

**Risks of Oryzalin Use to the  
Federally Threatened and Endangered  
California Tiger Salamander  
(*Ambystoma californiense*)**

**Pesticide Effects Determination**

**Environmental Fate and Effects Division  
Office of Pesticide Programs  
Washington, D.C. 20460**

**September 30, 2010**

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### List of Commonly Used Abbreviations and Nomenclature

µg/kg	Symbol for “micrograms per kilogram”
µg/L	Symbol for “micrograms per liter”
°C	Symbol for “degrees Celsius”
AAPCO	Association of American Pesticide Control Officials
a.i.	Active Ingredient
AIMS	Avian Monitoring Information System
Acc#	Accession Number
amu	Atomic Mass Unit
BCB	Bay Checkerspot Butterfly
BCF	Bioconcentration Factor
BEAD	Biological and Economic Analysis Division
bw	Body Weight
CAM	Chemical Application Method
CARB	California Air Resources Board
CAW	California Alameda Whipsnake
CBD	Center for Biological Diversity
CCR	California Clapper Rail
CDPR	California Department of Pesticide Regulation
CDPR-PUR	California Department of Pesticide Regulation Pesticide Use Reporting Database
CFWS	California Freshwater Shrimp
CI	Confidence Interval
CL	Confidence Limit
CTS	California Tiger Salamander
DPS	Distinct Population Segment
DS	Delta Smelt
EC	Emulsifiable Concentrate
EC <sub>05</sub>	5% Effect Concentration
EC <sub>25</sub>	25% Effect Concentration
EC <sub>50</sub>	50% (or Median) Effect Concentration
ECOTOX	EPA managed database of Ecotoxicology data
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division
<i>e.g.</i>	Latin <i>ergo</i> (“therefore”)
EIM	Environmental Information Management System
EPI	Estimation Programs Interface
ESU	Evolutionarily significant unit
<i>et al.</i>	Latin <i>et alii</i> (“and others”)
<i>etc.</i>	Latin <i>et cetera</i> (“and the rest” or “and so forth”)

EXAMS	Exposure Analysis Modeling System
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FQPA	Food Quality Protection Act
ft	Feet
GENEEC	Generic Estimated Exposure Concentration model
HPLC	High Pressure Liquid Chromatography
IC <sub>05</sub>	5% Inhibition Concentration
IC <sub>50</sub>	50% (or median) Inhibition Concentration
<i>i.e.</i>	Latin for <i>id est</i> (“that is”)
IECV1.1	Individual Effect Chance Model Version 1.1
KABAM	Kow (based) Aquatic BioAccumulation Model
kg	Kilogram(s)
kJ/mole	Kilojoules per mole
km	Kilometer(s)
K <sub>AW</sub>	Air-water Partition Coefficient
K <sub>d</sub>	Solid-water Distribution Coefficient
K <sub>F</sub>	Freundlich Solid-Water Distribution Coefficient
K <sub>OC</sub>	Organic-carbon Partition Coefficient
K <sub>OW</sub>	Octanol–water Partition Coefficient
LAA	Likely to Adversely Affect
lb a.i./A	Pound(s) of active ingredient per acre
LC <sub>50</sub>	50% (or Median) Lethal Concentration
LD <sub>50</sub>	50% (or Median) Lethal Dose
LOAEC	Lowest Observable Adverse Effect Concentration
LOAEL	Lowest Observable Adverse Effect Level
LOC	Level of Concern
LOD	Level of Detection
LOEC	Lowest Observable Effect Concentration
LOQ	Level of Quantitation
m	Meter(s)
MA	May Affect
MATC	Maximum Acceptable Toxicant Concentration
m <sup>2</sup> /day	Square Meters per Days
ME	Microencapsulated
mg	Milligram(s)
mg/kg	Milligrams per kilogram (equivalent to ppm)
mg/L	Milligrams per liter (equivalent to ppm)
mi	Mile(s)
mmHg	Millimeter of mercury
MRID	Master Record Identification Number

MW	Molecular Weight
n/a	Not applicable
NASS	National Agricultural Statistics Service
NAWQA	National Water Quality Assessment
NCOD	National Contaminant Occurrence Database
NE	No Effect
NLAA	Not Likely to Adversely Affect
NLCD	National Land Cover Dataset
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NOAEC	No Observable Adverse Effect Concentration
NOAEL	No Observable Adverse Effect Level
NOEC	No Observable Effect Concentration
NRCS	Natural Resources Conservation Service
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides and Toxic Substances
ORD	Office of Research and Development
PCE	Primary Constituent Element
PED	Pesticide Ecotoxicity Database
pH	Symbol for the negative logarithm of the hydrogen ion activity in an aqueous solution, dimensionless
pKa	Symbol for the negative logarithm of the acid dissociation constant, dimensionless
ppb	Parts per Billion (equivalent to µg/L or µg/kg)
ppm	Parts per Million (equivalent to mg/L or mg/kg)
PRD	Pesticide Re-Evaluation Division
PRZM	Pesticide Root Zone Model
QSAR	Quantitative Structural-Activity Relationship
ROW	Right of Way
RQ	Risk Quotient
SFGS	San Francisco Garter Snake
SJKF	San Joaquin Kit Fox
SLN	Special Local Need
SMHM	Salt Marsh Harvest Mouse
TG	Tidewater Goby
T-HERPS	Terrestrial Herpetofaunal Exposure Residue Program Simulation
T-REX	Terrestrial Residue Exposure Model
UCL	Upper Confidence Limit

USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
VELB	Valley Elderberry Longhorn Beetle
WP	Wettable Powder
wt	Weight

## **1. Executive Summary**

The purpose of this assessment is to evaluate potential direct and indirect effects on the Central California, Sonoma County, and Santa Barbara County Distinct Population Segments (DPSs) of the California tiger salamander (CTS; *Ambystoma californiense*) resulting from FIFRA regulatory actions regarding use of oryzalin on agricultural and non-agricultural sites. In addition, this assessment evaluates whether these actions can be expected to result in modification of designated critical habitat for the CTS. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998), procedures outlined in the Agency's Overview Document (USEPA, 2004), and is consistent with a suit brought against EPA (*Center for Biological Diversity (CBD) vs. EPA et al.* (Case No. 07-2794-JCS)) in which oryzalin was alleged to be of concern to the CTS.

### **1.1. Assessed Species**

The CTS is found in grassland and oak savannah plant communities in central California, where it seasonally utilizes standing bodies of water (*e.g.*, fishless ponds) for breeding, egg-laying, and as larval habitat. In August 2004, the USFWS listed the CTS as threatened throughout its range. Specifically, the Central California CTS DPS was newly listed as threatened, and the Santa Barbara County and Sonoma County CTS DPSs were downlisted from endangered to threatened. However, the downlisting of the Santa Barbara County and Sonoma County DPSs was vacated by the U.S. District Court in August 2005. As a result, the Santa Barbara County and Sonoma County CTS DPSs are currently listed as endangered, while the Central California CTS DPS is listed as threatened.

Critical habitat has been designated by the USFWS for the Central California and Santa Barbara County DPSs and has been proposed for the Sonoma County DPS. This assessment evaluates the potential for modification to primary constituent elements (PCEs) of only the finalized designated critical habitat (*i.e.*, for the Central California and Santa Barbara County DPSs).

Each DPS is considered separately in the risk assessment as they occupy different geographic areas. The main difference in the assessment will be in the spatial analysis. CTS utilizes vernal pools, semi-permanent ponds, and permanent ponds, and the terrestrial environment in California. The aquatic environment is essential for breeding and reproduction, and mammal burrows are also important habitat for aestivation.

### **1.2. Identity of Assessed Chemical and Assessed Uses**

Oryzalin is a dinitroaniline herbicide that is registered nationally for the control of annual grasses and certain broadleaf weeds in fruit and nut crops, vineyards, Christmas tree plantations, ornamentals, turf, and several other non-crop sites. Oryzalin is a root inhibitor; its herbicidal action is through inhibition of microtubule polymerization/function of cell division process leading to adverse effects on seed

germination and cellular respiration. Oryzalin is formulated as granules (0.4 to 1% a.i.), wettable powder (75% a.i.), water dispersible granules (60 to 85% a.i.), emulsifiable concentrate (2.84 to 40.4% a.i.), flowable concentrate (40.4% a.i.), and formulation intermediate/liquid (40.4% a.i.). Depending on the formulation, the registered products are applied to the soil surface prior to the emergence of weeds as broadcast spray or band treatment for liquid formulations (using low pressure ground equipment) or broadcast for granular formulations (using spreaders). To facilitate activation and movement of the chemical to the weed seed germination zone, a single ½ to 1 inch of rainfall or sprinkler irrigation is required.

Several degradates have been identified for oryzalin in various environmental fate studies. None of the degradates are considered to be of toxicological concern; therefore, this assessment is based on parent oryzalin only.

### **1.3. Assessment Procedures**

#### **1.3.1. Exposure Assessment**

Tier-II aquatic exposure models are used to estimate high-end exposures of oryzalin in aquatic habitats resulting from runoff and spray drift from different uses. The models used to predict aquatic EECs are the Pesticide Root Zone Model coupled with the Exposure Analysis Model System (PRZM/EXAMS). The AgDRIFT model is also used to estimate deposition of oryzalin on terrestrial and aquatic habitats from spray drift. These estimates are supplemented with analysis of available California surface water monitoring data from U.S. Geological Survey's National Water Quality Assessment (NAWQA) program and the California Department of Pesticide Regulation.

Estimates of oryzalin exposure in the terrestrial environment, as expected to result from registered uses of the chemical, are generated using the T-REX model for foliar uses, the AgDRIFT model for deposition of oryzalin from spray drift, and the TerrPlant model for foliar applications that drift or run off to plants inhabiting semi-aquatic and dry areas. In addition, estimates of exposure from the T-HERPS model are compared to values from the T-REX model to further characterize dietary exposures of terrestrial-phase amphibians.

#### **1.3.2. Toxicity Assessment**

The assessment endpoints include direct toxic effects on survival, reproduction, and growth of individuals, as well as indirect effects, such as reduction of the food source and/or modification of habitat. Federally-designated critical habitat has been established for the CTS in the Central California and Santa Barbara County DPSs but not in the Sonoma County DPS. Primary constituent elements (PCEs) were used to evaluate whether oryzalin has the potential to modify designated critical habitat. The Agency evaluated registrant-submitted studies and data from the open literature to characterize oryzalin toxicity. The most sensitive toxicity value available from acceptable or supplemental studies for each taxon relevant for estimating potential risks to the assessed species and/or their designated critical habitat was used.

### **1.3.3. Measures of Risk**

Acute and chronic risk quotients (RQs) are compared to the Agency's Levels of Concern (LOCs) to identify instances where oryzalin use has the potential to adversely affect the assessed species or modify their designated critical habitat. When RQs for a particular type of effect are below LOCs, the pesticide is considered to have "no effect" on the species and its designated critical habitat. Where RQs exceed LOCs, a potential to cause adverse effects or habitat modification is identified, leading to a conclusion of "may affect". If oryzalin use "may affect" the assessed species, and/or may cause effects to designated critical habitat, the best available additional information is considered to refine the potential for exposure and effects and distinguish actions that are "not likely to adversely affect" (NLAA) from those that are "likely to adversely affect" (LAA).

## **1.4. Summary of Conclusions**

### **1.4.1. Environmental Fate Summary**

Depending on the environmental conditions, the major route of oryzalin dissipation is aqueous photolysis (half-life = 0.06 days), photodegradation on soil surface (half-life = 3.8 days), and degradation under anaerobic soil condition (half-life = 10 days). Oryzalin appears to degrade slowly under aerobic soil conditions (half-life = 63 days) and is stable to hydrolysis. Under field conditions oryzalin appeared to be moderately persistent, with a half-life of about two months. Based on its low vapor pressure ( $1.0 \times 10^{-7}$  mm Hg at 25°C) and Henry's Law Constant ( $1.8 \times 10^{-8}$  atm·m<sup>3</sup>/mol), volatilization loss of oryzalin from soil and water systems is expected to be insignificant compared to dissipation by abiotic and biotic degradation. For this assessment, transport of oryzalin from initial application sites via runoff and spray drift are considered in evaluating quantitative estimates of oryzalin exposure to CTS, its prey, and its habitats.

### **1.4.2. Exposure Summary**

Since CTSs exist in both aquatic and terrestrial habitats, exposure of the CTS, its prey, and its habitats to oryzalin are assessed separately for the two habitats. Due to relatively low volatility and greater sensitivity to photolytic degradation, oryzalin is not expected to move by long-range transport. There is also no data for oryzalin in the California Pesticide Air Monitoring database; however, it is unknown whether or not oryzalin was targeted for sampling. Tier-II aquatic exposure models are used to estimate high-end exposures of oryzalin in aquatic habitats resulting from runoff and spray drift from different uses. Peak model-estimated environmental concentrations resulting from different oryzalin uses range from 3.5 to 141.89 µg/L. These estimates are supplemented with analysis of available California surface water monitoring data from U.S. Geological Survey's National Water Quality Assessment (NAWQA) program and the California Department of Pesticide Regulation (CDPR). The maximum concentration of oryzalin reported by CDPR for surface waters with agricultural watersheds is 110 µg/L.



To estimate oryzalin exposures to the terrestrial-phase CTS and its potential prey resulting from uses involving oryzalin applications, the T-REX model is used for both foliar and granular uses. The T-HERPS model is used to allow for further characterization of dietary exposures of terrestrial-phase CTSs relative to birds. The TerrPlant model is used to estimate oryzalin exposures to terrestrial-phase CTS habitat, including plants inhabiting semi-aquatic and dry areas, resulting from uses involving foliar oryzalin applications. AgDRIFT model is also used to estimate deposition of oryzalin on terrestrial and aquatic habitats from spray drift. Estimated concentrations of oryzalin on food items of the CTS ranged from approximately 300 mg/kg-fresh weight to 1000 mg/kg-fresh weight based depending on the application rate on the assessed commodity.

#### **1.4.3. Risk Summary**

Based on the best available information, the Agency makes a “may affect” and “likely to adversely affect” (LAA) determination for the Central California, Santa Barbara County, and Sonoma County CTS DPSs as a result of the labeled use of oryzalin. Additionally, the Agency has determined that there is the potential for modification of designated critical habitat of the CTS in the Central California and Santa Barbara County DPSs in association with use of oryzalin.

The “LAA” determination was concluded for the aquatic-phase CTS based on indirect effects related to a reduction in algae as food items for larvae and effects to aquatic non-vascular plants, sensitive herbaceous terrestrial plants, and riparian vegetation that comprise its habitat. For the terrestrial-phase CTS, an “LAA” determination was concluded for acute and chronic direct effects and indirect effects related to a reduction in mammals and terrestrial-phase amphibians as food items and herbaceous terrestrial plants and riparian vegetation as habitat. As such, modification of critical habitat is expected for both aquatic and terrestrial primary constituent elements (PCEs).

A summary of the risk conclusions and effects determinations for the CTS and its critical habitat is presented in **Tables 1.1** and **1.2**, respectively. Further information on the results of the effects determination is included as part of the Risk Description in **Section 5.2**. Oryzalin use-specific direct effects determinations for the CTS and indirect effects determinations for the prey items can be found in **Tables 1.3** and **1.4**, respectively.

<b>Table 1.1. Effects Determination Summary for Direct and Indirect Effects of Oryzalin on the CTS (Applies to the Central California, Santa Barbara County, and Sonoma County DPSs)</b>		
<b>Assessment Endpoint</b>	<b>Effects Determination for the CTS<sup>1</sup></b>	<b>Basis for Determination</b>
<i><b>Aquatic-Phase CTS (Eggs, Larvae, and Adults)</b></i>		
<u>Direct Effects:</u> Survival, growth, and reproduction of CTS individuals via direct effects on aquatic phases	NLAA	Using freshwater fish as a surrogate, no chronic LOCs are exceeded; acute LOCs are exceeded for one use (rights-of-ways). The RQ was 0.05. The probability of an individual mortality at an RQ of 0.05 was 1 in 3.03E+33. This suggests that the potential for an adverse effect is discountable. Therefore, the effects determination for rights-of-ways is NLAA. The effects determination for all other uses was no effect ( <b>Table 1.3.</b> )
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via effects to food supply ( <i>i.e.</i> , freshwater invertebrates, non-vascular plants, fish, and amphibians)	<u>Freshwater invertebrates:</u> NLAA	Oryzalin may affect sensitive aquatic invertebrates; however, the low probability (1 in 6.8E+22 at the highest RQ of 0.09) of an individual effect to an aquatic invertebrate resulting from the labeled uses of oryzalin suggests that the likelihood of any potential reduction in available food for the CTS is low enough to be considered a discountable effect.
	<u>Non-vascular aquatic plants:</u> LAA	LOCs are exceeded for applications of oryzalin to avocado, berries, olives, tree nuts, vineyards (wine grapes), forest trees, rights-of-ways, ornamentals (excluding bulbs), and uncultivated areas. Indirect effects to larvae that feed on algae, therefore, are possible.
	<u>Fish and amphibians:</u> NLAA	Using freshwater fish as a surrogate, no chronic LOCs are exceeded; acute LOCs are exceeded for one scenario (rights-of-ways) for which the effect was considered to be discountable.
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via indirect effects on habitat, cover, and/or primary productivity ( <i>i.e.</i> , aquatic plant community)	<u>Non-vascular aquatic plants:</u> LAA	LOCs are exceeded for non-vascular aquatic plants for applications of oryzalin to avocado, berries, olives, tree nuts, vineyards (wine grapes), forest trees, rights-of-ways, ornamentals (excluding bulbs), and uncultivated areas.
	<u>Vascular aquatic plants:</u> LAA	RQs for vascular plants exceeded LOCs for all oryzalin use patterns except citrus fruits, tropical fruits, turf, and residential areas.

**Table 1.1. Effects Determination Summary for Direct and Indirect Effects of Oryzalin on the CTS (Applies to the Central California, Santa Barbara County, and Sonoma County DPSs)**

Assessment Endpoint	Effects Determination for the CTS <sup>1</sup>	Basis for Determination
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via effects to riparian vegetation, required to maintain acceptable water quality and habitat in ponds and streams comprising the species' current range.	<u>Direct effects to forested riparian vegetation:</u> LAA  <u>Direct effects to grassy/herbaceous riparian vegetation:</u> LAA (ground applications): <364 ft (monocots); <154 ft (dicots) NLAA (ground applications): >364 ft (monocots); >154 ft (dicots)	Riparian vegetation may be affected because terrestrial plant RQs exceeded LOCs. Label statements caution against the use of oryzalin on some woody species. In addition, incidents have been reported in terrestrial plants.  Aquatic-phase CTSs may be indirectly affected by adverse effects to sensitive herbaceous vegetation (based on all oryzalin uses), which provides habitat and cover for the CTS and attachment sites for its egg masses.
<b><i>Terrestrial-Phase CTS (Juveniles and adults)</i></b>		
<u>Direct Effects:</u> Survival, growth, and reproduction of CTS individuals via direct effects on terrestrial phase adults and juveniles	LAA	The acute avian effects data was used as a surrogate for the terrestrial-phase CTS. Dose-based acute avian RQs, refined based on amphibian dietary intake using the T-HERPS model, exceeded LOCs for all uses. Chronic reproductive effects are possible based on non-granular uses of oryzalin. RQs ranged from approximately 1.53 to 7.53.
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via effects on prey ( <i>i.e.</i> , terrestrial invertebrates, small terrestrial vertebrates, including mammals and terrestrial phase amphibians)	<u>Terrestrial invertebrates:</u> LAA	Although oryzalin is classified as practically non-toxic to terrestrial invertebrates, there is uncertainty regarding toxicity at environmentally relevant concentrations. Because EECs were greater than the non-definitive LD <sub>50</sub> , reduction of terrestrial invertebrates, which are prey items of the CTS, cannot be precluded.
	<u>Mammals:</u> LAA	Acute risks cannot be precluded for the granular uses of oryzalin. Chronic RQs for non-granular formulations exceed LOCs.
	<u>Amphibians:</u> LAA	Chronic risks for terrestrial-phase amphibians exposed to broadcast spray applications of oryzalin may occur.

**Table 1.1. Effects Determination Summary for Direct and Indirect Effects of Oryzalin on the CTS (Applies to the Central California, Santa Barbara County, and Sonoma County DPSs)**

Assessment Endpoint	Effects Determination for the CTS <sup>1</sup>	Basis for Determination
<p><u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via indirect effects on habitat (<i>i.e.</i>, riparian vegetation)</p>	<p><u>Direct effects to forested riparian vegetation:</u> LAA</p> <p><u>Direct effects to grassy/herbaceous riparian vegetation:</u> LAA (ground applications): &lt;364 ft (monocots); &lt;154 ft (dicots) NLAA (ground applications): &gt;364 ft (monocots); &gt;154 ft (dicots)</p>	<p>Riparian vegetation may be affected because terrestrial plant RQs exceed LOCs. Label statements caution against the use of oryzalin on some woody species. In addition, incidents have been reported in terrestrial plants.</p> <p>Aquatic-phase CTSs may be indirectly affected by adverse effects to sensitive herbaceous vegetation (based on all oryzalin liquid spray and granular uses), which provides habitat and cover for the CTS and attachment sites for its egg masses.</p>

<sup>1</sup>NE = no effect; NLAA = may affect, but not likely to adversely affect; LAA = likely to adversely affect

**Table 1.2. Effects Determination Summary for the Critical Habitat Impact Analysis (Effects Determination for Critical Habitat Applies to the Central California and Santa Barbara County DPSs)**

Assessment Endpoint	Effects Determination <sup>1</sup>	Basis for Determination
<p><i>Aquatic-Phase CTS PCEs</i> <i>(Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)</i></p>		
Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CTSs.	Habitat modification	Both liquid and granular formulations of oryzalin may affect sensitive riparian seedlings. As a result, critical habitat may be modified by an increase in sediment deposition and reduction in herbaceous riparian vegetation that provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult aquatic-phase CTSs.
Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CTSs and their food source. <sup>2</sup>	Habitat modification	Both liquid and granular formulations of oryzalin may affect sensitive seedlings. As a result, critical habitat may be modified via turbidity and reduction in oxygen content necessary for normal growth and viability of juvenile and adult aquatic-phase CTSs.
Alteration of other chemical characteristics necessary for normal growth and viability of CTSs and their food source.	<p>No effects on growth and viability of CTS</p> <p>Habitat modification based on alteration of food source</p>	<p>Direct effects to the aquatic-phase CTS are not likely.</p> <p>Critical habitat of the CTS may be modified via oryzalin-related impacts (both formulations) to non-vascular aquatic plants as food items for tadpoles.</p>

**Table 1.2. Effects Determination Summary for the Critical Habitat Impact Analysis (Effects Determination for Critical Habitat Applies to the Central California and Santa Barbara County DPSs)**

Assessment Endpoint	Effects Determination <sup>1</sup>	Basis for Determination
Reduction and/or modification of aquatic-based food sources for pre-metamorphs (e.g., algae)	Habitat modification	Based on the results of the effects determinations for aquatic plants, critical habitat of the CTS may be modified via oryzalin-related impacts to non-vascular aquatic plants as food items for tadpoles.
<b>Terrestrial-Phase CTS PCEs (Upland Habitat and Dispersal Habitat)</b>		
Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CTSs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CTS shelter, forage, and predator avoidance	Habitat modification	Modification to critical habitat may occur via impacts of oryzalin on sensitive seedlings which provide habitat and cover for the terrestrial-phase CTS and its prey.
Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal	Habitat modification	
Reduction and/or modification of food sources for terrestrial phase juveniles and adults	Habitat modification	Based on the characterization of indirect effects to terrestrial-phase CTSs via reduction in the prey base, critical habitat may be modified via a reduction in mammals and terrestrial-phase amphibians as food items.
Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CTSs and their food source.	Habitat modification	Direct acute and chronic effects are likely for the terrestrial-phase CTS. Therefore, oryzalin may adversely affect critical habitat by altering chemical characteristics necessary for normal growth and viability of terrestrial-phase CTSs and their mammalian and amphibian food sources.

<sup>1</sup>NE = No effect; HM = Habitat modification

<sup>2</sup>Physico-chemical water quality parameters such as salinity, pH, and hardness are not evaluated because these processes are not biologically mediated and, therefore, are not relevant to the endpoints included in this assessment.

**Table 1.3. Oryzalin Use-specific Direct Effects Determinations<sup>1</sup> for the CTS**

Use Category	Application Method	Aquatic Phase		Terrestrial Phase	
		Acute	Chronic	Acute	Chronic
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Ornamentals (Excluding Bulbs)	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Ornamental Bulbs	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Christmas Tree Plantations	Ground Broadcast	NE	NE	LAA	LAA

**Table 1.3. Oryzalin Use-specific Direct Effects Determinations<sup>1</sup> for the CTS**

Use Category	Application Method	Aquatic Phase		Terrestrial Phase	
		Acute	Chronic	Acute	Chronic
	Granular	NE	NE	LAA	-
Forest Trees	Ground Broadcast	NE	NE	LAA	LAA
Turf	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Rights-of-ways	Ground Broadcast	NLAA	NE	LAA	LAA
	Granular	NLAA	NE	LAA	-
Residential areas	Granular	NE	NE	LAA	-
Uncultivated Areas	Ground Broadcast	NE	NE	LAA	LAA

<sup>1</sup>NE = No effect; NLAA = May affect, but not likely to adversely affect; LAA = Likely to adversely affect

-Not applicable

**Table 1.4. Oryzalin Use-specific Indirect Effects Determinations<sup>1</sup> Based on Effects to Prey**

Use Category	Application Method	Species Effects Determination	Critical Habitat Modification	Potential for Effect (Taxon for which LAA is determined)			
				Aquatic phase		Terrestrial Phase <sup>2</sup>	
				Direct	Indirect	Direct	Indirect
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	Ground Broadcast	LAA	Yes	--	Algae <sup>3</sup> Vascular plants <sup>4</sup>	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Algae <sup>3</sup> Vascular plants <sup>4</sup>	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Ornamentals (Excluding Bulbs)	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Ornamental Bulbs	Ground Broadcast	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Christmas Tree Plantations	Ground Broadcast	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Forest Trees	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Turf	Ground Broadcast	LAA	Yes	--	--	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants

**Table 1.4. Oryzalin Use-specific Indirect Effects Determinations<sup>1</sup> Based on Effects to Prey**

Use Category	Application Method	Species Effects Determination	Critical Habitat Modification	Potential for Effect (Taxon for which LAA is determined)			
				Aquatic phase		Terrestrial Phase <sup>2</sup>	
				Direct	Indirect	Direct	Indirect
	Granular	LAA	Yes	--	--	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Rights-of-ways	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Residential Areas	Granular	LAA	Yes	--	--	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Uncultivated Areas	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
<sup>1</sup> NE = No effect; NLAA = May affect but not likely to adversely affect; LAA = Likely to adversely affect; --Not applicable <sup>2</sup> Birds serve as a surrogate for terrestrial-phase amphibians. <sup>3</sup> “No effect” determination made for citrus, tropical, pome, and stone fruit. <sup>4</sup> “No effect” determination made for citrus fruit and tropical fruit.							

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated.

When evaluating the significance of this risk assessment’s direct/indirect and habitat modification effects determinations, it is important to note that pesticide exposures and predicted risks to the species and its resources (*i.e.*, food and habitat) are not expected to be uniform across the action area. In fact, given the assumptions of drift and downstream transport (*i.e.*, attenuation with distance), pesticide exposure and associated risks to the species and its resources are expected to decrease with increasing distance away from the treated field or site of application. Evaluation of the implication of this non-uniform distribution of risk to the species would require information and assessment techniques that are not currently available. Examples of such information and methodology required for this type of analysis would include the following:

- Enhanced information on the density and distribution of CTS life stages within specific recovery units and/or designated critical habitat within the action area. This information would allow for quantitative extrapolation of the present risk assessment’s predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the species.

- Quantitative information on prey base requirements for individual aquatic- and terrestrial-phase amphibians. While existing information provides a preliminary picture of the types of food sources utilized by the amphibian, it does not establish minimal requirements to sustain healthy individuals at varying life stages. Such information could be used to establish biologically relevant thresholds of effects on the prey base, and ultimately establish geographical limits to those effects. This information could be used together with the density data discussed above to characterize the likelihood of adverse effects to individuals.
- Information on population responses of prey base organisms to the pesticide. Currently, methodologies are limited to predicting exposures and likely levels of direct mortality, growth or reproductive impairment immediately following exposure to the pesticide. The degree to which repeated exposure events and the inherent demographic characteristics of the prey population play into the extent to which prey resources may recover is not predictable. An enhanced understanding of long-term prey responses to pesticide exposure would allow for a more refined determination of the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual amphibians and potential modification to critical habitat.

## 2. Problem Formulation

Problem formulation provides a strategic framework for the risk assessment. By identifying the important components of the problem, it focuses the assessment on the most relevant life history stages, habitat components, chemical properties, exposure routes, and endpoints. The structure of this risk assessment is based on guidance contained in USEPA's *Guidance for Ecological Risk Assessment* (USEPA, 1998), the Services' *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998) and is consistent with procedures and methodology outlined in the Overview Document (USEPA, 2004) and reviewed by the U.S. Fish and Wildlife Service and National Marine Fisheries Service (USFWS/NMFS, 2004).

### 2.1. Purpose

The purpose of this assessment is to evaluate potential direct and indirect effects of oryzalin (PC code: 104201) on the California tiger salamander (*Ambystoma californiense*) (referred to as CTS from now on) arising from FIFRA regulatory actions regarding use of oryzalin on agricultural and non-agricultural sites. In addition, this assessment evaluates whether these actions can be expected to result in modification of designated critical habitat. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998), procedures outlined in the Agency's Overview Document (USEPA, 2004), and with a stipulated



injunction in the case *Center for Biological Diversity (CBD) vs. EPA et al.* (Case No. 07-2794-JCS) issued by the Federal District Court for the Northern District of California.

The CTS is found in grassland and oak savannah plant communities in central California, where it seasonally utilizes standing bodies of water (*e.g.*, fishless ponds) for breeding, egg-laying, and as larval habitat. Three DPS are recognized: the Central California DPS, the Santa Barbara County DPS, and the Sonoma County DPS. The Santa Barbara County and Sonoma County DPSs are currently listed as endangered, while the Central California DPS is listed as threatened.

In this assessment, direct and indirect effects to the CTS and potential modification to its designated critical habitat are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA, 2004). Screening level methods include use of standard models such as PRZM-EXAMS, T-REX, TerrPlant, and AgDRIFT all of which are described at length in the Overview Document. Additional refinements include an analysis of California Pesticide Use Reporting (CA PUR) data and the use of the T-HERPS model to predict daily dietary intake specifically by the CTS of oryzalin residues in terrestrial invertebrates and small mammal dietary items. Use of such information is consistent with the methodology described in the Overview Document, which specifies that "the assessment process may, on a case-by-case basis, incorporate additional methods, models, and lines of evidence that EPA finds technically appropriate for risk management objectives" (Section V, page 31 of USEPA, 2004).

In accordance with the Overview Document, provisions of the ESA, and the Services' *Endangered Species Consultation Handbook*, the assessment of effects associated with registrations of oryzalin is based on an action area. The action area is the area directly or indirectly affected by the federal action, as indicated by the exceedance of the Agency's Levels of Concern (LOCs). It is acknowledged that the action area for a national-level FIFRA regulatory decision associated with a use of oryzalin may potentially involve numerous areas throughout the United States and its Territories. However, for the purposes of this assessment, attention will be focused on relevant sections of the action area including those geographic areas associated with locations of the CTS and its designated critical habitat within the state of California. As part of the "effects determination," one of the following three conclusions will be reached regarding the potential use of oryzalin in accordance with current labels:

- "No effect";
- "May affect but not likely to adversely affect"; or
- "May affect and likely to adversely affect".

Designated critical habitat identifies specific areas that have the physical and biological features, (known as primary constituent elements or PCEs) essential to the conservation of the listed species. The PCEs for CTSs are aquatic and upland areas where suitable breeding and non-breeding aquatic habitat is located, interspersed with upland foraging and dispersal habitat.

If the results of initial screening-level assessment methods show no direct or indirect effects (no LOC exceedances) upon individual CTSs or upon the PCEs of the species' designated critical habitat, a "no effect" determination is made for use of oryzalin as it relates to this species and its designated critical habitat. If, however, potential direct or indirect effects to individual CTSs are anticipated or effects may impact the PCEs of the CTS's designated critical habitat, a preliminary "may affect" determination is made for the FIFRA regulatory action regarding oryzalin.

If a determination is made that use of oryzalin within the action area(s) associated with the CTS "may affect" this species or its designated critical habitat, additional information is considered to refine the potential for exposure and for effects to the CTS and other taxonomic groups upon which these species depend (*e.g.*, aquatic and terrestrial vertebrates and invertebrates, aquatic plants, riparian vegetation, *etc.*). Additional information, including spatial analysis (to determine the geographical proximity of CTS habitat and oryzalin use sites) and further evaluation of the potential impact of oryzalin on the PCEs is also used to determine whether modification of designated critical habitat may occur. Based on the refined information, the Agency uses the best available information to distinguish those actions that "may affect but are not likely to adversely affect" from those actions that "may affect and are likely to adversely affect" the CTS or the PCEs of its designated critical habitat. This information is presented as part of the Risk Characterization in **Section 5** of this document.

The Agency believes that the analysis of direct and indirect effects to listed species provides the basis for an analysis of potential effects on the designated critical habitat. Because oryzalin is expected to directly impact living organisms within the action area (defined in **Section 2.7**), critical habitat analysis for oryzalin is limited in a practical sense to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes (*i.e.*, the biological resource requirements for the listed species associated with the critical habitat or important physical aspects of the habitat that may be reasonably influenced through biological processes). Activities that may modify critical habitat are those that alter the PCEs and appreciably diminish the value of the habitat. Evaluation of actions related to use of oryzalin that may alter the PCEs of the CTS's critical habitat form the basis of the critical habitat impact analysis. Actions that may affect the CTS's designated critical habitat have been identified by the Services and are discussed further in **Section 2.6**.

## **2.2. Scope**

The end result of the EPA pesticide registration process (*i.e.*, the FIFRA regulatory action) is an approved product label. The label is a legal document that stipulates how and where a given pesticide may be used. Product labels (also known as end-use labels) describe the formulation type (*e.g.*, liquid or granular), acceptable methods of application, approved use sites, and any restrictions on how applications may be conducted. Thus, the use or potential use of oryzalin in accordance with the approved product labels for California is "the action" relevant to this ecological risk assessment.

Although current registrations of oryzalin allow for use nationwide, this ecological risk assessment and effects determination addresses currently registered uses of oryzalin in portions of the action area that are reasonably assumed to be biologically relevant to the CTS and its designated critical habitat. Further discussion of the action area for the CTS and its critical habitat is provided in **Section 2.7**.

### **2.2.1. Evaluation of Degradates and Other Stressors of Concern**

Several degradates have been identified for oryzalin of which the main degrade is 4-hydroxy-3, 5-dinitrobenzenesulfonamide (OR 20). There is no evidence that any of these degradates are of toxicological concern, and none of them are found in significant amounts (>10.0%) except 2-ethyl-7-nitro-1-propyl-5-sulfonylaminobenzimidazole 3-oxide at 14% in an aquatic photodegradation study. Since 2-ethyl-7-nitro-1-propyl-5-sulfonylamino benzimidazole 3-oxide is not of toxicological concern (as determined by EPA's MARC committee and through structural analysis), this assessment is based on parent oryzalin only.

### **2.2.2. Evaluation of Mixtures**

The Agency does not routinely include in its risk assessments an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of multiple active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment to make regulatory decisions regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively in accordance with the Agency's Overview Document and the Services' Evaluation Memorandum (USEPA, 2004; USFWS/NMFS, 2004).

Oryzalin has ten registered products that contain multiple active ingredients (**Appendix B**). Based on a review of the available studies on oryzalin mixtures, it appears that the information presented in the papers pertain to efficacy and phytotoxicity of the mixtures for weed control. No information is available on the toxicity of individual components of oryzalin mixtures (**Appendix B**).

## **2.3. Previous Assessments**

Recently, the potential for oryzalin to adversely affect the California Red Legged Frog (CRLF) was evaluated. The CRLF and the CTS are both amphibians with similar dietary habits. Therefore, the models and assumptions used to evaluate potential exposures and risks are identical for both species. Oryzalin has not been approved for any new uses since the CRLF assessment was conducted, and no new environmental fate or toxicity data have been submitted. Therefore, this assessment on the CTS closely follows the 2008 CRLF assessment.

The 2008 CRLF assessment concluded that oryzalin is likely to adversely affect the CRLF from direct chronic effects and indirect effects via impacts to aquatic and terrestrial plants and may modify critical habitat. This assessment may be found at the following URL: <http://www.epa.gov/espp/litstatus/effects/redleg-frog/>

A number of other ecological risk assessments have been conducted by the Agency on oryzalin. Oryzalin was first registered in the United States in 1974 as a preemergence herbicide in fruits, nuts, vineyards, orchards, forestry, rights-of-ways, and agricultural crops. A Registration Standard was issued in 1987 (NTIS# PB89-102396) that evaluated the studies submitted on oryzalin to that date. Prior to the issuance of the Registration Standard, several agricultural crops were deleted. The only agricultural crop groups remaining on oryzalin labels are berries, vine and orchard crops (*i.e.*, avocado, citrus fruits, olive, pome fruits, stone fruits, tree nuts, tropical fruits, and vineyards). In addition, oryzalin has many non-agricultural uses including ornamentals, Christmas trees, forest trees, uncultivated areas, and established turf and rights-of-ways. A Data Call-in was issued in 1991 requiring additional phytotoxicity data, plant and animal analytical methods, and non-dietary exposure data. The Agency issued the Registration Eligibility Decision (RED) for oryzalin in September of 1994 by determining that all of the then registered oryzalin products were eligible for re-registration except for products labeled for use on residential lawns and turf. The results of the Agency's 1994 ecological risk assessment for oryzalin, which was conducted as part of the RED, suggest the potential for adverse acute effects to non-target aquatic animals in shallow waters (6 inches deep) and terrestrial and aquatic plants. No acute or sub-lethal chronic effects to birds were reported due to exposure to oryzalin. The Tolerance Reassessment Progress and Risk Management Decision (TRED) for oryzalin, dated May 26, 2006, determined that the lawn and turf uses for oryzalin are eligible for re-registration based on the submitted new studies on exposure monitoring on residential lawns and turf.

The Agency also completed an effects determination for the threatened and endangered Pacific anadromous salmon and steelhead in 2003 based on oryzalin uses in grapes and almonds in the Pacific Northwest as part of the settlement for the petition filed against EPA by Washington Toxics Coalition (filed November 26, 2002). The results of this endangered species risk assessment showed that oryzalin may affect but is not likely to adversely affect 17 ESUs (Evolutionarily Significant Units) and will have no effect on nine ESUs. These determinations were based on possible indirect effects to listed salmonids from loss of aquatic plant cover in spawning and rearing habitats.

## **2.4. Stressor Source and Distribution**

### **2.4.1. Environmental Fate Properties**

Best-available data defining the physical, chemical, fate and transport characteristics associated with oryzalin are summarized in **Table 2.1**. The major route of oryzalin dissipation is aqueous photolysis, photodegradation on soil surface, and degradation under anaerobic conditions. Oryzalin appears to degrade slowly under aerobic soil conditions and is stable to hydrolysis. Under field conditions oryzalin appeared to be moderately persistent, with a half-life of about two months. Based on its low vapor pressure ( $1.0 \times 10^{-7}$  mm Hg at 25°C) and Henry's Law Constant ( $1.8 \times 10^{-8}$  atm·m<sup>3</sup>/mol), volatilization loss of oryzalin from soil and water systems is expected to be insignificant compared to dissipation by abiotic and biotic degradation.

**Table 2.1. Summary of Oryzalin Chemical Identity and Environmental Fate Properties**

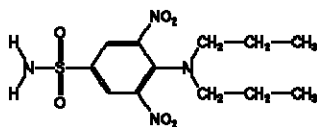
Parameter	Value	Major Degradates <i>Minor Degradates</i>	Source/ MRID #	Study Status
Common name	Oryzalin	---	USEPA, 1994	---
Chemical name	3,5-dinitro-N <sup>4</sup> ,N <sup>4</sup> -dipropylsulfanilamide	---	USEPA, 1994	---
Chemical family	Dinitroaniline	---	USEPA, 1994	---
CAS Number	19044-88-3	---	USEPA, 1994	---
Empirical formula	C <sub>12</sub> H <sub>18</sub> N <sub>4</sub> O <sub>6</sub> S	---	USEPA, 1994	---
Structure		---	USEPA, 1994	---
Molecular mass	346.35	---	USEPA, 1994	
Water solubility (20°C)	2.5 mg/L	---	MRID 41208101-2	Acceptable
Vapor pressure (25°C)	$1.0 \times 10^{-7}$ mm Hg at 25°C	---	MRID 40454801	Acceptable
Henry's Law Constant	$1.82 \times 10^{-8}$ atm m <sup>3</sup> /mol	---	Calculated <sup>1</sup>	---
Octanol/water partition coefficient (Log K <sub>ow</sub> )	3.73 at pH 7	---	USEPA, 1994	---
Hydrolysis	Stable (pH 5, 7, 9)	---	MRID 41378401	Acceptable
Direct Aqueous Photolysis	0.06 days	UN-2, 14.0% OR-3, 5.7%, OR-5, 4.0% OR-X, 2.9%	MRID 41278701	Supplemental <sup>2</sup>
Soil Photolysis	3.8 days	OR-3, 2.6%, OR-15, 3.2% OR-21, 4.6%.	MRID 41050001	Acceptable
Aerobic Soil Metabolism	63 days	OR-20 4.7 %, UN-1, UN-2, OR-2, OR-4, OR-9, OR-13, OR-15 and OR-41, ≤ 2.4%	MRID 41322801	Acceptable

Table 2.1. Summary of Oryzalin Chemical Identity and Environmental Fate Properties				
Parameter	Value	Major Degradates <i>Minor Degradates</i>	Source/ MRID #	Study Status
Anaerobic Soil Metabolism	10 Days	OR-20, <0.2% OR-15, <0.2% UN-1, <0.2% OR-2, <0.2%	MRID 41322802	Acceptable
Aerobic Aquatic Metabolism	data gap	---	---	Call in data
Anaerobic Aquatic Metabolism	data gap	---	---	Call in data
Soil Partition Coefficient (K <sub>oc</sub> : L kg o.c. <sup>-1</sup> ) <sup>3</sup>	722, 602, 803 and 1109 (average = 809)	---	MRID 41479802	Acceptable
Terrestrial Field Dissipation	FL: 68 days MI: 77-138 days CA: 58-146 days	---	MRID 42138001	Acceptable
Fish Bioconcentration Factor (BCF)	32x (edible) 105x (non-edible) 66x (whole fish)	---	MRID 40787501	Acceptable
<sup>1</sup> = Henry's Law (atm·m <sup>3</sup> /mole) = (VAPR/760)/(SOL/MWT), where VAPR is vapor pressure in torr, MWT is molecular weight in g/mol, and SOL is the solubility in water in mg/L. <sup>2</sup> = The supplemental information submitted in addition to the study (MRID 41278701) completely satisfy the data requirement (EFED Search Document 2002465). The OR-X degradate is identified as 3-nitro-5-aminosulfanilamide. <sup>3</sup> = Koc was calculated from Kd and % o.m. from raw data using the formulas % o.c. = % o.m./1.72 and Koc = (Kd/% o.c.) x 100				

Laboratory studies indicate that oryzalin is stable to hydrolysis at pHs 5, 7 and 9. (MRID 41378401) but exhibits susceptibility to rapid direct aqueous photolysis; the aqueous photolytic half-life is 1.4 hours (MRID 41278701). The degradates of aqueous photolysis are OR-5 (2.9%), OR-3 (5.7%), and UN-2 (14%). The chemical also readily photodegrades on the soil surface with an estimated half-life of 3.8 days, and the degradates are OR-3 (2.6%), OR-15 (3.2%) and OR-21 (4.6%) (MRID 41050001).

Oryzalin degrades aerobically with a half-life of 63 days in sandy loam soil (MRID 41322801). The main degradate is 4-hydroxy-3,5-dinitrobenzenesulfonamide (OR 20), which accounted for a maximum of 4.7% of radioactivity at 1 month post treatment in the soil aerobic metabolism study. Eight other degradates were identified, each accounting for ≤ 2.4% of the applied radioactivity (**Table 2.1**). The benzenesulfonamide ring remained intact in all of the identified metabolites. By the end of the experiment at 6.1 months, 63.1% of the applied radioactivity was nonextractable and 5.7% had been mineralized to CO<sub>2</sub>. Under anaerobic conditions oryzalin nitro groups undergo reduction to amines, dealkylation, and ring formation to produce benzimidazoles, with a half-life of 10 days (MRID 41322802). Anaerobic metabolites that accounted for < 0.2% are UN-1, OR-2, OR-15, and OR-20. **Table 2.2** provides names, structures and the occurrence of various degradates detected in environmental fate studies.

In the field, oryzalin appears to dissipate slowly with a half-life of 68 days in Florida sand soil and a first phase half-life of 58 days in California loam soil and 77 days in Michigan silty clay loam soil. The second phase half-lives were 146 days in California loam soil and 138 days in Michigan silty clay loam soil. Parent oryzalin did not appear to be mobile under field conditions. The parent was undetectable and always less than detection limits (*i.e.*, 0.01 ppm; MRID 42138001) below 12 inches of soil depth. Oryzalin degradates were not monitored in the field dissipation studies submitted. Although oryzalin does not appear to be mobile under field conditions, the soil partition coefficients ( $K_{oc} = 602$  to  $1109 \text{ L Kg}^{-1}$ ; MRID 41479802) indicate that chemical mobility will vary from moderately mobile to slightly mobile according to FAO Classification Scheme (FAO, 2000) depending on soil type and organic matter content.

Oryzalin has potential to contaminate surface water via spray drift and runoff. Substantial quantities of oryzalin could be available for runoff for a few days to months post-application depending on the degree of exposure to sunlight (photodegradation on soil half-life of 3.8 days; aerobic soil half-life of 63 days; terrestrial field dissipation half-lives of 77-138 and 58-146 days). The soil partitioning coefficients of oryzalin indicates that fractions of oryzalin could be transported via both dissolution in runoff water and adsorption to eroding soil in the event of significant rainfall occurring after application prior to soil incorporation. Based upon its  $K_{oc}$ , significant fractions of the oryzalin in receiving surface waters should exist both dissolved in the water column and adsorbed to suspended sediment. The susceptibility of oryzalin to direct photolysis in water (half-life = 1.4 hours) should limit its persistence in clear shallow waters with low light attenuation. However, its resistance to abiotic hydrolysis coupled with only a moderate susceptibility to aerobic biodegradation indicate that it will be somewhat more persistent in receiving surface waters that are deeper, have high light attenuation, low microbiological activities and long hydrological resident times.

Oryzalin is less likely to contaminate ground water resources due to reduction in the anaerobic soil layer. However, in sandy soils under some environmental conditions, such as excess precipitation, or where soil preferential flow conditions exist and exposure to sunlight is minimal, oryzalin residues may leach into ground water and undergo reduction to more polar compounds.

Based on a laboratory bioaccumulation study (MRID 40787501), oryzalin did not significantly bioconcentrate in bluegill sunfish. The BCFs were 32X in edible tissue, 105X in nonedible tissue, and 66X in whole fish. Depuration ranged from 79.2 to 80.8% after 24 hours and 88.7 to 95.1% after 14 days.

Nine degradates have been identified for oryzalin in the soil aerobic metabolism study. Three other degradates were also identified in various fate studies (**Table 2.2**). The main degradate is 4-hydroxy-3,5-dinitrobenzenesulfonamide, which accounted for a maximum of 4.7% of radioactivity at 1 month post-treatment in the soil aerobic metabolism study. Eight other degradates were isolated, but each comprised  $\leq 2.4\%$  of the applied radioactivity. The available data on degradates of oryzalin are insufficient to assess their runoff characteristics or persistence in surface waters. The registrant conducted a

mobility/adsorption/desorption study to determine the mobility of nine oryzalin degradates and whether or not degradate leaching is a major route of dissipation. Out of nine metabolites formed, three (OR-20, UN-2, and the unidentified compound UN-3; MRID 43433202) appeared to be very mobile.

<b>Table 2.2. Oryzalin Degradates Identified in Environmental Fate Studies</b>			
<b>Code</b>	<b>Structure</b>	<b>IUPAC Name</b>	<b>Percent Formation /Reference</b>
OR-2		3,5-dinitro-4-(propylamino) benzenesulfonamide	(≤2.4%) MRID 41322801 <sup>1</sup> (<0.2 %) MRID 41322802 <sup>2</sup>
OR-3		3,5-dinitro-4-amino benzenesulfonamide	(5.7%) MRID 41278701 <sup>3</sup> (2.6%) MRID 41050001 <sup>4</sup>
OR-4		3-amino-4-(dipropylamino)-5-nitrobenzenesulfonamide	(≤2.4%) MRID 41322801 MRID 41322802
OR-5		3-amino-4-propylamino)-5-nitrobenzenesulfonamide	(4.0%) MRID 41278701
OR-9		3,4,5-triaminobenzene-sulfonamide	(≤2.4%) MRID 41322801
OR-13		2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide	(≤2.4%) MRID 41322801 MRID 41322802
OR-15		2-ethyl-7-nitro-1H-benzimidazole-5-sulfonamide	(≤2.4%) MRID 41322801 (< 0.2%) MRID 41322802 (3.2%) MRID 41050001
OR-20		4-hydroxy-3,5-dinitro benzenesulfonamide	(4.7%) MRID 41322801 (< 0.2%) MRID 41322802



Table 2.2. Oryzalin Degradates Identified in Environmental Fate Studies			
Code	Structure	IUPAC Name	Percent Formation /Reference
OR-21		3,4-dinitro-4-dipropylamineo-sulfanalic acid	(4.6%) MRID 41050001
OR-41		4-[(2-hydroxypropylamino)]-3,5-dinitrobenzenesulfonamide	(≤2.4%) MRID 41322801
UN-1		3,3'-azoxybis[(4-propylamino)-5-nitro]benzenesulfonamide	(≤2.4%) MRID 41322801 (< 0.2%) MRID 41322802
UN-2		2-ethyl-7-nitro-1-propyl-1H-benzimidazole-5-sulfonamide-3-oxide	(≤2.4%) MRID 41322801 MRID 41322802 (14%) MRID 41278701
<sup>1</sup> Aerobic soil metabolism; <sup>2</sup> Anaerobic soil metabolism; <sup>3</sup> Aquatic photolysis; <sup>4</sup> Soil photolysis			

## 2.4.2. Environmental Transport Mechanisms

Potential transport mechanisms for oryzalin include surface water runoff, spray drift, and secondary drift of volatilized or soil-bound residues leading to deposition onto nearby or more distant ecosystems. Surface water runoff and spray drift are expected to be the major routes of exposure for oryzalin. Based on its low vapor pressure ( $1.0 \times 10^{-7}$  mm Hg at 25°C) and Henry's Law Constant ( $1.8 \times 10^{-8}$  atm·m<sup>3</sup>/mol), volatilization loss of oryzalin from soil and water systems is expected to be insignificant compared to dissipation by abiotic and biotic degradation. Based on low volatility and high sensitivity to photolytic degradation, oryzalin is not expected to be subject to long-range transport.

In general, deposition of drifting pesticides is expected to be greatest close to the site of application. A computer model of spray drift (AgDRIFT) is used to determine potential exposures to aquatic and terrestrial organisms via spray drift. Seedling emergence toxicity studies show that oryzalin is equally toxic to monocot and dicot terrestrial plants, thus the distance of potential impact away from the use sites (action area) is determined by the distance required to fall below the LOC for these non-target plants.

## 2.4.3. Mode of Action

Oryzalin is a broad spectrum herbicide that is used to control seedling grasses and some annual broadleaf weeds in both agricultural and non-agricultural settings. Depending on the formulation, the registered products of oryzalin are applied to the soil surface prior to

the emergence of weeds as broadcast spray or band treatment for liquid formulations (using low pressure ground equipment) or soil broadcast for granular formulations (using spreaders). To facilitate activation and movement of the chemical to the seed germination zone, a single ½ to 1 inch of rainfall or sprinkler irrigation is required. Depending on the rate of application, the soil residual activity of oryzalin ranges between 4 to 10 months.

Oryzalin is mainly absorbed by roots, has little or no foliar activity, and is not translocated within the plant. Thus the primary effect of oryzalin is on root development. Roots of affected plants are relatively few in number, short, thick, and club shaped. The inhibited root growth causes tops of plants to be stunted and become dark green.

Oryzalin, similar to the other members of the chemical family dinitroanilines, acts by disrupting the assembly of microtubules. As a result, mitosis or cell division of plants, ranging from single-celled algae to higher plants, is inhibited. Oryzalin, however, is ineffective against vertebrate and fungal microtubules.

#### **2.4.4. Use Characterization**

Analysis of label use information is the critical first step in evaluating the federal action. The current label for oryzalin represents the FIFRA regulatory action; therefore, use and application rates specified on the label form the basis of this assessment. The assessment of use information is critical to the development of the action area and selection of appropriate modeling scenarios and inputs.

Oryzalin is a dinitroaniline herbicide that is registered nationally for control of annual grasses and certain broadleaf weeds in fruit and nut crops, vineyards, Christmas tree plantations, ornamentals, turf, and several other non-crop sites. Oryzalin is formulated as granules (0.4 to 1% a.i.), wettable powder (75% a.i.), water dispersible granules (60 - 85% a.i.), emulsifiable concentrate (2.84 to 40.4% a.i.), flowable concentrate (40.4% a.i.), and formulation intermediate/liquid (40.4% a.i.). Depending on the formulation, oryzalin is typically applied using low pressure ground equipment or spreaders. The labels for oryzalin caution not to apply this herbicide to Douglas fir, slender deutzia, *Techny arborvitae*, eastern hemlock, begonia, and coleus due to phytotoxicity on the above species.

The following current labeled use categories for oryzalin are considered as part of the federal action evaluated in this assessment: avocado, berries, olives, pome fruits, stone fruits, citrus (selected scenarios are also surrogates for the tropical fruits, papaya and guava), tree nuts, vineyards, ornamentals (landscape gardens, containers, production fields, ornamental bulbs, and ground covers/perennials), Christmas tree plantations, turf, residential areas, forest trees, rights-of-ways, and uncultivated areas. There are no new pending uses for oryzalin at this time.

**Table 2.3** presents the uses and corresponding application rates (single and maximum), application interval, and methods of application considered in this assessment.

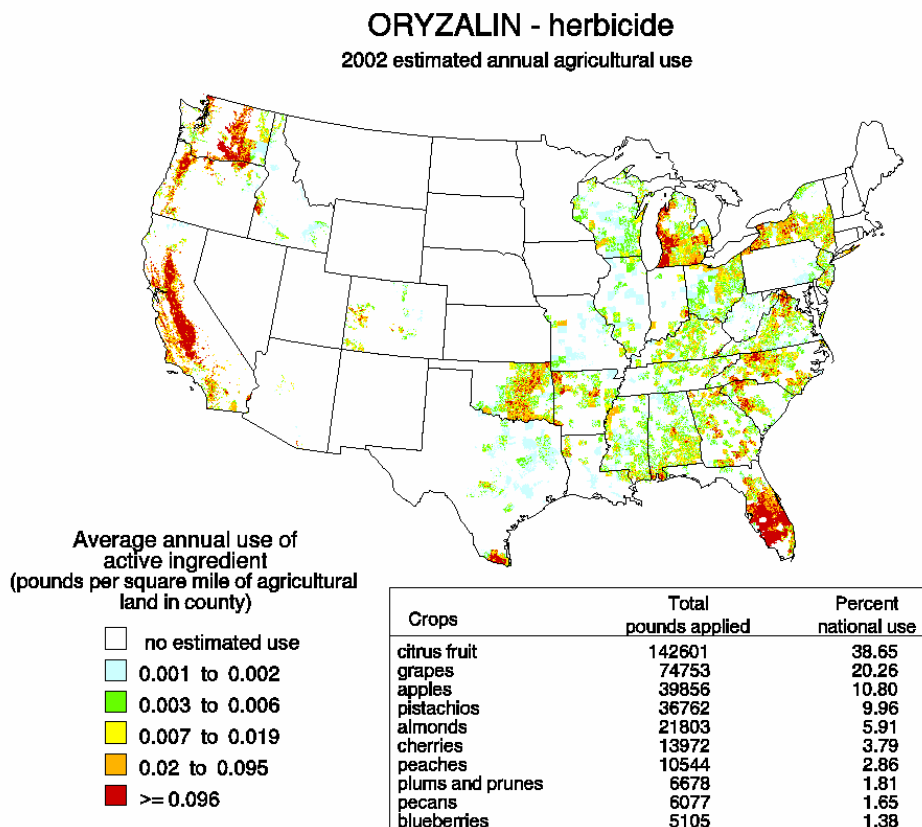
Table 2.3. Oryzalin Uses Assessed for the CTS						
Use Categories	Formulation Code <sup>1</sup>	Application Method	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Year (#)	Maximum Annual Application Rate (lb ai/A)	Application Interval (days)
<b>Avocado</b>  <b>Berries</b> Blackberry, blueberries, boysenberry, caneberries, currant, dewberry, elderberry, gooseberry, loganberry, raspberry  <b>Citrus Fruits</b> Grapefruit, kumquat, kiwi, lime, lemon, mandarin, tangerine, orange, pummelo  <b>Olives</b>  <b>Pome Fruits</b> Apple, crabapple, figs, loquat, mayhaw, pear, pomegranate, quince	EC/DF <sup>2</sup>	Low pressure ground sprayer/ Sprinkler irrigation /Broadcast/ Chemigation/ Soil broadcast treatment	6	2	12	75
<b>Tree Nuts</b> Almonds, cashew, chestnut chinquapin, filbert, hickory nut, macadamia nut, pecan, pistachio walnut  <b>Tropical Fruits</b> Papaya, guava  <b>Stone Fruits</b> Apricot, cherry, nectarine, peach, plum, prune  <b>Vineyards</b> Wine grapes, table grapes	G <sup>3</sup>	Granules by Spreader/ Broadcast	4	4	15	60
<b>Ornamentals</b> <sup>4</sup>	EC/DF/L/WP	Low pressure ground sprayer/ Sprinkler irrigation /Broadcast/ Chemigation/ Soil broadcast treatment	4	3	12	90

<b>Table 2.3. Oryzalin Uses Assessed for the CTS</b>						
<b>Use Categories</b>	<b>Formulation Code<sup>1</sup></b>	<b>Application Method</b>	<b>Maximum Single Application Rate (lb ai/A)</b>	<b>Maximum Number of Applications per Year (#)</b>	<b>Maximum Annual Application Rate (lb ai/A)</b>	<b>Application Interval (days)</b>
	G	Granule applicator Spreader, /Broadcast	4	4	15	60
<b>Ornamental bulbs</b>	EC/L	Low pressure ground sprayer/ Sprayer	1.5	2	2.25	90
	G	Granule applicator Spreader, /Broadcast	1.5	2	2.25	90
<b>Christmas Tree Plantation</b>	EC/DF/L/WP	Low pressure ground sprayer/ Sprayer/ Spreader /Broadcast/ Directed spray/ Soil broadcast treatment	4	2	8	60
	G	Granule applicator Spreader, /Broadcast	4	2	8	60
	G	Granule applicator Spreader, /Broadcast	3.34	5	15	90
<b>Forest Trees</b>	EC/L	Low pressure ground sprayer/ Broadcast	6	2	12	75
<b>Turf</b>	EC/L	Low pressure ground sprayer/ Sprayer	2	3	6	90
	G	Granule applicator Spreader, /Broadcast	1.5	4	6	90
<b>Rights-of-ways<sup>5</sup></b>	EC/L/WP	Low pressure ground sprayer/ Sprayer	6	2	12	180

<b>Table 2.3. Oryzalin Uses Assessed for the CTS</b>						
<b>Use Categories</b>	<b>Formulation Code<sup>1</sup></b>	<b>Application Method</b>	<b>Maximum Single Application Rate (lb ai/A)</b>	<b>Maximum Number of Applications per Year (#)</b>	<b>Maximum Annual Application Rate (lb ai/A)</b>	<b>Application Interval (days)</b>
	G	Granule applicator Spreader, /Broadcast	6	2	12	240
<b>Residential areas</b>	G	Granule applicator Spreader	2	3	6	56
<b>Uncultivated Areas</b>	DF	Low pressure ground sprayer	6	2	12	180
<sup>1</sup> Formulation codes: DF- Water Dispersible Granules (Dry Flowable); EC-Emulsifiable Concentrate; G-Granular; L-Liquid; WP-Wettable Powder <sup>2</sup> This rate applies to bearing trees only. The non-bearing rate was not considered a maximum labeled application rate (4 applications at 3 lb a.i./acre for a total of 12 lb a.i./acre/year); therefore, it was not modeled. <sup>3</sup> This rate applies to bearing and non-bearing trees. <sup>4</sup> Use in landscape gardens, container and field grown ornamentals, drainage areas under shadehouse benches, ground covers/perennials. Scenario includes landscape maintenance. <sup>5</sup> Scenario conservatively accounts for industrial areas (outdoor) and buildings and structures.						

A national map (**Figure 2.1**) showing the extent of estimated annual oryzalin uses across the United States as of 2002 is provided below. The map was downloaded from U.S. Geological Survey (USGS), National Water Quality Assessment Program (NAWQA) website. As of 2002, over 93% of total agricultural uses for oryzalin are in the crops listed in **Figure 2.1**. The highest poundage (142,601 lbs) of oryzalin was applied to citrus fruits. Grapes (74,753 lbs) and apples (39,855 lbs) represented the second and third highest total pounds of oryzalin applied.

**Figure 2.1. Oryzalin Use in Total Pounds per County**



The Agency's Biological and Economic Analysis Division (BEAD) provides an analysis of both national- and county-level usage information (Kaul and Jones, 2006) using state-level usage data obtained from USDA-NASS<sup>1</sup>, Doane ([www.doane.com](http://www.doane.com); the full dataset is not provided due to its proprietary nature) and the California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database<sup>2</sup>. CDPR PUR is considered a more comprehensive source of usage data than USDA-NASS or proprietary databases, and thus the usage data reported for oryzalin by county in this California-specific assessment were generated using CDPR PUR data. Ten years (1999-2008) of usage data were included in this analysis. Data from CDPR PUR were obtained for every pesticide application made on every use site at the section level (approximately one square mile) of the public land survey system. BEAD summarized these data to the county level by site, pesticide, and unit treated. Calculating county-level usage involved summarizing across all applications made within a section and then across all sections within a county for each use site and for each pesticide. The county level usage data that were calculated

<sup>1</sup>United States Department of Agriculture (USDA), National Agricultural Statistics Service (NASS) Chemical Use Reports provide summary pesticide usage statistics for select agricultural use sites by chemical, crop and state. See <http://www.usda.gov/nass/pubs/estindx1.htm#agchem>.

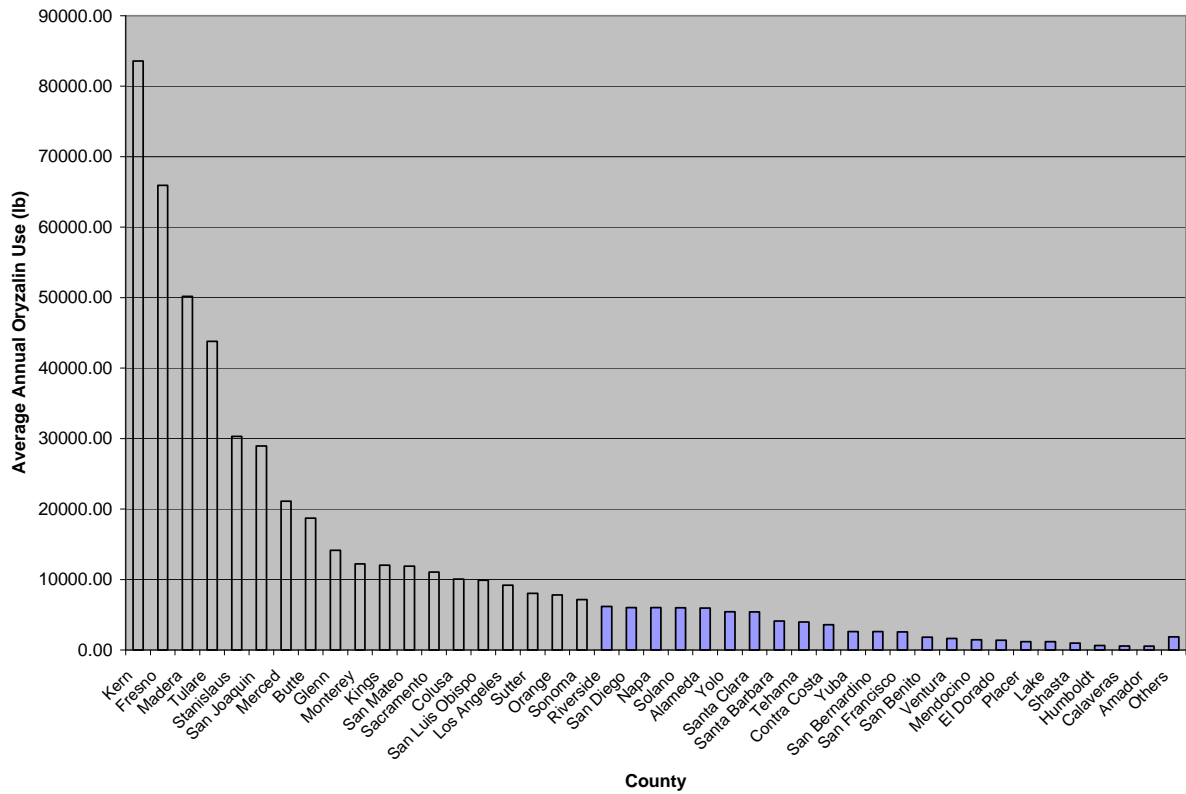
<sup>2</sup>The California Department of Pesticide Regulation's Pesticide Use Reporting database provides a census of pesticide applications in the state. See <http://www.cdpr.ca.gov/docs/pur/purmain.htm>.

include: average annual pounds applied, average annual area treated, and average and maximum application rate across all ten years.

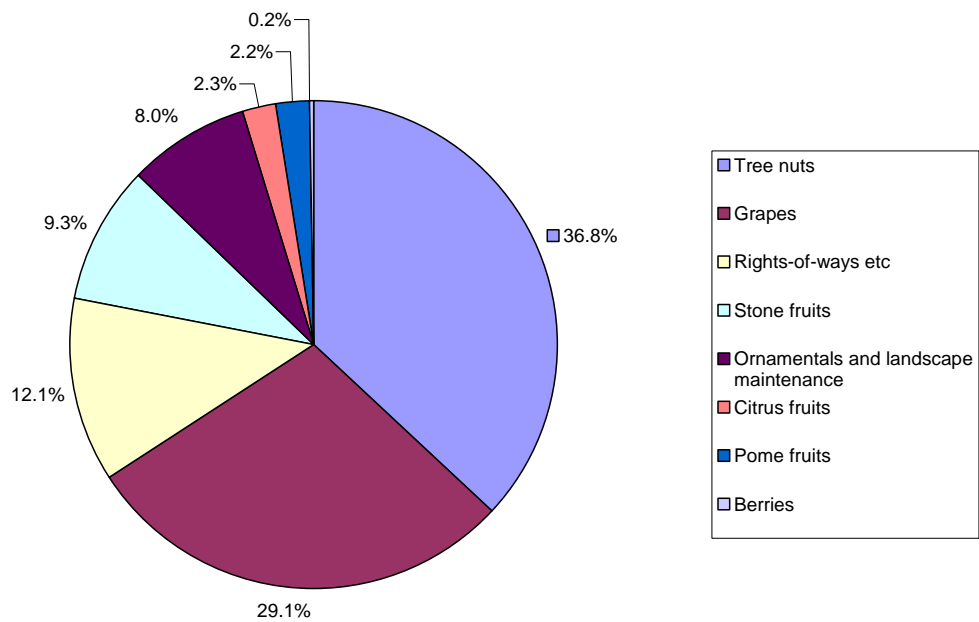
During the period 1999 to 2008, oryzalin use was reported in 55 counties in California. Of the 55 counties, 42 counties listed in **Figure 2.2** used more than 500 pounds of oryzalin per year on average during 1999-2008. The principal use categories were tree nuts, grapes, rights-of-ways, stone fruits, ornamentals and landscape maintenance, citrus fruits, pome fruits, and berries. The PUR data included approximately 1169 pounds of use information on crops for which oryzalin is not registered. Because these uses are not part of the federal action, they were not included in this assessment.

During 1999 - 2008, the percentage of total oryzalin use in California was highest on tree nuts (36.8% of total use), followed by grapes (29.1%), right-of ways and similar areas (12.1%), stone fruits (9.3%), ornamentals and landscape maintenance (8%), citrus fruits (2.3%), pome fruits (2.2%), and berries (0.2%) (**Figure 2.3**). The annual average for all reported uses over this ten-year period was 530,470 pounds per year. Use data from 1999 - 2008 for California indicate that oryzalin is applied throughout the year, with the majority of applications occurring during the late winter to early spring months (December -March). A summary of oryzalin usage for all California use sites is provided in **Table 2.4**.

**Figure 2.2. Oryzalin Usage in California (1999 - 2008) by County**



**Figure 2.3. Major Uses of Oryzalin in California during 1999 - 2008**





**Table 2.4. Summary of California Department of Pesticide Regulation (CDPR)'s Pesticide Use Reporting (PUR<sup>1</sup>) Data from 1999 to 2008 for Currently Registered Oryzalin Uses**

Site Name <sup>1</sup>	Average Annual Use (lb)	Average Application Rate All Uses	Average 95 <sup>th</sup> Percentile Application Rate	Average 99 <sup>th</sup> Percentile Application Rate	Average Maximum Application Rate
Tree nuts (almond, chestnut, pecan, pistachio, walnut)	194,635	2.0	4.4	5.7	24.8
Grapes (table and wine)	153,961	1.9	4.1	6.1	30.0
Rights-of-ways, Industrial sites, Ditch banks, Building/non- agricultural outdoor uses	63,968	1.2	2.5	3.5	3.5
Stone fruits (apricot, avocado, cherry, nectarine, olive, peach, plum, prune)	48,944	2.1	4.1	6.4	17.8
Ornamentals and landscape maintenance	42,220	2.9	6.2	19.3	55.9
Citrus fruits (grapefruit, kiwi, kumquat, lemon, orange, tangelo, tangerine)	12,390	2.7	4.3	6.1	10.8
Pome fruits (apple, fig, orchard floor, pear, pomegranate, quince)	11,741	2.3	3.9	13.0	30.6
Unknown or non-registered uses <sup>2</sup>	1,169	2.3	3.3	3.6	3.6
Berries (blackberry, blueberry, boysenberry, raspberry)	809	2.8	5.1	6.2	6.5
Uncultivated areas	542	3.0	6.1	8.7	9.7
Christmas tree plantations	66	1.4	4.0	4.0	4.0
Forest trees	13	2.1	5.0	5.0	5.0
Turf	12	1.9	3.1	3.2	3.2

<sup>1</sup>Use reports in CDPR PUR that represent misuse or misreporting are not included in this table.

<sup>2</sup>Crops include alfalfa, bean, corn, broccoli, melon, oat, persimmon, poultry, pumpkin, sorghum/milo, squash, strawberry, sunflower, and watermelon. Because the PUR data included crops on which oryzalin is no longer or was never registered for use, this category is not part of the federal action, and these uses are excluded from the assessment.

## 2.5. Assessed Species

**Table 2.5** provides a summary of the current distribution, habitat requirements, and life history parameters for the CTS. More detailed life-history and distribution information can be found in **Attachment 2**. The distribution of CTS within California is presented in **Figure 2.4**.

There are currently three CTS Distinct Population Segments (DPSs): the Sonoma County (SC) DPS, the Santa Barbara (SB) DPS, and the Central California (CC) DPS. Each DPS

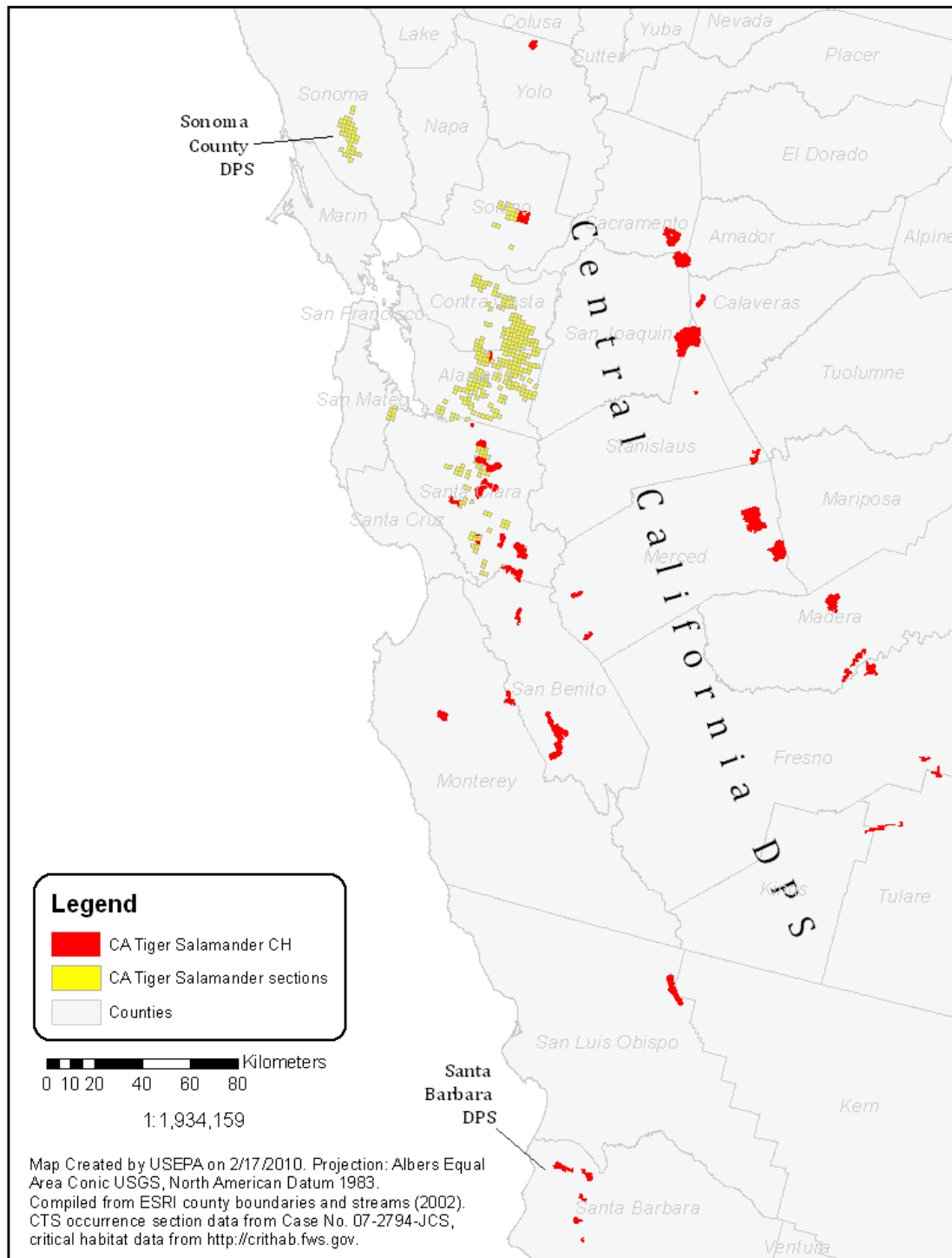
is considered separately in the risk assessment as they occupy different geographic areas. The main difference in the assessment will be in the spatial analysis. The CTS-SB and CTS-SC were downlisted from endangered to threatened in 2004 by the USFWS, however, the downlisting was vacated by the U.S. District Court. Therefore, the Sonoma and Santa Barbara DPSs are currently listed as endangered while the CTS-CC is listed as threatened. CTS utilize vernal pools, semi-permanent ponds, and permanent ponds, and the terrestrial environment in California. The aquatic environment is essential for breeding and reproduction and mammal burrows are also important habitat for aestivation.

The CTS is found in grassland and oak savannah communities in central California, where it seasonally utilizes standing bodies of water (*e.g.*, fishless ponds) for breeding, egg-laying, and as larval habitat. In 2004, the USFWS listed the CTS as threatened throughout its entire range; this included a downlisting of the Santa Barbara County and Sonoma County DPSs from endangered to threatened and a new listing of the Central California DPS as threatened. The downlisting of the Santa Barbara County and Sonoma County DPSs was vacated by the U.S. District Court in August 2005. As a result, the Santa Barbara County and Sonoma County CTS DPSs are currently listed as endangered, while the Central California CTS DPS remains listed as threatened.

**Table 2.5. Summary of Current Distribution, Habitat Requirements, and Life History Information for the CTS<sup>1</sup>**

Assessed Species	Size	Current Range	Habitat Type	Designated Critical Habitat?	Reproductive Cycle	Diet
California Tiger Salamander (CTS) ( <a href="#">Ambystoma californiense</a> )	50 g	<p>This assessment applies to three DPSs: Central California, Santa Barbara County, and Sonoma County.</p> <p>CTS-SC are primarily found on the Santa Rosa Plain in Sonoma County.</p> <p>CTS-CC occupies the Bay Area (central and southern Alameda, Santa Clara, western Stanislaus, western Merced, and the majority of San Benito Counties), Central Valley (Yolo, Sacramento, Solano, eastern Contra Costa, northeast Alameda, San Joaquin, Stanislaus, Merced, and northwestern Madera Counties), southern San Joaquin Valley (portions of Madera, central Fresno, and northern Tulare and Kings Counties), and the Central Coast Range (southern Santa Cruz, Monterey, northern San Luis Obispo, and portions of western San Benito, Fresno, and Kern Counties).</p> <p>CTS-SB are found in Santa Barbara County</p>	Freshwater pools or ponds (natural or man-made, vernal pools, ranch stock ponds, other fishless ponds); Grassland or oak savannah communities, in low foothill regions; Small mammal burrows	Yes  (Central California DPS and Santa Barbara County DPS)	<p><u>Emerge from burrows and breed:</u> fall and winter rains</p> <p><u>Eggs:</u> laid in pond Dec. – Feb., hatch: after 10 to 14 days</p> <p><u>Larval stage:</u> 3-6 months, until the ponds dry out, metamorphose late spring or early summer, migrate to small mammal burrows</p>	<p>Aquatic Phase: algae and zooplankton; small crustaceans, snails, and other invertebrates; smaller tadpoles of Pacific tree frogs, CRLF, and toads; small fish</p> <p>Terrestrial Phase: insects, worms, and other terrestrial invertebrates; amphibians; small mammals</p>

<sup>1</sup>For more detailed information on the distribution, habitat requirements, and life history information of the assessed listed species, see **Attachment 2.**



## 2.6. Designated Critical Habitat

Critical habitat has been designated for CTS in the Central California and Santa Barbara County DPSs. Potential modification of critical habitat is evaluated separately from risk to effects on the species. ‘Critical habitat’ is defined in the ESA as the geographic area occupied by the species at the time of the listing where the physical and biological features necessary for the conservation of the species exist and where there is a need for special management to protect the listed species. It may include areas outside the occupied area at the time of listing if such areas are essential to the conservation of the species. Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species or areas that contain certain primary constituent elements (PCEs), as defined in 50 CFR 414.12(b). **Table 2.6** describes the PCEs for the critical habitats designated for the CTS.

Table 2.6. Designated Critical Habitat PCEs for the CTS <sup>1</sup>		
Species	PCEs	Reference
California tiger salamander	Standing bodies of fresh water, including natural and man-made ( <i>e.g.</i> , stock) ponds, vernal pools, and dune ponds, and other ephemeral or permanent water bodies that typically become inundated during winter rains and hold water for a sufficient length of time ( <i>i.e.</i> , 12 weeks) necessary for the species to complete the aquatic (egg and larval) portion of its life cycle <sup>2</sup>	FR Vol. 69 No. 226 CTS, 68584, 2004
	Barrier-free uplands adjacent to breeding ponds that contain small mammal burrows. Small mammals are essential in creating the underground habitat that juvenile and adult California tiger salamanders depend upon for food, shelter, and protection from the elements and predation	
	Upland areas between breeding locations (PCE 1) and areas with small mammal burrows (PCE 2) that allow for dispersal among such sites	
<sup>1</sup> These PCEs are in addition to more general requirements for habitat areas that provide essential life cycle needs of the species such as, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species. <sup>2</sup> PCEs that are abiotic, including, physical-chemical water quality parameters such as salinity, pH, and hardness are not evaluated because these processes are not biologically mediated and, therefore, are not relevant to the endpoints included in this assessment.		

In addition to the PCEs listed above, critical habitat for the CTS includes a prey base suitable to sustain the individual CTS and the designated DPS. More detail on the designated critical habitat applicable to this assessment can be found in Attachment 2. Activities that may destroy or modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the species. Evaluation of actions related to use of oryzalin that may alter the PCEs of the designated critical habitat for the CTS form the basis of the critical habitat impact analysis.

As previously noted, the Agency uses the analysis of direct and indirect effects to listed species as the basis for analysis of potential effects on the designated critical habitat. Oryzalin may directly impact living organisms within the action area; for the purposes of this assessment, the critical habitat analysis for oryzalin is limited to the PCEs and other

elements (*i.e.*, prey base) of critical habitat that are biological or are linked to biologically mediated processes.

## **2.7. Action Area**

The action area is the geographic area that could be affected by the Federal action. The Federal action is the authorization or registration of pesticide use or uses as described on the label(s) of pesticide products containing a particular active ingredient. The action area is defined by the Endangered Species Act as, “all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action” (50 CFR §402.2). Based on an analysis of the Federal action, the action area is defined by the actual and potential use of the pesticide and areas where that use could result in effects. Specific measures of ecological effect for the assessed species that define the action area include any direct and indirect adverse (*e.g.*, toxic) effects to the assessed species, including reductions in survival, growth, and fecundity; sublethal effects described in the literature; and any potential modification of designated critical habitat.

The overall action area for the national registration of oryzalin is likely to encompass considerable portions of the United States, based on the large array of agricultural and/or non-agricultural uses. However, the scope of this assessment limits consideration of the overall action area to those portions that may be applicable to the protection of CTS and their designated critical habitat within the state of California. For this assessment, the entire state of California is considered the action area. The purpose of defining the action area as the entire state of California is to ensure that the initial area of consideration encompasses all areas where the pesticide may be used now and in the future, including the potential for off-site transport via spray drift and downstream dilution that could influence the CTS. For example, although the CTS primarily occupies standing bodies of water as aquatic habitat for breeding and larval development, these bodies of water may be connected with or supplied by flowing surface waters that can introduce oryzalin from the target application site. Additionally, the concept of a state-wide action area takes into account the potential for direct and indirect effects and potential modification to critical habitat based on ecological effect measures that are associated with reductions in survival, growth, and reproduction, as well as sublethal effects documented in the literature.

It is important to note that the state-wide action area does not imply that direct and/or indirect effects and/or critical habitat modification are expected or are likely to occur over the full extent of the action area, but rather to identify all areas that may potentially be affected by the action. The Agency uses more rigorous analysis including consideration of available land cover data, toxicity data, and exposure information to determine areas where CTS and designated critical habitat may be affected or modified via endpoints associated with reduced survival, growth, or reproduction.

### **2.7.1. Effects Determination Area**

A stepwise approach is used to define and assess risk within the Effects Determination Area. In the case of oryzalin, the Effects Determination Area includes each area where it

is expected that labeled use of the pesticide may directly or indirectly affect the CTS and/or modify its critical habitat, based upon the scope of the assessment, standard assessment procedures (see Attachment 2; USEPA), and effects endpoints related to survival, growth, and reproduction. In other words, this is the area where the “Potential Area of Effects” (initial area of concern, defined by the action area and oryzalin use patterns, plus drift distance and downstream dilution distance) overlaps with the designated portions of CTS range and/or critical habitat (*i.e.*, Central California, Santa Barbara County, and Sonoma County DPSs). If there is no overlap between the potential area of effects and the designated habitat or occurrence areas, or if overlap is present but the assessment indicates that adverse effects are not expected, a “no effect” determination is made. Alternatively, a “likely to adversely affect (LAA)” determination applies when it is expected that use of the pesticide will directly or indirectly affect the CTS and/or modify its designated critical habitat.

The first step in establishing the Effects Determination Area is to understand the federal action, as defined by the currently labeled uses for oryzalin. Based upon an analysis of labeled oryzalin uses and review of available product labels, the following agricultural uses are considered relevant to the CTS and, therefore, comprise the federal action evaluated in this assessment:

- Avocados
- Berries
  - Blackberries
  - Blueberries
  - Boysenberries
  - Caneberries
  - Currant
  - Dewberry
  - Elderberry
  - Gooseberry
  - Loganberries
  - Raspberries
- Citrus
  - Grapefruit
  - Kiwi
  - Kumquat
  - Lime
  - Lemon
  - Mandarin
  - Tangerine
  - Orange
  - Pummelo
- Olives

- Pome Fruits
  - Apples
  - Crabapple
  - Figs
  - Loquat
  - Mayhaw
  - Pear
  - Pomegranate
  - Quince
- Stone Fruits
  - Apricot
  - Cherries
  - Nectarine
  - Peach
  - Plum
  - Prune
- Tree nuts
  - Almonds
  - Cashew
  - Chestnut
  - Chinquapin
  - Filbert
  - Hickory nut
  - Macadamia nut
  - Pecan
  - Pistachio
  - Walnut
- Tropical Fruits
  - Guava
  - Papaya
- Vineyards
  - Grapes (wine)
  - Grape (table)

In addition, the following non-agricultural uses are considered:

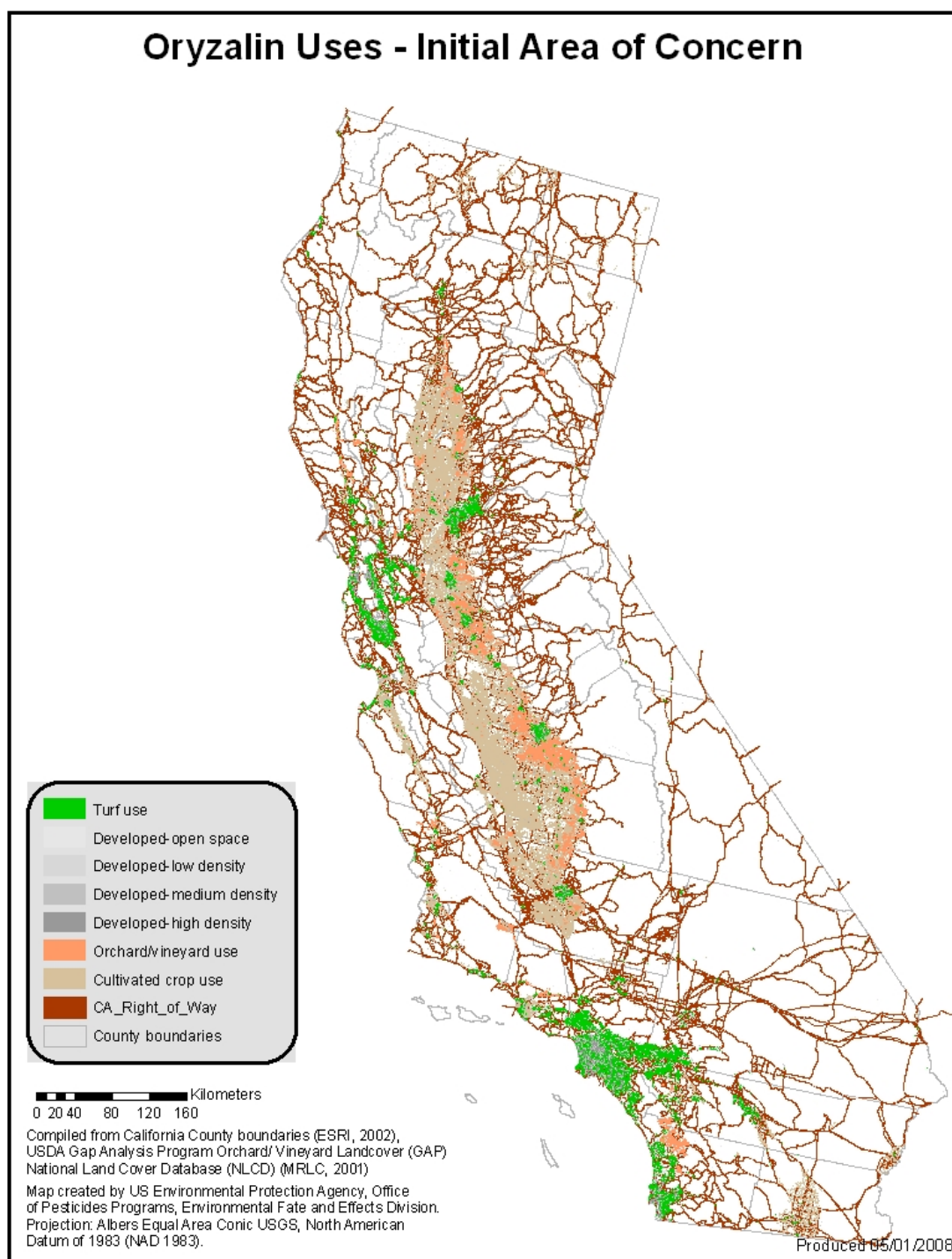
- Christmas Tree Plantations
- Landscape maintenance
- Rights-of-ways
- Residential areas/lawns
- Ornamentals



- Ornamentals bulbs
- Turf
- Forest trees
- Industrial areas (outdoor), buildings and structures
- Uncultivated areas/soils

Following a determination of the assessed uses, an evaluation of the potential “footprint” of oryzalin use patterns (*i.e.*, the area where pesticide application could occur) is determined. This “footprint” represents the initial area of concern, based on an analysis of available land cover data for the state of California. The initial area of concern is defined as all land cover types and the stream reaches within the land cover areas that represent the labeled uses described above. A map representing all the land cover types that make up the initial area of concern for oryzalin is presented in **Figure 2.5**. Additional GIS maps and related details are presented in **Appendix D**.

**Figure 2.5. Initial area of concern or “footprint” of potential uses for Oryzalin**



Once the initial area of concern is defined, the next step is to define the potential boundaries of the action area by determining the extent of offsite transport via spray drift and runoff where exposure of one or more taxonomic groups to the pesticide exceeds the listed species LOCs.

As previously discussed, the action area is defined by the most sensitive measure of direct and indirect ecological toxic effects including reduction in survival, growth, reproduction, and the entire suite of sublethal effects from valid, peer-reviewed studies.

Due to the positive results in both the carcinogenicity and mutagenicity tests (HED's Risk Assessment for Tolerance Reassessment Eligibility Decision (TRED) dated 5/18/2004, D300962; **Appendix J**), the spatial extent of the action area (*i.e.*, the boundary where exposures and potential effects are less than the Agency's LOC) for oryzalin cannot be determined because a threshold above which some effect to a component of the environment may occur cannot be defined. Therefore, it is assumed that the action area encompasses the entire state of California, regardless of the spatial extent (*i.e.*, initial area of concern or footprint) of the pesticide use(s).

## **2.8. Assessment Endpoints and Measures of Ecological Effect**

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected."<sup>3</sup> Selection of the assessment endpoints is based on valued entities (*e.g.*, CTS, organisms important in the life cycle of the CTS, and the PCEs of its designated critical habitat), the ecosystems potentially at risk (*e.g.*, water bodies, riparian vegetation, and upland and dispersal habitats), the migration pathways of oryzalin (*e.g.*, runoff, spray drift, etc.), and the routes by which ecological receptors are exposed to oryzalin (*e.g.*, direct contact, *etc.*).

### **2.8.1. Assessment Endpoints for the CTS**

Assessment endpoints for the CTS include direct toxic effects on the survival, reproduction, and growth of the CTS, as well as indirect effects, such as reduction of the prey base or modification of its habitat. In addition, potential modification of critical habitat is assessed by evaluating potential effects to PCEs, which are components of the habitat areas that provide essential life cycle needs of the CTS. Each assessment endpoint requires one or more "measures of ecological effect," defined as changes in the attributes of an assessment endpoint or changes in a surrogate entity or attribute in response to exposure to a pesticide. Specific measures of ecological effect are generally evaluated based on acute and chronic toxicity information from registrant-submitted guideline tests that are performed on a limited number of organisms. Additional ecological effects data from the open literature are also considered (**Appendix K** and **H**). It should be noted that assessment endpoints are limited to direct and indirect effects associated with survival, growth, and fecundity and do not include the full suite of sublethal effects used to define the action area. According the Overview Document (USEPA, 2004), the Agency relies on acute and chronic effects endpoints that are either direct measures of impairment of survival, growth, or fecundity or endpoints for which there is a scientifically robust, peer reviewed relationship that can quantify the impact of the measured effect endpoint on the assessment endpoints of survival, growth, and fecundity.

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<sup>3</sup> From USEPA (1992). *Framework for Ecological Risk Assessment*. EPA/630/R-92/001.

A complete discussion of all the toxicity data available for this risk assessment, including resulting measures of ecological effect selected for each taxonomic group of concern, is included in **Section 4** of this document. A summary of the assessment endpoints and measures of ecological effect selected to characterize potential assessed direct and indirect CTS risks associated with exposure to oryzalin is provided in **Table 2.7**.

<b>Table 2.7. Assessment Endpoints and Measures of Ecological Effects</b>	
<b>Assessment Endpoint</b>	<b>Measures of Ecological Effects<sup>4</sup></b>
<i>Aquatic-Phase CTS (Eggs, larvae, juveniles, and adults)<sup>1</sup></i>	
<i>Direct Effects</i>	
1. Survival, growth, and reproduction of CTS	1a. Bluegill sunfish LC <sub>50</sub> 1b. Fathead minnow chronic NOAEC
<i>Indirect Effects and Critical Habitat Effects</i>	
2. Survival, growth, and reproduction of CTS individuals via indirect effects on aquatic prey food supply ( <i>i.e.</i> , fish, freshwater invertebrates, non-vascular plants)	2a. Bluegill sunfish LC <sub>50</sub> 2b. Fathead minnow chronic NOAEC 2c. Water flea LC <sub>50</sub> 2d. Water flea NOAEC 2e. Non-vascular plant (green algae) EC <sub>50</sub>
3. Survival, growth, and reproduction of CTS individuals via indirect effects on habitat, cover, food supply, and/or primary productivity ( <i>i.e.</i> , aquatic plant community)	3a. Vascular plant acute EC <sub>50</sub> (duckweed) 3b. Non-vascular plant acute EC <sub>50</sub> (green algae)
4. Survival, growth, and reproduction of CTS individuals via effects to riparian vegetation	4a. Monocot and dicot EC <sub>25</sub> values 4b. Monocot and dicot NOAEC values
<i>Terrestrial-Phase CTS (Juveniles and adults)</i>	
<i>Direct Effects</i>	
5. Survival, growth, and reproduction of CTS individuals via direct effects on terrestrial phase adults and juveniles	5a. Bobwhite quail <sup>2</sup> acute LC <sub>50</sub> and LD <sub>50</sub> 5b. Bobwhite quail chronic NOAEC
<i>Indirect Effects and Critical Habitat Effects</i>	
6. Survival, growth, and reproduction of CTS individuals via effects on terrestrial prey ( <i>i.e.</i> , terrestrial invertebrates, small mammals, and amphibians)	6a. Honey bee oral acute LD <sub>50</sub> 6b. Rat acute LD <sub>50</sub> 6c. Rat chronic NOAEC 6d. Bobwhite quail <sup>b</sup> acute LC <sub>50</sub> and LD <sub>50</sub> 6e. Bobwhite quail chronic NOAEC
7. Survival, growth, and reproduction of CTS individuals via indirect effects on habitat ( <i>i.e.</i> , riparian and upland vegetation)	7a. Monocot EC <sub>25</sub> values (seedling emergence) 7b. Dicot EC <sub>25</sub> values (seedling emergence)
<sup>1</sup> Adult salamanders are no longer in the “aquatic phase” of the amphibian life cycle; however, submerged adult salamanders are considered “aquatic” for the purposes of this assessment because exposure pathways in the water are considerably different that exposure pathways on land; <sup>2</sup> Birds are used as surrogates for terrestrial phase amphibians.	

<sup>4</sup>All registrant-submitted and open literature toxicity data reviewed for this assessment are included in **Appendix A**.

### **2.8.2. Assessment Endpoints for Designated Critical Habitat**

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of oryzalin that may alter the PCEs of the assessed species' designated critical habitat. PCEs for the assessed species were previously described in **Section 2.6**. Actions that may modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the assessed species. Therefore, these actions are identified as assessment endpoints. It should be noted that evaluation of PCEs as assessment endpoints is limited to those of a biological nature (*i.e.*, the biological resource requirements for the listed species associated with the critical habitat) and those for which oryzalin effects data are available.

Assessment endpoints used to evaluate potential for direct and indirect effects are equivalent to the assessment endpoints used to evaluate potential effects to designated critical habitat. If a potential for direct or indirect effects is found, then there is also a potential for effects to critical habitat. Some components of these PCEs are associated with physical abiotic features (*e.g.*, presence and/or depth of a water body, or distance between two sites), which are not expected to be measurably altered by use of pesticides.

## **2.9. Conceptual Model**

### **2.9.1. Risk Hypotheses**

Risk hypotheses are specific assumptions about potential adverse effects (*i.e.*, changes in assessment endpoints) and may be based on theory and logic, empirical data, mathematical models, or probability models (USEPA, 1998). For this assessment, the risk is stressor-linked, where the stressor is the release of oryzalin to the environment. The following risk hypotheses are presumed in this assessment:

The labeled use of oryzalin within the action area may:

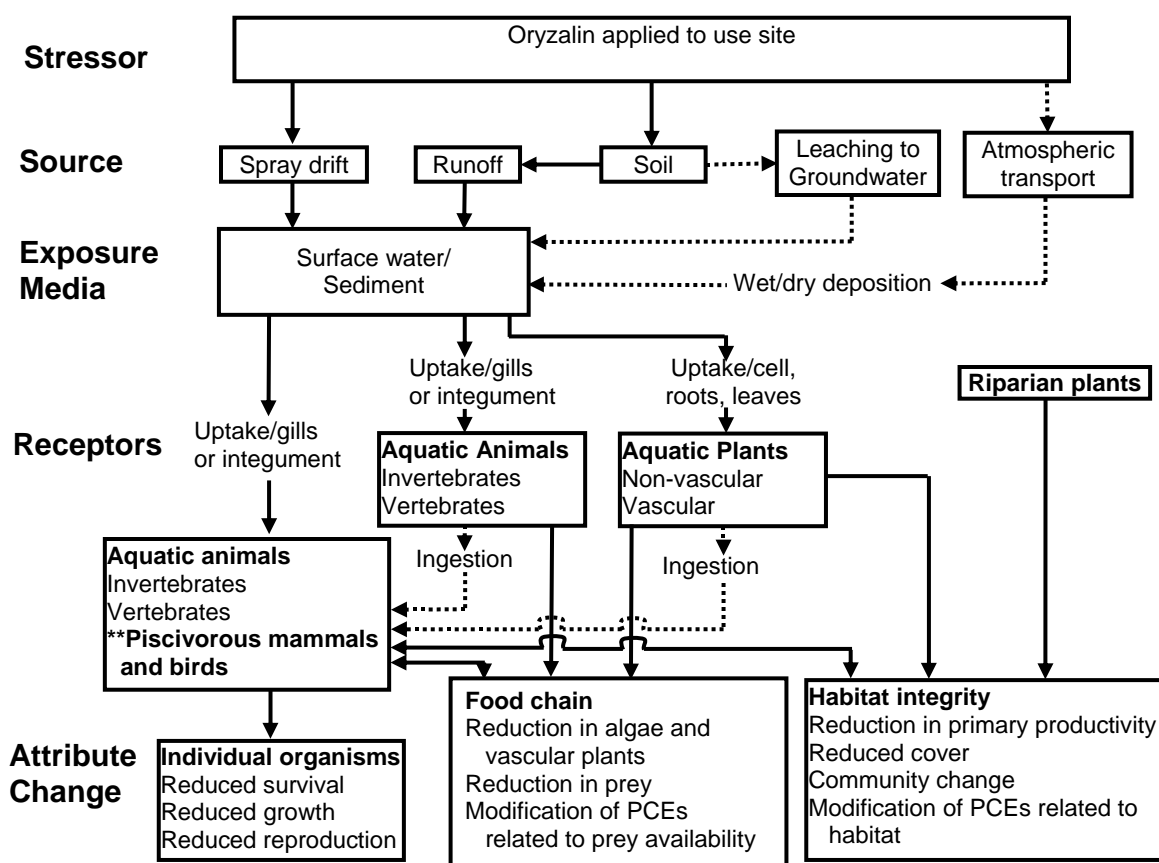
- directly affect CTS by causing mortality or by adversely affecting growth or fecundity;
- indirectly affect CTS and/or modify their designated critical habitat by reducing or changing the composition of food supply;
- indirectly affect CTS and/or modify their designated critical habitat by reducing or changing the composition of the aquatic plant community in the species' current range, thus affecting primary productivity and/or cover;
- indirectly affect CTS and/or modify their designated critical habitat by reducing or changing the composition of the terrestrial plant community in the species' current range;
- indirectly affect CTS and/or modify their designated critical habitat by reducing or changing aquatic habitat in their current range (via modification of water quality parameters, habitat morphology, and/or sedimentation);

- indirectly affect CTS and/or modify their designated critical habitat by reducing or changing terrestrial habitat in their current range (via reduction in small burrowing mammals leading to reduction in underground refugia/cover).

## 2.9.2. Diagram

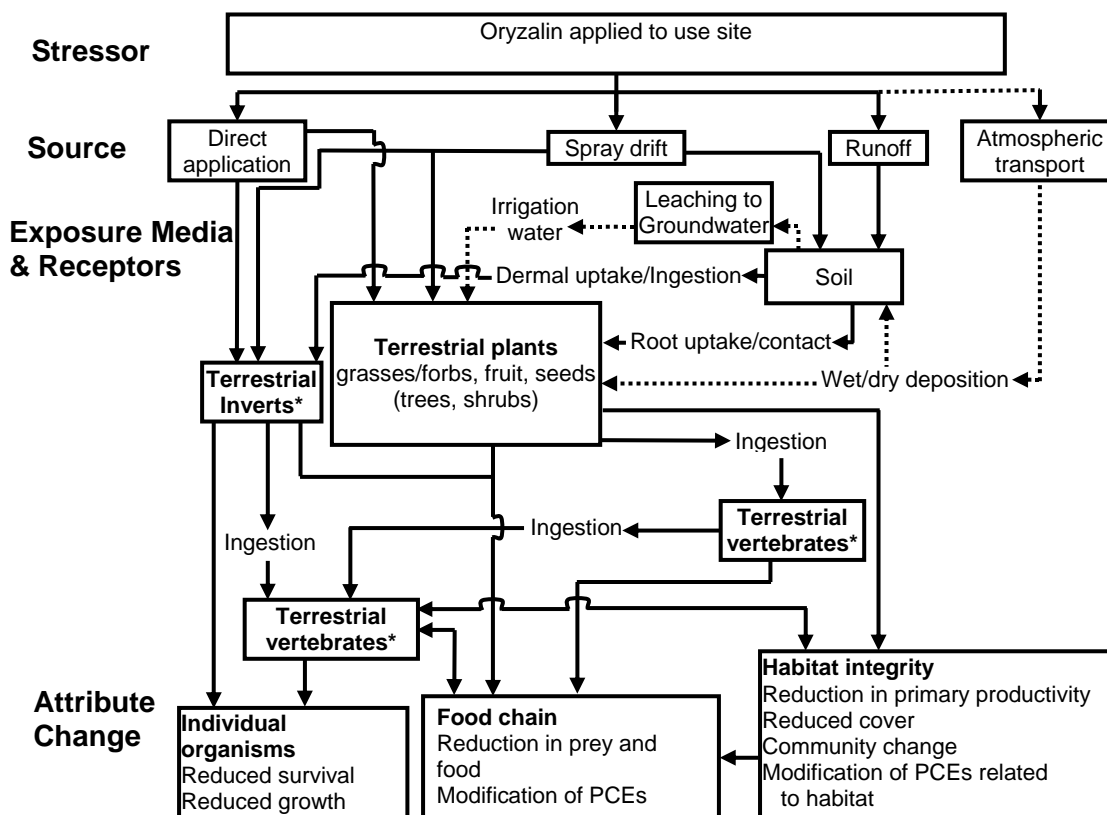
The conceptual model is a graphic representation of the structure of the risk assessment. It specifies the oryzalin release mechanisms, biological receptor types, and effects endpoints of potential concern. The conceptual models for aquatic and terrestrial phases of the CTS are shown in **Figures 2.6** and **2.7**, respectively. Exposure routes shown in dashed lines are not quantitatively considered because the contribution of those potential exposure routes to potential risks to the CTS and modification to designated critical habitat is expected to be negligible.

**Figure 2.6. Conceptual Model for Aquatic-Phase CTS**



**\*\* Route of exposure includes only ingestion of fish and aquatic invertebrates**

**Figure 2.7. Conceptual Model for Terrestrial-Phase CTS**



## 2.10. Analysis Plan

In order to address the risk hypothesis, the potential for direct and indirect effects to the CTS, its prey, and its habitat is estimated. In the following sections, the use, environmental fate, and ecological effects of oryzalin are characterized and integrated to assess the risks. This is accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA, 2004), the likelihood of effects to individual organisms from particular uses of oryzalin is estimated using the probit dose-response slope with either the level of concern (discussed below) or actual calculated risk quotient value.

### 2.10.1. Measures to Evaluate the Risk Hypothesis and Conceptual Model

#### 2.10.1.1. Measures of Exposure

The environmental fate properties of oryzalin along with available monitoring data indicate that runoff and spray drift are the principle potential transport mechanisms of

oryzalin to the aquatic and terrestrial habitats of the CTS. Based on the relatively low volatility and greater sensitivity to photolytic degradation, oryzalin has low potential for long-range transport. There is also no data for oryzalin in the California Pesticide Air Monitoring database; however, it is unknown whether sampling was targeted for oryzalin. Therefore, in this assessment, transport of oryzalin through runoff and spray drift is considered in deriving quantitative estimates of oryzalin exposure to CTS, its prey, and its habitats.

Measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) of oryzalin using maximum labeled application rates and methods of application. The models used to predict aquatic EECs are the Pesticide Root Zone Model coupled with the Exposure Analysis Model System (PRZM/EXAMS). The model used to predict terrestrial EECs on food items is T-REX. The model used to derive EECs relevant to terrestrial and wetland plants is TerrPlant. These models are parameterized using relevant reviewed registrant-submitted environmental fate data.

PRZM (v3.12.2, May 2005) and EXAMS (v2.98.4.6, April 2005) are screening simulation models coupled with the input shell `pe5.pl` (August 2007) to generate daily exposures and 1-in-10 year EECs of oryzalin that may occur in surface water bodies adjacent to application sites receiving oryzalin through runoff and spray drift. PRZM simulates pesticide application, movement and transformation on an agricultural field and the resultant pesticide loadings to a receiving water body via runoff, erosion and spray drift. EXAMS simulates the fate of the pesticide and resulting concentrations in the water body. The standard scenario used for ecological pesticide assessments assumes application to a 10-hectare agricultural field that drains into an adjacent 1-hectare water body, 2-meters deep (20,000 m<sup>3</sup> volume) with no outlet. PRZM/EXAMS was used to estimate screening-level exposure of aquatic organisms to oryzalin. The measure of exposure for aquatic species is the 1-in-10 year return peak or rolling mean concentration. The 1-in-10 year peak is used for estimating acute exposures of direct effects to the CTS, as well as indirect effects to the CTS through effects to potential prey items, including: algae, aquatic invertebrates, fish, and amphibians. The 1-in-10-year 60-day mean is used for assessing chronic exposure to the CTS and fish and amphibians serving as prey items; the 1-in-10-year 21-day mean is used for assessing chronic exposure for aquatic invertebrates, which are also potential prey items.

Exposure estimates for the terrestrial-phase CTS and terrestrial invertebrates and mammals (serving as potential prey) assumed to be in the target area or in an area exposed to spray drift are derived using the T-REX model (version 1.4.1). This model incorporates the Kenaga nomograph, as modified by Fletcher *et al.* (1994), which is based on a large set of actual field residue data. The upper limit values from the nomograph represented the 95th percentile of residue values from actual field measurements (Hoerger and Kenaga, 1972). For modeling purposes, direct exposures of the CTS to oryzalin through contaminated food are estimated using the EECs for the small bird (20 g), which consumes small insects. Dietary-based and dose-based exposures of potential prey (small mammals) are assessed using the small mammal (15



g), which consumes short grass. The small bird (20g) consuming small insects and the small mammal (15g) consuming short grass are used because these categories represent the largest RQs of the size and dietary categories in T-REX that are appropriate surrogates for the CTS and one of its prey items. Estimated exposures of terrestrial insects to oryzalin are bound by using the dietary based EECs for small insects and large insects.

Birds are currently used as surrogates for terrestrial-phase CTS. However, amphibians are poikilotherms (body temperature varies with environmental temperature) while birds are homeotherms (temperature is regulated, constant, and largely independent of environmental temperatures). Therefore, amphibians tend to have much lower metabolic rates and lower caloric intake requirements than birds or mammals. As a consequence, birds are likely to consume more food than amphibians on a daily dietary intake basis, assuming similar caloric content of the food items. Therefore, the use of avian food intake allometric equation as a surrogate to amphibians is likely to result in an over-estimation of exposure and risk for reptiles and terrestrial-phase amphibians. Therefore, T-REX has been refined to the T-HERPS model (v. 1.1), which allows for an estimation of food intake for poikilotherms using the same basic procedure as T-REX to estimate avian food intake.

EECs for terrestrial plants inhabiting dry and wetland areas are derived using TerrPlant (version 1.2.2, 12/26/2006). This model uses estimates of pesticides in runoff and in spray drift to calculate EECs. EECs are based on solubility, application rate and minimum incorporation depth.

The spray drift model AgDRIFT was used to assess exposures of terrestrial phase CTS and its prey to oryzalin deposited on terrestrial habitats by spray drift. In addition to the buffered area from the spray drift analysis, the downstream extent of oryzalin that exceeds the LOC for the effects determination is also considered.

#### **2.10.1.2. Measures of Effect**

Data identified in **Section 2.8** are used as measures of effect for direct and indirect effects to the CTS. Data were obtained from registrant submitted studies or from literature studies identified by ECOTOX. The ECOTOXicology database (ECOTOX) was searched in order to provide more ecological effects data and in an attempt to bridge existing data gaps. ECOTOX is a source for locating single chemical toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by the USEPA, Office of Research and Development, and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division.

The assessment of risk for direct effects to the terrestrial-phase CTS makes the assumption that toxicity of oryzalin to birds is similar to the toxicity to the terrestrial-phase CTS. The same assumption is made for fish and aquatic-phase CTS. Algae, aquatic invertebrates, fish, and amphibians represent potential prey of the CTS in the aquatic habitat. Terrestrial invertebrates, small mammals, and terrestrial-phase

amphibians represent potential prey of the CTS in the terrestrial habitat. Aquatic, semi-aquatic, and terrestrial plants represent habitat of CTS.

The acute measures of effect used for animals in this screening level assessment are the LD<sub>50</sub>, LC<sub>50</sub> and EC<sub>50</sub>. LD stands for "Lethal Dose", and LD<sub>50</sub> is the amount of a material, given all at once, that is estimated to cause the death of 50% of the test organisms. LC stands for "Lethal Concentration" and LC<sub>50</sub> is the concentration of a chemical that is estimated to kill 50% of the test organisms. EC stands for "Effective Concentration" and the EC<sub>50</sub> is the concentration of a chemical that is estimated to produce a specific effect in 50% of the test organisms. Endpoints for chronic measures of exposure for listed and non-listed animals are the NOAEL/NOAEC and NOEC. NOAEL stands for "No Observed-Adverse-Effect-Level" and refers to the highest tested dose of a substance that has been reported to have no harmful (adverse) effects on test organisms. The NOAEC (*i.e.*, "No-Observed-Adverse-Effect-Concentration") is the highest test concentration at which none of the observed effects were statistically different from the control. The NOEC is the No-Observed-Effects-Concentration. For non-listed plants, only acute exposures are assessed (*i.e.*, EC<sub>25</sub> for terrestrial plants and EC<sub>50</sub> for aquatic plants).

It is important to note that the measures of effect for direct and indirect effects to the CTS and its designated critical habitat are associated with impacts to survival, growth, and fecundity and do not include the full suite of sublethal effects used to define the action area. According the Overview Document (USEPA, 2004), the Agency relies on effects endpoints that are either direct measures of impairment of survival, growth, or fecundity or endpoints for which there is a scientifically robust, peer reviewed relationship that can quantify the impact of the measured effect endpoint on the assessment endpoints of survival, growth, and fecundity.

#### **2.10.1.3. Integration of Exposure and Effects**

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from agricultural and non-agricultural uses of oryzalin, and the likelihood of direct and indirect effects to CTS in aquatic and terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of oryzalin risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs) (USEPA, 2004) (see **Appendix C**).

For this assessment and effects determination, listed species LOCs are used for comparing RQ values for acute and chronic exposures of oryzalin directly to the CTS. If estimated exposures directly to the CTS of oryzalin resulting from a particular use are sufficient to exceed the listed species LOC, then the effects determination for that use is "may affect". When considering indirect effects to the CTS due to effects to animal prey (aquatic and terrestrial invertebrates, fish, amphibians, and mice), the listed species LOCs are also used. If estimated exposures to CTS prey of oryzalin resulting from a particular

use are sufficient to exceed the listed species LOC, then the effects determination for that use is a “may affect.” If the RQ being considered also exceeds the non-listed species acute risk LOC, then the effects determination is LAA. If the acute RQ is between the listed species LOC and the non-listed acute risk species LOC, then further lines of evidence (*i.e.*, probability of individual effects, species sensitivity distributions) are considered in distinguishing between a determination of NLAA and LAA. If the RQ being considered for a particular use exceeds the non-listed species LOC for plants, the effects determination is “may affect”. Further information on LOCs is provided in **Appendix C**.

### **2.10.2. Data Gaps**

A data gap in this assessment is toxicity data on amphibians. No studies are identified in the open literature that documented the acute or chronic exposure effects of oryzalin on amphibians. Therefore, acute and chronic toxicity data on fish and birds (which served as surrogate species for aquatic and terrestrial phase amphibians, respectively) were used. The Agency does not have registrant-submitted data for woody (riparian) plant species. For purposes of this effects determination, label statements, incidents, and open literature data were used as a weight of evidence to determine if oryzalin may affect woody plants.

## **3. Exposure Assessment**

Oryzalin is formulated as liquid, granular, water dispersible granules, wettable powder, and emulsifiable concentrate. Formulated products of oryzalin are applied pre-emergence to weeds as liquid spray (broadcast and band treatment using low pressure ground equipment or through irrigation water) or granular applications (using spreaders). Risks from both broadcast spray and granular applications are considered in this assessment because they are expected to result in the greatest off-target levels of oryzalin due to spray drift and/or runoff. Broadcast spray applications made to ground tend to have a higher potential for off-target movement via spray drift compared to granular applications. Therefore, it is expected that direct and indirect effects to aquatic and terrestrial-phase CTS will be greater from broadcast spray applications (*i.e.*, liquid formulations) compared to granular applications of oryzalin.

### **3.1. Label Application Rates and Intervals**

Oryzalin labels may be categorized into two types: labels for manufacturing uses (including technical grade oryzalin) and formulated or end-use products. While technical products, which contain oryzalin of high purity, are not used directly in the environment, they are used to make formulated products, which can be applied in specific areas to control weeds. The formulated product labels legally limit oryzalin’s potential use to only those sites that are specified on the labels. Currently registered uses for oryzalin within California include agricultural and non-agricultural uses. Application information for each use being assessed is summarized in **Table 3.1**.

**Table 3.1. Oryzalin Uses Assessed for the CTS**

Use Categories	Formulation Code <sup>1</sup>	Application Method	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Year (#)	Maximum Annual Application Rate (lb ai/A)	Application Interval (days)
<b>Avocado</b>  <b>Berries</b> Blackberry, blueberries, boysenberry, caneberries, currant, dewberry, elderberry, gooseberry, loganberry, raspberry  <b>Citrus Fruits</b> Grapefruit, kumquat, kiwi, lime, lemon, mandarin, tangerine, orange, pummelo  <b>Olives</b>  <b>Pome Fruits</b> Apple, crabapple, figs, loquat, mayhaw, pear, pomegranate, quince  <b>Tree Nuts</b> Almonds, cashew, chestnut chinquapin, filbert, hickory nut, macadamia nut, pecan, pistachio walnut  <b>Tropical Fruits</b> Papaya, guava  <b>Stone Fruits</b> Apricot, cherry, nectarine, peach, plum, prune  <b>Vineyards</b> Wine grapes, table grapes	EC/DF <sup>2</sup>	Low pressure ground sprayer/ Sprinkler irrigation /Broadcast/ Chemigation/ Soil broadcast treatment	6	2	12	75
<b>Ornamentals<sup>4</sup></b>	G <sup>3</sup>	Granules by Spreader/ Broadcast	4	4	15	60
	EC/DF/L/WP	Low pressure ground sprayer/ Sprinkler irrigation /Broadcast/ Chemigation/ Soil broadcast treatment	4	3	12	90

Table 3.1. Oryzalin Uses Assessed for the CTS						
Use Categories	Formulation Code <sup>1</sup>	Application Method	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Year (#)	Maximum Annual Application Rate (lb ai/A)	Application Interval (days)
	G	Granule applicator Spreader, /Broadcast	4	4	15	60
Ornamental bulbs	EC/L	Low pressure ground sprayer/ Sprayer	1.5	2	2.25	90
	G	Granule applicator Spreader, /Broadcast	1.5	2	2.25	90
Christmas Tree Plantation	EC/DF/L/WP	Low pressure ground sprayer/ Sprayer/ Spreader /Broadcast/ Directed spray/ Soil broadcast treatment	4	2	8	60
	G	Granule applicator Spreader, /Broadcast	4	2	8	60
	G	Granule applicator Spreader, /Broadcast	3.34	5	15	90
Forest Trees	EC/L	Low pressure ground sprayer/ Broadcast	6	2	12	75
Turf	EC/L	Low pressure ground sprayer/ Sprayer	2	3	6	90
	G	Granule applicator Spreader, /Broadcast	1.5	4	6	90
Rights-of-ways <sup>5</sup>	EC/L/WP	Low pressure ground sprayer/ Sprayer	6	2	12	180

<b>Table 3.1. Oryzalin Uses Assessed for the CTS</b>						
<b>Use Categories</b>	<b>Formulation Code<sup>1</sup></b>	<b>Application Method</b>	<b>Maximum Single Application Rate (lb ai/A)</b>	<b>Maximum Number of Applications per Year (#)</b>	<b>Maximum Annual Application Rate (lb ai/A)</b>	<b>Application Interval (days)</b>
	G	Granule applicator Spreader, /Broadcast	6	2	12	240
<b>Residential areas</b>	G	Granule applicator Spreader	2	3	6	56
<b>Uncultivated Areas</b>	DF	Low pressure ground sprayer	6	2	12	180
<sup>1</sup> Formulation codes: DF- Water Dispersible Granules (Dry Flowable); EC-Emulsifiable Concentrate; G-Granular; L-Liquid; WP-Wettable Powder <sup>2</sup> This rate applies to bearing trees only. The non-bearing rate was not considered a maximum labeled application rate (4 applications at 3 lb a.i./acre for a total of 12 lb a.i./acre/year); therefore, it was not modeled. <sup>3</sup> This rate applies to bearing and non-bearing trees. <sup>4</sup> Use in landscape gardens, container and field grown ornamentals, drainage areas under shadehouse benches, ground covers/perennials. Scenario accounts for landscape maintenance. <sup>5</sup> Scenario conservatively accounts for industrial areas (outdoor) and buildings and structures.						

## 3.2. Aquatic Exposure Assessment

### 3.2.1. Modeling Approach

Aquatic exposures are quantitatively estimated for all of the maximum labeled use rates using scenarios that tend to represent high-end exposure sites. Each of these sites represents a 10 hectare field that drains into a 1-hectare pond that is 2 meters deep and has no outlet. Exposure estimates generated using the standard pond are intended to represent a wide variety of vulnerable water bodies that occur at the top of watersheds including prairie pot holes, playa lakes, wetlands, vernal pools, man-made and natural ponds, and intermittent and first-order streams. As a group, there are factors that make these water bodies more or less vulnerable than the standard surrogate pond. Static water bodies that have larger ratios of drainage area to water body volume would be expected to have higher peak EECs than the standard pond. These water bodies will be either shallower or have large drainage areas (or both). Shallow water bodies tend to have limited additional storage capacity, and thus, tend to overflow and carry pesticide in the discharge whereas the standard pond has no discharge. As watershed size increases beyond 10 hectares, it becomes unlikely that the entire watershed is planted with a single crop that is all treated with the pesticide of concern. Headwater streams can also have peak concentrations higher than the standard pond, but they tend to persist for only short periods of time and are then carried downstream.

Crop-specific management practices for all of the assessed uses of oryzalin were used for modeling, including application rates, number of applications per year, application

intervals, and the first application date for each crop. Since oryzalin is a pre-emergence herbicide used to control annual grasses and certain broadleaf weeds, the date of first application was based on late winter (January 1<sup>st</sup>) to accommodate multiple applications and extended periods between application intervals for all crop and non-crop scenarios. While examination of California PUR data indicated that oryzalin was applied in all months, more applications took place in the winter months than other months (based on 2005 data).

### 3.2.2. Model Inputs

The physical, chemical, and environmental fate data for oryzalin used for generating model parameters are listed in **Table 2.1**. The input parameters used in simulating PRZM and EXAMS are listed in **Table 3.2**.

The CA rights-of-ways and CA impervious scenarios are used in tandem in order to model EECs resulting from use of oryzalin on rights of ways. The rights-of-ways scenario was developed specifically for the San Francisco Bay region using the conceptual approach developed for the Barton Springs salamander atrazine endangered species risk assessment (USEPA, 2006). The San Francisco area was selected to be representative of urbanized areas with CTS habitat present in the general vicinity. The impervious scenario was developed to represent the paved areas within a watershed. The EECs derived by PRZM/EXAMS for the two scenarios are further refined to be more representative of non-cropland areas, specifically rights-of-ways. These refinements, termed “post-processing” are described below.

<b>Table 3.2. Summary of PRZM/EXAMS Environmental Fate Data Used for Aquatic Exposure Inputs for Oryzalin Endangered Species Assessment for the CTS</b>		
<b>Fate Property</b>	<b>Value (unit)</b>	<b>MRID (or source)</b>
Molecular Weight	346.35	Registrant data
Henry's constant	$1.82 \times 10^{-8}$ atm·m <sup>3</sup> /mol	Calculated from solubility and vapor pressure
Vapor Pressure	$1 \times 10^{-7}$ mm Hg at 25 °C	MRID 40454801
Solubility in Water <sup>1</sup>	2.5 mg/l at 25 °C x 10	MRID 41208101-2
Photolysis in Water	0.06 days	MRID 41278701
Aerobic Soil Metabolism Half-lives <sup>2</sup>	189 days (63 x 3)	MRID 41322801
Hydrolysis	Stable	MRID 41378401
Aerobic Aquatic Metabolism <sup>3</sup>	378 days	See comments below
Anaerobic Aquatic Metabolism <sup>4</sup>	60 days	See comments below
Koc	941 L kg o.c. <sup>-1</sup> ( mean of 4 values)	MRID 41479802
Application rate and frequency	Variable	<b>Tables 3.1 and 3.2</b>

<b>Table 3.2. Summary of PRZM/EXAMS Environmental Fate Data Used for Aquatic Exposure Inputs for Oryzalin Endangered Species Assessment for the CTS</b>		
<b>Fate Property</b>	<b>Value (unit)</b>	<b>MRID (or source)</b>
Application intervals	Variable	<b>Tables 3.1 and 3.2</b>
Chemical Application Method (CAM)	1 (Soil application)	According to oryzalin labels
Application Efficiency	99% for ground application 100% for granular application	Default, EFED guidance
Spray Drift Fraction <sup>5</sup>	1% for ground application None for granular application	Default, EFED guidance
<sup>1</sup> Water solubility was multiplied by 10 according to Guidance for selecting input parameters in modeling for environmental fate and transport of pesticides Version II. February 27, 2002.		
<sup>2</sup> Multiplied by 3, according to Guidance for selecting input parameters in modeling for environmental fate and transport of pesticides Version II. February 27, 2002.		
<sup>3</sup> Assumed 2X of aerobic soil metabolism input value, according to Guidance for selecting input parameters in modeling for environmental fate and transport of pesticides Version II. February 27, 2002		
<sup>4</sup> Assumed 2X anaerobic soil metabolism half-life multiplied by three ( $T_{1/2} = 10$ days, MRID 41322802), according to Guidance for selecting input parameters in modeling for environmental fate and transport of pesticides Version II. February 27, 2002.		
<sup>5</sup> Spray drift not included in final EEC due to edge-of-field estimation approach		

### 3.2.2.1. Post-processing of PRZM/EXAMS outputs to develop EECs for non-cropland areas

Available data for California indicate that use of oryzalin on rights-of-ways represents a significant portion of the past (2002 - 2005) use of oryzalin (10.7% of total use). Of uses of oryzalin on non-cropland areas, 81.0% was applied to rights-of-ways (CPUR, 2007a).

Rights-of-ways include roads, highways, railroads, utilities, and pipelines. These areas contain both impervious (*i.e.*, cement, asphalt, metal surfaces) and pervious surfaces. It is assumed that oryzalin will be applied to the pervious surfaces, where weeds are expected to grow. It is also assumed that oryzalin is not applied to impervious surfaces in rights-of-ways but that there is a 1% incidental spray and 0.5% granular release onto impervious surfaces in the right-of-ways. Further details on how these values were derived and characterization of alternative assumptions are provided in the Barton Springs salamander endangered species risk assessment for atrazine (USEPA, 2006).

In a standard PRZM scenario, it is assumed that an entire 10 ha field is composed only of the identified crop and that the field has uniform surface properties throughout the field. In a right-of-way, this is not a reasonable assumption, since a right-of-way contains both impervious and pervious surfaces. Since the two surfaces have different properties (especially different curve numbers influencing the runoff from the surfaces) and different masses of applied oryzalin, the standard approach for deriving aquatic EECs is revised using the following approach:

- 1 Aquatic EECs are derived for the pervious portion of the right-of-way, using the maximum use rate of oryzalin on the CArighofway scenario. At this point, it is assumed that 100% of the right-of-way is composed of pervious surface. Specific inputs for this modeling are defined below.



- 2 Aquatic EECs are derived for the impervious portion of the right-of-way, using 1% for liquid formulation and 0.5% for granular formulation of the maximum use rate of oryzalin on the CAimpervious scenario. At this point, it is assumed that 100% of the right-of-way is composed of impervious surface.
- 3 The daily aquatic EECs (contained in the PRZM/EXAMS output file with the suffix “TS”) are input into a Microsoft® Excel® worksheet.
- 4 Daily aquatic EECs for the impervious surface are multiplied by 50%. Daily aquatic EECs for the pervious surface are multiplied by 50%. The resulting EECs for impervious and pervious surfaces are added together to get an adjusted EEC for each day of the 30-year simulation period (**Equation 1**).

$$\text{Equation 1: Revised EEC} = (\text{imperviousEEC} * 50\%) + (\text{perviousEEC} * 50\%)$$

- 5 Rolling averages for the relevant durations of exposure (21-day, and 60-day averages) are calculated. The 1-in-10 year peak, 21-day and 60-day values are used to define the acute and chronic EECs for the aquatic habitat.

In this approach, it is assumed that rights-of-way are composed of equal parts pervious and impervious surfaces (*i.e.*, in steps 4, the EECs of both surfaces are multiplied by 50%). This is more likely to be representative of a highway or road rights-of-way. It is likely that rights-of-way contain different ratios of the two surfaces. In general, incorporation of impervious surfaces into the exposure assessment results in increasing runoff volume in the watershed, which tends to reduce overall pesticide exposure (when assuming 1% and 0.5% overspray to the impervious surface).

### 3.2.3. Results

The aquatic EECs for the various scenarios and application practices are listed in **Table 3.3**. For agricultural uses that also had a granular application at the same or a lower single maximum rate, the higher liquid rate was assumed to conservatively represent the granular rate; therefore, the granular rate was not modeled for agricultural uses for aquatic exposure. For non-agricultural uses, the calculated highest peak oryzalin exposure concentration was 141.89 ppb for rights-of-ways and the lowest exposure concentration was 3.5 ppb for residential areas. Among the agricultural uses modeled, oryzalin use resulted in highest peak exposure concentration of 52.98 ppb for berries and wine grapes and lowest peak exposure concentration of 9.74 ppb for citrus and tropical fruits.

Table 3.3. Aquatic EECs for Oryzalin Uses at Maximum Labeled Rates in California					
Use Categories	PRZM/EXAMS Scenarios	Application Rate <sup>1</sup>	Peak EEC	21-day Average EEC	60-Day Average EEC
			µg/L		
Agricultural Uses					
Avocado	CAavocado_V2	2 apps @ 6 lb a.i./acre 75-day interval (L)	39.10	19.1	9.59
Berries Blackberry, blueberries, boysenberry, caneberries, currant, dewberry, elderberry, gooseberry, loganberry, raspberry	CAwinegrapes RLF_V2	2 apps @ 6 lb a.i./acre 75-day interval (L)	52.98	29.24	15.87
Citrus Fruits Grapefruit, kiwi, kumquat, lime, lemon, mandarin, tangerine, orange, pummelo, surrogate for tropical fruit (papaya and guava)	CACitrusSTD	2 apps @ 6 lb a.i./acre 75-day interval (L)	9.74	5.39	2.68
Pome Fruits Apple, crabapple, fig, loquat, mayhaw, pear, pomegranate, quince Stone Fruits Apricot, cherry, nectarine, peach, plum, prune	CAfruitsSTD	2 apps @ 6 lb a.i./acre 75-day interval (L)	22.85	12.48	6.23
Olive	CAoliveRLF_V2	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.65	11.98	6.39

<b>Table 3.3. Aquatic EECs for Oryzalin Uses at Maximum Labeled Rates in California</b>					
Use Categories	PRZM/EXAMS Scenarios	Application Rate <sup>1</sup>	Peak EEC	21-day Average EEC	60-Day Average EEC
			µg/L		
<b>Tree Nuts</b> Almonds, cashew, chestnut chinquapin, filbert, hickory nut, macadamia nut, pecan, pistachio, walnut	CAAlmondSTD	2 apps @ 6 lb a.i./acre 75-day interval (L)	49.36	26.28	14.15
<b>Vineyards</b> Table Grapes  Wine Grapes	CAGrapesSTD	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.45	11.34	5.84
	CAwinegrapesRLF_V2		52.98	29.24	15.87
<b>Non-agricultural Uses</b>					
<b>Ornamentals<sup>2</sup></b>	CANursery STD	3 apps @ 4 lb a.i./acre 90-day interval (L)	47.64	26.27	15.03
		3 apps @ 4 lb a.i./acre, 1 app @ 3 lb a.i./acre 60-day interval (G)	72.61	36.73	21.03
<b>Ornamental Bulbs</b>	CANursery STD	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 lb a.i./acre 90-day interval (L)	16.44	8.48	4.37
		1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 lb a.i./acre 90-day interval (G)	16.32	8.49	4.31
<b>Christmas Tree Plantation</b>	CA forestry RLF	2 apps @ 4 lb a.i./acre 60-day interval (L)	33.5	19.37	9.90
		4 apps @ 3.34 lb a.i./acre, 1 app @ 1.67 lb a.i./acre 90-day interval (G)	41.15	23.50	12.43
<b>Forest Trees</b>	CA forestry RLF	2 apps @ 6 lb a.i./acre 75-day interval (L)	68.59	39.27	19.82

<b>Table 3.3. Aquatic EECs for Oryzalin Uses at Maximum Labeled Rates in California</b>					
Use Categories	PRZM/EXAMS Scenarios	Application Rate <sup>1</sup>	Peak EEC	21-day Average EEC	60-Day Average EEC
			µg/L		
<b>Turf</b>	CA <sub>turf</sub> RLF	3 apps @ 2 lb a.i./acre 90-day interval (L)	5.42	2.75	1.65
		4 apps @ 1.5 lb a.i./acre 90-day interval (G)	8.21	4.16	1.92
<b>Rights-of-ways<sup>3</sup></b>	CA <sub>rightofways</sub> RLF_V2	2 apps @ 6 lb a.i./acre 180-day interval (L)	141.89	84.92	38.52
<b>Residential Areas</b>	CA Residential RLF	3 apps @ 2 lb a.i./acre 56-day interval (G)	3.5	1.82	1.21
<b>Uncultivated Areas</b>	CA <sub>arangelandhay</sub> RLF_V2	2 apps @ 6 lb a.i./acre 180-day interval (L)	93.82	50.50	24.10
<sup>1</sup> G = Granular formulation; L = liquid formulation <sup>2</sup> Use in landscape gardens, containers and field grown ornamentals, and ground covers/perennials. Scenario accounts for landscape maintenance. <sup>3</sup> Scenario conservatively accounts for industrial areas (outdoor) and buildings and structures.					

### 3.2.4. Existing Monitoring Data

A critical step in the process of characterizing EECs is comparing the modeled estimates with available surface water monitoring data. Most of this data is non-targeted (*i.e.*, study was not specifically designed to capture oryzalin concentrations in high use areas). Included in this assessment are oryzalin data from the USGS NAWQA program (<http://water.usgs.gov/nawqa>) and data from the California Department of Pesticide Regulation (CDPR). Typically, sampling frequencies employed in monitoring studies are insufficient to document peak exposure values. This coupled with the fact that these data are not temporally or spatially correlated with pesticide application times and/or areas limit the utility of these data in estimating exposure concentrations for risk assessment. These monitoring data are characterized in terms of general statistics including number of samples, frequency of detection, maximum concentration, and mean from all detections, where that level of detail is available.

#### 3.2.4.1. USGS NAWQA Surface Water Data

Surface water monitoring data from the United States Geological Survey (USGS) NAWQA program was accessed on August 16, 2010 and all data for the state of

California were downloaded. A total of 378 water samples were analyzed for oryzalin. Of these samples, 27 (7.14%) had positive detections of oryzalin. The maximum concentration detected was 1.51 µg/L in the Arcade Creek near Del Paso Heights, Sacramento and the Warm Creek near San Bernardino, CA. Oryzalin was detected in the Arcade Creek in 8 samples with concentrations ranging 0.08 -1.51 µg/L and in the Warm Creek in 5 samples with concentrations ranging from 0.05 -1.51 µg/L. Oryzalin was also detected in the Merced Residential Area River Road Bridge near Newman, CA (11 samples ranging in concentration 0.13 – 1.20 µg/L). Three more samples detected oryzalin at various areas with concentrations ranging 0.02 -0.43 µg/L. No clear pattern in oryzalin detections from different use sites is evident because oryzalin was detected in a number of different types of watersheds (agricultural, urban, mixed and other) as classified by the USGS land use information.

#### **3.2.4.2. USGS NAWQA Groundwater Data**

Groundwater monitoring data from the United States Geological Survey (USGS) NAWQA program were accessed on August 16, 2010 and all data for the state of California was downloaded. A total of 468 water samples were analyzed for oryzalin. Of these samples, oryzalin was not detected in any samples (below the range of quantitation).

#### **3.2.4.3. California Department of Pesticide Regulation (CDPR) Data**

Pesticide monitoring studies in surface water were primarily carried out by the California Department of Pesticide Regulation (CDPR), Environmental Hazard Assessment Program (EHAP), United States Geological Survey (USGS), and the Central Valley Regional Water Quality Control Board. Data from these and other studies are documented in EHAP's surface water database (SURF).

Surface water monitoring data was accessed from the CDPR on August 16, 2010 and all data with analysis for oryzalin were extracted. A total of 633 samples were available. Of these samples, oryzalin was detected in 28 samples for a frequency of detection of 4.42%. The maximum concentration detected was 110 µg/L. This detection was a result from normal ambient monitoring located where Lateral Drain #6 drains into the Stanislaus River, CA. All oryzalin residues were detected in various counties throughout the state at concentrations ranging between 0.05 –110 µg/L.

Ground water monitoring data was available in the form of a CDPR memo "Study GW07 – Summary of the Results for Fiscal Year 2006/07 Ground Water Protection List Monitoring For Napropamide and Oryzalin" dated 11 January 2008 written by Matthew Fossen, Ph.D. Seventy four wells were sampled in nine counties during March through June 2007. No residues of oryzalin were detected in any of the wells despite being located in high-use sections with vulnerable soils. Similar results were obtained in a GWPL monitoring study conducted in 1998–1999, in which 64 wells were sampled for napropamide and oryzalin (Weaver and Marade, 1999). The combined results of the 1998–1999 and 2006–2007 monitoring studies indicate that the active ingredients

napropamide and oryzalin have a low potential for contaminating California ground water due to legal agricultural use in vulnerable areas.

#### 3.2.4.4. Atmospheric Monitoring Data

Based on its low vapor pressure ( $1.0 \times 10^{-7}$  mm Hg at 25°C) and Henry's Law Constant ( $1.8 \times 10^{-8}$  atm·m<sup>3</sup>/mol), volatilization loss of oryzalin from soil and water systems is expected to be negligible. Based on relatively low volatility and high sensitivity to photolytic degradation, oryzalin is not expected to be subject to long-range transport. There is no data for oryzalin in the California Pesticide Air Monitoring database.

### 3.3. Terrestrial Animal Exposure Assessment

T-REX (Version 1.4.1) is used to calculate dietary and dose-based EECs of oryzalin for the CTS and its potential prey (*e.g.*, small mammals and terrestrial insects) inhabiting terrestrial areas. EECs used to represent the CTS are also used to represent exposure values for other amphibians serving as potential prey of CTS adults. T-REX simulates a 1-year time period. For this terrestrial assessment, broadcast spray and granular applications of oryzalin are considered separately, as discussed in **Section 3.3.1** and **3.3.2** below.

#### 3.3.1. Spray Applications

Terrestrial EECs for broadcast spray formulations of oryzalin were derived for the uses summarized in **Table 3.1**. The T-REX default foliar dissipation half-life period of 35 days was used to calculate the estimates for risk.

Use specific input values, including number of applications, application rate and application interval are provided in **Table 3.4**. An example output from T-REX is available in **Appendix E**.

<b>Table 3.4. Input Parameters for Spray Applications Used to Derive Terrestrial EECs for Oryzalin with T-REX</b>				
<b>Use Category</b>	<b>Application Rate (lb ai/A)</b>	<b>Number of Applications (#)</b>	<b>Maximum Application Rate (lb ai/A/year)</b>	<b>Application Interval (Days)</b>
<b>Agricultural Uses</b>				
Avocado, Berries, Citrus Fruits, Pome Fruits, Olives, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	6	2	12	75
<b>Non-agricultural Uses</b>				
Ornamentals	4	3	12	90
Ornamental Bulbs <sup>1</sup>	1.5	2	2.25	90
Christmas Tree Plantations	4	2	8	60
Forest Trees	6	2	12	75
Turf	2	3	6	90
Rights-of-ways	6	2	12	180

**Table 3.4. Input Parameters for Spray Applications Used to Derive Terrestrial EECs for Oryzalin with T-REX**

Use Category	Application Rate (lb ai/A)	Number of Applications (#)	Maximum Application Rate (lb ai/A/year)	Application Interval (Days)
Uncultivated Areas	6	2	12	180
<sup>1</sup> One application at 1.5 lb a.i./acre, followed by one application at 0.75 lb a.i./acre				

T-REX is also used to calculate EECs for terrestrial insects exposed to oryzalin. Dietary-based EECs calculated by T-REX for small and large insects (units of a.i./g) are used to bound an estimate of exposure to bees. Available acute contact toxicity data for bees exposed to oryzalin (in units of  $\mu\text{g}$  a.i./bee), are converted to  $\mu\text{g}$  a.i./g (of bee) by multiplying by 1 bee/0.128 g (*i.e.*, dividing  $\mu\text{g}$  a.i./g (of bee) by 0.128 g). The EECs are later compared to the adjusted acute contact toxicity data for bees in order to derive RQs.

For modeling purposes, exposures of the CTS to oryzalin through contaminated food are estimated using the EECs for the small bird (20 g) which consumes small insects. Dietary-based and dose-based exposures of potential prey are assessed using the small mammal (15 g) which consumes short grass. Upper-bound Kenaga nomogram values reported by T-REX for these two organism types are used for derivation of EECs for the CTS and its potential prey (**Table 3.5**). Dietary-based EECs for small and large insects reported by T-REX are available in **Table 3.6**.

**Table 3.5. Upper-bound Kenaga Nomogram EECs for Dietary- and Dose-based Exposures of the CTS and its Prey to Oryzalin (assumes 35-day foliar dissipation rate)**

Use	EECs for CTS		EECs for Prey (small mammals)	
	Dietary-based EEC (ppm)	Dose-based EEC (mg/kg-bw)	Dietary-based EEC (ppm)	Dose-based EEC (mg/kg-bw)
<b>Agricultural Uses</b>				
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	993	1131	1766	1684
<b>Non-agricultural Uses</b>				
Ornamentals	646	736	1149	1095
Ornamental Bulbs	202	231	360	343
Christmas Tree Plantations	705	802	1253	1194
Forest Trees	993	1131	1766	1684
Turf	323	368	574	548
Rights-of-ways	833	949	1481	1412
Uncultivated Areas	833	949	1481	1412

**Table 3.6. EECs (ppm) for Indirect Effects to the Terrestrial-Phase CTS via Effects to Terrestrial Invertebrate Prey Items**

Use	Small Insect	Large Insect
<b>Agricultural Uses</b>		
Avocado, Berries, Citrus Fruits, Olive Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	993	110
<b>Non-agricultural Uses</b>		
Ornamentals	646	72
Ornamental Bulbs	202	22
Christmas Tree Plantations	705	78
Forest Trees	993	110
Turf	323	36
Rights-of-ways	833	93
Uncultivated Areas	833	93

The upper bound Kenaga Nomogram-based EECs for terrestrial phase CTS and small mammal prey items suggests that exposure concentrations (both dose and dietary-based) were highest for agricultural uses (all crops) and lowest for non-agricultural uses of oryzalin. Terrestrial EECs were lowest for ornamental bulbs (**Table 3.5**). This is due to oryzalin's lowest use rate/application and lowest use rate/A/year for ornamental bulbs compared to the other modeled uses. Highest non-agricultural exposure concentrations were noted for oryzalin use on rights-of-ways. A similar trend was also noted for terrestrial invertebrate exposure concentrations (**Table 3.6**).

### 3.3.2. Granular Applications

Estimated environmental concentrations from granular applications (mg ai/square foot) for the CTS are also estimated using T-REX (1.4.1). T-REX assumes that 100% of the applied oryzalin granules are left on the ground unincorporated. Additionally, T-REX also assumes that no residual exposure is associated with granular applications and thus calculates EECs based on a single application of oryzalin.

Risk to terrestrial animals from ingesting granules is based on  $LD_{50}/ft^2$  values. Further description of the  $mg/ft^2$  index is provided in USEPA (1992 and 2004). In order to derive an estimate of the granular exposure per square foot, the granular application rates for oryzalin were converted from lb ai/A to  $mg/ft^2$  in **Table 3.7** using the following equation:  $EEC \text{ in } mg/ft^2 = (\text{application rate in lb ai/A} \times 453,590 \text{ mg/lb}) / 43,560 \text{ ft}^2/\text{A}$ . The  $LD_{50}/ft^2$  values are calculated using the avian toxicity value (adjusted  $LD_{50}$  of the assessed animal and its weight classes) as a surrogate for the terrestrial-phase CTS. Risk quotients were calculated by comparing the granular EECs ( $mg \text{ ai}/ft^2$ ) with adjusted avian  $LD_{50}$  values.



<b>Table 3.7. Input Parameters and Estimated Environmental Concentrations (EECs) for Terrestrial Animals for Granular Uses of Oryzalin</b>		
<b>Use Category</b>	<b>Application Rate (lb ai/A)</b>	<b>EEC (mg/ft<sup>2</sup>)</b>
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards and Ornamentals (Excluding Bulbs)	4	41.65
Ornamental Bulbs	1.5	15.62
Christmas Tree Plantations	4	41.65
Turf	1.5	15.62
Rights-of-ways	6	62.48
Residential Areas	2	20.83

Estimated environmental concentrations for terrestrial animals from granular uses of oryzalin are lowest for ornamental bulbs and turf (15.62 mg/ft<sup>2</sup> for both) and are highest for rights-of-ways (62.48 mg/ft<sup>2</sup>).

### 3.4. Terrestrial Plant Exposure Assessment

TerrPlant (Version 1.2.2) is used to calculate EECs for non-target plant species inhabiting dry and semi-aquatic areas. Parameter values for application rate, drift assumption, and incorporation depth are based upon the use and application method (**Table 3.8**). A runoff value of 0.01 is utilized based on oryzalin's solubility, which is classified by TerrPlant as <10 mg/L. For ground broadcast and granular application methods, drift is assumed to be 1% and 0%, respectively. EECs relevant to terrestrial plants consider pesticide concentrations in drift and in runoff. These EECs are listed by use in **Table 3.8**. An example output from TerrPlant v.1.2.2 is available in **Appendix G**.

Spray drift EECs are calculated for liquid formulations of oryzalin only, as no drift is associated with granular formulations (**Table 3.8**). Runoff EECs, in general, were greater for semi-aquatic areas compared to dry areas. Also, runoff EECs were lower for granular applications compared to broadcast spray applications.

<b>Table 3.8. TerrPlant Inputs and Resulting EECs for Plants Inhabiting Dry and Semi-aquatic Areas Exposed to Oryzalin via Runoff and Drift</b>						
<b>Use Category</b>	<b>Type of Application</b>	<b>Single Application Rate (lb ai/A)</b>	<b>Drift Value (%)</b>	<b>Spray drift EEC (lb ai/A)</b>	<b>Dry area EEC (lb ai/A)</b>	<b>Semi-aquatic area EEC (lb ai/A)</b>
<b>Agricultural Uses</b>						
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits and Vineyards	Ground Broadcast	6	1	0.06	0.12	0.66
	Granular	4	0	0	0.04	0.4

**Table 3.8. TerrPlant Inputs and Resulting EECs for Plants Inhabiting Dry and Semi-aquatic Areas Exposed to Oryzalin via Runoff and Drift**

Use Category	Type of Application	Single Application Rate (lb ai/A)	Drift Value (%)	Spray drift EEC (lb ai/A)	Dry area EEC (lb ai/A)	Semi-aquatic area EEC (lb ai/A)
<b>Non-agricultural Uses</b>						
Ornamentals	Ground Broadcast	4	1	0.04	0.08	0.44
	Granular	4	0	0	0.04	0.4
Ornamental Bulbs	Ground Broadcast	1.5	1	0.02	0.03	0.17
	Granular	1.5	0	0	0.02	0.15
Christmas Tree Plantations	Ground Broadcast	4	1	0.04	0.08	0.44
	Granular	4	0	0	0.04	0.4
Forest Trees	Ground Broadcast	6	1	0.06	0.12	0.66
Turf	Ground Broadcast	2	1	0.02	0.04	0.22
	Granular	1.5	0	0	0.02	0.15
Rights-of-ways	Ground Broadcast	6	1	0.06	0.12	0.66
	Granular	6	0	0	0.06	0.6
Residential areas	Granular	2	0	0	0.02	0.2
Uncultivated Areas	Ground Broadcast	6	1	0.06	0.12	0.66

#### 4. Effects Assessment

This assessment evaluates the potential for oryzalin to directly or indirectly affect the CTS or modify its designated critical habitat. As previously discussed in **Section 2.8**, assessment endpoints for the CTS effects determination include direct toxic effects on the survival, reproduction, and growth of CTS, as well as indirect effects, such as reduction of the prey base or modification of its habitat. In addition, potential modification of critical habitat is assessed by evaluating effects to the PCEs, which are components of the critical habitat areas that provide essential life cycle needs of the CTS. Direct effects to the aquatic-phase of the CTS are based on toxicity information for freshwater fish, while terrestrial-phase effects are based on avian toxicity data, given that birds are generally used as a surrogate for terrestrial-phase amphibians. Because the CTS's prey items and habitat requirements are dependent on the availability of freshwater fish and invertebrates, small mammals, terrestrial invertebrates, and aquatic and terrestrial plants, toxicity information for these taxa are also discussed. Acute (short-term) and chronic (long-term) toxicity information is characterized based on registrant-submitted studies and available open literature.

As described in the Agency's Overview Document (USEPA, 2004), the most sensitive endpoint for each taxon is used for risk estimation. For this assessment, evaluated taxa

include aquatic-phase amphibians, freshwater fish, freshwater invertebrates, aquatic plants, birds (surrogate for terrestrial-phase amphibians), mammals, terrestrial invertebrates, and terrestrial plants.

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (USEPA, 2004). Open literature data presented in this assessment were obtained from Reregistration Eligibility Decision document for oryzalin as well as ECOTOX information obtained in March 2010. In order to be included in the ECOTOX database, papers must meet the following minimum criteria:

- (1) the toxic effects are related to single chemical exposure;
- (2) the toxic effects are on an aquatic or terrestrial plant or animal species;
- (3) there is a biological effect on live, whole organisms;
- (4) a concurrent environmental chemical concentration/dose or application rate is reported; and
- (5) there is an explicit duration of exposure.

Data that pass the ECOTOX screen are evaluated along with the registrant-submitted data and may be incorporated qualitatively or quantitatively into this endangered species assessment. In general, effects data in the open literature that are more conservative than the registrant-submitted data are considered. The degree to which open literature data are quantitatively or qualitatively characterized for the effects determination is dependent on whether the information is relevant to the assessment endpoints (*i.e.*, maintenance of CTS survival, reproduction, and growth) identified in **Section 2.8**. For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, unless quantitative relationships between modifications and reduction in species survival, reproduction, and/or growth are available.

Citations of all open literature not considered as part of this assessment because they were either rejected by the ECOTOX screen or accepted by ECOTOX but not used (*e.g.*, the endpoint is less sensitive) are included in **Appendix H**. **Appendix H** also includes a rationale for rejection of those studies that did not pass the ECOTOX screen and those that were not evaluated as part of this endangered species risk assessment.

Open literature studies deemed relevant but classified invalid for use in this assessment and the rationale for their exclusion are presented in **Table A-10 of Appendix A**. **Appendix A** also includes a summary of the human health effects data for oryzalin.

In addition to registrant-submitted and open literature toxicity information, other sources of information, including use of the acute probit dose response relationship to establish the probability of an individual effect and reviews of incidents, are conducted to further refine the characterization of potential ecological effects associated with exposure to oryzalin. A search of the Ecological Incident Information System (EIIS) on August 2, 2010 yielded six incident reports, which are described in **Section 4.4**. A search of the

Avian Incident Monitoring System (AIMS) on August 2, 2010 did not yield any reports of incidents. In addition to EIIS and AIMS as potential sources of information, additional incidents have been reported to the Agency in an aggregated format. Pesticide registrants report certain types of incidents to the Agency as aggregate counts of incidents occurring per product per quarter. Ecological incidents reported in aggregate reports include those categorized as ‘minor fish and wildlife’ (W-B), ‘minor plant’ (P-B), and ‘other non-target’ (ONT) incidents. ‘Other non-target’ incidents include reports of adverse effects to insects and other terrestrial invertebrates. Two minor aggregate incident reports involving plants have been submitted to the Agency for oryzalin.

A summary of the available aquatic and terrestrial ecotoxicity information, use of the probit dose response relationship, and the incident information for oryzalin are provided in **Sections 4.1** through **4.4**, respectively.

No ecotoxicity data were submitted or were located in the open literature for oryzalin degradates, formulated products, or mixtures.

#### **4.1. Toxicity of Oryzalin to Aquatic Organisms**

**Table 4.1** summarizes the most sensitive aquatic toxicity endpoints for the CTS, based on an evaluation of the registrant-submitted studies. A brief summary of submitted data considered relevant to this ecological risk assessment for the CTS is presented in **Table 4.1** below and also in **Appendix A (Table A-1)**.

<b>Table 4.1. Freshwater Aquatic Toxicity Profile for Oryzalin</b>				
<b>Assessment Endpoint</b>	<b>Species</b>	<b>Toxicity Value Used in Risk Assessment</b>	<b>Citation MRID # (Author &amp; Date)</b>	<b>Comment</b>
Acute Direct Toxicity to Aquatic-Phase CTS	Bluegill sunfish	96-hour $LC_{50}$ = 2,880 $\mu\text{g/L}$  NOAEC = 1000 $\mu\text{g/L}$  Slope = 9.33 (95% Confidence Limits: 4.36 – 14.30)	00072595  Sleight, 1971	Acceptable  TGAI
Chronic Direct Toxicity to Aquatic-Phase CTS	Fathead minnow	NOAEC = 220 $\mu\text{g/L}$  LOAEC = 430 $\mu\text{g/L}$	00126841  Lilly Research Lab, 1982	Acceptable  TGAI  Mean larval weight is the most sensitive endpoint

<b>Table 4.1. Freshwater Aquatic Toxicity Profile for Oryzalin</b>				
<b>Assessment Endpoint</b>	<b>Species</b>	<b>Toxicity Value Used in Risk Assessment</b>	<b>Citation MRID # (Author &amp; Date)</b>	<b>Comment</b>
Indirect Toxicity to Aquatic-Phase CTS via Acute Toxicity to Freshwater Invertebrates (i.e. prey items)	Water flea	48-hour EC <sub>50</sub> = 1,500 µg/L  NOAEC = 1000 µg/L  Slope = 9.50 (95% Confidence Limits: 6.92 – 12.09)	00072596  Carter et al., 1980	Acceptable  TGAI
Indirect Toxicity to Aquatic-Phase CTS via Chronic Toxicity to Freshwater Invertebrates (i.e. prey items)	Water flea	NOAEC = 358 µg/L  LOAEC = 608 µg/L	43986901  Kirk et al., 1996	Acceptable  TGAI  Most sensitive endpoint is the dry weight of the first generation daphnid
Indirect Toxicity to Aquatic-Phase CTS via Acute Toxicity to Non-vascular Aquatic Plants	Freshwater diatom	5-day EC <sub>50</sub> = 42 µg/L  NOAEC = < 15.4 µg/L  EC <sub>05</sub> = 8 µg/L (outside of tested concentration range)	43136903  Hughes and Williams, 1994	Supplemental  TGAI
Indirect Toxicity to Aquatic-Phase CTS via Acute Toxicity to Vascular Aquatic Plants	Duckweed	14-day EC <sub>50</sub> = 13 µg/L  NOAEC = 3.28 µg/L	43136905  Hughes and Williams, 1994	Supplemental  TGAI

Toxicity to aquatic fish and invertebrates is categorized using the system shown in **Table 4.2** (USEPA, 2004). Toxicity categories for aquatic plants have not been defined.

<b>Table 4.2. Categories of Acute Toxicity for Aquatic Organisms</b>	
<b>LC<sub>50</sub> (mg/L or ppm)</b>	<b>Toxicity Category</b>
< 0.1	Very highly toxic
> 0.1 - 1	Highly toxic
> 1 - 10	Moderately toxic
> 10 - 100	Slightly toxic
> 100	Practically nontoxic

#### 4.1.1. Toxicity to Freshwater Fish

Freshwater fish data were used as a surrogate to estimate direct acute and chronic risks to the CTS. Freshwater fish toxicity data were also used to assess potential indirect effects of oryzalin to the CTS. Effects to freshwater fish resulting from exposure to oryzalin could indirectly affect the CTS via reduction in available food.

A summary of acute and chronic freshwater fish data is provided below in **Sections 4.1.1.1 through 4.1.1.3.**

#### **4.1.1.1. Freshwater Fish: Acute Exposure (Mortality) Studies**

Three freshwater fish studies (two on rainbow trout and one on bluegill sunfish), as shown in **Appendix A (Table A-2)**, are available to document the acute exposure effects of oryzalin on freshwater fish. Based on these studies, the 96-hour acute toxicity of oryzalin to the rainbow trout (MRID TN1078), rainbow trout (MRID 00072595) and the bluegill sunfish (MRID 00072595) were 3.45, 3.26 (NOAEC = 3.2 mg/L), and 2.88 (NOAEC = 1 mg/L) mg/L, respectively. The acute toxicity values for the above freshwater fish exceeded the expected water solubility for oryzalin of 2.5 mg/L at 20°C. The above three studies tested the technical grade active ingredient, concluded that oryzalin is moderately toxic to both fish species, and were classified as acceptable.

The bluegill sunfish LC<sub>50</sub> of 2.88 mg/L was selected as the freshwater fish toxicity endpoint to assess the direct acute effects of oryzalin to the CTS as it is the most sensitive endpoint. No additional valid data on the acute toxicity of oryzalin degradates to freshwater fish were located in the open literature.

#### **4.1.1.2. Freshwater Fish: Chronic Exposure (Growth/Reproduction) Studies**

Two scientifically sound freshwater fish chronic toxicity tests, conducted using technical grade oryzalin, were submitted (**Appendix A, Table A-3**). Species tested were rainbow trout (MRID 00126842) and fathead minnow (MRID 00126841). The rainbow trout study was a 66-day early life stage test, and the fathead minnow study was a 34-day early life stage test. The reported NOAEC/LOAEC values were 0.46/>0.46 and 0.22/0.43 mg/L for rainbow trout and fathead minnow, respectively, suggesting that fathead minnow is more sensitive to oryzalin than rainbow trout. Both studies were classified as acceptable.

No adverse effects were noted at any concentration tested in the rainbow trout study. Therefore, the NOAEC was the highest concentration tested in the study. In the chronic exposure study using fathead minnow, mean larval weights were affected at the highest oryzalin dose tested. The NOAEC value (0.22 mg/L) reported in the fathead minnow study was used in this assessment as this is the definitive and the most sensitive endpoint.

#### **4.1.1.3. Freshwater Fish: Sublethal Effects and Additional Open Literature Information**

No valid studies were located in the open literature that report endpoints on sublethal effects to freshwater fish that are less sensitive than the selected measures of effect summarized in **Table 4.1**. In addition, no laboratory freshwater fish early life-stage or life-cycle tests using oryzalin and/or its formulated products were located in the open literature.

#### **4.1.2. Toxicity to Freshwater Invertebrates**

Freshwater aquatic invertebrate toxicity data were used to assess potential indirect effects of oryzalin to the CTS. Effects to freshwater invertebrates resulting from exposure to oryzalin could indirectly affect the CTS via reduction in available food items. The main food source for juvenile aquatic- and terrestrial-phase CTSs is thought to be aquatic invertebrates found along the shoreline and on the water surface.

A summary of acute and chronic freshwater invertebrate data is provided below in **Sections 4.1.2.1 through 4.1.2.3.**

##### **4.1.2.1. Freshwater Invertebrates: Acute Exposure Studies**

Data on the acute exposure effects of oryzalin on aquatic invertebrates are available for the water flea (*Daphnia magna*) (MRID 00072596). Data on oryzalin toxicity to other freshwater invertebrates are not available. Results of acute toxicity tests with freshwater invertebrates are tabulated in **Appendix A (Table A-2).**

The 48-hr test on water flea reported an EC<sub>50</sub> of 1.5 mg/L and a slope of 9.5. At test concentrations greater than 1.6 mg/L, hypoactivity, prostration, and immobility were the effects noted. Reported NOAEC value was 1 mg/L based on immobility (mortality). Based on this data, oryzalin is categorized as moderately toxic to freshwater invertebrates on an acute basis. No additional data on the acute toxicity of oryzalin or its degradates to freshwater invertebrates were located in the open literature.

##### **4.1.2.2. Freshwater Invertebrates: Chronic Exposure Studies**

An aquatic invertebrate (*Daphnia magna*) lifecycle study (MRID 43986901) submitted for oryzalin (**Appendix A, Table A-3**) reported a NOAEC value of 0.358 mg/L and a LOAEC value of 0.608 mg/L. The above endpoints were based on the dry weights of the first generation daphnid. This study was classified as acceptable.

##### **4.1.2.3. Freshwater Invertebrates: Open Literature Data**

No freshwater invertebrate studies, based on acute or chronic exposure, were located for oryzalin from the open literature that provided more sensitive toxicity endpoints than those identified in registrant-submitted studies.

#### **4.1.3. Toxicity to Aquatic Plants**

Aquatic plant toxicity studies were used as one of the measures of effect to evaluate whether oryzalin may affect primary production and the availability of aquatic plants as food for CTS tadpoles. Primary productivity is essential for indirectly supporting the growth and abundance of the CTS.

#### 4.1.3.1. Aquatic Plants: Acute Exposure Studies

Tier II toxicity data for technical grade oryzalin are available for the vascular plant duckweed (*Lemna gibba*) and the following four non-vascular plants: blue-green algae (*Anabaena flos-aquae*), marine diatom (*Skeletonema costatum*), freshwater alga (*Selenastrum capricornutum*), and freshwater diatom (*Navicula pelliculosa*). A summary of acute toxicity of oryzalin to aquatic plants is provided in **Appendix A (Table A-4)**. All of these aquatic plant studies were classified as supplemental because of issues with recovery, potential contamination, significant differences with the solvent and negative control, and potential QA/QC issues within the laboratory.

In the 14-day acute toxicity study with the aquatic vascular plant duckweed, the EC<sub>50</sub> and NOAEC were determined to be 13 and 3.28 µg a.i./L, respectively. The above endpoints were based on mean frond counts.

Results for non-vascular plants indicate that the freshwater diatom, *Navicula pelliculosa*, is the most sensitive plant to oryzalin (MRID 43136903). Cell density or growth-based EC<sub>50</sub> values for the non-vascular plants were 42 µg a.i./L for freshwater diatom, 45 µg a.i./L for marine diatom, 52 µg a.i./L for green algae, and >13.5 mg a.i./L for blue-green algae. The respective NOAEC values for the above non-vascular plant species were <15.4 µg a.i./L (EC<sub>05</sub> = 8 µg a.i./L, outside of tested concentration range) for freshwater diatom, 30.6 µg a.i./L for marine diatom, 52 µg a.i./L for green algae, and 0.194 mg a.i./L for blue-green algae.

Due to the non-obligatory relationship between the CTS and the aquatic non-vascular plants, the EC<sub>50</sub> values are used as measurement endpoints to determine risk. The EC<sub>50</sub> values for *Navicula pelliculosa* (freshwater diatom) and *Lemna gibba* (duckweed) of 42 µg a.i./L and 13 µg a.i./L, respectively, were used to assess indirect effects to CTS.

No valid aquatic plant studies were located for oryzalin in the open literature that reported an endpoint less than the selected measures of effect summarized in **Table 4.1**.

#### 4.2. Toxicity of Oryzalin to Terrestrial Organisms

**Table 4.3** summarizes the most sensitive terrestrial toxicity endpoints for the CTS, based on an evaluation of the submitted studies. One study that evaluated the effects of oryzalin on a woody plant species is included for qualitative purposes. No studies on terrestrial animals were identified for oryzalin in the open literature. A brief summary of submitted data considered relevant to this ecological risk assessment for the CTS is presented below. Additional information can be found in **Appendix A**.



**Table 4.3. Terrestrial Toxicity Profile for Oryzalin**

Endpoint	Species	Toxicity Value Used in Risk Assessment	Citation MRID# (Author & Date)	Comment
Acute Direct Toxicity to Terrestrial-Phase CTS (LD <sub>50</sub> )	Bobwhite quail	LD <sub>50</sub> = 506.7 mg ai/kg-bw  Slope = 5.39 (95% Confidence Limits: 2.65 – 8.13)	00098462 Cochrane et al., 1982	Acceptable  Effects noted include lethargy, ataxia, ruffled appearance, emaciation, and yellow colored loose feces; dose-related decline in food consumption and body weight loss were also noted
Sub-acute Direct Toxicity to Terrestrial-Phase CTS (LC <sub>50</sub> )	Bobwhite quail/mallard duck	LC <sub>50</sub> = >5000 mg ai/kg-diet	00072593/ 00072594 Lilly Research Lab, 1980	Supplemental
Chronic Direct Toxicity to Terrestrial-Phase CTS	Bobwhite quail	NOAEC = 132 mg ai/kg  LOAEC = 311 mg ai/kg	44162201 Gallagher et al., 1996	Acceptable Female bodyweight
Indirect Toxicity to Terrestrial-Phase CTS (via acute toxicity to mammalian prey items) & Direct Toxicity (via secondary exposure)	Rat	LD <sub>50</sub> = >10 g ai/kg-bw	00026592 Lilly Research Lab, 1975	Acceptable
Indirect Toxicity to Terrestrial-Phase CTS (via chronic toxicity to mammalian prey items) & Direct Toxicity (via secondary exposure)	Rat	NOAEL = 13.8 mg ai/kg-bw/day LOAEL = 42.89 mg ai/kg-bw/day	00026779 Elanco Products Company, 1979 00044332 Carter et al., 1980 00070569 Todd, 1981	Acceptable Females more sensitive than males; decreased body weight gain, decreased hematology parameters, and increased microscopic findings in the thyroid were the noted effects
Indirect Toxicity to Terrestrial-Phase CTS (via acute toxicity to terrestrial invertebrate prey items) & Direct Toxicity (via secondary exposure)	Honey bee	LD <sub>50</sub> = >11 µg/bee	00066220	A summary study that evaluated toxicity of various pesticides to honey bees
Indirect Toxicity to Terrestrial- and Aquatic-Phase CTS (via toxicity to terrestrial plants)	<u>Seedling Emergence</u> Monocots Dicots	EC <sub>25</sub> = 0.014 lb ai/A EC <sub>25</sub> = 0.050 lb ai/A	42602401 Feutz, 1992	Supplemental TGAI ryegrass shoot length tomato shoot length
	<u>Vegetative Vigor</u> Monocots Dicots	EC <sub>25</sub> = 0.080 lb ai/A EC <sub>25</sub> = 0.030 lb ai/A	42602401 Feutz, 1992	Supplemental TGAI corn dry weight tomato dry weight

Acute toxicity to terrestrial animals is categorized using the classification system shown in **Table 4.4** (USEPA, 2004). Toxicity categories for terrestrial plants have not been defined.

<b>Table 4.4 Categories of Acute Toxicity for Avian and Mammalian Studies</b>		
<b>Toxicity Category</b>	<b>Oral LD<sub>50</sub></b>	<b>Dietary LC<sub>50</sub></b>
Very highly toxic	< 10 mg/kg	< 50 ppm
Highly toxic	10 - 50 mg/kg	50 - 500 ppm
Moderately toxic	51 - 500 mg/kg	501 - 1000 ppm
Slightly toxic	501 - 2000 mg/kg	1001 - 5000 ppm
Practically non-toxic	> 2000 mg/kg	> 5000 ppm

#### **4.2.1. Toxicity to Birds**

As specified in the Overview Document, the Agency uses birds as a surrogate for terrestrial-phase amphibians when amphibian toxicity data are not available (USEPA, 2004). No terrestrial-phase amphibian data are available for oryzalin; therefore, acute and chronic avian toxicity data are used to assess the potential direct effects of oryzalin to terrestrial-phase CTSs.

##### **4.2.1.1. Birds: Acute Exposure (Mortality) Studies**

Acute oral toxicity data (MRID 00098462) available on a single avian species, bobwhite quail (*Colinus virginianus*), is summarized in **Appendix A (Table A-5)**. Based on the LD<sub>50</sub> of 506.7 mg ai/kg-bw reported in this study, oryzalin is classified as slightly toxic to birds on an acute exposure basis. Toxic effects noted include lethargy, ataxia, ruffled appearance, emaciation, and yellow colored loose feces. Dose-related decline in food consumption and body weight loss were also noted. This study was classified as acceptable.

The results of the subacute dietary studies for the preferred test species, bobwhite quail and mallard duck (*A. platyrhynchos*), are summarized in **Appendix A (Table A-5)**. Subacute avian dietary toxicity values indicate that oryzalin is practically non-toxic to birds. Dietary studies on both the bobwhite quail (MRID# 00072593) and the mallard duck (MRID# 00072594) reported LC<sub>50</sub>s > 5000 ppm (the highest concentration tested). In the bobwhite quail study, there was one mortality at the 5000 ppm concentration but it was attributed to mechanical injury and was not considered a toxicant-related death. Even though there was no mortality observed, the bobwhite quail study did show reduced food consumption and reduction in body weight gain at all concentrations tested including the lowest concentration of 625 ppm. In the mallard duck study, there were no mortalities and no observable effects at any of the concentrations tested.

Based on a review of the open literature, no additional information on the acute and subacute toxicity of oryzalin to birds is available that indicates greater avian sensitivity than the registrant-submitted studies.

#### **4.2.1.2. Birds: Chronic Exposure (Growth, Reproduction) Studies**

Four avian reproduction studies, two on bobwhite quail (MRID 00129050 and MRID 44162201) and two on mallard duck (MRID 00126843 and MRID 44162202), have been submitted for oryzalin. These studies are summarized in **Appendix A (Table A-6)**.

The bobwhite quail (MRID 00129050) and the mallard duck (MRID 00126843) studies submitted in 1982 were classified as supplemental. While the bobwhite quail study did not fulfill guideline requirements due to mortality of birds in the control treatment, the mallard duck study determined a NOAEC of 1000 ppm, which is the highest dose tested in the study. The mallard duck study was classified as acceptable at the time the study was first reviewed in 1982; however, it was classified as supplemental in the RED because the application rates for a single application have increased 4-fold from 1.5 lb a.i./A to 6.0 lb a.i./A. To bridge this data gap and to satisfy the data requirements for avian reproduction, two new studies were submitted in 1996.

The most sensitive avian reproductive endpoint used in this assessment is based on the bobwhite quail study submitted in 1996 (MRID 44162201). The NOAEC was determined to be 132 mg/kg-food, based on reduction in the female body weight. No other reproductive effects were noted in this study. The reported LOAEC was 311 mg/kg.

In the mallard duck reproduction study of 1996 (MRID 44162202), oryzalin did not cause adverse effect on any of the endpoints evaluated even at the highest dose tested. The NOAEC/LOAEC values were determined to be >311 mg/kg-food. This study was classified as supplemental as mallard ducks were exposed to treatment for only 8 weeks prior to egg-hatching period, as opposed to the 10 week period stipulated in the guidelines.

Based on a review of the open literature, no additional information on the chronic toxicity of oryzalin to birds is available that suggests greater sensitivity than the registrant-submitted data.

#### **4.2.2. Toxicity to Mammals**

Mammalian toxicity data are used to assess potential indirect effects of oryzalin to the terrestrial-phase CTS. Effects to small mammals resulting from exposure to oryzalin could also indirectly affect the CTS via reduction in available food.

##### **4.2.2.1. Mammals: Acute Exposure (Mortality) Studies**

The acute mammalian toxicity data for oryzalin is summarized in **Appendix A (Table A-7)**. Rats exposed orally to technical grade oryzalin showed no mortality at the highest doses tested (MRID 00026592). The corresponding LD<sub>50</sub> value for the TGAI is >10,000 mg/kg-bw, which classifies technical grade oryzalin as practically non-toxic to mammals on an acute basis.

Based on a review of the open literature, no additional information on the acute toxicity of oryzalin to mammals is available that indicates greater sensitivity than the study discussed above.

#### **4.2.2.2. Mammals: Chronic Exposure (Growth, Reproduction) Studies**

Data on chronic developmental and reproductive effects of oryzalin on mammals are reported in **Appendix A (Table A-7)**. The chronic study that produced the most sensitive toxicity value for oryzalin toxicity on laboratory rats reported a NOAEL/LOAEL value of 13.82/42.89 mg/kg-bw-day based on reductions in body weight gain and decreased survival (MRID 000026779, 00044332, 00070569). Overall, female rats were more sensitive to oryzalin than males.

Based on a review of the open literature, no additional information on the chronic toxicity of oryzalin or its degradates to mammals is available that suggests greater sensitivity than the submitted data.

#### **4.2.3. Toxicity to Terrestrial Invertebrates**

Terrestrial invertebrate toxicity data are used to assess potential indirect effects of oryzalin to the terrestrial-phase CTS. Effects to terrestrial invertebrates resulting from exposure to oryzalin could also indirectly affect the CTS via reduction in available food.

##### **4.2.3.1. Terrestrial Invertebrates: Acute Exposure (Mortality) Studies**

Non-target invertebrates could be exposed to oryzalin during applications to crop fields, surrounding areas, and the other non-agricultural uses. The results of acute contact toxicity test (MRID 00066220) using formulated oryzalin on the honey bee, which is a surrogate for all terrestrial invertebrates, are summarized in **Appendix A (Table A-8)**. The LD<sub>50</sub> value for the contact test is >11 µg/bee. As a result, oryzalin is categorized as practically non-toxic to honeybees on an acute contact basis. The acute contact honey bee LD<sub>50</sub> of >11 µg/bee is used to assess potential indirect effects to the terrestrial-phase CTS.

No open literature studies that documented adverse effects on non-target insects were located for oryzalin.

#### **4.2.4. Toxicity to Terrestrial Plants**

Terrestrial plant toxicity data are used to evaluate the potential for oryzalin to affect riparian zone and upland vegetation within the action area for the CTS. Impacts to riparian and upland (*i.e.*, grassland, woodland) vegetation may result in indirect effects to both aquatic- and terrestrial-phase CTSs, as well as modification to designated critical habitat PCEs via increased sedimentation, alteration in water quality, and reduction of

upland and riparian habitat that provides shelter, foraging, predator avoidance and dispersal for juvenile and adult CTSs.

One open literature study that evaluated the effects of cytoskeletal disruption on pollen tube morphology of Norway spruce (*Picea abies*) was reviewed (E109533). Oryzalin was one of eight chemicals tested, and the following significant effects were noted: at 2  $\mu$ M, the percent pollen tubes with tip swelling and branches was increased, at 10  $\mu$ M, pollen tube lengths were inhibited, at 100  $\mu$ M, the percent germinated pollen grains were inhibited. These results are useful for qualitative purposes as they are indicative of oryzalin having the potential to affect reproduction of riparian species.

Registrant-submitted studies are conducted under conditions and with species defined in EPA toxicity test guidelines. Sub-lethal endpoints such as plant growth, dry weight, and biomass are evaluated for both monocots and dicots, and effects are evaluated at both seedling emergence and vegetative life stages. Guideline studies generally evaluate toxicity to ten crop species. A drawback to these tests is that they are conducted on herbaceous crop species only, and extrapolation of effects to other species, such as the woody shrubs and trees and wild herbaceous species, contributes uncertainty to risk conclusions.

Commercial crop species have been selectively bred, and may be more or less resistant to particular stressors than wild herbs and forbs. The direction of this uncertainty for specific plants and stressors, including oryzalin, is largely unknown. Homogenous test plant seed lots also lack the genetic variation that occurs in natural populations, so the range of effects seen from tests is likely to be smaller than would be expected from wild populations.

The results of the Tier II seedling emergence and vegetative vigor toxicity tests (MRID 42602401) on non-target plants (four monocots including corn, oats, onion, and ryegrass and six dicots including cabbage, cucumber, lettuce, tomato, soybean, and radish) are summarized in **Table 4.5** and also in **Appendix A (Table A-9)**. In both the seedling emergence and vegetative vigor tests, technical grade oryzalin was evaluated at 0.008, 0.025, 0.074, 0.222, 0.667, 2.0, and 6.0 lb ai/A on the above plants. Shoot length was found to be the most sensitive endpoint in the seedling emergence test, and dry weight was the most sensitive endpoint in the vegetative vigor test.

In the seedling emergence study, the most sensitive monocot and dicot species were ryegrass and tomato, respectively. The EC<sub>25</sub> values for ryegrass and tomato, which are based on a reduction in shoot length, were 0.014 lb ai/A and 0.050 lb ai/A, respectively. The NOAEC values for ryegrass and tomato in the seedling emergence study were 0.008 lb ai/A and <0.008 lb ai/A, respectively. In the event that a NOAEC is not definitive, the EC<sub>05</sub> is selected in place of the NOAEC. The EC<sub>05</sub> for tomato shoot length was calculated to be 0.0056 lb ai/A; however, this EC<sub>05</sub> is outside the tested concentration range and, therefore, there is little statistical confidence in this value.

In the vegetative vigor study, the most sensitive monocot and dicot species were corn and tomato, respectively. The EC<sub>25</sub> values for corn and tomato, which are based on a reduction in dry weight, were 0.080 lb ai/A and 0.030 lb ai/A, respectively. The NOAEC values for corn and tomato in the vegetative vigor study were 0.0740 lb ai/A and 0.0253 lb ai/A, respectively. These studies were classified supplemental due to the use of a technical grade active ingredient (TGAI) instead of a typical end-use product (TEP).

**Table 4.5. Non-target Terrestrial Plant Seedling Emergence and Vegetative Vigor Toxicity (Tier II) Data**

Crop	Type of Study Species	NOAEC (lb ai/A)	EC <sub>25</sub> (lb ai/A)	Most sensitive parameter
<b>Seedling Emergence</b>				
Monocots	Corn	0.667	ND	Shoot length
	Oat	0.0740	0.16	Shoot length
	Onion	0.222	0.12	Shoot length
	Ryegrass	0.0080	<b>0.014</b>	Shoot length
Dicots	Cabbage	0.222	0.52	Shoot length
	Cucumber	0.0667	0.78	Shoot length
	Lettuce	0.222	0.088	Shoot length
	Radish	2.00	>6.00	Shoot length
	Soybean	6.00	>6.00	Shoot length
	Tomato	0.0056 <sup>1</sup>	<b>0.050</b>	Shoot length
<b>Vegetative Vigor</b>				
Monocots	Corn	0.0740	<b>0.080</b>	Dry weight
	Oats	0.222	0.22	Shoot length
	Onion	2.00	>6.00	Shoot length
	Ryegrass	0.0253	0.097	Shoot length
Dicots	Cabbage	0.222	3.0	Shoot length
	Cucumber	0.222	1.5	Dry weight
	Lettuce	0.0253	0.040	Dry weight
	Radish	0.222	>6.00	Dry weight
	Soybean	2.00	3.1	Shoot length
	Tomato	0.0253	<b>0.030</b>	Dry weight

ND = Not determined

<sup>1</sup>EC<sub>05</sub> reported because a NOAEC could not be determined. However, the EC<sub>05</sub> was outside the tested concentration range; therefore, there is little statistical confidence in this value.

Based on a review of the open literature, no additional quantitative information is available that indicates greater non-target terrestrial plant sensitivity to oryzalin than the registrant-submitted studies discussed above, as the Norway spruce study (described above) is useful for qualitative purposes only.

#### 4.2.5. Sublethal Effects

No valid studies on aquatic and terrestrial organisms were located in the open literature that documented sublethal effects associated with exposure to oryzalin at levels lower than those used as assessment endpoints in this assessment.

#### 4.3. Use of Probit Slope Response Relationship to Provide Information on the Endangered Species Levels of Concern

The Agency uses the probit dose response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species (USEPA, 2004). As part of the risk characterization, an interpretation of acute RQ for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (*i.e.*, mortality or immobilization) should exposure at the EEC actually occur for a species with sensitivity to oryzalin on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency uses the slope of the dose response relationship available from the toxicity study used to establish the acute toxicity measures of effect for each taxonomic group that is relevant to this assessment. The individual effects probability associated with the acute RQ is based on the mean estimate of the slope and an assumption of a probit dose response relationship. In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects probability are also provided to account for variance in the slope, if available.

As presented in **Appendix A**, slope information is available for the acute toxicity tests on freshwater fish, freshwater invertebrates, and birds. A review of the reported slopes available for bluegill sunfish, water flea, and bobwhite quail indicates a range of 5.39 to 9.50 (**Table 4.6**).

Table 4.6. Probit Slope Information for Acute Toxicity Studies on Oryzalin				
Species Name	LC <sub>50</sub> /LD <sub>50</sub>	Slope of the Dose-Response Curve (Confidence Limits)	Chance of Individual Effect at Mean Slope Using LOC (at Confidence Limits)	MRID and Study Classification
Bluegill sunfish <i>Lepomis macrochirus</i>	2.88 mg/L	9.33 at 95% CI <sup>1</sup> (4.36 – 14.30)	1 in 3.03E+33 (1 in 1.42E+08 – 1 in 6.80E+76)	00072595 Acceptable
Water flea <i>Daphnia magna</i>	1.5 mg/L	9.50 at 95% CI (6.92 – 12.09)	1 in 4.64E+34 (1 in 9.12E+18 – 1 in 2.10E+55)	00072596 Acceptable
Bobwhite quail <i>Colinus virginianus</i>	506.7 mg/kg-bw	5.39 at 95% CI (2.65 – 8.13)	1 in 2.84E+07 (1 in 2.48E+02 – 1 in 4.66E+15)	00098462 Acceptable
<sup>1</sup> CI = confidence interval				

Individual effect probabilities are calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) developed by USEPA, OPP,

Environmental Fate and Effects Division (June 22, 2004). The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the acute RQ is entered as the desired threshold.

#### **4.4. Incident Database Review**

No incidents were found involving oryzalin in a search of the AIMS database on August 2, 2010. Two minor plant incidents were reported to the Agency in an aggregated format. A review of the EIIS database for ecological incidents involving oryzalin was completed on August 2, 2010. The results of this review for terrestrial wildlife, terrestrial plant, and aquatic incidents are discussed below in **Sections 4.4.1** through **4.4.3**, respectively. Associated uncertainties are included in **Appendix I**.

##### **4.4.1. Terrestrial Animal Incidents**

No ecological incidents involving terrestrial animals were reported for oryzalin.

##### **4.4.2. Terrestrial Plant Incidents**

The Washington State Department of Agriculture reported that 13 acres of merlot wine grapes in Grant County were damaged on April 3, 1998 due to direct application of oryzalin. The legality of use for this incident was listed as “registered use”. The certainty index for this incident (I013884-027) is unlikely as oryzalin is a registered pesticide in grape. The damage to grapes is possibly due to the application of norflurazon, the legality of which was listed as “misuse”.

A plant incident (7/3/1992) that resulted in damage to trees and shrubs (specific plants not reported) was reported from Benton County, Washington in 1992. The incident resulted due to applicator error of mixing oryzalin with bromacil/diuron. The legality of this use was reported as “undetermined”. The certainty index for this incident (I014409-062) is possible.

A nursery in Washington County, Oregon reported on February 2, 2002 that six acres of tulips were damaged by exhibiting twisting of leaves. The certainty index for this incident (I013636-027) is possible. The legality of this use was reported as “registered use”. The report mentions that isoxaben was used along with glyphosate, diclofop-methyl, fenhexamid, iprodione, and oryzalin and that diclofop-methyl was used previously in the sprayer.

Dow Elanco reported an incident in 1994 that 676,000 Douglas fir seedlings treated with Snapshot herbicide (a mixture of isoxaben and oryzalin) had to be discarded as they turned chlorotic and swollen. The certainty index for this incident (I001485-001) is possible and the legality was reported as “undetermined”. The incident report noted that little information was provided to determine which herbicide in the mixture caused the damage.



An acre of Idaho strain fir trees experienced loss of turgidity, necrosis, stem brittleness, fissures, and death in Washington in 1989/90. Pesticide application history indicated use of oxyfluorfen at planting, napropamide one month after planting, oxyfluorfen five months after planting, and oryzalin eleven months after planting. The legality of use for this incident was listed as “intentional misuse” as the label for Surflan (oryzalin) clearly states “do not apply to Douglas fir”. The certainty index for this incident (I001734-001) is probable.

#### **4.4.3. Aquatic Incidents**

Approximately 450 bluegill sunfish and largemouth bass were killed between April 6 and 13, 2001 in Georgia, following the application of a formulated product of oryzalin (Surflan) on March 31. Rain fell on 4 April and it is possible that the pond was contaminated by either spray drift or runoff. The legality of use for this incident was listed as “misuse”. Residues in fish tissue and water were not measured. The certainty index for this incident (I011444-011) is possible. However, the biologist reporting the incident stated that the kill may have been caused by a bacterial infection. Based on the toxicity profile, if this incident was related to oryzalin exposure, it is more likely that oryzalin caused indirect effects (to aquatic plants) and/or synergistic effects rather than direct toxicity to fish.

### **5. Risk Characterization**

Risk characterization is the integration of the exposure and effects characterizations. Risk characterization is used to determine the potential for direct and/or indirect effects to the CTS or for modification to its designated critical habitat from the use of oryzalin in CA. The risk characterization provides an estimation (**Section 5.1**) and a description (**Section 5.2**) of the likelihood of adverse effects; articulates risk assessment assumptions, limitations, and uncertainties; and synthesizes an overall conclusion regarding the likelihood of adverse effects to the CTS or its designated critical habitat (*i.e.*, “no effect,” “may affect and likely to adversely affect,” or “may affect but not likely to adversely affect”).

#### **5.1. Risk Estimation**

Risk is estimated by calculating the ratio of exposure to toxicity. This ratio is the risk quotient (RQ), which is then compared to pre-established acute and chronic levels of concern (LOCs) for each category evaluated (**Appendix C**). For acute exposures to the CTS and its animal prey in aquatic habitats, as well as terrestrial invertebrates, the LOC is 0.05. For acute exposures to the CTS and mammals in the terrestrial habitat, the LOC is 0.1. The LOC for chronic exposures to CTS and its prey, as well as acute exposures to plants is 1.0.

Risk to the aquatic-phase CTS is estimated by calculating the ratio of exposure to toxicity using 1-in-10 year EECs based on the label-recommended oryzalin usage scenarios summarized in **Table 3.1** and the appropriate aquatic toxicity endpoint from **Table 4.1**. Risks to the terrestrial-phase CTS and its prey (*e.g.*, terrestrial insects, small mammals

and terrestrial-phase amphibians) are estimated based on exposures resulting from broadcast spray and granular applications of oryzalin (**Tables 3.6, 3.7, and 3.8**) and the appropriate toxicity endpoint from **Table 4.3**. Exposures are also derived for terrestrial plants, as summarized in **Table 3.9**, based on the highest application rates of oryzalin use within the action area.

### 5.1.1. Exposures in the Aquatic Habitat

#### 5.1.1.1. Direct Effects to Aquatic-Phase CTS

Direct effects to the aquatic-phase CTS are based on peak EECs in the standard pond and the lowest acute toxicity value for freshwater fish. In order to assess direct chronic risks to the CTS, 60-day EECs and the lowest chronic toxicity value for freshwater fish are used.

Acute RQs met the endangered species LOC of 0.05 for direct effects to the aquatic-phase CTS based on oryzalin use on rights-of-ways (**Table 5.1**). Risk quotients for all other modeled uses did not exceed the Agency's LOC. Chronic RQs for all uses are well below the Agency's LOC of 1.0 for all the modeled uses. Direct effects associated with chronic exposure to oryzalin are not expected to occur for the aquatic-phase CTS. Chronic RQs were calculated only for the use that resulted in the highest EEC (rights-of-ways at 12 lb ai/A/year). The preliminary effect determination is "may affect" based on direct acute effects to aquatic phase CTS from rights-of-way uses only and is "no effect" for all other uses for direct effects to aquatic phase CTS.

<b>Table 5.1. Summary of Direct Effect RQs<sup>1</sup> for the Aquatic-phase CTS</b>						
<b>Use Scenario &amp; Application Rate</b>	<b>Surrogate Species</b>	<b>Toxicity Value (µg/L)</b>	<b>EEC (µg/L)<sup>2</sup></b>	<b>RQ</b>	<b>Probability of Individual Effect<sup>3</sup> (95% Confidence Limits)</b>	<b>LOC Exceedance and Risk Interpretation</b>
<b>Acute Direct Toxicity</b>						
Rights-of-ways 2 apps @ 6 lb a.i./acre (L)	Bluegill sunfish	LC <sub>50</sub> = 2,880	Peak: 141.9	<b>0.05</b>	1 in 3.03E+33 (1 in 1.42E+08 – 1 in 6.80E+76)	<b>Yes<sup>4</sup></b>
<b>Chronic Direct Toxicity</b>						
Rights-of-ways 2 apps @ 6 lb a.i./acre (L)	Fathead minnow	NOAEC = 220	60-day: 51.38	0.23	Not calculated for chronic endpoints	<b>No<sup>5</sup></b>
<sup>1</sup> RQs associated with acute and chronic direct toxicity to the CTS are also used to assess potential indirect effects to the CTS based on a reduction in freshwater fish and amphibians as food items. <sup>2</sup> The highest EEC based on oryzalin use on rights-of-ways (see <b>Table 3.3</b> ). <sup>3</sup> The probit slope value for the acute bluegill sunfish toxicity test is 9.33 (95% confidence limits: 4.36 – 14.30). <sup>4</sup> RQ ≥ acute endangered species LOC of 0.05. <sup>5</sup> RQ < chronic LOC of 1.0.						

#### 5.1.1.2. Indirect Effects to Aquatic-Phase CTS via Reduction in Prey (non-vascular aquatic plants, aquatic invertebrates, fish, and amphibians)

##### Non-vascular Aquatic Plants

Indirect effects of oryzalin to the aquatic-phase CTS (larva) via reduction in non-vascular aquatic plants in its diet are based on peak EECs from the standard pond and the lowest acute toxicity value for aquatic non-vascular plants. Risk quotients exceeded the LOC ( $RQ \geq 1.0$ ) for aquatic plants due to applications of oryzalin to some crops such as avocado, berries, tree nuts, olives, and vineyards (**Table 5.2**). Regarding non-agricultural uses, acute risk quotients exceeded the Agency's LOC from applications to ornamentals (excluding bulbs), rights-of-ways, forest trees, and uncultivated areas. No acute risk LOCs were exceeded for turf, ornamental bulbs, residential areas, and Christmas tree plantations. Thus, the preliminary effects determination is "may affect", based on indirect effects to aquatic-phase CTSs through a reduction in non-vascular aquatic plants due to uses on avocado, berries, olives, tree nuts, vineyards, rights-of-ways, ornamentals (excluding bulbs), forest trees, and uncultivated areas.

<b>Table 5.2. Summary of Acute RQs Used to Estimate Indirect Effects to the CTS via Effects to Non-vascular Aquatic Plants (diet of CTS in larval life stage and habitat of aquatic-phase CTS)</b>			
<b>Uses</b>	<b>Application Rate<sup>1</sup></b>	<b>Peak EEC (µg/L)</b>	<b>Indirect Effects RQ<sup>2</sup> (Food and Habitat)</b>
<b>Agricultural Uses</b>			
Avocado	2 apps @ 6 lb a.i./acre 75-day interval (L)	39.1	<b>1.0</b>
Berries	2 apps @ 6 lb a.i./acre 75-day interval (L)	52.98	<b>1.3</b>
Citrus fruits (surrogate for Tropical fruits)	2 apps @ 6 lb a.i./acre 75-day interval (L)	9.74	0.2
Pome and Stone fruits	2 apps @ 6 lb a.i./acre 75-day interval (L)	22.85	0.6
Olives	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.65	<b>1.4</b>
Tree nuts	2 apps @ 6 lb a.i./acre 75-day interval (L)	49.36	<b>1.2</b>
Vineyards	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.45 (table grapes) 52.98 (wine grapes)	0.5 <b>1.3</b>
<b>Non-agricultural Uses</b>			
Ornamentals	3 apps @ 4 lb a.i./acre 90-day interval (L)	47.64	<b>1.2</b>

**Table 5.2. Summary of Acute RQs Used to Estimate Indirect Effects to the CTS via Effects to Non-vascular Aquatic Plants (diet of CTS in larval life stage and habitat of aquatic-phase CTS)**

Uses	Application Rate <sup>1</sup>	Peak EEC (µg/L)	Indirect Effects RQ <sup>2</sup> (Food and Habitat)
	3 apps @ 4 lb a.i./acre, 1 app @ 3 lb a.i./acre 60-day interval (G)	72.61	<b>1.8</b>
Ornamental bulbs	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 a.i./acre 90-day interval (L)	16.4	0.4
	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 a.i./acre 90-day interval (G)	16.3	0.4
Christmas tree plantations	2 apps @ 4 lb a.i./acre 60-day interval (L)	33.5	0.8
	2 apps @ 4 lb a.i./acre 60-day interval (G)	33.6	0.8
	4 apps @ 3.34 lb a.i./acre, 1 app @ 1.67 lb a.i./acre 90-day interval (G)	41.15	0.98
Forest Trees	2 apps @ 6 lb a.i./acre 75-day interval (L)	68.59	<b>1.63</b>
Turf	3 apps @ 2 lb a.i./acre 90-day interval (L)	5.4	0.1
	4 apps @ 1.5 lb a.i./acre 90-day interval (G)	8.2	0.2
Rights-of-ways	2 apps @ 6 lb a.i./acre 180-day interval (L)	141.9	<b>3.5</b>
Residential areas	3 apps @ 2 lb a.i./acre 56-day interval (G)	3.5	0.1
Uncultivated Areas	2 apps @ 6 lb a.i./acre 180-day interval (L)	93.82	<b>2.23</b>

**Table 5.2. Summary of Acute RQs Used to Estimate Indirect Effects to the CTS via Effects to Non-vascular Aquatic Plants (diet of CTS in larval life stage and habitat of aquatic-phase CTS)**

Uses	Application Rate <sup>1</sup>	Peak EEC (µg/L)	Indirect Effects RQ <sup>2</sup> (Food and Habitat)
<sup>1</sup> L = liquid formulation; G = granular formulation <sup>2</sup> LOC exceedances (RQ ≥ 1) are bolded; RQ = use-specific peak EEC/42 ppb (most sensitive endpoint for non-vascular aquatic plant (freshwater diatom))			

### **Aquatic Invertebrates**

Indirect acute effects to the aquatic-phase CTS via effects to prey (invertebrates) in aquatic habitats are based on peak EECs in the standard pond and the lowest acute toxicity value for freshwater invertebrates. For chronic risks, 21-day EECs and the lowest chronic toxicity value for invertebrates are used to derive RQs. A summary of the acute and chronic RQ values for exposure to aquatic invertebrates (as prey items of aquatic-phase CTSs) is provided in **Table 5.3**.

**Table 5.3. Summary of Acute and Chronic RQs Used to Estimate Indirect Effects to the CTS via Direct Effects on Aquatic Invertebrates as Dietary Food Items (prey of CTS juveniles and adults in aquatic habitats)**

Uses	Application Rate <sup>1</sup> (lb ai/A)	Peak EEC (µg/L)	21-day EEC (µg/L)	Indirect Effects Acute RQ*	Indirect Effects Chronic RQ*
<b>Agricultural Uses</b>					
Avocado	2 apps @ 6 lb a.i./acre 75-day interval (L)	39.1	76.17	0.03	0.05
Berries	2 apps @ 6 lb a.i./acre 75-day interval (L)	52.48	29.24	0.04	0.08
Citrus fruits (surrogate for Tropical fruit)	2 apps @ 6 lb a.i./acre 75-day interval (L)	9.74	5.39	0.01	0.02
Pome and Stone fruits	2 apps @ 6 lb a.i./acre 75-day interval (L)	22.85	12.48	0.02	0.03
Olives	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.65	11.98	0.01	0.03
Tree nuts	2 apps @ 6 lb a.i./acre 75-day interval (L)	49.36	26.28	0.03	0.07

**Table 5.3. Summary of Acute and Chronic RQs Used to Estimate Indirect Effects to the CTS via Direct Effects on Aquatic Invertebrates as Dietary Food Items (prey of CTS juveniles and adults in aquatic habitats)**

Uses	Application Rate <sup>1</sup> (lb ai/A)	Peak EEC (µg/L)	21-day EEC (µg/L)	Indirect Effects Acute RQ*	Indirect Effects Chronic RQ*
Vineyards	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.45 (table grapes) 52.98 (wine grapes)	11.34 (table grapes) 29.24 (wine grapes)	0.01 0.04	0.03 0.08
<b>Non-agricultural Uses</b>					
Ornamentals	3 apps @ 4 lb a.i./acre 90-day interval (L)	47.64	26.27	0.03	0.07
	3 apps @ 4 lb a.i./acre, 1 app @ 3 lb a.i./acre 60-day interval (G)	72.61	36.73	<b>0.05</b>	0.1
Ornamental bulbs	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 a.i./acre 90-day interval (L)	16.4	8.48	0.01	0.02
	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 a.i./acre 90-day interval (G)	16.3	8.49	0.01	0.02
Christmas tree plantations	2 apps @ 4 lb a.i./acre 60-day interval (L)	33.5	19.37	0.02	0.05
	2 apps @ 4 lb a.i./acre 60-day interval (G)	33.6	19.72	0.02	0.06
	4 apps @ 3.34 lb a.i./acre, 1 app @ 1.67 lb a.i./acre 90-day interval (G)	41.15	23.50	0.03	0.07
Forest Trees	2 apps @ 6 lb a.i./acre 75-day interval (L)	68.59	39.27	<b>0.05</b>	0.11
Turf	3 apps @ 2 lb a.i./acre 90-day interval (L)	5.4	2.75	<0.01	0.01

**Table 5.3. Summary of Acute and Chronic RQs Used to Estimate Indirect Effects to the CTS via Direct Effects on Aquatic Invertebrates as Dietary Food Items (prey of CTS juveniles and adults in aquatic habitats)**

Uses	Application Rate <sup>1</sup> (lb ai/A)	Peak EEC (µg/L)	21-day EEC (µg/L)	Indirect Effects Acute RQ*	Indirect Effects Chronic RQ*
	4 apps @ 1.5 lb a.i./acre 90-day interval (G)	8.2	4.16	0.01	0.01
Rights-of-ways	2 apps @ 6 lb a.i./acre 180-day interval (L)	141.9	115.97	<b>0.09</b>	0.24
Residential areas	3 apps @ 2 lb a.i./acre 56-day interval (G)	3.5	1.82	<0.01	0.01
Uncultivated Areas	2 apps @ 6 lb a.i./acre 180-day interval (L)	93.82	50.50	<b>0.06</b>	0.14

<sup>1</sup>L = liquid formulation; G = granular formulation

\*LOC exceedances (acute RQ  $\geq 0.05$ ; chronic RQ  $\geq 1.0$ ) are bolded. Acute RQ = use-specific peak EEC/1500 ppb (most sensitive acute freshwater invertebrate endpoint). Chronic RQ = use-specific 21-day EEC/358 ppb (most sensitive chronic freshwater invertebrate endpoint).

The chance of an individual effect at the highest RQ (0.09) is 1 in 6.8E+22 (based on a slope of 9.50).

Acute RQs for various modeled oryzalin uses ranged between <0.01 and 0.1 and were less than LOCs (RQ = 0.5) for non-listed species. However, acute RQs exceeded the LOCs for listed species (RQ  $\geq 0.05$ ) due to applications of oryzalin to forest trees, rights-of-ways, uncultivated areas, and ornamentals excluding bulbs (granular only). Chronic RQs are less than the chronic LOC (RQ  $\geq 1.0$ ) for aquatic invertebrates for all modeled oryzalin uses. The preliminary effects determination is “may affect” for indirect effects to aquatic-phase CTSs based on a reduction of freshwater invertebrates as prey (via direct acute toxicity to freshwater invertebrates). However, reduction in the freshwater invertebrate prey base via chronic toxicity is not expected.

### **Fish and Amphibians**

Fish and amphibians also represent potential prey items of adult aquatic-phase CTSs. RQs associated with acute and chronic direct toxicity to the CTS (**Table 5.1**) are used to assess potential indirect effects to the CTS based on a reduction in freshwater fish and amphibians as food items. Given that acute RQs for direct toxicity to the CTS exceeded the Agency’s LOCs for oryzalin uses on rights-of-ways, indirect effects based on a reduction of fish and amphibians as prey items may occur. However, the effects of potential reductions in food to the CTS are discussed in the context of an effects determination in **Section 5.2**.

#### **5.1.1.3. Indirect Effects to CTS via Reduction in Habitat and/or Primary Productivity (Freshwater Vascular Aquatic Plants)**

Indirect effects to the CTS via direct toxicity to aquatic plants are estimated using the most sensitive non-vascular and vascular plant toxicity endpoints. Because there are no obligate relationships between the CTS and any aquatic plant species, the most sensitive EC<sub>50</sub> values, rather than NOAEC values, were used to derive RQs.

Except for oryzalin application in citrus and tropical fruits, turf, and residential areas, RQs exceeded the LOC of 1 for vascular aquatic plants for all other modeled scenarios (**Table 5.4**). Therefore, the preliminary effects determination is “may affect”, based on indirect effects to habitat and/or primary productivity for the aquatic-phase CTS.

Table 5.4. Summary of Acute RQs Used to Estimate Indirect Effects to the CTS via Effects to Vascular Aquatic Plants (habitat of aquatic-phase CTS) <sup>1</sup>			
Use Category	Application Rate <sup>2</sup> (lb ai/A)	Peak EEC (µg/L)	Indirect effects RQ <sup>3</sup>
Agricultural Uses			
Avocado	2 apps @ 6 lb a.i./acre 75-day interval (L)	39.1	3.01
Berries	2 apps @ 6 lb a.i./acre 75-day interval (L)	52.98	4.08
Citrus fruits (surrogate for Tropical fruits)	2 apps @ 6 lb a.i./acre 75-day interval (L)	9.74	0.075
Pome and Stone fruits	2 apps @ 6 lb a.i./acre 75-day interval (L)	22.85	1.76
Olives	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.65	1.66
Tree nuts	2 apps @ 6 lb a.i./acre 75-day interval (L)	49.36	3.80
Vineyards	2 apps @ 6 lb a.i./acre 75-day interval (L)	21.45 (table grapes)	1.65
		52.98 Wine grapes)	4.08
Non-agricultural Uses			
Ornamentals	3 apps @ 4 lb a.i./acre 90-day interval (L)	47.64	3.66
	3 apps @ 4 lb a.i./acre, 1 app @ 3 lb a.i./acre 60-day interval (G)	72.61	5.58
Ornamental bulbs	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 a.i./acre 90-day interval (L)	16.4	1.26



**Table 5.4. Summary of Acute RQs Used to Estimate Indirect Effects to the CTS via Effects to Vascular Aquatic Plants (habitat of aquatic-phase CTS)<sup>1</sup>**

Use Category	Application Rate <sup>2</sup> (lb ai/A)	Peak EEC (µg/L)	Indirect effects RQ <sup>3</sup>
	1 app @ 1.5 lb a.i./acre, 1 app @ 0.75 a.i./acre 90-day interval (G)	16.3	<b>1.25</b>
Christmas tree plantations	2 apps @ 4 lb a.i./acre 60-day interval (L)	33.5	<b>2.58</b>
	2 apps @ 4 lb a.i./acre 60-day interval (G)	33.6	<b>2.58</b>
	4 apps @ 3.34 lb a.i./acre, 1 app @ 1.67 lb a.i./acre 90-day interval (G)	41.15	<b>3.16</b>
Forest Trees	2 apps @ 6 lb a.i./acre 75-day interval (L)	68.59	<b>5.28</b>
Turf	3 apps @ 2 lb a.i./acre 90-day interval (L)	5.4	0.42
	4 apps @ 1.5 lb a.i./acre 90-day interval (G)	8.2	0.63
Rights-of-ways	2 apps @ 6 lb a.i./acre 180-day interval (L)	141.9	<b>10.92</b>
Residential areas	3 apps @ 2 lb a.i./acre 56-day interval (G)	3.5	0.27
Uncultivated Areas	2 apps @ 6 lb a.i./acre 180-day interval (L)	93.82	<b>7.22</b>

<sup>1</sup>RQs used to estimate indirect effects to the CTS via toxicity to non-vascular aquatic plants are summarized in **Table 5.2**; <sup>2</sup>L = liquid formulation; G = granular formulation; <sup>3</sup>LOC exceedances (RQ ≥ 1) are bolded. RQ = use-specific peak EEC/13 ppb (most sensitive endpoint for vascular aquatic plant)

## 5.1.2. Exposures in the Terrestrial Habitat

### 5.1.2.1. Direct Effects to Terrestrial-phase CTS

As previously discussed in **Section 3.3**, potential direct effects to terrestrial-phase CTSs are based on broadcast spray and granular applications of oryzalin.

#### **Broadcast Spray Applications**

Potential direct acute effects to the terrestrial-phase CTS are derived by considering dose- and dietary-based EECs modeled in T-REX for a small bird (20 g) consuming small invertebrates (**Table 3.6**) and acute oral and subacute dietary toxicity endpoints for avian species.

Risk quotients calculated using the bobwhite quail oral LD<sub>50</sub> value of 506.7 mg a.i./kg-bw suggests that acute RQs exceeded the LOCs for listed species ( $RQ \geq 0.1$ ) for all use categories (**Table 5.5**). The range for dose-based avian acute RQs is 0.63 to 3.10. On the other hand, definitive dietary-based acute RQ values for terrestrial-phase CTSs could not be derived because the acute avian effects data, which are used as a surrogate for terrestrial-phase amphibians, showed no mortality to both the mallard duck and bobwhite quail at the highest tested level of oryzalin (LC<sub>50</sub> > 5,000 mg/kg-diet). Since the predicted dietary-based EECs (which ranged between 202 and 993 ppm) were several fold lower than the avian LC<sub>50</sub> value of > 5,000 mg/kg-diet, dietary-based acute avian and terrestrial-phase CTS mortality is unlikely. The preliminary effects determination for direct acute effects to the terrestrial-phase CTS is “may affect” for all uses.

<b>Table 5.5. Summary of Acute RQs<sup>1</sup> Used to Estimate Direct Effects to the Terrestrial-Phase CTS (Broadcast Spray Application)</b>			
<b>Use Category</b>	<b>Dose-based EEC</b>	<b>Dose-based Acute RQ<sup>2</sup></b>	<b>Probability of Individual Effect<sup>3</sup></b>
<b>Agricultural Uses</b>			
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	1131	<b>3.10</b>	1 in 1.00
<b>Non-agricultural Uses</b>			
Ornamentals	736	<b>2.02</b>	1 in 1.05
Ornamental Bulbs	231	<b>0.63</b>	1 in 7.16
Christmas Tree Plantations	802	<b>2.20</b>	1 in 1.03
Forest Trees	1131	<b>3.10</b>	1 in 1.00
Turf	368	<b>1.01</b>	1 in 1.96
Rights-of-ways	949	<b>2.60</b>	1 in 1.01
Uncultivated Areas	949	<b>2.60</b>	1 in 1.01
<sup>1</sup> LOC exceedances (acute RQ $\geq 0.5$ and acute endangered species RQ $\geq 0.1$ ) are bolded.			
<sup>2</sup> Based on bobwhite quail oral LD <sub>50</sub> of 506.7 mg/kg			
<sup>3</sup> The probit slope value for the acute bobwhite quail toxicity test is 5.39.			

Potential direct chronic effects of oryzalin to the terrestrial-phase CTS are derived by considering dietary-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates. Chronic effects are estimated using the lowest available toxicity data for birds. EECs are divided by toxicity values to estimate chronic dietary-based RQs. As shown in **Table 5.6**, chronic RQs, which ranged from 1.53 to 7.53, exceed LOCs for all modeled broadcast spray applications of oryzalin. Therefore, the preliminary effects determination is “may affect” for direct chronic effects to the terrestrial-phase CTS.

**Table 5.6. Summary of Chronic RQs Used to Estimate Direct Effects to the Terrestrial-Phase CTS (Broadcast Spray Application)**

Use	Dietary-based EEC	Dietary-based Chronic RQ <sup>1</sup>
<b>Agricultural Uses</b>		
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruit and Vineyards	993	<b>7.53</b>
<b>Non-agricultural Uses</b>		
Ornamentals	646	<b>4.89</b>
Ornamental Bulbs	202	<b>1.53</b>
Christmas Tree Plantations	705	<b>5.34</b>
Forest Trees	993	<b>7.53</b>
Turf	323	<b>2.45</b>
Rights-of-ways	833	<b>6.31</b>
Uncultivated Areas	833	<b>6.31</b>

<sup>1</sup>LOC exceedances (chronic RQ  $\geq 1$ ) are bolded and are based on bobwhite quail NOAEC of 132 ppm.

### **Granular Applications**

As previously discussed in **Section 3.3.2**, direct effects to the terrestrial-phase CTS via exposure to oryzalin granules are derived based on LD<sub>50</sub>/ft<sup>2</sup> values. A comparison of EECs derived for granular applications of oryzalin with adjusted avian LD<sub>50</sub> values for two weight classes of 20g and 100g (representative of juvenile and adult terrestrial-phase CTSs) is presented in **Table 5.7**.

**Table 5.7. Comparison of Granular EECs to Adjusted LD<sub>50</sub><sup>1</sup> Value Used to Estimate Direct Effects to the Terrestrial-phase CTS**

Use	Application Rate (lb ai/A)	EEC (mg/ft <sup>2</sup> )	LD <sub>50</sub> /ft <sup>2</sup>	
			20 g (juvenile)	100g (adult)
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, Vineyards and Ornamentals (Excluding Bulbs)	4	41.65	<b>5.71*<sup>+</sup></b>	<b>0.90*<sup>+</sup></b>
Ornamental Bulbs	1.5	15.62	<b>2.14*<sup>+</sup></b>	<b>0.34*</b>
Christmas Tree Plantations	4	41.65	<b>5.71*<sup>+</sup></b>	<b>0.90*<sup>+</sup></b>
Turf	1.5	15.62	<b>2.14*<sup>+</sup></b>	<b>0.34*</b>
Rights-of-ways	6	62.48	<b>8.56*<sup>+</sup></b>	<b>1.34*<sup>+</sup></b>
Residential areas	2	20.83	<b>2.85*<sup>+</sup></b>	<b>0.45*</b>

<sup>1</sup>Adjusted Avian LD<sub>50</sub> = LD<sub>50</sub> (AW/TW)<sup>(1.15<sup>-1</sup>)</sup> ; Actual Avian (bobwhite quail) LD<sub>50</sub> = 506.7 mg/kg-bw; Weight of tested species (TW) (bobwhite quail) = 178 g; Assessed weight of juvenile and adult amphibians (AW) = 20 and 100 g, respectively; Adjusted LD<sub>50</sub> Value (mg/kg-bw) for 20 g juvenile and 100 g adult was calculated to be 365 and 465, respectively.

\*Exceeds acute endangered species LOC of 0.1.

+Also exceeds acute LOC of 0.5.

LD<sub>50</sub>/ft<sup>2</sup> analysis indicates that LOCs were exceeded for all uses. LD<sub>50</sub>/ft<sup>2</sup> values ranged from 0.34 to 8.56. Overall, the preliminary effects determination for direct effects to the terrestrial-phase CTS via granular application of oryzalin is “may affect” for all uses.

Further qualitative discussion of potential acute risks to birds associated with exposure to granular oryzalin is provided in **Section 5.2.1.2**.

#### **5.1.2.2. Indirect Effects to Terrestrial-Phase CTS via Reduction in Prey (terrestrial invertebrates, mammals, and amphibians)**

##### **Terrestrial Invertebrates**

In order to assess the risks of oryzalin to terrestrial invertebrates, which are considered prey of CTS in terrestrial habitats, the honey bee is used as a surrogate for terrestrial invertebrates. The toxicity value for terrestrial invertebrates is normally calculated by multiplying the lowest available acute contact LD<sub>50</sub> of >11µg a.i./bee by 1 bee/0.128g, which is based on the weight of an adult honey bee. EECs (µg a.i./g of bee) calculated by T-REX for small and large insects are divided by the calculated toxicity value for terrestrial invertebrates, which is > 86µg a.i./g of bee.

As the toxicity endpoint for honey bee is non-definitive (*i.e.*, the LD<sub>50</sub> value is greater than the highest test concentration), RQs were not calculated. Potential risks are described in **Section 5.2**.

##### **Mammals (Broadcast Spray Applications)**

Risks are derived for dietary-based and dose-based exposures modeled in T-REX for a small mammal (15g) consuming short grass. Acute and chronic effects are estimated using the most sensitive mammalian toxicity data. EECs are divided by the toxicity value to estimate acute and chronic dose-based RQs as well as chronic dietary-based RQs.

Because the mammalian LD<sub>50</sub> value is >10,000 mg/kg-bw, acute dose-based RQs were not calculated. Potential risks are described in **Section 5.2**.

Chronic dose-based and dietary-based RQ values exceed the chronic risk LOC (RQ ≥ 1.0) for mammals considered as potential prey species for CTS for all modeled uses of oryzalin (**Table 5.8**). Therefore, the preliminary effects determination for indirect effects to terrestrial-phase CTSs via reduction in small mammals (exposed to broadcast spray applications of oryzalin) as dietary food items is “may affect”.

<b>Table 5.8. Summary of Chronic RQs Used to Estimate Indirect Effects to the Terrestrial-phase CTS via Direct Effects on Small Mammals as Dietary Food Items (Broadcast Spray Application)</b>		
<b>Use</b>	<b>Chronic RQ<sup>1</sup></b>	
	<b>Dose-based Chronic RQ<sup>2</sup></b>	<b>Dietary-based Chronic RQ<sup>3</sup></b>
<b>Agricultural Uses</b>		
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	<b>55.44</b>	<b>6.39</b>
<b>Non-agricultural Uses</b>		
Ornamentals	<b>36.06</b>	<b>4.16</b>
Ornamental Bulbs	<b>11.3</b>	<b>1.3</b>

**Table 5.8. Summary of Chronic RQs Used to Estimate Indirect Effects to the Terrestrial-phase CTS via Direct Effects on Small Mammals as Dietary Food Items (Broadcast Spray Application)**

Use	Chronic RQ <sup>1</sup>	
	Dose-based Chronic RQ <sup>2</sup>	Dietary-based Chronic RQ <sup>3</sup>
Christmas Tree Plantations	<b>39.32</b>	<b>4.53</b>
Forest Trees	<b>55.44</b>	<b>6.39</b>
Turf	<b>18.03</b>	<b>2.08</b>
Rights-of-ways	<b>46.48</b>	<b>5.36</b>
Uncultivated Areas	<b>46.48</b>	<b>5.36</b>

<sup>1</sup>LOC exceedances (chronic RQ  $\geq 1$ ) are bolded  
<sup>2</sup>Based on dose-based EEC and oryzalin rat NOAEL of 13.82 mg/kg-bw  
<sup>3</sup>Based on dietary-based EEC and oryzalin rat NOAEC of 276.4 mg/kg-diet

### **Mammals (Granular Applications)**

Risks to small mammals that may consume oryzalin granules are based on LD<sub>50</sub>/ft<sup>2</sup> values. However, LD<sub>50</sub>/ft<sup>2</sup> values were not calculated because the mammalian LD<sub>50</sub> value was reported as >10,000 mg/kg-bw (*i.e.*, 50% mortality was not observed in the highest treatment levels of oryzalin). Potential acute risks to mammals based on exposure to granules are described in **Section 5.2**.

### **Amphibians**

Additional prey items of the adult terrestrial-phase CTS are amphibians. In order to assess risks to these organisms, dietary-based and dose-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates are used. As previously discussed in **Section 5.1.2.1**, direct acute (dose-based) (RQs = 0.63 – 3.10) and chronic (RQs = 1.53 – 7.53) effects to amphibians are possible, based on the available avian acute and chronic toxicity data. Therefore, the preliminary effects determination for indirect effects to terrestrial-phase CTSs via reduction in other species of amphibians as dietary food items is “may affect”.

#### **5.1.2.3. Indirect Effects to CTS via Reduction in Terrestrial Plant Community (Riparian and Upland Habitat)**

Potential indirect effects to the CTS resulting from direct effects on riparian and upland vegetation are assessed using RQs from terrestrial plant seedling emergence and vegetative vigor EC<sub>25</sub> data as a screen. Based on the results of the submitted terrestrial plant toxicity tests, it appears that both monocot and dicot plants are more sensitive to applications of oryzalin at the seedling emergence stage than at the vegetative stage. Seedling emergence of corn, soybean, and radish and vegetative vigor of onion, cabbage, cucumber, radish, and soybean were not affected following exposure to oryzalin. The results of these tests indicate that a variety of terrestrial plants that may inhabit riparian and upland zones may be sensitive to oryzalin exposure.

**Table 5.9. RQs for Monocots Inhabiting Dry and Semi-Aquatic Areas Exposed to Oryzalin via Runoff and Drift**

Use Category	Type of Application	Application Rate (lb ai/A)	Drift Value (%)	Dry area RQ	Semi-aquatic area RQ	Spray drift RQ
<b>Agricultural Uses</b>						
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	Ground Broadcast	6	1	<b>8.57</b>	<b>47.14</b>	<b>4.29</b>
	Granular	4	0	<b>2.86</b>	<b>28.57</b>	<0.1
<b>Non-agricultural Uses</b>						
Ornamentals	Ground Broadcast	4	1	<b>5.71</b>	<b>31.43</b>	<b>2.86</b>
	Granular	4	0	<b>2.86</b>	<b>28.57</b>	<0.1
Ornamental Bulbs	Ground Broadcast	1.5	1	<b>2.14</b>	<b>11.79</b>	<b>1.07</b>
	Granular	1.5	0	<b>1.07</b>	<b>10.71</b>	<0.1
Christmas Tree Plantations	Ground Broadcast	4	1	<b>5.71</b>	<b>31.43</b>	<b>2.86</b>
	Granular	4	0	<b>2.86</b>	<b>28.57</b>	<0.1
Forest Trees	Ground Broadcast	6	1	<b>8.57</b>	<b>47.14</b>	<b>4.29</b>
Turf	Ground Broadcast	2	1	<b>2.86</b>	<b>15.71</b>	<b>1.43</b>
	Granular	1.5	0	<b>1.07</b>	<b>10.71</b>	<0.1
Rights-of-ways	Ground Broadcast	6	1	<b>8.57</b>	<b>47.14</b>	<b>4.29</b>
	Granular	6	0	<b>4.29</b>	<b>42.86</b>	<0.1
Residential areas	Granular	2	0	<b>1.43</b>	<b>14.29</b>	<0.1
Uncultivated Areas	Ground Broadcast	6	1	<b>8.57</b>	<b>47.14</b>	<b>4.29</b>
LOC exceedances (RQ $\geq$ 1) are bolded						

Dry area and semi-aquatic area RQs exceeded the LOC (RQ  $\geq$  1.0) for monocots for all applications of oryzalin (**Tables 5.9 and 5.10**). Spray drift RQs exceeded the LOC for monocots for all liquid spray applications. For dicots, dry area RQs exceeded the LOC for liquid spray applications to ornamentals (excluding bulbs), Christmas tree plantations, forest trees, rights-of-ways, and uncultivated areas. The LOC was also exceeded for granular applications to rights-of-ways. All semi-aquatic area RQs exceeded the LOCs for dicots except the agricultural uses. All spray drift RQs exceeded the LOC for dicots for liquid spray applications except ornamental bulbs and turf. Example output from TerrPlant v.1.2.2 is provided in **Appendix F**. The preliminary effects determination for indirect effects to terrestrial- and aquatic-phase CTSs via reduction in the terrestrial plant community is “may affect”.

<b>Table 5.10. RQs for Dicots Inhabiting Dry and Semi-Aquatic Areas Exposed to Oryzalin via Runoff and Drift</b>						
<b>Use Category</b>	<b>Type of Application</b>	<b>Application Rate (lbs ai/A)</b>	<b>Drift Value (%)</b>	<b>Dry Area RQ</b>	<b>Semi-Aquatic Area RQ</b>	<b>Spray Drift RQ</b>
<b>Agricultural Uses</b>						
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	Ground Broadcast	6	1	2.40	13.20	<b>2.00</b>
	Granular	4	0	0.80	8.00	<0.1
<b>Non-agricultural Uses</b>						
Ornamentals	Ground Broadcast	4	1	<b>1.60</b>	<b>8.80</b>	<b>1.33</b>
	Granular	4	0	0.80	<b>8.00</b>	<0.1
Ornamental Bulbs	Ground Broadcast	1.5	1	0.60	<b>3.30</b>	0.50
	Granular	1.5	0	0.30	<b>3.00</b>	<0.1
Christmas Tree Plantations	Ground Broadcast	4	1	<b>1.60</b>	<b>8.80</b>	<b>1.33</b>
	Granular	4	0	0.80	<b>8.00</b>	<0.1
Forest Trees	Ground Broadcast	6	1	<b>2.40</b>	<b>13.20</b>	<b>2.00</b>
Turf	Ground Broadcast	2	1	0.80	<b>4.40</b>	0.67
	Granular	1.5	0	0.30	<b>3.00</b>	<0.1
Rights-of-ways	Ground Broadcast	6	1	<b>2.40</b>	<b>13.20</b>	<b>2.00</b>
	Granular	6	0	<b>1.20</b>	<b>12.00</b>	<0.1
Residential areas	Granular	2	0	0.40	<b>4.00</b>	<0.1
Uncultivated Areas	Ground Broadcast	6	1	<b>2.40</b>	<b>13.20</b>	<b>2.00</b>
LOC exceedances (RQ $\geq$ 1) are bolded						

### 5.1.3. Primary Constituent Elements of Designated Critical Habitat

#### 5.1.3.1. Aquatic-Phase (Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)

Three of the four assessment endpoints for the aquatic-phase primary constituent elements (PCEs) of designated critical habitat for the CTS are related to potential effects to aquatic and/or terrestrial plants:

- Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian

vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CTSs.

- Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CTSs and their food source.
- Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae).

The preliminary effects determination for aquatic-phase PCEs of designated habitat related to potential effects on aquatic and/or terrestrial plants is “habitat modification”, based on the risk estimation provided in **Sections 5.1.1.2, 5.1.1.3, and 5.1.2.3.**

The remaining aquatic-phase PCE is “alteration of other chemical characteristics necessary for normal growth and viability of CTSs and their food source.” To assess the impact of oryzalin on this PCE, acute and chronic freshwater fish and invertebrate toxicity endpoints, as well endpoints for aquatic non-vascular plants, are used as measures of effects. RQs for these endpoints were calculated in **Sections 5.1.1.1 and 5.1.1.2.** Based on these results, the preliminary effects determination for alteration of characteristics necessary for normal growth and viability of the CTS is “habitat modification” (see **Section 5.1.1.1**). Aquatic invertebrate and non-vascular aquatic plant food items of the CTS may be affected; therefore the preliminary effects determination for potential impacts to these food items is “habitat modification” (see **Section 5.1.1.2**).

#### **5.1.3.2. Terrestrial-Phase (Upland Habitat and Dispersal Habitat)**

Two of the four assessment endpoints for the terrestrial-phase PCEs of designated critical habitat for the CTS are related to potential effects to terrestrial plants:

- Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CTSs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian n habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CTS shelter, forage, and predator avoidance
- Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal

The preliminary effects determination for terrestrial-phase PCEs of designated habitat related to potential effects on terrestrial plants is “habitat modification”, based on the risk estimation provided in **Section 5.1.2.3.**

The third terrestrial-phase PCE is “reduction and/or modification of food sources for terrestrial phase juveniles and adults.” To assess the impact of oryzalin on this PCE, acute and chronic toxicity endpoints for birds, mammals, and terrestrial invertebrates are used as measures of effects. RQs for these endpoints, calculated in **Section 5.1.2.2.**



exceed the LOCs for all oryzalin uses. The preliminary effects determination for this PCE via impacts of oryzalin to terrestrial-phase CTS food items is “habitat modification”.

The fourth terrestrial-phase PCE is based on alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CTSs and their food source. Direct acute and chronic RQs for terrestrial-phase CTSs are presented in **Section 5.1.2.1**. Both direct acute effects (via mortality) and chronic reproductive effects are possible with all the spray and granular applications of oryzalin for the terrestrial-phase CTS (see **Section 5.1.2.1**). Therefore the preliminary effects determination for this PCE is “habitat modification” due to direct acute effects to terrestrial-phase CTSs and “habitat modification” based on chronic exposures to oryzalin.

## 5.2. Risk Description

The risk description synthesizes an overall conclusion regarding the likelihood of adverse impacts leading to an effects determination (*i.e.*, “no effect,” “may affect, but not likely to adversely affect,” or “likely to adversely affect”) for the CTS and its designated critical habitat.

If the RQs presented in the Risk Estimation (**Section 5.1**) show no direct or indirect effects for the CTS, and no modification to PCEs of the CTS’s designated critical habitat, a “no effect” determination is made, based on oryzalin’s use within the action area. However, if direct or indirect effect LOCs are exceeded or effects may modify the PCEs of the CTS’s critical habitat, the Agency concludes a preliminary “may affect” determination for the FIFRA regulatory action regarding oryzalin. A summary of the results of the risk estimation (*i.e.*, “no effect” or “may affect” finding) is provided in **Table 5.11** for direct and indirect effects to the CTS and in **Table 5.12** for the PCEs of designated critical habitat for the CTS.

<b>Table 5.11. Preliminary Effects Determination Summary for Oryzalin - Direct and Indirect Effects to CTS</b>		
<b>Assessment Endpoint</b>	<b>Preliminary Effects Determination</b>	<b>Basis For Preliminary Determination</b>
<i>Aquatic Phase (eggs, larvae, tadpoles, juveniles, and adults)</i>		
Survival, growth, and reproduction of CTS individuals via direct effects on aquatic phases	Fish: May affect	Using the bluegill sunfish (a freshwater fish) as a surrogate, no chronic LOCs are exceeded for any use ( <b>Table 5.1</b> ). However, acute LOCs are exceeded for 1 use (rights-of-ways).

<b>Table 5.11. Preliminary Effects Determination Summary for Oryzalin - Direct and Indirect Effects to CTS</b>		
<b>Assessment Endpoint</b>	<b>Preliminary Effects Determination</b>	<b>Basis For Preliminary Determination</b>
Survival, growth, and reproduction of CTS individuals via effects to food supply ( <i>i.e.</i> , freshwater invertebrates, non-vascular plants)	<p>Aquatic non-vascular plants: May affect</p> <p>Freshwater invertebrates: May affect</p> <p>Fish and amphibians: May affect</p>	<p>Except for citrus, tropical, pome, and stone fruits, table grapes, Christmas tree plantations, ornamental bulbs, residential areas, and turf, non-vascular plant RQs exceeded LOCs for all other modeled scenarios (<b>Table 5.2</b>).</p> <p>Acute invertebrate RQs exceeded LOCs for forest trees, rights-of-ways, and uncultivated areas, as well as ornamentals excluding bulbs (granular only). Chronic aquatic invertebrate RQs did not exceed Agency's LOC for any of the modeled scenarios (<b>Table 5.3</b>).</p> <p>Acute LOCs are exceeded for rights-of-ways only based on the most sensitive toxicity data for freshwater fish (<b>Table 5.1</b>). No chronic LOC exceedances were noted for freshwater fish with any of the modeled scenarios.</p>
Survival, growth, and reproduction of CTS individuals via indirect effects on habitat, cover, and/or primary productivity ( <i>i.e.</i> , aquatic plant community)	Aquatic plants: May affect	LOCs are exceeded for non-vascular aquatic plants (all scenarios except citrus, tropical, pome, and stone fruits, ornamental bulbs, Christmas tree plantations, turf, and residential areas) and vascular plants (all scenarios except citrus, tropical, turf, and residential areas) ( <b>Tables 5.2 and 5.4</b> ).
Survival, growth, and reproduction of CTS individuals via effects to riparian vegetation, required to maintain acceptable water quality and habitat in ponds and streams comprising the species' current range.	Terrestrial plants: May affect	Most uses are likely to adversely affect CTS via effects to riparian vegetation. Both upland and semi-aquatic plants are expected to be significantly impacted by oryzalin use at exposure levels included in this assessment ( <b>Tables 5.9 and 5.10</b> ).
<b>Terrestrial Phase (Juveniles and adults)</b>		
Survival, growth, and reproduction of CTS individuals via direct effects on terrestrial phase adults and juveniles	<p>Acute bird: May affect</p> <p>Chronic bird: May affect</p>	<p>Based on the available avian acute toxicity data, which is used as a surrogate for terrestrial-phase amphibians, RQs exceed LOCs for all modeled scenarios (<b>Table 5.5 and 5.7</b>). Therefore, direct adverse effects may occur on terrestrial phase adults and juveniles.</p> <p>Dietary-based chronic RQs exceeded the LOC for all modeled broadcast spray applications of oryzalin (<b>Table 5.6</b>).</p>

**Table 5.11. Preliminary Effects Determination Summary for Oryzalin - Direct and Indirect Effects to CTS**

Assessment Endpoint	Preliminary Effects Determination	Basis For Preliminary Determination
Survival, growth, and reproduction of CTS individuals via effects on prey ( <i>i.e.</i> , terrestrial invertebrates, small terrestrial mammals and terrestrial phase amphibians) <sup>1</sup>	Acute bird: May affect  Chronic birds and mammals: May affect	RQs exceeded LOCs for all modeled scenarios ( <b>Table 5.5 and 5.7</b> ).  Dietary-based chronic RQs for mammals and birds exceed the LOCs for all modeled non-granular uses of oryzalin ( <b>Tables 5.6 and 5.8</b> ).
Survival, growth, and reproduction of CTS individuals via indirect effects on habitat ( <i>i.e.</i> , riparian vegetation)	Terrestrial plants: May affect	LOCs are exceeded for both monocots and dicots for all modeled uses of oryzalin ( <b>Tables 5.9 and 5.10</b> ).
<sup>1</sup> Preliminary effects determinations for acute risks to terrestrial invertebrates and mammals are not included because RQs were not calculated since toxicity values were non-definitive. Potential risks will be described in the sections below, after which an effects determination will be made.		

**Table 5.12. Preliminary Effects Determination Summary for Oryzalin – PCEs of Designated Critical Habitat for the CTS**

Assessment Endpoint	Preliminary Effects Determination	Basis For Preliminary Determination
<b><i>Aquatic Phase PCEs</i></b> <b><i>(Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)</i></b>		
Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CTSs.	Habitat modification	LOCs are exceeded for both monocots and dicots for all modeled uses of oryzalin ( <b>Tables 5.9 and 5.10</b> ).
Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CTSs and their food source.	Habitat modification	LOCs are exceeded for both monocots and dicots for all modeled uses of oryzalin ( <b>Tables 5.9 and 5.10</b> ).
Alteration of other chemical characteristics necessary for normal growth and viability of CTSs and their food source.	Growth and viability of CTS: Habitat modification	Acute LOCs exceeded for freshwater fish for rights-of-ways only ( <b>Table 5.1</b> ).
	Food source: Habitat modification	Acute aquatic non-vascular plant and freshwater invertebrate RQs exceed LOCs for most uses ( <b>Tables 5.2 and 5.3</b> ).
Reduction and/or modification of aquatic-based food sources for pre-metamorphs ( <b>e.g.</b> , algae)	Habitat modification	Acute LOCs are exceeded for non-vascular aquatic plants for most uses ( <b>Table 5.2</b> ).

<b>Table 5.12. Preliminary Effects Determination Summary for Oryzalin – PCEs of Designated Critical Habitat for the CTS</b>		
<b>Assessment Endpoint</b>	<b>Preliminary Effects Determination</b>	<b>Basis For Preliminary Determination</b>
<b><i>Terrestrial Phase PCEs (Upland Habitat and Dispersal Habitat)</i></b>		
Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CTSs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CTS shelter, forage, and predator avoidance	Habitat modification	LOCs are exceeded for both monocots and dicots for all modeled uses of oryzalin ( <b>Tables 5.9 and 5.10</b> ).
Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal	Habitat modification	LOCs are exceeded for both monocots and dicots for all modeled uses of oryzalin ( <b>Tables 5.9 and 5.10</b> ).
Reduction and/or modification of food sources for terrestrial phase juveniles and adults <sup>1</sup>	Habitat modification	Based on likely effects to small amphibians and mammals, reduction in food sources is expected ( <b>Tables 5.5, 5.6, 5.7, and 5.8</b> ).
Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CTSs and their food source. <sup>1</sup>	Habitat modification	Chronic RQs for mammals and birds exceed the LOCs for all modeled non-granular uses of oryzalin ( <b>Tables 5.6 and 5.8</b> ). Therefore, chronic effects are possible for small insectivorous mammals that are food items of the CTS.
<sup>1</sup> Preliminary effects determinations for acute risks to terrestrial invertebrates and mammals are not included because RQs were not calculated since toxicity values were non-definitive. Potential risks will be described in the sections below, after which an effects determination will be made.		

Following a preliminary “may affect” or “habitat modification” determination, additional information is considered to refine the potential for exposure at the predicted levels based on the life history characteristics (*i.e.*, habitat range, feeding preferences, *etc.*) of the CTS. Based on the best available information, the Agency uses the refined evaluation to distinguish those actions that “may affect but are not likely to adversely affect” from those actions that “may affect and are likely to adversely affect” the CTS and its designated critical habitat.

The criteria used to make determinations that the effects of an action are “not likely to adversely affect” the CTS and its designated critical habitat include the following:

- **Significance of Effect:** Insignificant effects are those that cannot be meaningfully measured, detected, or evaluated in the context of a level of effect where “take” occurs for even a single individual. “Take” in this context means to harass or harm, defined as the following:

- Harm includes significant habitat modification or degradation that results in death or injury to listed species by significantly impairing behavioral patterns such as breeding, feeding, or sheltering.
- Harass is defined as actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding, or sheltering.
- Likelihood of the Effect Occurring: Discountable effects are those that are extremely unlikely to occur.
- Adverse Nature of Effect: Effects that are wholly beneficial without any adverse effects are not considered adverse.

A description of the risk and effects determination for each of the established assessment endpoints for the CTS and its designated critical habitat is provided in **Sections 5.2.1** through **5.2.4**.

### **5.2.1. Direct Effects**

#### **5.2.1.1. Aquatic-Phase CTS**

The aquatic-phase considers life stages of the salamander that are obligatory aquatic organisms, including eggs and larvae. It also considers submerged terrestrial-phase juveniles and adults, which spend a portion of their time in water bodies that may receive runoff and spray drift-containing oryzalin. Based on the highest modeled EECs for oryzalin use on rights-of-ways (6 lb ai/A) and the most sensitive freshwater fish (bluegill sunfish for acute toxicity and fathead minnow for chronic toxicity) (both used as surrogates for aquatic-phase amphibians), the acute RQ exceeds the Agency's listed species LOC for oryzalin uses on rights-of-ways only (**Table 5.1**). However, chronic toxicity did not exceed the risk LOC for any of the modeled scenarios.

Model-estimated peak environmental concentrations resulting from different oryzalin uses ranged from 3.5 to 141.89 µg/L. Comparison of the highest modeled surface water EEC (peak = 141.89 µg/L) with available CDPR surface water monitoring data (110 µg/L) indicates that the highest peak modeled EEC is less than 1.5 times higher than the maximum concentration of oryzalin detected in the Stanislaus River.

While the acute RQ for mortality effects for the aquatic-phase CTS exceeded the listed species LOC for only one non-food use (rights-of-ways), the probability of individual effects was low enough that the likelihood of measuring such an effect was considered improbable. The bluegill sunfish study reported a slope of 9.33. The calculated RQ was 0.05 (liquid spray) for applications on rights-of-ways. The corresponding estimated chance of an individual acute mortality to the aquatic-phase CTS is 1 in 3.03E+33. This probability is considered to be discountable for this biological evaluation. Given the low probability of an individual mortality occurrence based on acute exposure and in view of chronic RQs that are well below LOCs, oryzalin is not likely to cause direct adverse effects to aquatic-phase CTSs.

Only one freshwater aquatic incident involving a fish kill (450-500 bluegill sunfish and largemouth bass) was reported for oryzalin. The incident, which happened in 2001 in Georgia, was classified as misuse as it resulted possibly from either spray drift or run off following a rain event. It is unclear whether this incident was caused by oryzalin exposure. Residues in fish and water were not measured. The certainty index associated with this incident was “possible.” However, the biologist reporting the incident stated that the kill may have been caused by a bacterial infection. Based on the toxicity profile, if this incident was related to oryzalin exposure, it is more likely that oryzalin caused indirect effects (to aquatic plants) and/or synergistic effects rather than direct toxicity to fish. More details on the incident can be found in **Appendix I**.

In summary, the Agency concludes a “not likely to adversely affect (NLAA)” determination for rights of ways and a “no effect” determination for all other labeled uses for direct effects to the aquatic-phase CTS (Central California, Sonoma County, and Santa Barbara County Distinct Population Segments), via mortality, growth, or fecundity, based on all available lines of evidence.

#### **5.2.1.2. Terrestrial-phase CTS**

Acute LOCs were exceeded for birds, which are used as surrogates for the terrestrial-phase CTS via exposure to spray and granular applications of oryzalin. The acute avian dose-based RQs exceed the listed species LOC for all uses of oryzalin suggesting concerns for risk. Therefore, direct effects to the terrestrial-phase CTS via ingestion of terrestrial food items may occur.

Before concluding LAA or NLAA for acute direct effects to the terrestrial-phase CTS, a refinement of the risks posed to the terrestrial-phase CTS from ingestion of residues on small insects was performed. As the avian acute RQs exceeded the listed species acute LOC (0.1) when calculated with T-REX, the likelihood of the risk should be considered in light of the results of the T-HERPS model. This refinement was performed because the avian acute dose-based RQ values in **Table 5.5**, used as screening surrogates for terrestrial-phase amphibians, likely overestimated risks to amphibians. Overestimation is due to the higher energy requirements of birds over amphibians of the same body weight, which results in a higher daily food intake rate value and a resultant higher dose-based exposure for birds than would occur for an amphibian of the same body weight. The T-HERPS model refines the RQ values based on dietary intake rate of an amphibian, rather than a dietary intake rate of a bird. Results of the analysis performed with T-HERPS are presented in **Table 5.13a, b, c, and d**.

The results suggest that potential risks from dietary consumption of contaminated prey remain above the listed species LOC for all uses. Applications to berries, citrus, vineyards, olive, pome fruit, tree nuts, tropical fruits, stone fruits, and forest trees (2 applications @ 6 lb a.i./Acre, 75-day interval) resulted in LOCs being exceeded for consumption of small insects and consumption of potentially contaminated mammals

(Table 5.13a). Lower application rates were also modeled, and RQs still exceeded LOCs (Table 5.13b, c, and d).

<b>Table 5.13a. T-HERPS Analysis for Berries, Citrus, Vineyards, Olive, Pome Fruit, Tree Nuts, Tropical Fruits, Stone Fruits, and Forest Trees (6 lb a.i./Acre, 2 applications, 75-Day Interval)</b>			
<b>Dose-based RQs (Dose-based EEC/adjusted LD50)</b>	<b>Amphibian/Reptile Acute RQs for Small, Medium, and Large Species (grams)</b>		
	<b>2</b>	<b>20</b>	<b>200</b>
Small Insect	<b>0.21</b>	0.09	0.04
Large Insect	0.02	0.01	<0.01
Herbivore mammals	NA	<b>3.24</b>	<b>0.84</b>
Insectivore mammals	NA	<b>0.20</b>	0.05
Terrestrial phase amphibian	NA	0.07	0.03

<b>Table 5.13b. T-HERPS Analysis for Rights-of-Ways (6 lb a.i./Acre, 2 applications, 180-day interval)</b>			
<b>Dose-based RQs (Dose-based EEC/adjusted LD50)</b>	<b>Amphibian/Reptile Acute RQs for Small, Medium, and Large Species (grams)</b>		
	<b>2</b>	<b>20</b>	<b>200</b>
Small Insect	<b>0.18</b>	0.08	0.03
Large Insect	0.02	0.01	<0.01
Herbivore mammals	NA	<b>2.71</b>	<b>0.70</b>
Insectivore mammals	NA	<b>0.17</b>	0.04
Terrestrial phase amphibian	NA	0.05	0.02

<b>Table 5.13c. T-HERPS Analysis for Christmas Trees (4 lb a.i./Acre, 2 applications, 60-Day Interval)</b>			
<b>Dose-based RQs (Dose-based EEC/adjusted LD50)</b>	<b>Amphibian/Reptile Acute RQs for Small, Medium, and Large Species (grams)</b>		
	<b>2</b>	<b>20</b>	<b>200</b>
Small Insect	<b>0.15</b>	0.06	0.03
Large Insect	0.02	0.01	<0.01
Herbivore mammals	NA	<b>2.30</b>	<b>0.60</b>
Insectivore mammals	NA	<b>0.14</b>	0.04
Terrestrial phase amphibian	NA	0.05	0.02

<b>Table 5.13d. T-HERPS Analysis for Turf (2 lb a.i./Acre, 3 applications, 90-Day Interval)</b>			
<b>Dose-based RQs (Dose-based EEC/adjusted LD50)</b>	<b>Amphibian/Reptile Acute RQs for Small, Medium, and Large Species (grams)</b>		
	<b>2</b>	<b>20</b>	<b>200</b>
Small Insect	0.07	0.03	0.01
Large Insect	0.01	<0.01	<0.01

**Table 5.13d. T-HERPS Analysis for Turf (2 lb a.i./Acre, 3 applications, 90-Day Interval)**

Dose-based RQs (Dose-based EEC/adjusted LD50)	Amphibian/Reptile Acute RQs for Small, Medium, and Large Species (grams)		
	2	20	200
Herbivore mammals	NA	<b>1.05</b>	<b>0.27</b>
Insectivore mammals	NA	0.07	0.02
Terrestrial phase amphibian	NA	0.02	0.01

T-HERPS analysis suggests that considering the lower daily food intake for terrestrial phase amphibians relative to birds does not preclude the potential for an individual effect. RQs remained above the LOC for CTSs that consume small herbivore and insectivore mammals and other terrestrial-phase amphibians. The LOC was also exceeded for CTSs that consume small insects at the 6 lb a.i./Acre and 4 lb a.i./Acre application rates. This analysis was performed using a 35-day foliar dissipation half life.

LOCs were exceeded for CTSs that consume mammals. This analysis assumes that the pesticide is retained in the gut of a prey mammal for a sufficient period of time to allow for secondary exposure to the CTS. This is considered a conservative assumption. Based on RQs of 3.24 to 0.14, approximately 3% to 71% retention of oryzalin in/on a mammal would be sufficient to result in an LOC exceedance. For this reason, the potential for a single individual CTS to be adversely impacted from consuming a contaminated mammal could not be precluded.

**Table 5.13e. T-HERPS Analysis for Dietary-based Chronic Risk**

Dietary-based RQs (Dietary-based EEC/LC50 or NOAEC)	Berries, Citrus, Vineyards, Olive, Pome Fruit, Tree Nuts, Tropical Fruits, Stone Fruits, and Forest Trees (6 lb a.i./Acre, 2 applications, 75-Day Interval)	Rights-of-Ways (6 lb a.i./Acre, 2 applications, 180-day interval)	Christmas Trees (4 lb a.i./Acre, 2 applications, 60-Day Interval)	Turf (2 lb a.i./Acre, 3 applications, 90-Day Interval)
Small Insect	<b>7.53</b>	<b>6.31</b>	<b>5.34</b>	<b>2.45</b>
Large Insect	0.84	0.70	0.59	0.27
Herbivore mammals	<b>13.43</b>	<b>11.26</b>	<b>9.52</b>	<b>4.37</b>
Insectivore mammals	0.84	0.70	0.60	0.27
Terrestrial phase amphibian	0.27	0.23	0.19	0.09

Dietary-based chronic RQs exceed the Agency's LOCs for all of the non-granular uses of oryzalin. With chronic dietary-based RQ values ranging from approximately 2.45 to 7.53, terrestrial-phase CTSs foraging on small insects experience reduction in offspring survival due to reproductive effects due to exposure to the contaminated food items



(**Table 5.13e**). The chronic dietary-based RQ values ranged from 4.37 to 13.43 for terrestrial-phase CTSs feeding on herbivorous mammals. Chronic risks to the terrestrial-phase CTS were evaluated using a bobwhite quail NOAEC value of 132 mg/kg-diet, which is based on reduction in female body weight. Based on the bobwhite quail NOAEC value of 132 mg/kg-diet, chronic LOCs are exceeded for terrestrial-phase CTSs that consume small insects for the modeled scenarios.

For granular applications, an LD<sub>50</sub>/ft<sup>2</sup> analysis was performed. This measure of risk is not limited to dietary consumption of granules but includes all potential exposure routes. Therefore, although the CTS may not ingest granules, exposure may occur from dermal contact if they are present in close proximity to a treated field, and the LD<sub>50</sub>/ft<sup>2</sup> analysis was not further refined.

No ecological incidents involving birds or amphibians were reported for oryzalin.

In summary, the Agency concludes a “likely to adversely affect” or “LAA” effects determination based on both acute and chronic direct effects to the terrestrial-phase CTS via current liquid spray and granular uses of oryzalin.

### **5.2.2. Indirect Effects (via Reductions in Prey Base)**

#### **5.2.2.1. Algae (non-vascular plants)**

The diet of CTS larvae may consist, in part, of algae. Risk quotients for non-vascular plants were calculated based on the EC<sub>50</sub> value of 42 µg/L for freshwater diatom (*Navicula pelliculosa*). Risk quotients exceeded acute aquatic plant risk LOCs for all the modeled scenarios except citrus and tropical fruits, pome and stone fruits, Christmas tree plantations, ornamental bulbs, turf, and residential areas (**Table 5.2**).

Oryzalin may affect sensitive aquatic non-vascular plants. The measured peak concentration of oryzalin in California watersheds (110 ppb) is higher than the EC<sub>50</sub> for freshwater diatom. Thus, it is likely that oryzalin could indirectly affect the CTS via reduction in aquatic non-vascular plants as food items.

The effects determination for indirect effects of oryzalin to CTS larvae via reductions in non-vascular plants is “likely to adversely affect” or “LAA” for oryzalin uses in avocado, berries, olives, tree nuts, vineyards, ornamentals (excluding bulbs), forest trees, rights-of-ways, and uncultivated areas. Oryzalin uses in citrus fruits, tropical, pome, and stone fruits, Christmas tree plantations, ornamental bulbs, turf, and residential areas are not expected to indirectly impact CTS larvae (via a reduction in non-vascular plants as food) because all RQs for these uses are below LOCs. The effects determination for these uses is “no effect” with respect to potential indirect effects resulting from reduced aquatic plant growth. According to the 1999-2008 CA PUR data described in **Section 2.4.4** and summarized in **Table 2.4**, the highest oryzalin usage in California is reported for tree nuts, grapes, rights-of-ways, stone fruits, ornamentals and landscape maintenance, citrus fruits, pome fruits, and berries. Therefore, the overall effects determination for indirect

effects of oryzalin to CTS tadpoles via reductions in non-vascular plants is “likely to adversely affect” or “LAA”.

#### **5.2.2.2. Aquatic Invertebrates**

Acute RQs exceeded the LOCs for listed species ( $RQ \geq 0.05$ ) for applications to forest trees, rights-of-ways, and uncultivated areas, as well as ornamentals excluding bulbs (granular only) (**Table 5.3**). Although acute RQs exceeded the acute listed species LOC of 0.05 for the above uses, they are less than the non-listed acute LOC of 0.5. Chronic RQs for aquatic invertebrates are less than the chronic LOC ( $RQ \geq 1.0$ ) for aquatic invertebrates for all modeled oryzalin uses.

Predicted chance of individual effect using probit dose-response curve slope from the daphnid study (slope = 9.5) and median lethal estimate ( $LC_{50} = 1500$  ppb) to a freshwater invertebrate at an RQ level of 0.1 (highest calculated RQ) is 1 in  $9.53E+20$ . At the lower RQ range of 0.05, the corresponding estimated chance of an individual acute mortality/immobilization to a freshwater invertebrate is 1 in  $4.64E+34$ .

The potential for oryzalin to elicit indirect effects to the CTS via effects on freshwater invertebrate food items is dependent on several factors including: (1) the potential magnitude of effect on freshwater invertebrate individuals and populations; and (2) the number of prey species potentially affected relative to the expected number of species needed to maintain the dietary needs of the CTS. Together, these data provide a basis to evaluate whether the number of individuals within a prey species is likely to be reduced such that it may indirectly affect the CTS.

Oryzalin may affect sensitive aquatic invertebrates; however, the low probability of an individual effect suggests that oryzalin is not likely to indirectly affect the CTS via a reduction in aquatic invertebrate prey items. Any potential effects to the CTS resulting from reductions in aquatic invertebrate as food items are considered discountable. Therefore, the effects determination for indirect effects to the CTS via effects on freshwater invertebrates as prey is “not likely to adversely affect” or “NLAA”.

#### **5.2.2.3. Fish and Aquatic-phase Amphibians**

The Agency concluded a “NLAA” determination for direct effects to the aquatic-phase CTS, via mortality, growth, or fecundity. Therefore, indirect effects to the CTS via a reduction in freshwater fish and other aquatic-phase amphibian species as prey items are not expected.

#### **5.2.2.4. Terrestrial Invertebrates**

When the terrestrial-phase CTS reaches juvenile and adult stages, its diet is mainly composed of terrestrial invertebrates. RQs were not calculated in the risk estimation section for terrestrial invertebrates because the  $LD_{50}$  was non-definitive. A comparison of the terrestrial EECs (202 – 993 ppm for small insects; 22 – 110 ppm for large insects)

to the LD<sub>50</sub> value (>86µg a.i./g of bee) would yield RQs ranging from <2.35 to <11.55 for small insects and <0.26 to <1.28 for large insects. While these RQs are non-definitive, the extent to which the acute RQs may fall below the terrestrial invertebrate listed species LOC of 0.05 is uncertain. Given the uncertainty in the toxicity of oryzalin at the exposure levels estimated on treated fields, this assessment concludes that oryzalin is “likely to adversely affect” (LAA) the CTS via reduction in terrestrial invertebrates as food items. This determination is made because the potential for a single CTS to be impacted via reduction in food items cannot be precluded.

#### **5.2.2.5. Mammals**

Life history data for terrestrial-phase CTSs indicate that large adult salamanders consume terrestrial vertebrates, including mice. As previously discussed, definitive acute RQ values could not be derived because the mammalian LD<sub>50</sub> value is >10,000 mg/kg-bw. A comparison of dose-based EECs for broadcast spray applications to the non-definitive LD<sub>50</sub> would yield RQs ranging from <0.02 to <0.08. Because these RQs do not exceed the LOC (0.1), the effects determination for acute risks to mammals due to broadcast spray applications is “no effect”. However, when comparing the granular EECs (15.62 – 62.48 mg/ft<sup>2</sup>) to the adjusted LD<sub>50</sub>, the resulting LD<sub>50</sub>/ft<sup>2</sup> range from <0.05 to <0.19. While the RQs are non-definitive, the extent to which the acute RQs may fall below the mammalian listed species LOC of 0.1 is uncertain for granular application rates of 4 or 6 (Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, Vineyards, Ornamentals (Excluding Bulbs), Christmas Tree Plantations, and Rights-of-ways). Given the uncertainty in the toxicity of oryzalin at the exposure levels estimated on treated fields for granular applications, this assessment concludes that oryzalin is “likely to adversely affect” (LAA) the CTS via reduction in mammals as food items.

Chronic RQs (1.3 to 55.44) representing oryzalin exposures to small mammals indicate risks resulting from all broadcast spray (non-granular) uses. Based on the available toxicity data, chronic exposure of laboratory rats to oryzalin resulted in consistent reductions in adult body weight in females at 42.89 mg/kg/day and decreased survival and decreased weight gain in males at 112.5 mg/kg/day. The corresponding NOAEC was 13.8 and 36.9 mg/kg-diet for males and females, respectively, suggesting that females were more sensitive to oryzalin than males. Indirect effects are possible for large CTS adults through decreases in mammalian prey via chronic exposure to non-granular uses of oryzalin. Therefore, the effects determination for indirect effects to terrestrial-phase CTSs via reduction in small mammals as prey is “likely to adversely affect” or LAA for all modeled uses.

#### **5.2.2.6. Terrestrial-phase Amphibians**

Terrestrial-phase adult CTSs also consume other amphibians. RQ values representing direct exposures of oryzalin to terrestrial-phase CTSs are used to represent exposures of oryzalin to amphibians in terrestrial habitats. Based on estimated exposures resulting from granular and non-granular uses of oryzalin, both acute (dose-based) and chronic

risks to terrestrial phase amphibians are possible. Therefore, the effects determination for indirect effects to CTS adults that feed on other species of amphibians as prey, via acute and chronic exposure to oryzalin, is “likely to adversely affect” or LAA.

### **5.2.3. Indirect Effects (via Habitat Effects)**

#### **5.2.3.1. Aquatic Plants (Vascular and Non-Vascular)**

Aquatic plants serve several important functions in aquatic ecosystems. Non-vascular aquatic plants are primary producers and provide the autochthonous energy base for aquatic ecosystems. Vascular plants provide structure, rather than energy, to the system, as attachment sites for many aquatic invertebrates, and refugia for juvenile organisms, such as fish and amphibians. Emergent plants help reduce sediment loading and provide stability to near shore areas and lower stream banks. In addition, vascular aquatic plants are important as attachment sites for egg masses of CTSs.

Potential indirect effects to the CTS based on impacts to habitat and/or primary production are assessed using RQs from freshwater aquatic vascular and non-vascular plant data. Based on RQs for non-vascular plants (previously described in **Section 5.2.2.1** and summarized in **Table 5.2**), LOCs are exceeded for RQs for applications of oryzalin to avocado, berries, olives, tree nuts, vineyards (wine grapes), ornamentals (excluding bulbs), forest trees, rights-of-ways, and uncultivated areas. Vascular plant RQs are less than the LOC of 1 for citrus and tropical fruits, turf, and residential uses only (**Table 5.4**). Therefore, indirect effects to the CTS via direct effects to vascular plants as habitat are expected.

As previously discussed in **Section 5.2.2.1**, the range of toxic endpoints for three out of the four non-vascular plants and the vascular plant included in this assessment fell within the range of peak modeled oryzalin concentrations (3.5 to 141.89 µg/L). Even though the CTS depends on a wide range of non-vascular and vascular plants, it is expected that oryzalin, being a herbicide, would elicit adverse impacts on other vascular and non-vascular plants resulting in indirect effects to CTSs via direct habitat-related impacts to non-vascular and vascular plants. Therefore, the effects determination for indirect effects of oryzalin to CTSs via impacts to habitat and/or primary production through direct effects to non-vascular plants is “likely to adversely affect” or “LAA”.

#### **5.2.3.2. Terrestrial Plants**

Terrestrial plants serve several important habitat-related functions for the CTS. In addition to providing habitat and cover for invertebrate and vertebrate prey items of the CTS, terrestrial vegetation also provides shelter for the CTS and cover from predators while foraging. Upland vegetation including grassland and woodlands provides cover during dispersal. Riparian vegetation helps to maintain the integrity of aquatic systems by providing bank and thermal stability, serving as a buffer to filter out sediment, nutrients, and contaminants before they reach the watershed, and serving as an energy source.

Loss, destruction, and alteration of habitat were identified as a threat to the CTS in the USFWS Recovery Plan (USFWS, 2002). Herbicides can adversely impact habitat in a number of ways. In the most extreme case, herbicides in spray drift and runoff from the site of application have the potential to kill (or reduce growth and/or biomass in) all or a substantial amount of the vegetation, thus removing or impacting structures which define the habitat, and reducing the functions (*e.g.*, cover, food supply for prey base) provided by the vegetation.

Oryzalin is a herbicide that is absorbed mainly through the roots of developing plants. It has little or no foliar activity and is not translocated within the plant. Thus the primary effect of oryzalin is on root development of emerging plants. Roots of affected plants are relatively few in number, short, thick, and club shaped. The inhibited root growth causes tops of plants to be stunted and demonstrate a dark green color.

Riparian vegetation typically consists of three tiers of vegetation, which include a groundcover of grasses and forbs, an understory of shrubs and young trees, and an overstory of mature trees. CTSs spend a considerable amount of time resting and feeding in riparian vegetation; the moisture and cover of the riparian plant community provides good foraging habitat, and may facilitate dispersal in addition to providing pools and backwater aquatic areas for breeding. Upland habitat includes grassland and woodlands, as well as scrub/shrub habitat. No guideline data are available on the toxicity of oryzalin to woody plants. While oryzalin is labeled for use around numerous woody species including citrus, tree nuts, tropical fruits, and grapes, as well as uses associated with tree plantations and nurseries, toxicity to woody plants may be possible, especially considering the label warning against the use on Douglas fir. Additionally, a few plant incidents have been reported that indicate damage to woody species is possible.

As shown in **Tables 5.9 and 5.10**, RQs exceed LOCs for monocots and dicots inhabiting dry and semi-aquatic areas exposed to liquid formulations of oryzalin via runoff and drift. Spray drift RQs did not exceed LOCs for granular formulations.

In summary, based on exceedance of the terrestrial plant LOCs for all oryzalin use patterns following runoff and spray drift to semi-aquatic and dry areas, the following general conclusions can be made with respect to potential harm to riparian habitat:

- Oryzalin may enter riparian areas via runoff and/or spray drift where it may be taken up by the roots of sensitive emerging seedlings.
- Based on oryzalin's mode of action and a comparison of seedling emergence EC<sub>25</sub> values to EECs estimated using TerrPlant, emerging or developing seedlings may be affected. However, this does not preclude the potential for effects to established plants. Furthermore, based on the residual nature of oryzalin, it is expected to impact germinating seedlings and emerging plants for several months after application. Inhibition of new growth could result in degradation of high quality riparian habitat over time because as older growth

dies from natural or anthropogenic causes, plant biomass may be prevented from being replenished in the riparian area.

- Because several species in each of the seedling emergence and vegetative vigor studies were affected, it is likely that many species of herbaceous plants may be potentially affected by exposure to oryzalin via runoff and spray drift.

A review of the oryzalin incidents for terrestrial plants revealed 5 incidents. Photo-toxicity or plant death reported in almost all of these incidents was due to the use of other herbicides that have the potential to cause injury either in a mixture or due to use before and/or after the oryzalin applications. Although the reported number of oryzalin incidents for terrestrial plants is low, an absence of reports does not necessarily provide evidence of an absence of incidents. The only plant incidents that are reported are those that are alleged to occur on more than 45 percent of the acreage exposed to the pesticide. Therefore, an incident could impact 40% of an exposed crop and not be reported by a registrant.

In summary, terrestrial plant RQs exceed LOCs; therefore, upland and riparian vegetation may be affected. Given that both upland and riparian areas are comprised of a mixture of both non-sensitive woody (trees and shrubs) and sensitive grassy herbaceous vegetation, CTSs may be indirectly affected by adverse effects to herbaceous and woody vegetation, which provides habitat and cover for the CTS and its prey. Therefore, the effects determination for this assessment endpoint is “likely to adversely affect” or “LAA” for all assessed oryzalin use patterns.

The distance required to dissipate spray drift to below the LOC was determined using AgDrift based on the EC<sub>25</sub> levels for terrestrial plants. The Tier I ground scenario was used in AgDrift, and input parameters included a high boom and ASAE fine to medium/coarse droplet sizes. Theoretically, dissipation to the no effect level should be modeled in order to provide potential buffer distances that are protective of endangered terrestrial plant species. This distance beyond the site of application is considered as the action area for oryzalin. However, because no obligate relationship exists between the CTS and terrestrial plants, the portion of the action area that is relevant to the CTS is defined by the dissipation distance to the EC<sub>25</sub> level (*i.e.*, the potential buffer distance required to protect non-endangered terrestrial plant species).

Spray drift dissipation distances for typical oryzalin use rates are presented in **Table 5.14**. Based on the endpoints derived for seedling emergence and vegetative vigor, adverse effects to terrestrial plants might reasonably be expected to occur up to 364 feet for monocots and up to 154 feet for dicots from the use site for ground applications of oryzalin. The dissipation distance is expected to increase based on a decrease in droplet size as fine drops will result in more drift. In some cases, topography (such as an intervening ridge) or weather conditions (such as prevailing winds towards or away from the amphibian habitat) could affect the estimates presented in **Table 5.14**.

<b>Table 5.14. Spray Drift Dissipation Distances for Oryzalin (Distance to no LOC Exceedance)</b>				
<b>Oryzalin Application Rate (lb ai/A)</b>	<b>Dissipation Distance (ft)</b>			
	<b>Seedling Emergence</b>		<b>Vegetative Vigor</b>	
	<b>Monocot</b>	<b>Dicot</b>	<b>Monocot</b>	<b>Dicot</b>
6	364	82	46	154
4	233	49	26	92
2	102	23	13	39
1.5	69	16	10	26

In addition to the buffered area from the spray drift analysis, the Potential Area of LAA Effects area also typically considers the downstream extent of predicted pesticide concentrations that would exceed the LOC based on downstream dilution analysis. However, due to the widespread use of oryzalin across multiple land cover classes, this analysis was not performed.

#### **5.2.4. Modification to Designated Critical Habitat**

##### **5.2.4.1. Aquatic-Phase PCEs**

Three of the four assessment endpoints for the aquatic-phase primary constituent elements (PCEs) of designated critical habitat for the CTS are related to potential effects to aquatic and/or terrestrial plants:

- Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CTSs.
- Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CTSs and their food source.
- Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae).

The effects determinations for indirect effects to the CTS via direct effects to aquatic and terrestrial plants are used to determine whether modification to critical habitat may occur. Based on the results of the effects determinations for aquatic plants (see **Sections 5.2.2.1** and **5.2.3.1**), critical habitat of the CTS may be modified via oryzalin-related impacts to non-vascular aquatic plants as food items for tadpoles and habitat for aquatic-phase CTSs. Critical habitat may be modified by an increase in sediment deposition and associated turbidity (via impacts to herbaceous riparian vegetation), potential reduction in oxygen (via impacts to the aquatic plant community and primary productivity), and reduction in herbaceous riparian vegetation that provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult aquatic-phase CTSs. Oryzalin uses may result in modification to critical habitat via direct effects to non-vascular plants.

Based on the results of the effects determination for terrestrial plants (see **Section 5.2.3.2**), oryzalin-related effects on shading (*i.e.*, temperature), bank stabilization, and structural diversity (height classes) of vegetation are possible because some woody plants may be sensitive to environmentally-relevant concentrations of oryzalin. In addition, modification to critical habitat may occur via oryzalin-related impacts to sensitive herbaceous vegetation, which provide habitat and cover for the CTS and its prey, based on all assessed uses of oryzalin.

The remaining aquatic-phase PCE is “alteration of other chemical characteristics necessary for normal growth and viability of CTSs and their food source.” Other than impacts to algae as food items for tadpoles (discussed above), this PCE was assessed by considering direct and indirect effects to the aquatic-phase CTS via acute and chronic freshwater fish and invertebrate toxicity endpoints as measures of effects. As discussed in **Section 5.2.1.1**, direct effects to the aquatic-phase CTS, via mortality are possible for one use. Therefore, oryzalin is likely to adversely affect critical habitat by altering chemical characteristics necessary for normal growth and viability of aquatic-phase CTSs and their non-plant food sources.

#### **5.2.4.2. Terrestrial-Phase PCEs**

Two of the four assessment endpoints for the terrestrial-phase PCEs of designated critical habitat for the CTS are related to potential effects to terrestrial plants:

- Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CTSs: Upland areas within 200 ft of the edge of the riparian vegetation or drip line surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CTS shelter, forage, and predator avoidance.
- Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal.

As discussed above, modification to critical habitat may occur via oryzalin-related impacts to sensitive herbaceous vegetation, which provides habitat, cover, and a means of dispersal for the terrestrial-phase CTS and its prey, based on all assessed uses of oryzalin. Modification to critical habitat is not expected to occur in woodland areas because most woody plants are not sensitive to environmentally relevant concentrations of oryzalin.

The third terrestrial-phase PCE is “reduction and/or modification of food sources for terrestrial phase juveniles and adults.” To assess the impact of oryzalin on this PCE, acute and chronic toxicity endpoints for terrestrial invertebrates, mammals, and terrestrial-phase amphibians are used as measures of effects. Based on the characterization of indirect effects to terrestrial-phase CTSs via reduction in the prey base (see **Section 5.2.2.4** for terrestrial invertebrates, **Section 5.2.2.5** for mammals, and **5.2.2.6**



for amphibians), critical habitat may be modified via a reduction in mammals and terrestrial-phase amphibians as food items.

The fourth terrestrial-phase PCE is based on alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CTSs and their food source. As discussed in **Section 5.2.1.2**, direct acute effects, via mortality, are expected for the terrestrial-phase CTS. Furthermore, chronic reproductive effects are also possible for all non-granular uses of oryzalin. Therefore, oryzalin may adversely affect critical habitat by altering chemical characteristics necessary for normal growth and viability of terrestrial-phase CTSs and their mammalian and amphibian food sources.

## **6. Uncertainties**

### **6.1. Exposure Assessment Uncertainties**

#### **6.1.1. Maximum Use Scenario**

The screening-level risk assessment focuses on characterizing potential ecological risks resulting from a maximum use scenario, which is determined from labeled statements of maximum application rate and number of applications with the shortest time interval between applications. The frequency at which actual uses approach this maximum use scenario may be dependent on pest resistance, timing of applications, cultural practices, and market forces.

#### **6.1.2. Aquatic Exposure Modeling of Oryzalin**

The standard ecological water body scenario (EXAMS pond) used to calculate potential aquatic exposure to pesticides is intended to represent conservative estimates, and to avoid underestimations of the actual exposure. The standard scenario consists of application to a 10-hectare field bordering a 1-hectare, 2-meter deep (20,000 m<sup>3</sup>) pond with no outlet. Exposure estimates generated using the EXAMS pond are intended to represent a wide variety of vulnerable water bodies that occur at the top of watersheds including prairie pot holes, playa lakes, wetlands, vernal pools, man-made and natural ponds, and intermittent and lower order streams. As a group, there are factors that make these water bodies more or less vulnerable than the EXAMS pond. Static water bodies that have larger ratios of pesticide-treated drainage area to water body volume would be expected to have higher peak EECs than the EXAMS pond. These water bodies will be either smaller in size or have larger drainage areas. Smaller water bodies have limited storage capacity and thus may overflow and carry pesticide in the discharge, whereas the EXAMS pond has no discharge. As watershed size increases beyond 10-hectares, it becomes increasingly unlikely that the entire watershed is planted with a single crop that is all treated simultaneously with the pesticide. Headwater streams can also have peak concentrations higher than the EXAMS pond, but they likely persist for only short periods of time and are then carried and dissipated downstream.

The Agency acknowledges that there are some unique aquatic habitats that are not accurately captured by this modeling scenario and modeling results may, therefore, under- or over-estimate exposure, depending on a number of variables. For example, aquatic-phase CTSs may inhabit water bodies of different size and depth and/or are located adjacent to larger or smaller drainage areas than the EXAMS pond. The Agency does not currently have sufficient information regarding the hydrology of these aquatic habitats to develop a specific alternate scenario for the CTS. Therefore, the EXAMS pond is assumed to be representative of exposure to aquatic-phase CTSs. In addition, the Services agree that the existing EXAMS pond represents the best currently available approach for estimating aquatic exposure to pesticides (USFWS/NMFS, 2004).

In general, the linked PRZM/EXAMS model produces estimated aquatic concentrations that are expected to be exceeded once within a ten-year period. The Pesticide Root Zone Model is a process or “simulation” model that calculates what happens to a pesticide in an agricultural field on a day-to-day basis. It considers factors such as rainfall and plant transpiration of water, as well as how and when the pesticide is applied. It has two major components: hydrology and chemical transport. Water movement is simulated by the use of generalized soil parameters, including field capacity, wilting point, and saturation water content. The chemical transport component can simulate pesticide application on the soil or on the plant foliage. Dissolved, adsorbed, and vapor-phase concentrations in the soil are estimated by simultaneously considering the processes of pesticide uptake by plants, surface runoff, erosion, decay, volatilization, foliar wash-off, advection, dispersion, and retardation.

Uncertainties associated with each of these individual components add to the overall uncertainty of the modeled concentrations. Additionally, model inputs from the environmental fate degradation studies are chosen to represent the upper confidence bound on the mean values that are not expected to be exceeded in the environment approximately 90 percent of the time. Mobility input values are chosen to be representative of conditions in the environment. The natural variation in soils adds to the uncertainty of modeled values. Factors such as application date, crop emergence date, and canopy cover can also affect estimated concentrations, adding to the uncertainty of modeled values. Factors within the ambient environment such as soil temperatures, sunlight intensity, antecedent soil moisture, and surface water temperatures can cause actual aquatic concentrations to differ for the modeled values.

Unlike spray drift, tools are currently not available to evaluate the effectiveness of a vegetative setback on runoff and loadings. The effectiveness of vegetative setbacks is highly dependent on the condition of the vegetative strip. For example, a well-established, healthy vegetative setback can be a very effective means of reducing runoff and erosion from agricultural fields. Alternatively, a setback of poor vegetative quality or a setback that is channelized can be ineffective at reducing loadings. Until such time as a quantitative method to estimate the effect of vegetative setbacks on various conditions on pesticide loadings becomes available, the aquatic exposure predictions are likely to overestimate exposure where healthy vegetative setbacks exist and underestimate exposure where poorly developed, channelized, or bare setbacks exist.

In order to account for uncertainties associated with modeling, available monitoring data were compared to PRZM/EXAMS estimates of peak EECs for the different uses. As discussed above, several data values were available from NAWQA and CDPR for oryzalin concentrations measured in surface waters receiving runoff from agricultural areas. The specific use patterns (*e.g.*, application rates and timing, crops) associated with the agricultural areas are unknown; however, they are assumed to be representative of potential oryzalin use areas. The maximum concentration of oryzalin reported by CDPR for surface waters with agricultural watersheds is 110 µg/L. This number falls in the range of EECs estimated using PRZM/EXAMS. Therefore, use of the PRZM/EXAMS EECs is assumed to represent an appropriate measure of exposure.

### **6.1.3. Usage Uncertainties**

County-level usage data were obtained from California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database. Ten years of data (1999 – 2008) were included in this analysis because statistical methodology for identifying outliers, in terms of area treated and pounds applied, was provided by CDPR for these years only. CDPR PUR documentation indicates that errors in the data may include the following: a misplaced decimal; incorrect measures, area treated, or units; and reports of diluted pesticide concentrations. In addition, it is possible that the data may contain reports for pesticide uses that have been cancelled. The CPDR PUR data does not include homeowner-applied pesticides; therefore, residential uses are not likely to be reported. As with all pesticide usage data, there may be instances of misuse and misreporting. The Agency made use of the most current, verifiable information; in cases where there were discrepancies, the most conservative information was used.

### **6.1.4. Terrestrial Exposure Modeling of Oryzalin**

The Agency relies on the work of Fletcher *et al.* (1994) for setting the assumed pesticide residues in wildlife dietary items. These residue assumptions are believed to reflect a realistic upper-bound residue estimate, although the degree to which this assumption reflects a specific percentile estimate is difficult to quantify. It is important to note that the field measurement efforts used to develop the Fletcher estimates of exposure involve highly varied sampling techniques. It is entirely possible that much of these data reflect residues averaged over entire above ground plants in the case of grass and forage sampling.

It was assumed that ingestion of food items in the field occurs at rates commensurate with those in the laboratory. Although the screening assessment process adjusts dry-weight estimates of food intake to reflect the increased mass in fresh-weight wildlife food intake estimates, it does not allow for gross energy differences. Direct comparison of a laboratory dietary concentration- based effects threshold to a fresh-weight pesticide residue estimate would result in an underestimation of field exposure by food consumption by a factor of 1.25 – 2.5 for most food items.

Differences in assimilative efficiency between laboratory and wild diets suggest that current screening assessment methods do not account for a potentially important aspect of food requirements. Depending upon species and dietary matrix, bird assimilation of wild diet energy ranges from 23 – 80%, and mammal's assimilation ranges from 41 – 85% (USEPA, 1993). If it is assumed that laboratory chow is formulated to maximize assimilative efficiency (*e.g.*, a value of 85%), a potential for underestimation of exposure may exist by assuming that consumption of food in the wild is comparable with consumption during laboratory testing. In the screening process, exposure may be underestimated because metabolic rates are not related to food consumption.

For the terrestrial exposure analysis of this risk assessment, a generic bird or mammal was assumed to occupy either the treated field or adjacent areas receiving a treatment rate on the field. Actual habitat requirements of any particular terrestrial species were not considered, and it was assumed that species occupy, exclusively and permanently, the modeled treatment area. Spray drift model predictions suggest that this assumption leads to an overestimation of exposure to species that do not occupy the treated field exclusively and permanently.

#### **6.1.5. Spray Drift Modeling**

It is unlikely that the same organism would be exposed to the maximum amount of spray drift from every application made. In order for an organism to receive the maximum concentration of oryzalin from multiple applications, each application of oryzalin would have to occur under identical atmospheric conditions (*e.g.*, same wind speed and same wind direction) and (if it is an animal) the animal being exposed would have to be located in the same location (which receives the maximum amount of spray drift) after each application. Additionally, other factors, including variations in topography, cover, and meteorological conditions over the transport distance are not accounted for by the AgDRIFT model (*i.e.*, it model spray drift from aerial and ground applications in a flat area with little to no ground cover and a steady, constant wind speed and direction). Therefore, in most cases, the drift estimates from AgDRIFT may overestimate exposure, especially as the distance increases from the site of application, since the model does not account for potential obstructions (*e.g.*, large hills, berms, buildings, trees, *etc.*). Furthermore, conservative assumptions are made regarding the droplet size distributions being modeled (“ASAE Fine to Medium/Coarse” for agricultural and non-agriculture uses), and the application method (*i.e.*, ground), and release heights. Alterations in any of these inputs would decrease the area of potential effect.

### **6.2. Effects Assessment Uncertainties**

#### **6.2.1. Age Class and Sensitivity of Effects Thresholds**

It is generally recognized that test organism age may have a significant impact on the observed sensitivity to a toxicant. The acute toxicity data for fish are collected on juvenile fish between 0.1 and 5 grams. Aquatic invertebrate acute testing is performed on

recommended immature age classes (*e.g.*, first instar for daphnids, second instar for amphipods, stoneflies, mayflies, and third instar for midges).

Testing of juveniles may overestimate toxicity at older age classes for pesticide active ingredients that act directly without metabolic transformation because younger age classes may not have the enzymatic systems associated with detoxifying xenobiotics. In so far as the available toxicity data may provide ranges of sensitivity information with respect to age class, this assessment uses the most sensitive life-stage information as measures of effect for surrogate animals, and is therefore, considered as protective of the CTS.

#### **6.2.2. Use of Surrogate Species Effects Data**

Guideline toxicity tests and open literature data on oryzalin are not available for salamanders or any other amphibian; therefore, freshwater fish are used as surrogate species for aquatic-phase amphibians and birds are used as surrogate species for terrestrial-phase amphibians. Endpoints based on freshwater fish and avian ecotoxicity data are assumed to be protective of potential direct effects to amphibians including the CTS, and extrapolation of the risk conclusions from the most sensitive tested species to the CTS is likely to overestimate the potential risks to those species. Efforts are made to select the organisms most likely to be affected by the type of compound and usage pattern; however, there is an inherent uncertainty in extrapolating across class. In addition, the Agency's LOCs are intentionally set very low, and conservative estimates are made in the screening level risk assessment to account for these uncertainties.

#### **6.2.3. Sublethal Effects**

When assessing acute risk, the screening risk assessment relies on the acute mortality endpoint as well as a suite of sublethal responses to the pesticide, as determined by the testing of species response to chronic exposure conditions and subsequent chronic risk assessment. Consideration of additional sublethal data in the effects determination is exercised on a case-by-case basis and only after careful consideration of the nature of the sublethal effect measured and the extent and quality of available data to support establishing a plausible relationship between the measure of effect (sublethal endpoint) and the assessment endpoints. However, the full suite of sublethal effects from valid open literature studies is considered for the purposes of defining the action area.

No studies were identified in the submitted studies or open literature that documented sublethal effects (other than the assessment endpoints such as growth, survival, and reproduction) associated with exposure to oryzalin. To the extent to which sublethal effects are not considered in this assessment, the potential direct and indirect effects of oryzalin on CTS may be underestimated.

#### **6.2.4. Location of Wildlife Species**

For the terrestrial exposure analysis of this risk assessment, a generic bird or mammal was assumed to occupy either the treated field or adjacent areas receiving a treatment rate on the field. Actual habitat requirements of any particular terrestrial species were not considered, and it was assumed that species occupy, exclusively and permanently, the modeled treatment area. Spray drift model predictions suggest that this assumption leads to an overestimation of exposure to species that do not occupy the treated field exclusively and permanently.

## **7. Risk Conclusions**

In fulfilling its obligations under Section 7(a)(2) of the Endangered Species Act, the information presented in this endangered species risk assessment represents the best data currently available to assess the potential risks of oryzalin to the CTS and its designated critical habitat.

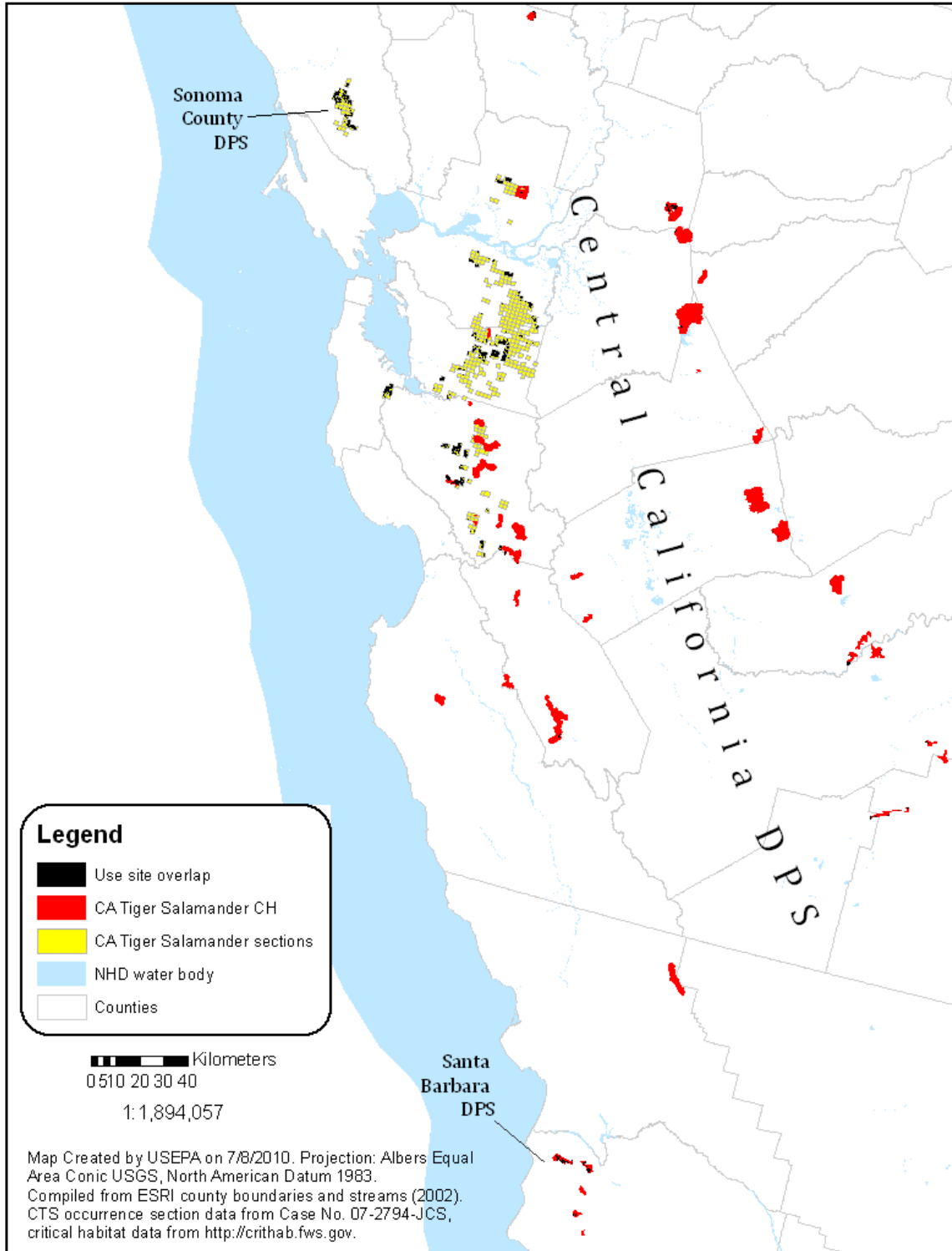
Based on the best available information, the Agency makes a “likely to adversely affect” determination for CTS in the Central California, Santa Barbara County, and Sonoma County DPSs. Additionally, the Agency has determined that there is the potential for modification of the designated critical habitat for the Central California and Santa Barbara County CTS DPSs associated with the use of oryzalin. Given the LAA determination and potential modification of designated critical habitat for CTS, a description of the baseline status and cumulative effects is provided in **Attachment 3**.

The spatial extent of the effects determination is based on the initial area of concern for application of oryzalin on cultivated crops, orchards/vineyards, turf, rights of way, and developed, open space, low, medium, and high densities, and expanded to include the total area where there is potential for direct or indirect effects to occur via off-site transport mechanisms. The extent of potential off-site transport is determined by deriving the spray drift area and the run-off area based on downstream dilution. The identified direct and indirect effects are anticipated to occur only for those currently occupied core areas, CNDDDB occurrence sections, and areas of designated critical habitat for the CTS that are located up to 364 feet from legal use sites where oryzalin can be applied. In addition to the buffered area from the spray drift analysis, the Potential Area of LAA Effects area also typically considers the downstream extent of predicted pesticide concentrations that would exceed the LOC based on downstream dilution analysis. However, due to the widespread use of oryzalin across multiple land cover classes, this analysis was not performed.

Using ARCGIS9, the National Land-Cover Dataset (NLCD, 2001), and the CTS habitat information provided by the USFWS, the Agency has identified the areas where indirect effects to the CTS and modification to designated critical habitat are anticipated to occur (**Figure 7.1**). Additional details on the GIS maps can be obtained from **Appendix D**.

A summary of the risk conclusions and effects determinations for the CTS and its critical habitat, given the uncertainties discussed in **Section 6**, is presented in **Tables 7.1** and **7.2**.

## Use Site Overlap with CTS Habitat



**Figure 7.1. Map showing overlap of CTS habitat with Oryzalin potential use sites**

**Table 7.1. Effects Determination Summary for Direct and Indirect Effects of Oryzalin on the CTS (Applies to the Central California, Santa Barbara County, and Sonoma County DPSs)**

Assessment Endpoint	Effects Determination for the CTS <sup>1</sup>	Basis for Determination
<i>Aquatic-Phase CTS (Eggs, Larvae, and Adults)</i>		
<u>Direct Effects:</u> Survival, growth, and reproduction of CTS individuals via direct effects on aquatic phases	NLAA	Using freshwater fish as a surrogate, no chronic LOCs are exceeded; acute LOCs are exceeded for 1 use (rights-of-ways). The RQ was 0.05. The probability of an individual mortality at an RQ of 0.05 was 1 in 3.03E+33. This suggests that the potential for an adverse effect is discountable. Therefore, the effects determination for rights of ways is NLAA. The effects determination for all other uses was no effect ( <b>Table 1.3.</b> )
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via effects to food supply ( <i>i.e.</i> , freshwater invertebrates, non-vascular plants, fish, and amphibians)	<u>Freshwater invertebrates:</u> NLAA	Oryzalin may affect sensitive aquatic invertebrates; however, the low probability (1 in 6.8E+22 at the highest RQ of 0.09) of an individual effect to an aquatic invertebrate resulting from the labeled uses of oryzalin suggests that the likelihood of any potential reduction in available food for the CTS is low enough to be considered a discountable effect.
	<u>Non-vascular aquatic plants:</u> LAA	LOCs are exceeded for applications of oryzalin to avocado, berries, olives, tree nuts, vineyards (wine grapes), forest trees, rights-of-ways, ornamentals (excluding bulbs), and uncultivated areas. Indirect effects to larvae that feed on algae, therefore, are possible.
	<u>Fish and amphibians:</u> NLAA	Using freshwater fish as a surrogate, no chronic LOCs are exceeded; acute LOCs exceeded for 1 scenario (rights-of-ways) for which the effect was considered to be discountable.
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via indirect effects on habitat, cover, and/or primary productivity ( <i>i.e.</i> , aquatic plant community)	<u>Non-vascular aquatic plants:</u> LAA	LOCs are exceeded for non-vascular aquatic plants for applications of oryzalin to avocado, berries, olives, tree nuts, vineyards (wine grapes), forest trees, rights-of-ways, ornamentals (excluding bulbs), and uncultivated areas.
	<u>Vascular aquatic plants:</u> LAA	RQs for vascular plants exceeded LOCs for all oryzalin use patterns except citrus fruits, tropical fruits, turf, and residential areas.



**Table 7.1. Effects Determination Summary for Direct and Indirect Effects of Oryzalin on the CTS (Applies to the Central California, Santa Barbara County, and Sonoma County DPSs)**

Assessment Endpoint	Effects Determination for the CTS <sup>1</sup>	Basis for Determination
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via effects to riparian vegetation, required to maintain acceptable water quality and habitat in ponds and streams comprising the species' current range.	<u>Direct effects to forested riparian vegetation:</u> LAA  <u>Direct effects to grassy/herbaceous riparian vegetation:</u> LAA (ground applications): <364 ft (monocots); <154 ft (dicots) NLAA (ground applications): >364 ft (monocots); >154 ft (dicots)	Riparian vegetation may be affected because terrestrial plant RQs are above LOCs. Label statements caution against the use of oryzalin on some woody species. In addition, incidents have been reported in terrestrial plants.  Aquatic-phase CTSs may be indirectly affected by adverse effects to sensitive herbaceous vegetation, which provides habitat and cover for the CTS and attachment sites for its egg masses.
<b><i>Terrestrial-Phase CTS (Juveniles and adults)</i></b>		
<u>Direct Effects:</u> Survival, growth, and reproduction of CTS individuals via direct effects on terrestrial phase adults and juveniles	LAA	The acute avian effects data was used as a surrogate for the terrestrial-phase CTS. Dose-based acute avian RQs, refined based on amphibian dietary intake using the T-HERPS model, exceeded LOCs for all of the modeled uses. Chronic reproductive effects are possible based on non-granular uses of oryzalin. RQs ranged from approximately 1.53 to 7.53.
<u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via effects on prey ( <i>i.e.</i> , terrestrial invertebrates, small terrestrial vertebrates, including mammals and terrestrial phase amphibians)	<u>Terrestrial invertebrates:</u> LAA	Although oryzalin is classified as practically non-toxic to terrestrial invertebrates, there is uncertainty regarding toxicity at environmentally relevant concentrations. Because EECs were greater than the LD <sub>50</sub> , reduction of terrestrial invertebrates, which are prey items of the CTS, cannot be precluded.
	<u>Mammals:</u> LAA	Acute risks cannot be precluded for the granular uses of oryzalin. Chronic RQs for non-granular formulations exceed LOCs.
	<u>Amphibians:</u> LAA	Chronic risks for terrestrial-phase amphibians exposed to broadcast spray applications of oryzalin may occur.

**Table 7.1. Effects Determination Summary for Direct and Indirect Effects of Oryzalin on the CTS (Applies to the Central California, Santa Barbara County, and Sonoma County DPSs)**

Assessment Endpoint	Effects Determination for the CTS <sup>1</sup>	Basis for Determination
<p><u>Indirect Effects:</u> Survival, growth, and reproduction of CTS individuals via indirect effects on habitat (<i>i.e.</i>, riparian vegetation)</p>	<p><u>Direct effects to forested riparian vegetation:</u> LAA</p> <p><u>Direct effects to grassy/herbaceous riparian vegetation:</u> LAA (ground applications): &lt;364 ft (monocots); &lt;154 ft (dicots) NLAA (ground applications): &gt;364 ft (monocots); &gt;154 ft (dicots)</p>	<p>Riparian vegetation may be affected because terrestrial plant RQs exceed LOCs. Label statements caution against the use of oryzalin on some woody species. In addition, incidents have been reported in terrestrial plants.</p> <p>Aquatic-phase CTSs may be indirectly affected by adverse effects to sensitive herbaceous vegetation, which provides habitat and cover for the CTS and attachment sites for its egg masses.</p>

<sup>1</sup>NE = no effect; NLAA = may affect, but not likely to adversely affect; LAA = likely to adversely affect

**Table 7.2. Effects Determination Summary for the Critical Habitat Impact Analysis (Effects Determination for Critical Habitat Applies to the Central California and Santa Barbara County DPSs)**

Assessment Endpoint	Effects Determination <sup>1</sup>	Basis for Determination
<p><i>Aquatic-Phase CTS PCEs</i> <i>(Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)</i></p>		
Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CTSs.	Habitat modification	Both liquid and granular formulations of oryzalin may affect sensitive riparian seedlings. As a result, critical habitat may be modified by an increase in sediment deposition and reduction in herbaceous riparian vegetation that provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult aquatic-phase CTSs.
Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CTSs and their food source. <sup>2</sup>	Habitat modification	Both liquid and granular formulations of oryzalin may affect sensitive seedlings. As a result, critical habitat may be modified via turbidity and reduction in oxygen content necessary for normal growth and viability of juvenile and adult aquatic-phase CTSs.
Alteration of other chemical characteristics necessary for normal growth and viability of CTSs and their food source.	<p>No effects on growth and viability of CTS</p> <p>Habitat modification based on alteration of food source</p>	<p>Direct effects to the aquatic-phase CTS are not likely.</p> <p>Critical habitat of the CTS may be modified via oryzalin-related impacts (both formulations) to non-vascular aquatic plants as food items for tadpoles.</p>

**Table 7.2. Effects Determination Summary for the Critical Habitat Impact Analysis (Effects Determination for Critical Habitat Applies to the Central California and Santa Barbara County DPSs)**

Assessment Endpoint	Effects Determination <sup>1</sup>	Basis for Determination
Reduction and/or modification of aquatic-based food sources for pre-metamorphs (e.g., algae)	Habitat modification	Based on the results of the effects determinations for aquatic plants, critical habitat of the CTS may be modified via oryzalin-related impacts to non-vascular aquatic plants as food items for tadpoles.
<b>Terrestrial-Phase CTS PCEs</b> <b>(Upland Habitat and Dispersal Habitat)</b>		
Elimination and/or disturbance of upland habitat; ability of habitat to support food source of CTSs: Upland areas within 200 ft of the edge of the riparian vegetation or dipline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/or wetland/riparian plant species that provides the CTS shelter, forage, and predator avoidance	Habitat modification	Modification to critical habitat may occur via impacts of oryzalin on sensitive seedlings, which provide habitat and cover for the terrestrial-phase CTS and its prey.
Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal	Habitat modification	
Reduction and/or modification of food sources for terrestrial phase juveniles and adults	Habitat modification	Based on the characterization of indirect effects to terrestrial-phase CTSs via reduction in the prey base, critical habitat may be modified via a reduction in mammals and terrestrial-phase amphibians as food items.
Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CTSs and their food source.	Habitat modification	Direct acute and chronic effects are likely for the terrestrial-phase CTS. Therefore, oryzalin may adversely affect critical habitat by altering chemical characteristics necessary for normal growth and viability of terrestrial-phase CTSs and their mammalian and amphibian food sources.
<sup>1</sup> NE = No effect; HM = Habitat modification <sup>2</sup> Physico-chemical water quality parameters such as salinity, pH, and hardness are not evaluated because these processes are not biologically mediated and, therefore, are not relevant to the endpoints included in this assessment.		

**Table 7.3. Oryzalin Use-specific Direct Effects Determinations<sup>1</sup> for the CTS**

Use(s)	Application Method	Aquatic Phase		Terrestrial Phase	
		Acute	Chronic	Acute	Chronic
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Ornamentals (Excluding Bulbs)	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Ornamental Bulbs	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Christmas Tree Plantations	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-

**Table 7.3. Oryzalin Use-specific Direct Effects Determinations<sup>1</sup> for the CTS**

Use(s)	Application Method	Aquatic Phase		Terrestrial Phase	
		Acute	Chronic	Acute	Chronic
Forest Trees	Ground Broadcast	NE	NE	LAA	LAA
Turf	Ground Broadcast	NE	NE	LAA	LAA
	Granular	NE	NE	LAA	-
Rights-of-ways	Ground Broadcast	NLAA	NE	LAA	LAA
	Granular	NLAA	NE	LAA	-
Residential areas	Granular	NE	NE	LAA	-
Uncultivated Areas	Ground Broadcast	NE	NE	LAA	LAA

<sup>1</sup>NE = No effect; NLAA = May affect, but not likely to adversely affect; LAA = Likely to adversely affect

-Not applicable

**Table 7.4. Oryzalin Use-specific Indirect Effects Determinations<sup>1</sup> Based on Effects to Prey**

Use Category	Application Method	Species Effects Determination	Critical Habitat Modification	Potential for Effect (Taxon for which LAA is determined)			
				Aquatic phase		Terrestrial Phase <sup>2</sup>	
				Direct	Indirect	Direct	Indirect
Avocado, Berries, Citrus Fruits, Olive, Pome Fruits, Stone Fruits, Tree Nuts, Tropical Fruits, and Vineyards	Ground Broadcast	LAA	Yes	--	Algae <sup>3</sup> Vascular plants <sup>4</sup>	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Algae <sup>3</sup> Vascular plants <sup>4</sup>	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Ornamentals (Excluding Bulbs)	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Ornamental Bulbs	Ground Broadcast	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Christmas Tree Plantations	Ground Broadcast	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Forest Trees	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Turf	Ground Broadcast	LAA	Yes	--	--	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants

**Table 7.4. Oryzalin Use-specific Indirect Effects Determinations<sup>1</sup> Based on Effects to Prey**

Use Category	Application Method	Species Effects Determination	Critical Habitat Modification	Potential for Effect (Taxon for which LAA is determined)			
				Aquatic phase		Terrestrial Phase <sup>2</sup>	
				Direct	Indirect	Direct	Indirect
	Granular	LAA	Yes	--	--	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Rights-of-ways	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
	Granular	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Residential Areas	Granular	LAA	Yes	--	--	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
Uncultivated Areas	Ground Broadcast	LAA	Yes	--	Algae Vascular plants	Birds	Small mammals Birds Terrestrial invertebrates Terrestrial plants
<sup>1</sup> NE = No effect; NLAA = May affect but not likely to adversely affect; LAA = Likely to adversely affect; --Not applicable <sup>2</sup> Birds serve as a surrogate for terrestrial-phase amphibians. <sup>3</sup> “No effect” determination made for citrus, tropical, pome, and stone fruit. <sup>4</sup> “No effect” determination made for citrus and tropical fruit.							

Based on the above, the Agency makes a “likely to adversely affect” determination for the CTS from the use of oryzalin. Oryzalin is not likely to adversely affect the aquatic-phase CTS by direct toxic effects or by indirect effects resulting from effects to aquatic invertebrates, fish, and other aquatic-phase amphibians as food items. However, an “LAA” determination was concluded for the aquatic-phase CTS, based on indirect effects related to a reduction in algae as food items for larvae and on aquatic non-vascular plants and sensitive herbaceous terrestrial plants and riparian vegetation that comprise its habitat. For the terrestrial-phase CTS, an “LAA” determination was concluded for acute and chronic direct effects and indirect effects related to a reduction in mammals and terrestrial-phase amphibians as food items and herbaceous terrestrial plants and riparian vegetation as habitat. As such, modification of critical habitat is also expected for both aquatic and terrestrial primary constituent elements (PCEs). A summary of the risk conclusions and effects determinations for the CTS and its critical habitat is presented in **Tables 1.1** and **1.2**. Further information on the results of the effects determination is included as part of the Risk Description in **Section 5.2**.

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated.

When evaluating the significance of this risk assessment’s direct/indirect and adverse habitat modification effects determinations, it is important to note that pesticide exposures and predicted risks to the species and its resources (*i.e.*, food and habitat) are

not expected to be uniform across the action area. In fact, given the assumptions of drift and downstream transport (*i.e.*, attenuation with distance), pesticide exposure and associated risks to the species and its resources are expected to decrease with increasing distance away from the treated field or site of application. Evaluation of the implication of this non-uniform distribution of risk to the species would require information and assessment techniques that are not currently available. Examples of such information and methodology required for this type of analysis would include the following:

- Enhanced information on the density and distribution of CTS life stages within specific recovery units and/or designated critical habitat within the action area. This information would allow for quantitative extrapolation of the present risk assessment's predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the species.
- Quantitative information on prey base requirements for individual aquatic- and terrestrial-phase CTS. While existing information provides a preliminary picture of the types of food sources utilized by the CTS, it does not establish minimal requirements to sustain healthy individuals at varying life stages. Such information could be used to establish biologically relevant thresholds of effects on the prey base, and ultimately establish geographical limits to those effects. This information could be used together with the density data discussed above to characterize the likelihood of adverse effects to individuals.
- Information on population responses of prey base organisms to the pesticide. Currently, methodologies are limited to predicting exposures and likely levels of direct mortality, growth or reproductive impairment immediately following exposure to the pesticide. The degree to which repeated exposure events and the inherent demographic characteristics of the prey population play into the extent to which prey resources may recover is not predictable. An enhanced understanding of long-term prey responses to pesticide exposure would allow for a more refined determination of the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual salamanders and potential modification to critical habitat.

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