the mechanism for the phenoxy herbicides (i.e., mimicry of the plant growth hormone auxin). The risk assessment only assesses parent quinclorac risks. For most fate processes the parent compound is stable. While quinclorac may be relatively rapidly photo-labile in natural waters, the available studies of this fate process have not chemically identified degradates or their rate of production. There is therefore insufficient information to assess degradate risks with any useful degree of confidence and no information is available to suggest that any degradates could be biologically active.

4. STRESSOR SOURCE AND DISTRIBUTION

The stressor of this assessment is identified by the chemical name 3,7-dichloro-8-quinolinecarboxylic acid. The trade name for this compound is quinclorac, the CAS number is 84087-01-4, and the PC code is 128974. Currently, quinclorac is applied as ground spray, aerial spray, aerial granular, ground granular applications.

Laboratory data indicate that quinclorac is stable to hydrolysis, photolysis in sterile water, as well as aerobic and anaerobic metabolism in soil. Conversely, quinclorac undergoes rapid photolysis in non-sterile rice paddy, natural river waters, and solutions containing activated sewage sludge (half-lives of 5-10 days). Photolysis on soil surface is also a route of dissipation with a mean half life of 141 days. Field studies reviewed to date indicate that quinclorac is moderately persistent (18-176 days half-lives) in terrestrial environment.

The adsorption coefficients K_d of less than 1 suggest that leaching could be a route of dissipation. In the field, some leaching was observed, as quinclorac was detected below the 12 inch soil depth in the several of the terrestrial field dissipation studies (1988/1989 studies): detections of residues of quinclorac and its degradates in the soil down to 42-48 inches (quinclorac), 12-18 inches (BH 514-2-OH) and 6-12 inches (BH 514-ME) were noted in terrestrial field studies performed in KS, CA, MO, and NJ.

Runoff under normal field situations to near surface water is also expected, since K_d is low (<1.0) and the chemical can be applied near the soil surface (pre emergence).

5. OVERVIEW OF PESTICIDE USAGE

Quinclorac is a pre- and post-emergent herbicide to control broadleaf and grass weeds on residential/commercial turf grasses and on other turf grasses (picnic grounds, athletic field, golf, and sod farms), agricultural fallow/ idleland, agricultural rights of way/ fence rows/ hedge rows, grasses grown for seed, rice, sorghum and wheat. In addition, quinclorac controls submerged and emergent aquatic weed species in impounded waters for EUPs.

The highest annual application rate among all registered and proposed uses is via Drive 75 DF and Quinclorac G-Pro 75 DF labels, which allows 2 to 3 ground broadcast or spray spot applications of 0.25, 0.50, or 0.75 lb ai/A per application, not exceeding 1.5 lb ai/A/year. Sequential applications should be timed 14 days apart. Additional maximum rate application scenarios are provided in **Table 1** for aerial, ground and granular applications based on BEAD 2007 information. **Table 30** provides all current registrations and EUPs based on BEAD 2007 information.

Table 1 Maximum Quinclorac Aerial, Ground and Granular application rate scenarios derived from BEAD 2007 to be used in future risk assessments*

Type of application	Label	Maximum application rate	Maximum # apps	Maximum application per season
aerial spray and aerial granular applications	7969-158 Facet GR(aerial), 42750-88 Quinclorac 75 DF AG,7969-93 Facet 50 WP	0.5 lb ai/A	1	0.5 lb ai/A
aerial spray application	42750-131 Quinclorac SWF	0.375 lb ai/A	2	0.75lb ai/A
ground granular application	583-296 Scotts turf builder	0.75 Lb ai/A	2	Not specified (assume 2@ 0.75) 60 day interval
ground spray application	7969-130 Drive 75 DF and 79676-00022 Quinclorac G-Pro 75 DF	0.75lb ai/A	2	1.5 lb ai/A

*assume 14 day interval unless indicated

The application rate for emergent vegetation control is indicated on the proposed label for the EUP to be a maximum of 3 lbs a.i. per year, with up to two applications in a calendar year. Applications can be made to drawn down water bodies to expose vegetation. In such cases re-flooding may occur 14 days after application. The application rate for submerged vegetation is quinclorac applied in sufficient quantity to reach a water concentration of 0.5 mg/L. Up to two application of quinclorac per year can be made.

6. ENVIRONMENTAL FATE SUMMARY

ENVIRONMENTAL FATE

For **persistence**, laboratory data indicate that quinclorac is stable to hydrolysis, photolysis in sterile water, as well as aerobic and anaerobic metabolism in soil. Conversely, quinclorac undergoes rapid photolysis in non-sterile rice paddy, natural river waters, and solutions containing activated sewage sludge (half-lives of 5-10 days). Photolysis on soil surface is also a route of dissipation with a mean half life of 141 days. Field studies reviewed to date indicate that quinclorac is moderately persistent (18-176 days half-lives) in terrestrial environment.

For **mobility in terrestrial environment**, the adsorption coefficients K_d of less than 1 suggest that leaching could be a route of dissipation. In the field, some leaching was observed, as quinclorac was detected below the 12 inch soil depth in the several of the terrestrial field dissipation studies (1988/1989 studies): detections of residues of quinclorac and its degradates in the soil down to 42-48 inches (quinclorac), 12-18 inches (BH 514-2-OH) and 6-12 inches (BH 514-Me ester) were noted in terrestrial field studies performed in KS, CA, MO, and NJ. It is not clear from these studies whether or not the metabolite BH 514-1 was analyzed for at the time the studies were conducted. However, as referenced in the April 25, 1996 letter to Mr Robert Taylor, RD, EPA, the registrant claimed a reanalysis (no analysis date was specified) of the soil samples from the 1988/1999 studies did not detect presence of this carboxylic acid metabolite. Additional studies performed between 1989 and 1990 in FL, WI, and NY only showed movement of parent quinclorac to a maximum depth of 24 inches, while the degradate BH-514-1 was not found at any sampling interval and/or sampling depths. These studies and the details of the reanalyses of BH 514-1 have not yet been received nor reviewed by EFED. Two guideline leaching and adsorption/desorption studies (MRID 45598701 and 45598702) for BH 514 2-OH and BH 514-HMe-ester were submitted to the Agency, in 2002, however not yet reviewed. EFED SCI-GROW model predicts an upper bound ground water exposure concentration of 29 µg/L for parent quinclorac.
In summary, based on all "Acceptable" guideline studies, EFED concludes that quinclorac has has the potential to leach and runoff in the soil environment and into groundwater. Furthermore, BH 514-1, the primary degradate of quinclorac, also has the potential to leach to the groundwater in soil containing low amount of clay or organic matter. EFED notes that quinclorac and BH-514-1 are both carboxylic acids; therefore, they are expected to be anions under the normal environmental pH range (5.5-8.5). This suggests that these two chemicals have great potential to be mobile in mineral soils.

Runoff under normal field situations to near surface water is also expected, since K_d is low (<1.0) and the chemical can be applied near the soil surface (pre emergence). For 1 in 10 year annual peak (acute) surface water residue, EFED PRZM/EXAMS estimates a value of 22.9 µg/L; for 1 in 10 year annual mean (chronic), 14.5 µg/L; and for 30 year annual mean (cancer), 10.3

µg/L. Note that all values were based on post emergence non residential turf uses ,such as picnic grounds, athletic fields, sod farms, etc, … The acute value was estimated from the FL Turf scenario, and the chronic and cancer from the PA Turf scenario.

According to the aerobic soil metabolism and field dissipation studies and the research cited in the literature reviews, the fate of quinclorac can be described as such:

1. Quinclorac is initially metabolized to the primary degradate, 3-chloro-8-quinoline carboxylic acid (BH 514-1). This degradate undergoes further degradation to 5-chloro-2-hydroxy-nicotinic acid, which in turn is metabolized to 5-chloro-2,6-dihydroxy-nicotinic acid, 2 hydroxy-3-chloro-8-quinoline carboxylic acid (BH 514 2-OH), 7-chloro-8-quinoline carboxylic acid, 8-quinoline carboxylic acid, and other small fragments. These compounds can then bind with or become incorporated into the soil or humic material of the soil as a part of natural soil components (i.e., carbon pool of the soil), and/or can degrade to CO_2, a major terminal product.
2. The only volatile compound detected in the aerobic soil metabolism study (MRID 44084503) was CO_2 at a maximum concentration of 7.1% TRR. Other than parent, residues identified at maximum concentrations were: BH 514 2-OH (14.9% TRR), BH 514-Me ester (7.8% TRR). Parent was found at maximum concentrations of 58.1% TRR.
3. BH 541-1 was also reported in the aerobic aquatic metabolism (MRID 42294102), at maximum of 55.7% of the initial radioactivity after 6 months and 30.8% after 12 months. Adsorption/desorption studies determine that this degradate is less mobile than its parent, with K_d's ranging from 1.56 in sand soil, 1.97 in sandy loam soil, 11.4 in loam soil, 13.3 in clay loam soil, and 30.2 in silty clay soil. This degradate was not reported in any of the terrestrial field dissipation studies, at any soil depth.

For **mobility in aquatic environment**, aquatic field dissipations studies with rice indicate that the compound is less stable than predicted by the laboratory and is probably not mobile under normal use conditions.

For **volatility**, both vapor pressure (7.5×10^{-8} mm Hg at 20^{o} C) and Henry's Law Constant (1.22 to 24.3×10^{-15} $atm.m^3\ mol^{-1}$) indicate a low possibility of volatilization from soil and water. **Bioaccumulation in fish** is not expected according to the acceptable fish accumulation study, which showed that after 28 days of exposure, quinclorac did not accumulate in channel catfish. No BCF value was reported (MRID 40320819 and 41063559). Furthermore, the octanol/water partition coefficient (K_{OW}) of 0.266 also suggests that quinclorac has low potential to bioaccumulate.

A detailed assessment of the environmental fate of Quinclorac could be found in the "Environmental Fate and Ecological Effects Assessment and Characterization for a Section 3 for Use on Wheat and Sorghum" report dated March 05, 1999 (DP Barcodes: 250179, 248882, 248884, 192866, 231399, and 238400). The chemical structures of quinclorac and its 2 major metabolites (BH 514-1 and BH 514 2-OH) are shown in **Table 29.**

7. ECOLOGICAL EFFECTS SUMMARY

Table 2 provides taxonomic groups and test species used to indicate the potential for ecological effects in this screening-level risk assessment. Within each of these very broad taxonomic groups, an acute and/or chronic endpoint is selected from the available test data.

Table 2. Taxonomic Groups and Most Sensitive Test Species Evaluated for Ecological Effects of Quinclorac *

Taxonomic group	Example(s) of representative species	Endpoint Used
Birds[a]	Bobwhite quail (*Colinus virginianus*) Mallard duck (*Anas platyrhynchos*) Bobwhite quail (*Colinus virginianus*)	Acute LC_{50} 5000 mg/kg-diet Acute LD_{50} >1900 mg/kg-bw Chronic, NOAEC 500 mg/kg-diet
Mammals	Laboratory rat (*Wistar*)	Acute LD_{50} 2190 mg/kg-bw NOAEC 160 mg/kg-bw/day
Terrestrial insects	Honeybees (*Apis mellifera*)	Acute Contact LD_{50}>181 ug/bee
Freshwater fish[b]	Bluegill sunfish (*Lepomis macrochirus*) Fathead minnow *(Pimephales promelas)*	Acute LC_{50} 31.6 mg/L Chronic NOAEC 16 mg/L
Freshwater invertebrates	Water flea (*Daphnia magna*)	Acute EC_{50} 29.8 mg/L NOAEC 110 mg/L
Estuarine/marine fish	Sheepshead minnow (Cyprinodon variegatus)	Acute LC_{50} >94.4 mg/L NOAEC no studies submitted or values determined. However, estimated values derived from acute to chronic ratios will be used in future risk assessments.

Table 2. Taxonomic Groups and Most Sensitive Test Species Evaluated for Ecological Effects of Quinclorac *		
Taxonomic group	**Example(s) of representative species**	**Endpoint Used**
Estuarine/marine invertebrates	Mysid shrimp (*Mysidopsis bahia*)	Acute EC_{50} 69.4 mg/L NOAEC no studies submitted or values determined. However, estimated values derived from acute to chronic ratios will be used in future risk assessments.
Terrestrial plants*	Dicots – carrot Dicots- tomato	Seedling Emergence EC_{25} 0.004 lb a.i./acre, NOAEC <0.004 lb a.i./acre Vegetative Vigor EC_{25} EC_{25} 0.007 lb a.i./acre, NOAEC 0.5 lb a.i./acre
Vascular aquatic plants	Duckweed *(Lemna gibba)* Tier1	Acute EC_{50} >0.5 mg/L NOAEC 0.5 mg/L
Non-vascular aquatic plants	Green algae (*Selanastrum capricornutum)* Freshwater diatom *(Navicula pelliculosa)* Marine diatom *(Skeletonema costatum)* Bluegreen alga *(Anabaena flos-aquae)*	Acute EC_{50} >0.5 mg/L NOAEC 0.5 mg/L

[a]Birds are used as surrogates for terrestrial phase amphibians and reptiles (US EPA, 2004).
[b]Freshwater fish are used as surrogates for aquatic phase amphibians (US EPA, 2004).
* Dicots were the most sensitive terrestrial plant species tested, however the most sensitive monocots for seedling emergence is onion (EC_{25} 0.118 lb, NOAEC<0.118 lb ai/A) and for vegetative vigor is corn (EC_{25} 1.09 lb a.i./acre, NOAEC 0.5 lb ai/A)

8. ECOSYSTEMS AT RISK

The ecosystems that could be potentially at risk due to agricultural and ornamental turf use of quinclorac include terrestrial and aquatic (lakes, ponds, streams and estuarine marine water bodies) habitats in proximity to quinclorac use areas. These habitats may be at risk from drift and/or runoff of quinclorac from use areas.

Organisms of concern include birds, mammals, reptiles, fish, and terrestrial and aquatic invertebrates, plants, and amphibians. The assessment endpoints are intended to reflect population sustainability and community structure within ecosystems and hence relate back to ecosystems at risk. If risks are expected for given species/taxa based on the screening-level assessment, then risks might be expected to translate to higher levels of biological organization.

Identifying specific ecosystems at risk in a screening-level assessment is beyond the scope of the effort.

8.1 Receptors

The aquatic receptors likely to be exposed to quinclorac from turf and rice applications include fish, invertebrates, aquatic stages of amphibians and plants living in waterways adjacent to or downstream from treated areas.

Terrestrial receptors likely to be exposed to quinclorac include birds, mammals, reptiles, and terrestrial stages of amphibians that may occur in treated fields and terrestrial plants adjacent to, or down slope from treated areas. The above taxonomic groups exposed to quinclorac are simular for impounded waters as well.

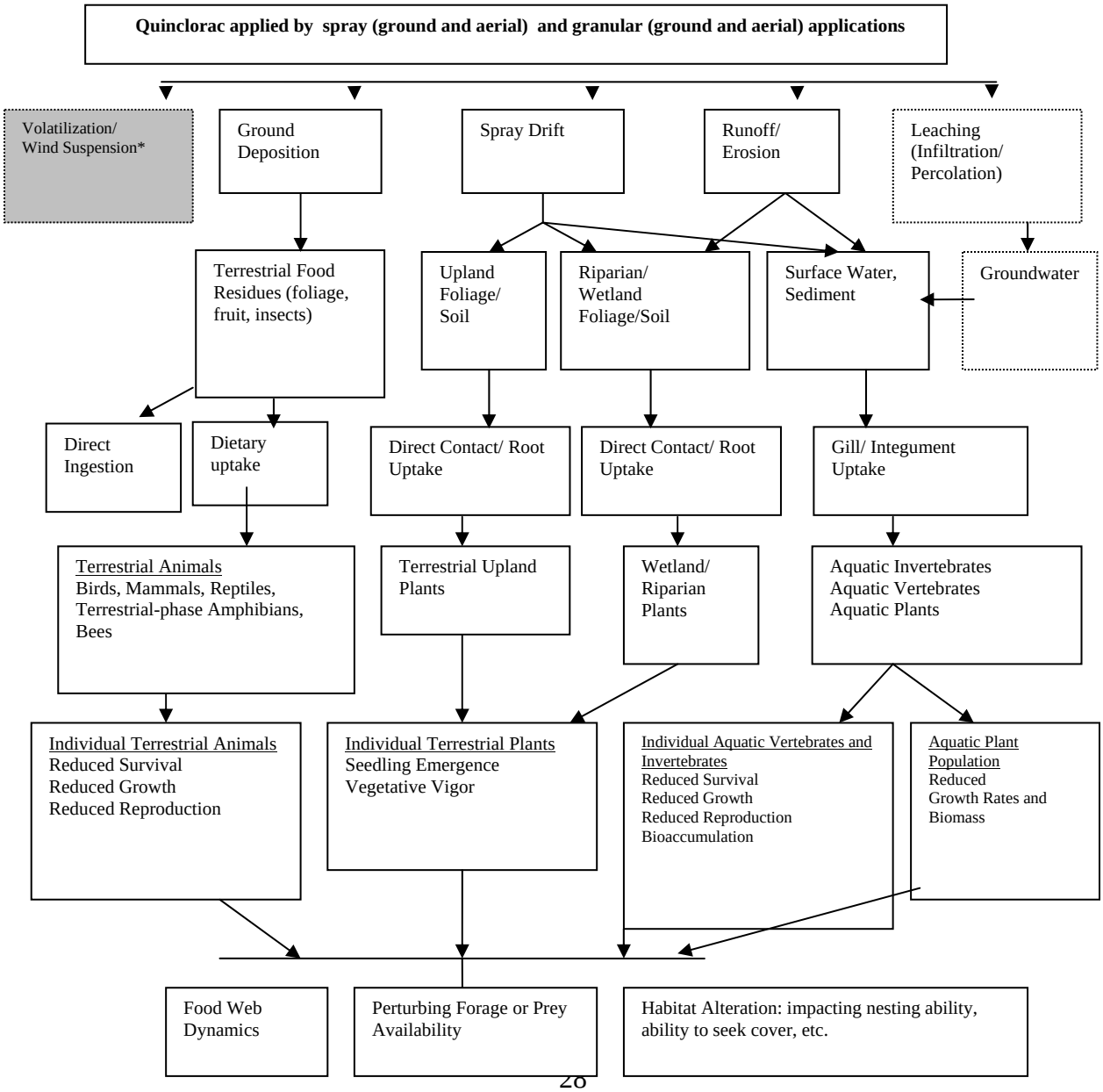
8.2. Assessment Endpoints

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Operationally, the environmental value is represented by an ecological entity and associated attributes or characteristics. The assessment endpoints for this ecological risk assessment will be survival, growth, and reproduction of terrestrial and aquatic animals and plants. Specifically, this assessment will address birds, mammals, reptiles, amphibians, terrestrial and aquatic invertebrates, terrestrial and aquatic plants, and fish. These endpoints, in turn, are meant to reflect population sustainability and community diversity within ecosystems.

Assessment endpoints and toxicity data used to evaluate the assessment endpoints are identified in **Table 2**.

9. CONCEPTUAL MODEL

Figure 1. No conceptual model was provided in previous assessments, however this new conceptual model of the fate/transport and effects of Quinclorac applied to the terrestrial environment will be applied in future assesssments. In addition, granular applications will be assessed in future risk assessments.



*The vapor pressure of quinclorac, reported to be 1 x 10^{-7} mbar (0.76 x 10^{-7} mm Hg) at 20^{o} C, and Henry's Law Constant both indicate a low possibility of volatilization.

For direct application to the aquatic environment, the conceptual model of the fate/transport and effects of Quinclorac will be used from the May 17, 2007 Ecological Risk Assessment for Experimental Use Permit for Quinclorac for Aquatic Weed Control DP Barcode: D334717.

10. RISK HYPOTHESES

Used in accordance with proposed or existing labels quinclorac may:

- adversely affect growth, survival, or fecundity of birds and/or small mammals (and terrestrial amphibians and reptiles) ingesting the incidentally contaminated vegetation, seeds, fruits, or invertebrates associated with direct application to terrestrial plants, soil surface, drained impounded water bodies or the intentionally treated bait or seed stock,

- adversely affect growth, survival, and or reproduction of aquatic invertebrates, fish, amphibians in both freshwater and estuarine marine environments,

- adversely affect the emergence or growth of terrestrial plants receiving exposure either by drift from treated areas under conditions of ground or aerial spray.

11. ANALYSIS PLAN

The analysis plan is the final step in problem formulation. During this step measures of exposure and measures of effect are used to evaluate the risk hypotheses and are listed in **Tables 2 and 3** for a specific assessment endpoint. The RQ is obtained by dividing the measures of exposure for a particular assessment endpoint by the measures of effect for that endpoint.

11.1. Measures of Exposure

Measures of exposure for quinclorac that will be used in this assessment are obtained from modeling efforts only, since national-scale monitoring data were not identified. Exposure models used for this assessment include the suite of standard exposure models commonly used in pesticide risk assessments (EPA, 2004). Generally, aquatic exposure estimates are generated from EFED models and incorporate maximum proposed use rates and empirically-derived fate

properties. Aquatic exposure will be estimated using the Tier 1 GENEEC model and will consist of aquatic EECs derived using a water body that is vulnerable and representative of static ponds and first order waterways.

Measures of exposure for terrestrial mammals, birds, reptiles, and amphibians similarly incorporate maximum proposed use rates but rely less on fate properties. Instead, terrestrial exposure estimates are derived directly from empirically determined observations of pesticide residues on various terrestrial food items. For numerous applications for a given use, the exposure model incorporates a first-order decay rate dependent on the soil half-life of the chemical. In place of unavailable foliar dissipation data, the default foliar dissipation half-life of 35 days will be used. The currently used terrestrial exposure model is TREX v.1.3.1.

Exposure to terrestrial plants will be estimated using the TerrPlant model that assumes quinclorac drifts or moves with runoff to adjacent areas.

Listed Species Assessment

Based on preliminary EECs from terrestrial application scenarios and the assumptions discussed above, acute risks at the highest labeled application rate are expected for listed birds based on the non-definitive LD50 of >1900 mg/kg-bw (1.5 lbs a.i./A per season) Risks are expected as well for listed species of terrestrial plants (monocots and dicots) inhabiting semi-aquatic and dry areas based on exposures of quinclorac originating from the maximum application rate.

Based on preliminary EECs from direct application to a water body and the assumptions discussed above, acute risks at the highest labeled application rate are expected for listed birds, mammals, terrestrial plants (monocots and dicots) and aquatic non-vascular plants.

Because of the potential risk from direct effects to the listed and non-listed taxa described above, should exposure occur, listed species in all taxa may potentially be affected indirectly due to alterations in their habitat (*e.g.*, food sources, shelter, and areas to reproduce). An evaluation of risk conclusions based on direct and indirect effects for each taxonomic group will be summarized in the future assessment for all proposed labels.

If the planned ecological risk assessment continues to indicate that quinclorac may potentially impact, either directly or indirectly, listed species or critical habitat, and therefore does not support a “not likely to adversely affect” determination, further refinements will be made. This will involve determining whether use of quinclorac “may affect” a particular listed species, and if so, whether it is “likely to adversely affect” the species, or in the case of designated critical habitat, whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat, and if so, whether the expected impacts are “likely to adversely affect” the critical habitat. The first step in the process is to improve the exposure estimates

based on refining the geographic proximity of quinclorac use and the listed species and/or critical habitat. If there is no geographic proximity, this information would support a determination that quinclorac use will have no effect on the species or critical habitat. If after conducting the first step of this analysis the Agency determines that geographic proximity exists, both potential direct effects and any potential indirect effects of the pesticide use will be examined. This process is consistent with the Agency's Overview Document. The Agency will consult as necessary with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (collectively 'the Services'), consistent with the Services' regulations.

If the screening level risk assessment identifies potential concerns for indirect effects on listed species, the next step for EPA and the Services would be to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether quinclorac potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into, the taxa that may be directly or indirectly impacted by quinclorac. Then EPA would determine whether the use of quinclorac overlaps the critical habitat or the occupied range of those listed species.

11.2. Measures of Effect

EFFECTS ASSESSMENT

The Effects assessment for this risk assessment has been based on previous risk assessment data evaluations conducted in 1999. There has been no update of the toxicological review of the compound in the intervening years. These risk assessments DO NOT include a search and evaluation of the ECOTOX database.

Toxicity to Terrestrial Animals

Acute and Subacute Avian Toxicity

The results of available avian acute toxicity tests are listed in **Table 3**. The most sensitive species is the mallard duck (LD_{50} >1900 mg/kg, LD_{50} value expressed on a bodyweight-based dose), which serve as the toxicological endpoint in avian single oral dose exposure risk calculations.

Table 3 Avian Acute Oral Toxicity Data

Species	% Active Ingredient	LD_{50} (confidence limits)	MRID No.	Classification

		(mg/kg-bw)		
Northern bobwhite quail *Colinus virginianus*	98	>2000 (no mortality at 2000)	41063547	acceptable
Mallard duck *Anas platyrhynchos*	98	>1900 (no mortality at 970, 20% mortality and convulsions at 1900)	40320810	supplemental*

LD_{50}: Lethal dose to 50% of test population
NOAEL: No observed adverse effect level
* listed as supplemental due to questionable husbandry practices (e.g., the necks of ducks bound with bands to prevent regurgitation)

The results of available avian sub-acute dietary testing are summarized in **Table 4**. The LC_{50} of >5000 mg/kg-diet exhibited for both northern bobwhite quail and the mallard duck serve as the basis of the toxicological endpoint for sub-acute dietary exposure risk calculations.

Table 4 Avian Subacute Dietary Toxicity Data

Species	% Active Ingredient	LC_{50} (confidence limits) (mg/kg-diet)	MRID No.	Classification
Northern bobwhite quail *Colinus virginianus*	96	>5000 (no mortality to 2500)	40320812	acceptable
Mallard duck *Anas platyrhynchos*	96	>5000 (no mortality to 5000)	40320811	acceptable

LC_{50}: Lethal dietary concentration to 50% of test population
NOAEC: No observed adverse effect concentration

Chronic Avian Exposure Effects

The results of avian reproduction testing are listed in **Table 5**. The northern bobwhite reproduction NOAEL of 500 mg/kg-diet serves as the reproduction toxicity endpoint for avian reproduction risk calculations. This NOAEL is established with respect to the most sensitive toxicity endpoint observed for the study, reduced survival of 14-day old hatchlings from eggs set.

Table 5 Avian Reproduction Toxicity Data

Species	% Active Ingredient	LOAEC (mg/kg-diet)	NOAEC (mg/kg-diet)	MRID No.	Classification
Northern bobwhite quail *Colinus*	99.19	1000 (reduced 14 day	500	44129201	acceptable

virginianus		survivors of egg set)			
Mallard duck *Anas platyrhynchos*	99.19	>1000	1000	44084501	acceptable

LOAEC: Lowest observed adverse effect concentration
NOAEC: No observed adverse effect concentration

Acute and Chronic Mammalian Toxicity

Acute mammalian toxicity data are summarized in **Table 6**. The most sensitive acute endpoint is for the laboratory rat (Wistar strain), with a minimum LD_{50} of 2190 mg/kg bodyweight.

Table 6 Mammal Acute Toxicity Data

Species	% Active Ingredient	LD_{50} (mg/kg)	MRID No.	Classification
Rat (Wistar)	technical	male: 3060 female: 2190	41063506	acceptable
Mouse (B6C3F1)	technical	>2000	41063507	acceptable

LD_{50}: Lethal dose to 50% of test population
NOAEL: No observed adverse effect level

The following table summarizes the reproduction, and developmental toxicity data for laboratory mammals chronically exposed to quinclorac. For the purposes of this risk assessment, the rat 2-generation reproduction study NOAEL of 160 mg/kg-bw/day for reduced pup viability was selected as the threshold for mammals chronically exposed to quinclorac. This value is quite similar to the threshold for rabbit developmental data, in which the NOAEL for increased fetal resorptions was 200 mg/kg-bw/day.

Table 7 Mammal Chronic, Reproduction, and Developmental Toxicity Data

Species	% Active	Duration/ Study Type	LOAEL (mg/kg-diet) or (mg/kg-bw/day)	NOAEL (mg/kg-diet) or (mg/kg-bw/day)	MRID No.	Classification
Rat (Wistar)	96.5	3 month feeding	12000 mg/kg-diet slight nephritis	4000 mg/kg-diet	41063516	supplemental
Rat (Wistar)	96.5	Developmental		>438 mg/kg-bw/day	41063524	minimum
Rabbit	98.3	Developmental	600 mg/kg-bw/day increased fetal resorptions	200 mg/kg-bw/day	41063525	minimum

Rat (Wistar)	97.40-98.3	2 generation reproduction	480 mg/kg-bw/day reduced pup viability	160 mg/kg-bw/day	41063526 41910001	minimum

LOAEL: Lowest observed adverse effect level
NOAEL: No observed adverse effect level

Beneficial Insect Toxicity

The available studies of quinclorac effects on honeybees (**Table 8**) indicate that technical quinclorac and the 50% formulation are relatively non-toxic to bees on an acute contact basis

Table 8 Beneficial Insect Toxicity Data

Species	% Active Ingredient	LD_{50} (µg/bee)	NOAEL (µg/bee)	MRID No.	Classification
Honeybee *Apis mellifera*	98	>357	238	41063575	acceptable
Honeybee *Apis mellifera*	50	>181	<60.4 (lowest dose tested)	41063576	acceptable

LD_{50}: Lethal dose to 50% of test population
NOAEL: No observed adverse effect level

Terrestrial Plant Toxicity

Table 9 summarizes the available data for the effects of quinclorac on terrestrial plants. The toxicological threshold for seedling emergence used in the risk assessment is based on the carrot EC_{25} of 0.004 lb a.i./acre. The toxicological threshold for vegetative vigor used in the risk assessment is based on the tomato EC_{25} of 0.007 lb a.i./acre.

Table 9 Terrestrial Plant Toxicity Data

Species	% Active Ingredient	Test Type	EC_{25} (lb a.i./acre)	NOAEC (lb a.i./acre)	MRID No.	Classification for all
Soybean *Glycine max*	96	SE	0.047	<0.047	41403501	acceptable
	96	VV	0.203	0.125	41403503	
Lettuce *Lactuca sativa*	96	SE	0.013	<0.01	41403501	
	96	VV	0.01	<0.01	41403503	
Carrot *Daucus carota*	96	SE	0.004	<0.004	41403501	
	96	VV	0.027	0.02	41403503	

Species	% Active Ingredient	Test Type	EC_{25} (lb a.i./acre)	NOAEC (lb a.i./acre)	MRID No.	Classification for all
Tomato *Lycopersion esculentum*	96	SE	0.026	0.02	41403501	
	96	VV	0.007	0.005	41403503	
Cucumber *Cucumis sativus*	96	SE	0.012	<0.012	41403501	
	96	VV	0.028	0.012	41403503	
Cabbage *Brassica oleracea*	96	SE	0.162	0.125	41403501	
	96	VV	26.0	2.0	41403503	
Oat *Avena sativa*	96	SE	0.771	<0.77	41403501	
	96	VV	68.3	2.0	41403503	
Ryegrass *Lolium perenne*	96	SE	0.271	<0.27	41403501	
	96	VV	>2.0	2.0	41403503	
Corn *Zea mays*	96	SE	0.211	<0.211	41403501	
	96	VV	1.09	0.5	41403503	
Onion *Allium cepa*	96	SE	0.118	<0.118	41403501	
	96	VV	12.33	2.0	41403503	

SE: seedling emergence
VV: vegetative vigor
EC_{25}: Effective concentration for 25% reduction in emergence or growth measures
NOAEL: no observed adverse effect level

Toxicity to Aquatic Animals

Freshwater Fish Acute Toxicity

The results for available acute toxicity testing with freshwater fish (**Table 10**) indicate that quinclorac is slightly toxic to fish on an acute basis. The guideline requirement (72-1) is fulfilled. The bluegill sunfish LC_{50} of 31.6 mg/L is used as the acute freshwater toxicity endpoint for the risk assessment.

Table 10 Freshwater Fish Acute Toxicity Data

Species	% Active Ingredient	LC_{50} (confidence limit) (mg/L)	MRID No.	Classification
Bluegill sunfish *Lepomis macrochirus*	96	31.6 (26.7-39.6)	41063555	acceptable

Rainbow trout *Oncorhynchus mykiss*	96	>83.5 (no mortality at highest dose tested)	41063548	acceptable

LC_{50}: Lethal concentration to 50% of test population
NOAEC: No observed adverse effect concentration

Freshwater Fish Toxicity from Chronic Exposure

The following table summarizes the available freshwater fish toxicity data from chronic exposure.

Table 11 Freshwater Fish Chronic Toxicity Data (Early Life Stage Study)

Species	% Active Ingredient	LOAEC (mg/L)	NOAEC (mg/L)	MRID No.	Classification
Fathead minnow *Pimephales promelas*	technical	31 (larval growth)	16	44084502	acceptable

LOAEC: Lowest observed adverse effect concentration
NOAEC: No observed adverse effect concentration

Freshwater Invertebrate Acute Toxicity

Results of invertebrate toxicity testing are listed in **Table 12**. The results indicate that quinclorac is slightly toxic to aquatic invertebrates on an acute basis. The *Daphnia magna* EC_{50} of 29.8 mg/L serves as the freshwater invertebrate toxicity endpoint for risk assessment. A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to assess the toxicity of a pesticide to freshwater invertebrates. Results of invertebrate toxicity testing are listed in the table below. The results indicate that quinclorac is slightly toxic to aquatic invertebrates on an acute basis. The guideline requirement (72-2) is fulfilled. Quinclorac was conducted on a formulated product (quinclorac plus surfactant) instead of TGAI. Therefore, use of the available acute data as the toxicity endpoint for all freshwater systems represents an uncertainty.

Table 12 Freshwater Invertebrate Acute Toxicity Data

Species	% Active Ingredient	EC_{50} (confidence limit) (mg/L)	MRID No.	Classification
Daphnia magna	96	29.8 (23.8-42.4)	41063556	acceptable

EC_{50}: Effective concentration to 50% of test population
NOAEC: No observed adverse effect concentration

Freshwater Invertebrate Toxicity from Chronic Exposure

Data for freshwater invertebrate chronic toxicity are listed in **Table 13**. The guideline requirement (72-4) is fulfilled.

The *Daphnia magna* 21-day NOAEC of 110 mg/L is used as the freshwater invertebrate toxicity endpoint for chronic exposure. It should be noted that the 21-day NOAEC unexpectedly exceeds the 48-hour EC_{50} for the same species. This observation is likely the result of differences in test water conditions, or as the result of surfactant use in the acute toxicity test. As quinclorac is an acid subject to dissociation in water, differences in water hardness may influence the toxicity of the compound. The available data suggest that quinclorac is more toxic to freshwater invertebrates in soft water (48-hour LC_{50}= 28.9 mg/l in water 40-48 mg $CaCO_3$/L) compared to harder water (21-day NOAEC 110 mg/l in water >150 mg $CaCO_3$/L). An alternative explanation for the disparate toxicity results may be the presence of surfactant in the acute test, whereas no surfactant is evident for the chronic test. The use of the available 21-day chronic data as the toxicity endpoint for all freshwater systems represents an uncertainty.

Table 13 Freshwater Invertebrate Chronic Toxicity Data (21-day life cycle test)

Species	% Active Ingredient	LOAEC (mg/L)	NOAEC (mg/L)	MRID No.	Classification
Daphnia magna	technical	>110	110	44129202	acceptable

LOAEC: Lowest observed adverse effect concentration
NOAEC: No observed adverse effect concentration

Estuarine and Marine Animal Acute Toxicity

Table 14 summarizes the data available for quinclorac effects on estuarine and marine animals. For the purposes of this risk assessment, the sheepshead minnow LC_{50} of > 94.4 mg/L will be used as the acute toxicity threshold for estuarine/marine fish and the mysid EC50 of 69.4 will serve as the threshold for estuarine/marine invertebrates.

Table 14 Estuarine and Marine Animal Acute Toxicity Data

Species	% Active Ingredient	EC_{50}/LC_{50} (confidence limit) (mg/L)	MRID No.	Classification
Sheepshead minnow *Cyprinodon variegatus*	96	>94.4 (no mortality at highest dose)	41063549	core
Quahog clam *Mercenaria mercenaria*	96	>96.1 (26% reduction in number of normal larvae at highest dose)	41063552	core
Mysid *Mysidopsis bahia*	96	69.4 (50.4-118)	41063553	core
Blue crab	96	>94.4	41063551	supplemental*

Callinectes sapidus		(no mortality at highest dose)		

LC_{50}: Lethal concentration to 50% of test population
EC_{50}: Effective concentration to 50% of test population
NOAEC: No observed adverse effect concentration
*not listed acceptable test species

Estuarine and Marine Animal Toxicity from Chronic Exposure

No data are available for the toxicity of quinclorac to estuarine and marine animals following chronic exposures.

Aquatic Plant Toxicity

Table 15 summarizes the available aquatic plant toxicity data for quinclorac

Table 15 Aquatic Plant Toxicity Data

Species	% Active Ingredient	EC_{50} (mg/L)	NOAEC (mg/L)	MRID No.	Classification
Freshwater diatom *Navicula pelliculosa*	96	>0.5	0.5	41063574	acceptable
Green alga *Selenastrum capricornutum*	96	>0.5	0.5	41063574	
Marine diatom *Skeletonema costatum*	96	>0.5	0.5	41063574	
Duckweed *Lemna gibba*	96	>0.5	0.5	41063574	
Bluegreen alga *Anabaena flos-aquae*	96	>0.5	0.5	41063574	

EC_{50}: Effective concentration for 50% inhibition
NOAEC: No observed adverse effect concentration

11.3. Preliminary Identification of Data Gaps for Fate and Ecological Assessment

Table 16 identifies fate and ecological studies which are missing or are not acceptable, and may be requested to assess risk to the environment:

Table 16 Preliminary Identification of Data Gaps for Fate and Ecological Assessment

Fate and Ecological Taxa studies	Description of study	Projected status of data gap	Basis for decision
Chronic freshwater invertebrate	Chronic freshwater invertebrate NOAEC value was greater than the acute LD50 value for freshwater aquatic invertebrates	Study requested	A new study is requested due to uncertainties with the NOAEC value which is greater than the acute LD50 value for freshwater aquatic invertebrates. In addition, this study will be used to estimate chronic estuarine marine invertebrate toxicity
Acute freshwater invertebrate	Acute freshwater invertebrate study used a surfactant which it is uncertain that this surfactant effected the results of the toxicity test	Study requested	A new study is requested due to uncertainties with the LD_{50} value which is less than the chronic NOAEC value for freshwater aquatic invertebrates. In addition, this study was based on a formulated product (quinclorac and surfactant). This study will be used to estimate chronic estuarine marine invertebrate toxicity
Estuarine/marine fish	Chronic study for estuarine/marine fish was not submitted	Study not requested	Acute to chronic ratios will be sufficient to not request study
Estuarine/marine invertebrate	Chronic study for estuarine/marine invertebrate was not submitted	Study not requested	Acute to chronic ratios will be sufficient to not request study pending a chronic freshwater invertebrate daphnia magna study based on TGAI .

Data on the degradates (BH514-1 and BH 514 2-OH; >10% applied)) and one minor (BH514-HMe-ester; 8% applied) to determine risks to groundwater	The registrant claimed that studies performed later between 1989 and 1990 in FL, WI, and NY showed no movement of quinclorac degradates below surface levels	Studies requested	The degradates (BH514-1 and BH 514 2-OH; >10% applied)) and one minor (BH514-HMe-ester; 8% applied) studies have not yet been received nor reviewed by EFED. Until these studies which were performed 1989-1990 are submitted, reviewed, and deemed acceptable by the Agency, the above mentioned metabolites are considered potential contaminants of groundwater resources.
Foliar dissipation residue data	Foliar dissipation data studies or related data were not available	Study not requested	Acute and chronic mammal exceedences did not occur with LD50 and NOAEC values. Acute avian LOCs occurred with the non-definitive LD50 of >1900 mg/kg-bw. Fate studies indicate that half-lives may be greater than one year. Therefore,A default foliar dissipation rate of 35 days will be used in the modeling in place of the data if study is not submitted.
Small scale prospective groundwater contamination study	Small scale prospective groundwater contamination study for the quinclorac under the expected conditions of the currently registered crops.	Study requested	Based on the environmental persistence of quinclorac, its potential to enter groundwater as modeled by SCI-GROW and indicated in terrestrial field studies, the potential for groundwater impacts to non-target crops via contaminated groundwater a small scale prospective groundwater a contamination study for the compound under the expected conditions of use in wheat and sorghum is requested

.

12. OPEN LITERATURE

Previous assessments did not include open literature data as identified by ORD, MED ECOTOX literature search program.

13. NEW ASSESSMENT DECISION

EFED needs additional data (or will apply alternate effects assumptions) and would need to conduct new assessments for all registered outdoor uses. The new assessments are needed because of the following:

(a) Some uses and application type scenarios were not assessed for ecological risk or did not include current terrestrial or aquatic models.

(b) Open literature data, as identified by ORD, MED ECOTOX literature search program, were not included in previous assessments.

(dc) A new drinking water assessment needs to be completed based on a 14 day interval and aerial applications.

14. SUMMARY OF RISK

Summary of risks identified from previous assessments and anticipated risks for maximum use rate application scenarios.

Estimated LOC exceedences for are summarized in **Table 17** below. The risk conclusions are based on previously conducted risk assessments and anticipated exceedences for maximum use rates. The most recent comprehensive risk assessment was conducted on wheat and sorghum (1999). The most recent EUP was conducted on aquatic weed control in impounded waters (2007). The label maximum single application rates for quinclorac: (1) wheat and sorghum with a maximum seasonal rate of 0.75 lb ai /acre (2 applications @ 0.375lb ai/A, intervals were not included in terrestrial RQ calculations); (2) aquatic weed control with a maximum seasonal rate of 3.0 lb ai /acre. Acute dose based for avian exposure to quinclorac exceeded the LOCs with RQs ranging from 0.12- 0.83 for the both of the above application scenarios. Terrestrial plant RQs exceeded the LOCs for the wheat, sorghum and aquatic weed control application scenarios with RQs ranging 1 to 40.

Nonvascular and vascular plants exceeded the LOCs for the aquatic weed control scenario with RQs exceedences of 1.0. LOCs were exceeded for acute mammalian exposure with the maximum RQ of 0.14 for aquatic weed control scenarios. Chronic LOCs were exceeded for mammals and birds for the aquatic weed control scenario with a maximum RQs of 1.95 (mammals) and 1.4 (birds).

Anticipated LOCs are based on the maximum use and application rate for quinclorac for turf at 1.50 lb ai/A (2 applications@ 0.75 lb ai/A and 14 day intervals). Anticipated LOC exceedences from the above maximum use rate are for acute birds (RQs 0.16- 0.37) and acute terrestrial plants (RQs 2.33- 95.63) for monocots and dicots. The acute avian LOC exceedence was based on the non-definitive LD_{50} value of >1900 mg/kg-bw. It is necessary that these exceedences derived from the non-definitive LD_{50} value of >1900 will be characterized with additional data in future assessments. No chronic avian LOC exceedences occurred with higher application rates.

Aquatic EECs for the maximum application rates for labeled crops and additional GENEEC scenarios need to be determined. However, no acute or chronic exceedences are anticipated for aquatic fish or invertebrates. Uncertainty exists for chronic risks to estuarine marine invertebrates until further data is submitted. Chronic risks to estuarine marine fish will be estimated from acute to chronic ratios. LOC exceedences for aquatic plants based on direct application to impounded waters result in RQs of 1.0.

Table 17 LOC Exceedences from Use on Wheat, Sorghum, Turf and Aquatic weed control.

Use	Endpoint	Birds	Mammals	Terr. Plants	Insects	FW fish	SW Fish	FW Inverts	SW Inverts	Aquatic Plants
Turf 1.50 lb ai/A per season 2applications @0.75 per app, 14 day interval)	Acute	✓ based on non-definitive value		✓(listed and nonlisted)						
	Reproductive									
Wheat and sorghum 0.75lb ai/A per season[1]	Acute	✓ based on non-definitive value		✓(listed and nonlisted)						
	Reproductive									
Aquatic weed control 3 lbs a.i./season[1,2]	Acute	✓ based on non-definitive value	✓	✓(listed and nonlisted)						✓ (listed)
	Reproductive	✓	✓							

[1]All risk conclusions are based on previously conducted risk assessments Degradate toxicity was not included.

[2]This EUP was based on aquatic weed control applied at 3lbs ai/season to reach a water concentration of 0.5mg/L

✓ Risk is anticipated to be > any of the Agency's LOC

Blank cells indicate no LOC exceedences

Aquatic Organisms

Based on the (GENEEC) modeling, the 1999 risk assessment on turf showed no acute LOC exceedence for aquatic organisms. The highest modeled application rate scenario for the above crops was turf, which was based on 2 ground applications at a single rate of 0.375 lb ai/acre. The peak EEC is selected to represent exposures for acute effect risks. The 56-day and 21-day average EECs serve as the exposures for chronic effects to fish and invertebrates, respectively.

Tables 18 to 22 summarizes the quinclorac RQs, EECs ((peak), (21-day), (56-day)) and the toxicity data used in the 1999 assessment on turf with ground and aerial applications. No acute or chronic LOCs were exceeded for the exposure scenarios assessed. There are no

estuarine/marine organism toxicity data from chronic exposures available for use in calculating chronic risk quotients for these organisms. However, the similar acute sensitivities of these organisms to freshwater fish and invertebrates, coupled with the very low chronic risk quotients calculated for freshwater organisms; suggests that chronic risk concerns for estuarine and marine fish and invertebrates are likely to be minimal.

Table 18 Acute and Chronic Risk Quotients for Freshwater Fish

Product[1]/ Application Method	Peak EEC (µg/L)	LC_{50} (µg/L)	Acute RQ (Peak EEC/LC_{50})	56-day EEC (µg/L)	NOAEC (µg/L)	Chronic RQ (56-d EEC/NOAEC)
Paramount™/Aerial 90 and 14-day intervals	40.28	31,600	0.0013	40.17	16,000	0.0025
	40.28	31,600	0.0013	40.17	16,000	0.0025
Paramount™/ Ground Spray 90 and 14-day intervals	40.20	31,600	0.0013	40.10	16,000	0.0025
	40.20	31,600	0.0013	40.10	16,000	0.0025
Paramount™ BW/ Aerial 1 application	13.16	31,600	0.0004	13.11	16,000	0.0008
Paramount™ BW/ Ground Spray 1 application	13.13	31,600	0.0004	12.10	16,000	0.0008

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

Table 19 Acute and Chronic Risk Quotients for Freshwater Invertebrates

Product[1]/ Application Method	Peak EEC (µg/L)	LC_{50} (µg/L)	Acute RQ (Peak EEC/LC_{50})	21-day EEC (µg/L)	NOAEC (µg/L)	Chronic RQ (21-d EEC/NOAEC)
Paramount™/Aerial 90 and 14-day intevals	40.28	29,800	0.0014	40.23	110,000	0.0004
	40.28	29,800	0.0014	40.23	110,000	0.0004
Paramount™/ Ground Spray 90 and 14 day intervals	40.20	29,800	0.0013	40.16	110,000	0.0004
	40.20	29,800	0.0013	40.16	110,000	0.0004
Paramount™ BW/ Aerial	13.16	29,800	0.0004	13.14	110,000	0.0001

Paramount™ BW/ Ground Spray	13.13	29,800	0.0004	13.12	110,000	0.0001

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

Table 20 Acute and Chronic Risk Quotients for Estuarine/Marine Fish

Product[1]/ Application Method	Peak EEC (µg/L)	LC_{50} (µg/L)	Acute RQ (Peak EEC/LC_{50})	56-day EEC (µg/L)	NOAEC (µg/L)	Chronic RQ (56-d EEC/NOAEC)[2]
Paramount™/Aerial 90 and 14-day intervals	40.28	>94,400	<0.0004	40.17	no data	--
	40.28	>94,400	<0.0004	40.17	no data	--
Paramount™/ Ground Spray 90 and 14-day intervals	40.20	>94,400	<0.0004	40.10	no data	--
	40.20	>94,400	<0.0004	40.10	no data	--
Paramount™ BW/ Aerial	13.16	>94,400	<0.0001	13.11	no data	--
Paramount™ BW/ Ground Spray	13.13	>94,400	<0.0001	12.10	no data	--

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

[2] -- lack of toxicity data precludes calculation of quotient

Table 21 Acute and Chronic Risk Quotients for Estuarine/Marine Invertebrates

Product[1]/ Application Method	Peak EEC (µg/L)	LC_{50} (µg/L)	Acute RQ (Peak EEC/LC_{50})	21-day EEC (µg/L)	NOAEC (µg/L)	Chronic RQ (21-d EEC/NOAEC)[2]
Paramount™/Aerial 90 and 14-day intervals	40.28	69,400	0.0006	40.23	no data	--
	40.28	69,400	0.0006	40.23	no data	--
Paramount™/ Ground Spray 90 and 14-day intervals	40.20	69,400	0.0006	40.16	no data	--
	40.20	69,400	0.0006	40.16	no data	--
Paramount™ BW/ Aerial	13.16	69,400	0.0002	13.14	no data	--
Paramount™ BW/ Ground Spray	13.13	69,400	0.0002	13.12	no data	--

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

[2] -- lack of toxicity data precludes calculation of quotient

Table 22 Aquatic Plant Risk Quotients

Product[1]/ Application Method	Peak EEC (µg/L)	Alga EC_{50} (µg/L)	*Lemna gibba* EC_{50} (µg/L)	*Lemna gibba* NOAEC (µg/L)	Algal RQ[2]	Acute Aquatic Vascular Plant RQ[3]	Endangered Aquatic Plant RQ[4]
Paramount™/Aerial 90 and 14-day intervals	40.28	>500	>500	500	<0.081	<0.081	0.0806
	40.28	>500	>500	500	<0.081	<0.081	0.0806
Paramount™/ Ground Spray 90 and 14-day intervals	40.20	>500	>500	500	<0.080	<0.080	0.0804
	40.20	>500	>500	500	<0.080	<0.080	0.0804
Paramount™ BW/ Aerial	13.16	>500	>500	500	<0.026	<0.026	0.0263
Paramount™ BW/ Ground Spray	13.13	>500	>500	500	<0.026	<0.026	0.0263

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.
[2] EEC/alga EC_{50}
[3] EEC/*Lemna gibba* EC_{50}
[4] EEC/*Lemna gibba* NOAEC

Terrestrial Organisms
Risk Assessment for Nontarget Terrestrial Animals

Avian Acute and Chronic Risks

The acute and chronic risk quotients for broadcast applications of quinclorac formulations are listed in **Tables 23 and 24** based on the 1999 risk assessment for a single seasonal application rate of 0.25 lb ai/A and 0.75 lb ai/A . No levels of concern (LOCs) are exceeded under the exposure scenarios assessed.

Table 23 Avian Acute Risk Quotients for Single Application of Quinclorac Products (Aerial and Ground Spray) Based on a Northern Bobwhite Quail LC50 of >5000 mg/kg-diet

Product[1]	Application Rate (lbs ai/A)	Food Items	Maximum EEC (mg/kg-diet)	LC_{50} (mg/kg-diet)	Acute RQ (EEC/LC_{50})
Paramount™	0.75 per season	Short grass	180	>5000	<0.036
		Tall grass	82.5	>5000	<0.017
		Broadleaf plants/Insects	101.3	>5000	<0.020
		Seeds	11.3	>5000	<0.002
Paramount™DW	0.25 per season	Short grass	60.0	>5000	<0.012
		Tall grass	27.5	>5000	<0.006
		Broadleaf plants/Insects	33.8	>5000	<0.007
		Seeds	3.8	>5000	<0.001

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

Table 24 Avian Chronic Risk Quotients for Single Application of Quinclorac Products (Aerial and Ground Spray Based on a Northern Bobwhite Quail NOAEC of 500 mg/kg-diet)

Product[1]	Application Rate (lbs ai/A)	Food Items	Maximum EEC (mg/kg-diet)	NOAEC (mg/kg-diet)	Chronic RQ (EEC/NOAEC)
Paramount™	0.75 per season	Short grass	180	500	0.36
		Tall grass	82.5	500	0.17
		Broadleaf plants/Insects	101.3	500	0.20
		Seeds	11.3	500	0.02
Paramount™BW	0.25 per season	Short grass	60.0	500	0.12
		Tall grass	27.5	500	0.06
		Broadleaf plants/Insects	33.8	500	0.07
		Seeds	3.8	500	0.01

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

Mammalian Acute and Chronic Risks

Mammalian acute risk quotients were calculated using the daily oral dose estimates for a 15 g mammal consuming 95% of its bodyweight as diet and the LD50 for laboratory rats. The results of these calculations are expressed in terms of LD_{50}s per day. **Table 25** summarizes the results of these risk quotient calculations. None of the acute risk quotient results exceed EFED levels of concern.

Mammalian chronic risk quotients were calculated using the daily oral estimates for the same 15 g mammal and the daily oral dose corresponding to the NOAEL for reproduction effects in laboratory rats. **Table 26** summarizes the results of these risk quotients calculations based on the 1999 assessment. In all cases, except for consumption of short grass (RQ = 1.07), the EFED level of concern was not exceeded.

Table 25 Mammalian Acute Risk Quotients for Application of Quinclorac Products (Aerial and Ground Spray Based on a Laboratory Rat LD50 of 2190 mg/kg-bw

Product[1]	Application Rate (lbs ai/A)	Food Items	Daily Oral Dose (mg/kg-bw/day)	LD_{50} (mg/kg-bw)	Acute RQ (LD50/day or Dose/LD_{50})
Paramount™	0.75 per season	Short grass	171.6	2190	0.08
		Tall grass	78.7	2190	0.04
		Broadleaf plants/Insects	96.5	2190	0.04
		Seeds	10.7	2190	0.005
Paramount™DW	0.25 per season	Short grass	57.2	2190	0.03
		Tall grass	26.2	2190	0.01
		Broadleaf plants/Insects	32.2	2190	0.01
		Seeds	3.6	2190	0.002

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

Table 26 Mammalian Chronic (Reproduction) Risk Quotients for Application of Quinclorac Products (Aerial and Ground Spray Based on a Laboratory Rat NOAEL of 160 mg/kg-bw/day

Product[1]	Application Rate (lbs ai/A)	Food Items	Daily Oral Dose (mg/kg-bw/day)	NOAEL (mg/kg-bw/day)	RQ (Dose/NOAEL)
Paramount™	0.75 per season	Short grass	171.6	160	1.07
		Tall grass	78.7	160	0.49
		Broadleaf plants/Insects	96.5	160	0.60
		Seeds	10.7	160	0.067
Paramount™BW	0.25 per season	Short grass	57.2	160	0.36
		Tall grass	26.2	160	0.16
		Broadleaf plants/Insects	32.2	160	0.20
		Seeds	3.6	160	0.023

[1] Risks for Paramount™BW are for the quinclorac component alone, no assessment has been performed for the 2,4-D component of this product.

Risks to Beneficial Insects

Currently, EFED has no procedure for assessing risk to nontarget insects. However, the results of acceptable toxicity studies are used for recommending appropriate label precautions. The relatively non-toxic nature of quinclorac with respect to honeybees suggests no concern that quinclorac will directly impact beneficial insects.

15. RESIDUES OF QUINCLORAC IN WATER AND THE TERRESTRIAL ENVIRONMENT

DRINKING WATER RESIDUE PROFILE

The Agency does not have monitoring data available to perform a quantitative drinking water risk assessment for quinclorac at this time

A Tier II screening-level drinking water assessment for quinclorac (3,7-dichloro-8-quinolinecarboxylic acid , BAS 514-H was provided in support of the new proposed uses of this herbicide to control broadleaf and grass weeds on residential/commercial turf grasses and on other turf grasses (picnic grounds, athletic field, and sod farms) (see September 13, 2007,

EFED believes that quinclorac has the potential for movement into ground water. Furthermore, since quinclorac is not tightly bound to soils, it could be available to run off in surface water as well as by erosion to surface waters. **Tables 27** and **28** list the EDWCs of quinclorac residues in surface and ground water, respectively, as reported in the aforementioned drinking water assessment. These concentrations are based on the current environmental fate data for quinclorac, the maximum use rate from registered and proposed uses (Drive 75DF Herbicide label turf use, 2 to 3 applications of 0.25 – 0.75 lb ai/A/ appl at 21-day interval, not to exceed 1.5 lb ai/A per year) and EFED aquatic models (PRZM/EXAMS for surface water and SCI-GROW for ground water.

Quinclorac major degradation products such as BH 514-1 and BH 514 2-OH were not considered in this assessment. Although these degradates were detected in the laboratory studies, they seem to be intermediate degradates (see Environmental Fate section), and were not found in the terrestrial field dissipation studies at any significant levels (>10% of total applied). Furthermore, since quinclorac is persistent and mobile, it is expected to be the predominant residue in ground and surface waters.

Table 27 – Surface Water DWECs for Quinclorac use on Turfgrasses, ground application

Scenario	Surface Water EWDCs (µg/L)					
	1 in 10 year annual peak (acute)		1 in 10 year annual mean (chronic)		30 year annual mean (cancer)	
PCA / CAF	1.00*	0.82**	1.00	0.82	1.00	0.82
0.5 lb ai/A, 3 appl, 21 days apart						
PA Turf – pre emergence	17.5	14.3	12.3	10.1	8.7	7.1
PA Turf – post emergence	21.2	17.4	**14.5**	**11.9**	**10.3**	**8.4**
FL Turf – pre-emergence	17.9	14.7	10.7	8.8	6.3	5.2
FL Turf – post emergence	**22.9**	**18.8**	12.7	10.4	7.1	5.8
0.75 lb ai/A, 2 appl, 21 days apart						
PA Turf – post emergence	22.5	18.5	14.2	11.6	9.9	8.1
FL Turf – post emergence	21.4	17.5	11.6	9.5	6.9	5.7

*Results with PCA of 1 can be used for other turf use, such as picnic grounds, athletic fields, sod farms, …

**Results adjusted with CAF of 0.82 represents the maximum percent treated on turf, residential and commercial use. This assumes four houses of 2000ft^2 each per acre and does not take into account driveway, sidewalk, or porches, …

Note that the EDWCs were estimated for both pre and post emergence uses for the 0.5 lb ai/A applications. The differences between the two sets of data result from the method of application (soil applied vs. foliar applied) and the application dates. Only post emergence uses are allowed for the 0.75 lb ai/A applications.

Table 28 - Ground Water EDWCs for Quinclorac use on Turfgrasses (3 applications of 0.5 lb ai/A/application)

Ground Water EDWCs (µg/L) (3 appl of 0.5 lb ai/A/appl)	29.0
Ground Water EDWCs (µg/L) (2 appl of 0.75 lb ai/A/appl)	28.9

The groundwater concentrations generated by SCI-GROW are based on the largest 90-day average recorded during the sampling period. Since there is relatively little temporal variation in groundwater concentrations compared to surface water, the concentration of **29µg/L** can be considered as both the acute and chronic values.

Although current uses also include aerial applications with an assumed shorter re-application interval (14 days) on certain crops (sorghum, wheat, non agricultural rights of way/ fence row/ hedgerows, agricultural fallowland/idleland, grasses grown for seed), it is not expected that the EDWCs from these crops will exceed those reported from turf use as listed in above **Tables 28 and 29.** Granular applications do not need to be incorporated in the drinking water assessment because the application rates are less than ground and aerial spray applications.

Chemical structures for quinclorac are summarized in **Table 29**.

Table 29 Chemical name and structure of quinclorac and its degradates BH514-1 and BH5142-OH

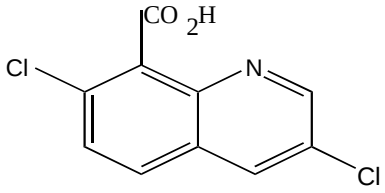
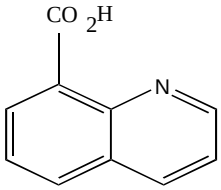
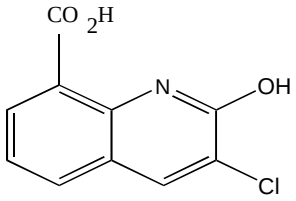
Common Name	Chemical Structure
Quinclorac	
BH514-1	
BH5142-OH	

Table 30 list all the current registrations and EUPs based on BEAD information 2007.

Table 30 Current Registrations and EUPs for Quinclorac based on BEAD information (2007)

Registration #	Name	Status	Company Name	Percent Active Ingredient
228-423	DQD SELECTIVE HERBICIDE	Conditionally Registered (06-Apr-2005)	NUFARM AMERICAS INC.	7.91
228-531	NUP 12D02 HERBICIDE	Conditionally Registered (24-Aug-2007)	NUFARM AMERICAS INC.	8.25
239-2689	LAWN CRABGRASS AND WEED KILLER	Conditionally Registered (03-Sep-2004)	THE ORTHO BUSINESS GROUP	0.1
538-296	TURF BUILDER WITH WEED CONTROL III	Conditionally Registered (09-Dec-2002)	SCOTTS COMPANY, THE	0.52
1381-209	QUINCLORAC 75 DF	Registered (11-Oct-2006)	WINFIELD SOLUTIONS, LLC	75
2217-885	EH-1426 HERBICIDE	Conditionally Registered (18-Jan-2006)	PBI/GORDON CORP	3.49
2217-886	EH-1427 HERBICIDE	Conditionally Registered (18-Jan-2006)	PBI/GORDON CORP	5.69
2217-887	EH-1428 HERBICIDE	Conditionally Registered (18-Jan-2006)	PBI/GORDON CORP	0.121
2217-888	EH-1425 HERBICIDE	Conditionally Registered (18-Jan-2006)	PBI/GORDON CORP	8.38
2217-894	EH-1432 HERBICIDE	Conditionally Registered (21-Apr-2006)	PBI/GORDON CORP	1.61
2217-896	EH-1437 HERBICIDE	Conditionally Registered (25-Aug-2006)	PBI/GORDON CORP	2.13
2217-901	EH-1434 HERBICIDE	Conditionally Registered (30-Jan-2007)	PBI/GORDON CORP	5.65
2217-906	EH-1449 HERBICIDE	Conditionally Registered (27-Aug-2007)	PBI/GORDON CORP	0.104

7969-93	FACET 50 WP	Conditionally Registered (13-Oct-1992)	BASF CORPORATION	50
7969-109	QUINCLORAC MANUFACTURING USE PRODUCT	Conditionally Registered (28-Oct-1992)	BASF CORPORATION	98
7969-113	FACET 75 DF HERBICIDE	Registered (09-Nov-1994)	BASF CORPORATION	75
7969-130	DRIVE 75 DF HERBICIDE	Conditionally Registered (09-Nov-1998)	BASF CORPORATION	75
7969-152	PARAMOUNT BW HERBICIDE	Conditionally Registered (04-Jun-1999)	BASF CORPORATION	15
7969-158	FACET GR HERBICIDE 46	Conditionally Registered (27-Apr-1998)	BASF CORPORATION	1.5
7969-172	DRIVE 75 MANUFACTURERS CONCENTRATE	Conditionally Registered (10-Dec-1998)	BASF CORPORATION	75
7969-222	CLEARPATH HERBICIDE	Registered (12-Jul-2004)	BASF CORPORATION	61.98
34704-920	QUINCLORAC 75DF HERBICIDE	Conditionally Registered (03-Mar-2006)	LOVELAND PRODUCTS, INC.	75
42750-85	QUINCLORAC TECHNICAL	Conditionally Registered (10-Oct-2005)	ALBAUGH INC	99
42750-88	QUINCLORAC 75DF AG	Conditionally Registered (10-Oct-2005)	ALBAUGH INC	75
42750-90	QUINCLORAC 75DF SP	Conditionally Registered (10-Oct-2005)	ALBAUGH INC	75
42750-131	QUINCLORAC 75 SWF	Conditionally Registered (06-Feb-2006)	ALBAUGH INC	75
71085-26	RICEPRO	Registered (13-Mar-2007)	RICECO LLC	2
73220-15	QUALI-PRO QUINCLORAC 75	Registered (02-Oct-2007)	FARMSAVER.COM, LLC	75
79676-22	QUINCLORAC G-PRO 75 DF	Conditionally Registered (14-Dec-2005)	GRO-PRO, LLC	75

81927-21	ALLIGARE QUINCLORAC 75 WDG	Registered (18-Oct-2007)	ALLIGARE, LLC	75
AR070006	RICEPRO	Under Review (07-May-2007)	RICECO LLC	2
UT990003	FACET 75 DF HERBICIDE	Registered (20-Sep-1999)	BASF CORPORATION	75
7969-EUP-25		Issued (20-Mar-1991)	BASF CORPORATION	100
7969-EUP-27		Issued (14-Jan-1991)	BASF CORPORATION	50
7969-EUP-29		Issued (22-May-1991)	BASF CORPORATION	50
7969-EUP-40		Issued (23-May-2007)	BASF CORPORATION	75
98ND20		Issued (19-Sep-1998)	ND Dept. of Agriculture	
98NE07		Issued (25-Jun-1998)	NE Department of Agriculture	

V. Human Health Effects Scoping Document

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Date: September 26, 2007

SUBJECT: Quinclorac (PC code 128974). Human Health Risk Problem Formulation Document in Support of Registration Review. DP Barcode 344486.

FROM: Yan Donovan, Risk Assessor
Health Effects Division (7509P)
Office of Pesticide Programs

THRU: Ray Kent, Branch Chief
Susan Hummel, Senor Scientist
Reregistration Action Branch 4
Health Effects Division (7509P)
Office of Pesticide Programs

TO: Sherrie Kinard
Chemical Review Manager
Special Review and Reregistration Division (7508P)
Office of Pesticide Programs

Executive Summary

Attached is Health Effects Division's (HED) human health risk assessment status update for quinclorac as part of the Registration Review process. Quinclorac is a systemic herbicide currently registered for use on rice, sorghum, and wheat. It is also registered for use on residential lawns, ornamentals, and turf grass. The most recent comprehensive risk assessment for quinclorac was conducted in association with the establishment of import tolerance on barley (September, 2007). The toxic effects being regulated are developmental effects such as increased resorptions and post-implantation loss, decreased number of live fetuses, and reduced fetal body weight. Chronic effects include decreased body weights. Based on the 2005 Guidelines for Carcinogen Risk Assessment, quinclorac was tentatively classified as "Not likely

to be carcinogenic to humans" since only benign tumors were seen in only one sex and in one species. Aggregate risk assessments included dietary exposure (food + water) and residential post-application exposure from use on grass. Risk estimates were based on conservative, health-protective assumptions and the resulting aggregate risk estimates are not of concern. Neither residential handler nor occupational risks were assessed.

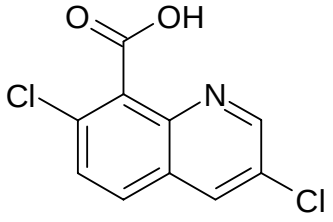
HED's problem formulation conclusions are: 1) The toxicology endpoint selections are adequate. However, the toxicology database for quinclorac is incomplete at this time. A 90-day inhalation toxicity study in the rat is required to assess inhalation exposure from spray uses. 2) The dietary exposure database is complete. However, the newly submitted aspirated grain fraction (AGF) studies on wheat and sorghum have not been reviewed. A full review of these AGF studies is needed. AGF and livestock tolerances may need to be revised based on the review of the AGF studies. The drinking water assessment is adequate. The dietary exposure assessment (included food and water) is adequate. 3) The residential post application exposure assessment is adequate. However, no residential handler risks were assessed; therefore, a new residential handler assessment is needed for the Registration Review of quinclorac. 4) Aggregate risk assessment is adequate. 5) No occupational risk assessments have been conducted before. A new occupational assessment is required for Registration Review.

Introduction

HED has evaluated the existing human health risk assessments for quinclorac to determine whether sufficient data are available and whether a new human health risk assessment is needed to support Registration Review. HED has considered the most recent risk assessments for quinclorac (HED memo of 9/13/2007, M. Doherty, D325790, and HED memo of 12/15/98, M. Nelson, D238399), updates to its toxicity, exposure and usage databases, information available through HED and OPPIN database, literature search, and current Agency science policies and risk assessment methods. Quinclorac is a persistent and mobile, systemic herbicide currently registered for use on weed control in rice, sorghum, and wheat. It is also registered for use on residential lawns, ornamentals, and turf grass. The mechanism of action of herbicidal effects is not completely understood. Permanent tolerances are currently established for parent quinclorac *per se* in/on rice, sorghum, wheat, and livestock commodities [40 CFR 180.463]. Some quinclorac products also contain other active ingredients such as 2,4-dichlorophenoxyacetic acid [2,4-D]. The problem formulation conducted in this review is for quinclorac only.

Chemical Identity

Table 1. Quinclorac Nomenclature

Chemical structure	
Common name	Quinclorac
Empirical formula	$C_{10}H_5Cl_2NO_2$
Molecular weight	242.1
PC Code	128974
IUPAC name	3,7-dichloroquinoline-8-carboxylic acid
CAS name	3,7-dichloro-8-quinolinecarboxylic acid
CAS registry number	84087-01-4

Hazard Identification/Toxicology

Quinclorac (technical grade material) has a low order of acute toxicity as demonstrated by classification into Toxicity Category III by the oral, dermal, and inhalation routes. The chemical is a mild eye irritant, is not a skin irritant, but was positive for dermal sensitization. Subchronic toxicity includes decreased body weight gains, increased water intake, increased liver enzymes and focal chronic interstitial nephritis. Chronic toxic effects include body weight decrement, increase in kidney and liver weights, and hydropic degeneration of the kidneys. At high doses, chronic toxicity also includes increased incidences of pancreatic acinar cell hyperplasia and adenomas. Developmental toxicities include increased resorptions, post-implantation loss, decreased number of live fetuses, and reduced fetal body weight. These effects occurred at much

higher dose than the maternal effects which demonstrated by increased mortality, decrease in food consumption and increase in water consumption, decreased body weight gain, clinical signs of reduced defecation, diarrhea, apathy, and poor general state. Because there is no evidence of neurotoxic effects, no acute, subchronic, or developmental neurotoxicity studies are required. Evaluated under the 2005 Guidelines for Carcinogen Risk Assessment, quinclorac was tentatively classified as "Not likely to be carcinogenic to humans" since only benign tumors were seen in only one sex and in one species. The chronic RfD would adequately account for all chronic effects, including the observed adenomas, likely to result from exposure to quinclorac. The acute dietary endpoint was based on developmental toxicity, while the chronic dietary endpoint was based on decreased body weight in the 18-month carcinogenicity study. No data were available on the inhalation toxicity of quinclorac. Inhalation endpoint was based maternal toxicity from the rabbit developmental study and assuming inhalation absorption of 100%.

The FQPA Safety Factor was reduced from 10X to 1X for infants and children based upon the fact that the toxicology database for quinclorac is complete and there is no indication of increased susceptibility of rat or rabbit fetuses to in utero and/or postnatal exposure in the developmental and reproductive toxicity data. A summary of the toxicological endpoint decisions from the most recent human health risk assessment of quinclorac is given in Appendix A.

Conclusions: The HED Registration Review problem formulation team has re-evaluated the above toxicity endpoints and dose response according to the current policies. HED concluded that the endpoint selections in the most recent risk assessment **are adequate**. A 28-day subchronic inhalation study is recommended.

Dietary Exposures

The residue of concern in food and water was determined to be quinclorac *per se*. The estimated drinking water concentration (EDWC) from groundwater (29 µg/L) was used in the dietary assessment as these are greater than the surface water values. Since there is relatively little temporal variation in groundwater concentrations compared to surface water, the concentration (29 ug/L) was used for both acute and chronic exposure assessment. Acute and chronic aggregate dietary (food + drinking water) exposure were conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which use food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. Both the acute and chronic dietary assessment are based on tolerance-level residues for all agricultural commodities, assume 100% crop treated, use DEEM 7.81 default processing factors, and directly incorporate modeled quinclorac EDWCs.

The acute assessment provides a risk estimate of < 1% of the acute population-adjusted dose (aPAD) at the 95th percentile of exposure for females 13-49 years of age. Risk estimates for the chronic assessment vary by population group and range from < 1% of the chronic PAD (cPAD) to 2% of the cPAD.

Conclusions: The residue chemistry database is complete with the newly submitted AGF studies. These new studies have not been reviewed. A review of these studies is needed. Existing AGF tolerance was previously determined by applying the maximum theoretical concentration factor (200X) to the proposed tolerance (6 ppm) on grain sorghum grain which is

1200 ppm. The new AGF tolerance will likely be a lot lower based on the new AGF studies and as a result, the animal dietary burden will likely be lower, hence the residues in meat and meat byproducts will likely be lower as well. Revisions to the existing AGF and livestock tolerances may be needed. The drinking water assessment is adequate. The dietary exposure assessment is also adequate. No new dietary assessment is needed.

Residential Exposure

Based on the registered use pattern, there are residential handler and residential post application exposure scenarios. Post-application incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposures were evaluated using the maximum application rates (0.0172 lb ai per 1000 sq ft). The combined MOE (5,000) is greater than 100 and, therefore, is not of concern to HED.

Conclusions: The post-application exposure assessments are adequate. However, no residential handler assessment was conducted. A new residential handler assessment is needed for the Registration Review of quinclorac.

Aggregate

Aggregate risk assessments were conducted for acute, chronic, and short-term. There is no risk for concern.

Conclusions: HED problem formulation team concluded that the most recent aggregate risk assessment is adequate. No new aggregate risk assessment is needed for the Registration Review of quinclorac.

Occupational Exposure

There are occupational exposure scenarios based on the use patterns. However, no occupational risk assessments have been conducted before. A new occupational assessment is required for the Registration Review once the inhalation endpoint is selected.

Incident Report

No incident report has been generated for quinclorac. A new incident report is needed with the Registration Review.

Cumulative

Quinclorac has not been identified as a member of common mechanism group; therefore, accumulative assessment has not been conducted for quinclorac.

Human Studies

No human studies were used in either hazard or exposure assessment.

Codex MRLs

No Codex or Mexico MRLs are reported. The U.S. tolerances on livestock fat and meat byproducts are not harmonized with Canada MRLs (see Appendix B for details). Future work is needed to harmonize these tolerances.

Conclusions/Future Actions Needed

Below are the detailed actions needed in the future Registration Review for quinclorac:

Exposure

The 1998 risk assessment indicated the need for data on aspirated grain fractions as a data gap in the residue chemistry database, and submission of such data should be made a **condition of registration**. Since then, residue data on wheat and sorghum aspirated grain fractions have been submitted but not been reviewed. They are:

45598703 Haughey, D.; Abdel-Baky, S.; Daussin, S. (2000) Magnitude of BAS 514 H Residues in Wheat Aspirated Grain Fraction: Lab Project Number: 2000/5187: 59553. Unpublished study prepared by BASF Corp. 61 p. {OPPTS 860.1500}.

45598704 Haughey, D.; Daussin, S. (2000) Magnitude of BAS 514 H Residues in Sorghum Aspirated Grain Fraction: Lab Project Number: 59552: 2000/5186. Unpublished study prepared by BASF Corp. 61 p. {OPPTS 860.1500}.

Tolerances on AGF and livestock commodities may need to be revised based on the review of the above studies.

A residential handler assessment is needed.

Occupational Exposure and Risk

A new occupational assessment is needed.

Incident Report

A new incident report is needed.

Data Requirements

A 28-day subchronic inhalation study is recommended.

References

1) HED memo of 9/13/07, M. Doherty, D325790;
2) HED memo of 12/15/98, M. Nelson, D238399;
3) Bibliography for Quinclorac (OPPIN database).

Appendix A

Summary of Toxicological Doses and Endpoints from the Most Recent Risk Assessment.				
Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (General Population, including Infants and Children)	Not applicable. An endpoint for acute dietary exposure to the general population was not selected because there was no available endpoint that was appropriate for this scenario (effects observed in the available studies are presumed to require more than one exposure).			
Acute Dietary (Females 13-49 years of age)	NOAEL (developmental) = 200 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Acute NOAEL = 200 mg/kg/day aPAD = 2.0 mg/kg/day	Developmental toxicity study in rabbits Developmental toxicity LOAEL = 600 mg/kg/day based on increased early resorptions and postimplantation loss, decreased live fetuses, decreased fetal weight. These fetal effects are presumed to occur after a single dose.
Chronic Dietary (All Populations)	NOAEL= 37.5 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Chronic NOAEL = 37.5 mg/kg/day cPAD = 0.38 mg/kg/day	Dietary carcinogenicity study in mice LOAEL = 150 mg/kg/day based on decreased body weight.
Incidental Oral Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL= 70 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Residential LOC for MOE = 100	Developmental toxicity study in rabbits. Maternal toxicity LOAEL = 200 mg/kg/day based on decreased maternal body weight gain and food consumption (and increased water consumption).
Dermal (all durations)	Not applicable. A dermal endpoint was not selected because an appropriate endpoint was not available (no dermal toxicity at limit dose of 1000 mg/kg/day in a 21-day dermal toxicity study).			
Inhalation Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL= 70 mg/kg/day [Inhalation absorption rate = 100% relative to oral absorption]	UF_A= 10x UF_H= 10x FQPA SF= 1x	Residential LOC for MOE = 100	Developmental toxicity study in rabbits. Maternal toxicity LOAEL = 200 mg/kg/day based on decreased maternal body weight gain and food consumption (and increased water consumption). (Supported by subchronic and chronic dietary data on mice).
Inhalation Long-Term (>6 months)	Not applicable. Long-term inhalation exposure is not anticipated under current use scenarios.			

Summary of Toxicological Doses and Endpoints from the Most Recent Risk Assessment.				
Exposure/ Scenario	Point of Departure	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	Available carcinogenicity studies indicate that there was equivocal evidence of an increase in the incidence of pancreatic acinar cell adenomas in the male rat, but no treatment-associated increases in tumors were observed in female rats or in mice. A quantification of cancer risk is not warranted because the chronic RfD of 0.4 mg/kg/day is approximately 1200-fold lower than the dose (487 mg/kg/day) that induced the benign pancreatic tumors. Thus, the chronic RfD will adequately account for all chronic effects, including the observed adenomas, likely to result from exposure to quinclorac. If quinclorac is evaluated under the current 2005 Guidelines for Carcinogen Risk Assessment, quinclorac will be classified as "Not Likely to be Carcinogenic to Humans" since only benign tumors were seen in only one sex and in one species.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key date (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

Appendix B

Quinclorac

US		Canada	Mexico	Codex
Residue Definition:				
Quinclorac (3,7-dichloro-8-quinoline carboxylic acid) 40CFR180.463		3,7-dichloroquinolin-8-carboxylic acid	none	none
Commodity Tolerance (ppm) /Maximum Residue Limit (mg/kg)				
Cattle, fat	0.7	0.05		
Cattle, meat byproducts	1.5	0.05		
Cattle, meat	0.05	0.05		
Egg	0.05	0.05		
Goat, fat	0.7	0.05		
Goat, meat byproducts	1.5	0.05		
Goat, meat	0.05	0.05		
Grain, aspirated fractions	1200	-		
Hog, fat	0.7	0.05		
Hog, meat byproducts	1.5	0.05		
Hog, meat	0.05	0.05		
Horse, fat	0.7	0.05		
Horse, meat byproducts	1.5	0.05		
Horse, meat	0.05	0.05		
Milk	0.05	0.05		
Poultry, fat	0.05	0.05		
Poultry, meat byproducts	0.1	0.05		
Poultry, meat	0.05	0.05		
Rice, bran	15.0	-		
Rice, grain	5.0	5		
Rice, straw	12.0	-		
Sheep, fat	0.7	0.05		
Sheep, meat byproducts	1.5	0.05		
Sheep, meat	0.05	0.05		
Sorghum, grain, forage	3.0	-		
Sorghum, grain, grain	6.0	-		
Sorghum, grain, stover	1.0	-		
Wheat, forage	1.0	-		
Wheat, germ	0.75	-		
Wheat, grain	0.5	0.5		
Wheat, hay	0.5	-		
Wheat , straw	0.1	-		
Barley	2.0	2.0		