

**Risks of Metolachlor and S-Metolachlor Use to Federally
Threatened Delta Smelt (*Hypomesus transpacificus*) and
California Tiger Salamander (*Ambystoma californiense*)
(Central California Distinct Population Segment) and
Federally Endangered Sonoma County and Santa
Barbara County Distinct Population Segments of
California Tiger Salamander**

Pesticide Effects Determinations

**PC Codes: 108801 (Metolachlor) and 108800 (S-Metolachlor)
CAS Numbers: 51218-45-2 (Metolachlor) and 87392-12-9
(S-Metolachlor)**

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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. or ai	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
CTS-CC	California Tiger Salamander Central California Distinct Population Segment
CTS-SB	California Tiger Salamander Santa Barbara County Distinct Population Segment
CTS-SC	California Tiger Salamander Sonoma County Distinct Population Segment
DS	Delta Smelt
EC	Emulsifiable Concentrate
EC ₀₅	5% Effect Concentration
EC ₂₅	25% Effect Concentration
EC ₅₀	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>exempli gratia</i> (“for example”)
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 ₀₅	5% Inhibition Concentration
IC ₅₀	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	<u>K</u> _{ow} (based) <u>A</u> quatic <u>B</u> io <u>A</u> ccumulation <u>M</u> odel
kg	Kilogram(s)
kJ/mole	Kilojoules per mole
km	Kilometer(s)
K _{AW}	Air-water Partition Coefficient
K _d	Solid-water Distribution Coefficient
K _F	Freundlich Solid-Water Distribution Coefficient
K _{OC}	Organic-carbon Partition Coefficient
K _{OW}	Octanol–water Partition Coefficient
LAA	Likely to Adversely Affect
lb a.i./A	Pound(s) of active ingredient per acre
LC ₅₀	50% (or Median) Lethal Concentration
LD ₅₀	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 ² /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
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides and Toxic Substances
ORD	Office of Research and Development
PCE	Primary Constituent Element
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
ROW	Right of Way
RQ	Risk Quotient
SFGS	San Francisco Garter Snake
SJKF	San Joaquine 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

1.1. Purpose of Assessment

The purpose of this assessment is to evaluate potential direct and indirect effects of metolachlor (PC code: 108801) on delta smelt (*Hypomesus transpacificus*) (referred to as DS from now on) and S-metolachlor (PC code: 108800) on DS and California tiger salamander (*Ambystoma californiense*) (referred to as CTS from now on) arising from FIFRA regulatory actions regarding use of metolachlor and S-metolachlor 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 DS and 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 consistent with a stipulated injunction ordered by the Federal District Court for the Northern District of California in the case *Center for Biological Diversity (CBD) vs. EPA et al.* (Case No. 07-2794-JCS).

The DS was listed as threatened on March 5, 1993 (58 FR 12854) by the USFWS (USFWS, 2007a). Delta smelt are mainly found in the Suisun Bay and the Sacramento-San Joaquin estuary near San Francisco Bay. During spawning DS move into freshwater.

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 SC and SB DPSs are currently listed as endangered while the CC DPS is listed as threatened. 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. Scope of Assessment

1.2.1. Uses Assessed

Metolachlor is a racemic mixture of r- and s-enantiomers (stereo isomers that are mirror images). Enantiomers have the same chemical and physical properties except for the direction they rotate plane polarized light. Since the S-enantiomer is shown to be more phytotoxic than the originally registered metolachlor, an enriched technical product is registered separately as S-metolachlor. Metolachlor consists of 50% each of the R-enantiomer and the S-enantiomer whereas the S-metolachlor is comprised of 88% S-enantiomer and 12% R-enantiomer. The Agency has determined that environmental fate (D236884) and ecotoxicity (D233184) data submitted for racemic metolachlor and S-metolachlor are comparable and could be bridged. For the purpose of this assessment, most sensitive endpoints from the registrant-submitted guideline studies or open-literature studies will be used regardless of whether the endpoint was derived from studies

conducted with metolachlor or S-metolachlor, similar to the assessments in the past. In other words, no differentiation will be made between metolachlor and S-metolachlor in terms of fate properties, ecotoxicity, or effect determinations to DS and CTS.

Both metolachlor and S-metolachlor are pre-emergence or pre-plant incorporated broad spectrum herbicides in the chloroacetamide chemical family. Both are used to control seedling grasses, nutsedges and certain annual broadleaf weeds such as nightshades, lambsquarter, and pigweeds in both agricultural and non-agricultural settings. Both metolachlor and S-metolachlor are seedling shoot and meristematic growth inhibitors and do not control emerged plants. The primary site of absorption and action of these herbicides on broadleaf species is the roots, while the primary site of absorption and action on grass species is the shoot, especially the coleoptilar node and growing point.

Metolachlor and S-metolachlor are typically applied to or incorporated into the soil prior to planting or crop/weed emergence. Germinating weed seedlings come in contact with the soil-applied metolachlor through its movement in xylem along with water. Since metolachlor and S-metolachlor are not readily translocated in the plant, placement and availability in the root zone where germinating weed seeds are present are important for effective weed control. Phytotoxicity symptoms include stunting of shoots which result in abnormal seedlings that do not emerge from the soil. The site of action of metolachlor is not completely known, but is speculated to inhibit the synthesis of very long-chain fatty acids.

Registered formulation types include emulsifiable concentrate for metolachlor and emulsifiable concentrate (EC), granules (G), and ready to use (RTU) formulations for S-metolachlor. The liquid emulsifiable concentrate is the most commonly used formulation. Ground application is most commonly used, although aerial, irrigation, and chemigation applications are also permitted. Formulated metolachlor and S-metolachlor products are typically 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 aircraft or soil broadcast for granular formulations using spreaders or aircraft. 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.

Currently, metolachlor and S-metolachlor are used throughout the United States. While metolachlor is labeled for use in food crops only, S-metolachlor is used on a wide variety of food and non-food crops. Nationally, metolachlor is registered for use in corn (all types), cotton, peanut, potato, safflower, sorghum, soybean, tomato, citrus, grape, and tree nuts. Labeled food uses for S-metolachlor include silage corn, corn (all types), silage sorghum, sorghum, legumes (vegetables and dry beans), alfalfa, Swiss chard, rhubarb, radish, soybean, cotton, cabbage, onion, horseradish, peanut, celery, tomato, pepper, (green and tabasco), pumpkin, potato, spinach, sugarbeet, sunflower, safflower, and peach whereas non-food uses include meadowfoam, sod grasses, and ornamental sod, herbs, shrubs, trees, and turf. All the above-specified labeled uses for metolachlor and S-metolachlor are considered as part of the federal action evaluated in this assessment.

1.2.2. Environmental Fate Properties of Metolachlor/S-Metolachlor

Metolachlor is a racemic mixture of r- and s-enantiomers (stereo isomers that are mirror images). Enantiomers have the same chemical and physical properties except for the direction they rotate plane polarized light. The Agency has concluded that both metolachlor and S-metolachlor have similar environmental behavior (D236884). Therefore the environmental fate data were bridged from metolachlor to S-metolachlor.

Environmental fate data indicate that parent metolachlor/S-metolachlor appear to be moderately persistent to persistent. Metolachlor/S-metolachlor degradation appear to be dependent of microbially-mediated (aerobic soil metabolism $t_{1/2}$ = 13.9, 14.9, 37.8, 66, and 50.3 days; anaerobic soil metabolism $t_{1/2}$ = 81 days) and abiotic processes (photodegradation in water $t_{1/2}$ = 70 days under natural sunlight and photodegradation on soil $t_{1/2}$ = 8 days under natural sunlight).

Depending on the soil (i.e. organic matter content), metolachlor/S-metolachlor has the potential to range from a moderately mobile to mobile with Kd values ranging from 0.11 to 44.8, and Koc values ranging from 21.6 to 367. Both herbicides have been detected extensively in surface water and groundwater. The Agency concluded that there is no difference in soil sorption affinity between metolachlor and S-metolachlor as there was no statistical difference between Koc coefficients in non-paired batch equilibrium studies (mean Koc=249.3 and 265.9 for metolachlor and S-metolachlor, respectively).

Field dissipation studies indicate that metolachlor/S-metolachlor is persistent in surface soil with half lives ranging from 7 to 292 days in the upper six inch soil layer depending on geographic location. Metolachlor/S-metolachlor was reportedly detected as deep as 36 to 48 inch soil layer in some of the studies.

1.2.3. Evaluation of Degradates and Stressors of Concern

The major degradates for metolachlor/S-metolachlor were identified as CGA-51202 (metolachlor oxanilic acid or metolachlor-OA), CGA-50720, CGA-41638, CGA-37735, CGA-13656, and CGA-354743 (metolachlor ethane sulfonic acid or metolachlor-ESA). Among these major degradates, metolachlor-ESA and metolachlor-OA have been identified as potentially of toxicological concern. For this reason, both of these degradates are considered in the assessment.

1.3. Assessment Procedures

A description of routine procedures for evaluating risk to the San Francisco Bay Species are provided in **Attachment 1**.

1.3.1. Exposure Assessment

1.3.1.a. Aquatic Exposures

Tier-II aquatic exposure models are used to estimate high-end exposures of metolachlor/S-metolachlor in aquatic habitats resulting from runoff and spray drift from different uses. The 1-in-10 years peak model-estimated aquatic exposure concentrations for parent metolachlor/S-metolachlor resulting from different uses ranged from 1.29 (meadowfoam) to 50.66 µg/L (Swiss chard). Estimated 1-in-10 year peak metolachlor-ESA and OA concentrations, based on runoff only, ranged from 0.16 to 10.26 µg/L and 0.26 to 17.05 µg/L, respectively.

The above 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 metolachlor reported by NAWQA (from August 1993 to June 2007) for California surface waters with agricultural watersheds was 3.88 µg/L. Surface water monitoring data from the CDPR (assessed on March 30, 2010) reported highest concentrations of 1.77, 0.50 and 0.11 µg/L, respectively, for metolachlor, metolachlor-OA and metolachlor-ESA. Based on the above, modeled-estimates were an order of magnitude higher for metolachlor and two orders of magnitude higher for metolachlor degradates than the actual monitored values.

1.3.1.b. Terrestrial Exposures

To estimate exposures to terrestrial species resulting from uses involving metolachlor and S-metolachlor applications, the T-REX model is used for foliar and granular uses. AgDRIFT model is also used to estimate deposition of metolachlor and S-metolachlor on terrestrial habitats from spray drift. The TerrPlant model is used to estimate metolachlor and S-metolachlor exposures to terrestrial-phase habitat, including plants inhabiting semi-aquatic and dry areas. The T-HERPS model is used to allow for further characterization of dietary exposures of terrestrial-phase amphibians relative to birds.

1.3.2. Toxicity Assessment

Consistent with the process described in the Overview Document (US EPA 2004), this risk assessment uses a surrogate species approach in its evaluation of metolachlor/S-metolachlor. Toxicological data generated from surrogate test species, which are intended to be representative of broad taxonomic groups, are used to extrapolate the potential effects on a variety of species (receptors) included under these taxonomic groupings. Based on this approach, birds serve as surrogates for terrestrial-phase amphibians and reptiles and freshwater fish serve as surrogates for aquatic-phase amphibians.

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 DS and CTS. Primary constituent elements (PCEs) were used to evaluate whether metolachlor and S-

metolachlor has the potential to modify designated critical habitat. The Agency evaluated registrant-submitted studies and data from the open literature to characterize metolachlor and S-metolachlor 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.

The Agency has determined that ecotoxicity data submitted for metolachlor and S-metolachlor are comparable and could be bridged (D233184). For the purpose of this assessment, most sensitive endpoints from the registrant-submitted guideline studies or open-literature studies, regardless of metolachlor or S-metolachlor will be used. Thus, this assessment does not make any distinction between metolachlor and S-metolachlor in terms of toxicity effects to DS and CTS (all 3 DPSs).

Section 4 summarizes the ecotoxicity data available on metolachlor and S-metolachlor. Metolachlor/S-metolachlor is moderately toxic to freshwater and estuarine fish and invertebrates on an acute exposure basis. In general, freshwater fish and invertebrates are slightly more sensitive to metolachlor/S-metolachlor compared to the estuarine/marine species. On a chronic exposure basis, metolachlor/S-metolachlor reduced larval dry weight in fathead minnow and sheepshead minnow, number of young per female in daphnids, and growth of female mysid shrimp.

Metolachlor/S-metolachlor is practically nontoxic to birds on an acute oral and subacute dietary exposure basis and to mammals on an acute oral exposure basis. Chronic exposure to metolachlor/S-metolachlor resulted in reduced number of eggs laid in bobwhite quail and reduced pup weights in rats. Metolachlor/S-metolachlor is classified as practically nontoxic to honey bees on an acute oral and contact exposure basis.

As expected of an herbicide, plants, both aquatic and terrestrial, are more sensitive to metolachlor/S-metolachlor compared to aquatic animals. Green algae is the most sensitive aquatic plant where as ryegrass (a monocot) is the most sensitive terrestrial plant species. Effects on terrestrial plants are more pronounced at the seedling emergence stage than the vegetative stage.

Parent metolachlor/S-metolachlor, in general, is more toxic to non-target organisms compared to the degradates. Toxicity to freshwater fish and invertebrates of degradates metolachlor-OA and metolachlor-ESA is an order of magnitude lower compared to the parent compound. Similarly, toxicity of metolachlor degradates to aquatic and terrestrial plants is lower by 3 and 2 orders of magnitude, respectively.

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 metolachlor/S-metolachlor use has the potential to adversely affect the assessed species or adversely 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. When RQs exceed LOCs, a potential to cause adverse

effects or habitat modification is identified, leading to a conclusion of “may affect”. If metolachlor and S-metolachlor 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

Based on the best available information, the Agency makes a May Affect, and Likely to Adversely Affect determination for DS and CTS (all 3 DPSs) from the use of metolachlor/S-metolachlor. Additionally, the Agency has determined that there is the potential for modification of designated critical habitat for DS and CTS (all 3 DPSs) from the use of both the chemicals. A summary of the risk conclusions and effects determinations for each listed species assessed here and their designated critical habitat is presented in **Tables 1-1 and 1-2**, respectively. Use-specific determinations are provided in **Tables 1-3 and 1-4**. Further information on the results of the effects determination is included as part of the Risk Description in Section 5.2. Given the LAA determination for the DS and CTS (all 3 DPSs) and potential modification of designated critical habitat for DS and CTS (all 3 DPSs), a description of the baseline status and cumulative effects for DS and CTS is provided in **Attachment 2**.

Table 1-1. Effects Determination Summary for Effects of Metolachlor/S-Metolachlor on the DS and CTS (all 3 DPSs)

Species	Effects Determination	Basis for Determination
California Tiger Salamander (<i>Ambystoma californiense</i>)	May Affect and Likely to Adversely Affect (LAA)	Potential for Direct Effects
		<i>Aquatic-phase (Eggs, Larvae, and Adults):</i> Based on freshwater fish endpoints as surrogate for the aquatic-phase CTS, acute (for both the parent and the degradates) RQs did not exceed the listed or non-listed species risk LOC for any metolachlor/S-metolachlor use. However, chronic RQs exceeded for 5 (Swiss chard, spinach, sorghum, safflower, and cabbage) metolachlor /S-metolachlor uses. Probit analysis, which suggested that the probability of an individual effect is low (1 in 1.57E+82 at LOC) and fish incident data which indicated that the certainty is unlikely, confirm that direct effects to aquatic-phase CTS (all 3 DPSs) are unlikely.
		<i>Terrestrial-phase (Juveniles and Adults):</i> Avian data were used as a surrogate to estimate direct effects to the terrestrial-phase CTS. In the absence of definitive acute toxicity endpoints, acute risk quotients were not calculated. Comparison of EECs with the acute endpoints (as if they were definitive) suggested that resulting RQs were an upper bound estimate (acute dose-based and dietary-based RQs were <0.6 and <0.2, respectively) and how much lower cannot be determined. A refinement of the above RQs based on THERPS suggested that acute RQs dropped below endangered species LOCs for all uses. Chronic RQs, on the other hand, exceeded endangered species LOC for all metolachlor/S-metolachlor uses. Based on the above, direct effects to all 3 DPSs of CTS are likely.
		Potential for Indirect Effects
		<i>Aquatic prey items, aquatic habitat, cover and/or primary productivity</i> Except for chronic risk LOC exceedances for aquatic invertebrates, no other LOC exceedances were noted for any other aquatic prey items. Based on an analysis of full toxicity data set, monitoring data, modeled EECs, incident data, and chance of an individual effect, indirect effects on aquatic prey items for CTS (all 3 DPSs) appear unlikely.
		Acute risk LOCS exceeded for aquatic vascular and nonvascular plants for most metolachlor/S-

Species	Effects Determination	Basis for Determination
		<p>metolachlor (parent only) uses. However, acute risk LOCS were not exceeded for either metolachlor-OA or metolachlor-ESA for any use. As acute risk LOCs exceeded for uses in crops where the reported annual use is highest (example: corn), indirect effects to CTS (all 3 DPSs) are likely.</p> <hr/> <p><i>Terrestrial prey items, riparian habitat</i> Risk to terrestrial invertebrates could not be calculated as the available acute toxicity endpoints were non-definitive. However, calculated acute and chronic mammalian RQs suggest that endangered species LOC was exceeded for almost all uses.</p> <p>Terrestrial plant risk LOC exceedances were noted for both monocots and dicots in wetlands and uplands adjacent to use sites for all crops in which metolachlor/S-metolachlor is registered. Therefore, indirect effects to CTS through habitat modification are likely.</p>
<p>Delta smelt (<i>Hypomesus transpacificus</i>)</p>	<p>May Affect and Likely to Adversely Affect (LAA)</p>	<p>Potential for Direct Effects</p> <hr/> <p><i>Freshwater Life Stages (Eggs, Larvae, and Breeding Adults) and Saltwater Life Stages (Juveniles and Adults):</i> Acute (for both the parent and the degradates) RQs did not exceed the listed or non-listed species risk LOC for any metolachlor/S-metolachlor use. However, chronic RQs exceeded for only 5 (Swiss chard, spinach, sorghum, safflower, and cabbage) metolachlor /S-metolachlor uses. The above metolachlor/S-metolachlor uses are associated with low annual application rates. Probit analysis, which suggested that the probability of an individual effect is low (1 in 1.57E+82 and 1 in 4.18 E+08 at LOC for freshwater and estuarine/marine fish, respectively), and fish incident data which indicated that the certainty is unlikely, confirm that direct effects to freshwater and estuarine/marine fish are unlikely.</p> <hr/> <p>Potential for Indirect Effects:</p> <p><i>Aquatic prey items, aquatic habitat, cover and/or primary productivity</i></p> <p>No acute RQs exceeded the listed or non-listed species LOCs for freshwater or estuarine/marine invertebrate species due to liquid or granular applications of metolachlor/S-metolachlor. No freshwater invertebrate acute risk LOC exceedances were noted with either metolachlor degradates for any of the uses. While none of the estuarine/marine invertebrate chronic RQs exceeded LOCs for parent metolachlor/S-metolachlor, chronic risk LOCs were exceeded for freshwater invertebrates for all uses. However, based on the analysis of full toxicity data set for invertebrate prey items, monitoring data, modeled EECs, incident data, and chance of an individual effect, indirect effects on aquatic prey items for DS appear unlikely.</p> <p>Acute risk LOCs exceeded for aquatic vascular and nonvascular plants for most parent metolachlor/S-metolachlor uses. However, acute risk LOCs were not exceeded for metolachlor degradates. As acute risk LOCs exceeded for parent metolachlor/S-metolachlor uses in crops where the reported annual use is highest (example: corn), indirect effects to DS are likely.</p> <p><i>Terrestrial prey items, riparian habitat</i> Terrestrial plant risk LOC exceedances were noted for both monocots and dicots in wetlands and uplands adjacent to use site for all crops in which metolachlor/S-metolachlor is registered. Therefore, indirect effects to DS through habitat modification are likely.</p>

Table 1-2. Effects Determination Summary for the Critical Habitat Impact Analysis

Designated Critical Habitat for:	Effects Determination	Basis for Determination
DS and CTS (all 3 DPSs)	May Affect and Likely to Adversely Affect (LAA)	<p>As summarized in Table 1-1, chronic risk LOCs were exceeded for freshwater invertebrate prey items of DS and aquatic-phase CTS (all 3 DPSs). Both acute and chronic risk LOCs were exceeded for terrestrial vertebrate prey items of the aquatic-phase CTS. Based on the above, metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and/or affect their designated critical habitat by reducing or changing the composition of the food supply.</p> <p>Data analysis suggests that both aquatic and terrestrial plants are at risk from metolachlor/S-metolachlor uses. Acute risk LOCS exceeded for aquatic vascular and nonvascular plants for most metolachlor/S-metolachlor uses. Terrestrial plant risk LOC exceedances were noted for both monocots and dicots in wetlands and uplands adjacent to use site for all crops in which metolachlor/S-metolachlor is registered. Overall, risk to terrestrial plants is significantly higher compared to the aquatic plants. Even though the DS and CTS depend on a wide range of aquatic and terrestrial plants, it is expected that metolachlor/S-metolachlor, being an herbicide, would elicit adverse impacts on plant communities. Based on the above, metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and/or affect 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, the terrestrial plant community in the species' current range, and aquatic habitat in their current range via modification of water quality parameters, habitat morphology, and/or sedimentation.</p>

Table 1-3. Use Specific Summary of the Potential for Adverse Effects to Aquatic Taxa

Uses	Potential for Effects to Identified Taxa Found in the Aquatic Environment									
	Freshwater Vertebrates ¹		Estuarine/Marine Vertebrates ²		Freshwater Invertebrates ³		Estuarine/Marine Invertebrates ⁴		Vascular Plants ⁵	Non-vascular Plants ⁵
	Acute	Chronic ⁶	Acute	Chronic ⁶	Acute	Chronic	Acute	Chronic		
All Uses	No	Yes	No	Yes	No	Yes ⁷	No	No	Yes ⁸	Yes ⁹

¹A yes in this column indicates a potential for direct and indirect effects to DS

²A yes in this column indicates a potential for direct and indirect effects to DS. A yes also indicates a potential for direct and indirect effects for the CTS-CC, CTS-SC, and CTS-SB

³A yes in this column indicates a potential for CTS-CC, CTS-SB, CTS-SC, and DS

⁴A yes in this column indicates a potential for indirect effects to DS

⁵A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, CTS-SB, and DS

⁶All uses except cabbage, Swiss chard, spinach, sorghum, and safflower

⁷All uses except meadowfoam

⁸Except legume vegetables, celery, pepper, Tabasco pepper, rhubarb, pumpkin, onion, radish, horse radish, peach, meadowfoam and ornamental turf, herbs, and shrubs

⁹LOC exceeded for cabbage, Swiss chard, spinach, tomato, sunflower, safflower, and sorghum

Table 1-4. Use Specific Summary of the Potential for Adverse Effects to Terrestrial Taxa

Uses	Potential for Effects to Identified Taxa Found in the Terrestrial Environment						
	Small Mammals ¹		Small Birds ²		Invertebrates ³	Dicots ⁴	Monocots ⁴
	Acute ⁵	Chronic ⁶	Acute	Chronic ⁷	Acute ⁸		
All Uses	Yes	Yes	No	Yes	No	Yes	Yes

¹A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, and CTS-SB

²A yes in this column indicates a potential for direct and indirect effects to the, CTS-CC, CTS-SC, and CTS-SB

³A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, and CTS-SB

⁴A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, CTS-SB, and DS; LOC exceedances are evaluated based on the non-listed species

⁵All uses except alfalfa, cabbage and potato

⁶All uses except meadowfoam and spinach

⁷LOC exceeded for corn and potato only

⁸Risk is not assumed based on data generated from toxicity studies

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 listed 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 DS and CTS life stages within the action area and/or applicable designated critical habitat. 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 assessed species.
- Quantitative information on prey base requirements for the assessed species. While existing information provides a preliminary picture of the types of food sources utilized by the assessed species, 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 species 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 U.S. EPA'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/NOAA, 2004).

2.1. Purpose

The purpose of this endangered species assessment is to evaluate potential direct and indirect effects on individuals of the delta smelt (*Hypomesus transpacificus*) and DS and California tiger salamander (*Ambystoma californiense*) on agricultural and non-agricultural sites arising from FIFRA regulatory actions based on metolachlor uses in corn, cotton, grape, legume crops, peanut, potato, safflower, sorghum, soybean, tomato, and tree nuts and S-metolachlor uses in alfalfa, corn (all types), cabbage, celery, cotton, horse radish, legume crops (including legume vegetables), meadowfoam, onion, peach, peanut, pepper, potato, pumpkin, radish, rhubarb, safflower, sorghum, silage sorghum, soybean, spinach, sugar beet, sunflower, Swiss chard, tabasco pepper, tomato, grasses for sod, ornamental sod and turf, and ornamental herbs, shrubs, and shade trees.

In this assessment, direct and indirect effects to the DS and CTS and potential modification to designated critical habitat for the DS and CTS are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA, 2004). The DS was listed as threatened on March 5, 1993 (58 FR 12854) by the USFWS (USFWS, 2007a). DS are mainly found in the Suisun Bay and the Sacramento-San Joaquin estuary near San Francisco Bay. During spawning DS move into freshwater. The CTS was down-listed from endangered to threatened in its entire range in 2004 by the USFWS, however, the down-listing was vacated by the U.S. District Court. Therefore, the Sonoma and Santa Barbara DPSs are currently listed as endangered while all other CTSs are listed as threatened. The CTS is restricted to vernal pools and seasonal ponds in grassland and oak savannah plant communities in central California.

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 metolachlor and S-metolachlor 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 metolachlor and S-metolachlor 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 DS and CTS and their designated critical habitat within the state of California. As part of the "effects determination,"

one of the following three conclusions will be reached separately for each of the assessed species regarding the potential use of metolachlor and S-metolachlor in accordance with current labels:

- “No effect”;
- “May affect, but not likely to adversely affect”; or
- “May affect and likely to adversely affect”.

Additionally, for habitat and PCEs, a “No Effect” or a “Habitat Modification” determination is made.

A description of routine procedures for evaluating risk to the San Francisco Bay Species are provided in **Attachment 1**.

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 metolachlor and S-metolachlor in accordance with the approved product labels for California is “the action” relevant to this ecological risk assessment.

Metolachlor and S-metolachlor, members of the chloroacetamide family of herbicides, are pre-plant/pre-emergence herbicides used for selective broad spectrum weed control in both monocot and dicot crops. Metolachlor is a mixture of R and S enantiomers, which are exact replicates of one another, only with opposite construction, as if viewed with a mirror. Since S-enantiomer is shown to be more phytotoxic than the originally registered racemic metolachlor, an enriched technical product is registered separately as S-metolachlor. Metolachlor consists of 50% each of the R-enantiomer and the S-enantiomer whereas the S-metolachlor is comprised of 88% of S-enantiomer and 12% of R-enantiomer. Registered formulations include emulsifiable concentrate (EC) for metolachlor and emulsifiable concentrate, granules (G), and ready to use (RTU) formulations for S-metolachlor.

Currently, S-metolachlor is used on a range of food and non-food crops. Food crops include silage corn, corn (all types), silage sorghum, sorghum, legumes (vegetables and dry beans), alfalfa, Swiss chard, rhubarb, radish, soybean, cotton, cabbage, onion, horseradish, peanut, celery, tomato, pepper, (green and tabasco), pumpkin, potato, spinach, sugarbeet, sunflower, safflower, and peach. Non-food crops include meadowfoam, sod grasses, and ornamental sod, herbs, shrubs, trees, and turf. Unlike S-metolachlor, metolachlor is only registered for food uses in corn (all types), cotton, peanut, potato, safflower, sorghum, soybean, tomato, citrus, grape, and tree nuts.

The Agency has determined that environmental fate (D236884) and ecotoxicity (D233184) data submitted for metolachlor and S-metolachlor are comparable and could be bridged. For the purpose of this assessment, most sensitive endpoints from the registrant-submitted guideline

studies or open-literature studies will be used regardless of metolachlor or S-metolachlor. In other words, no differentiation will be made between metolachlor and S-metolachlor in terms of fate properties, ecotoxicity, or effect determinations to DS and CTS.

Although current registrations of metolachlor and S-metolachlor allow for use nationwide, this ecological risk assessment and effects determination addresses currently registered uses of metolachlor and S-metolachlor in portions of the action area that are reasonably assumed to be biologically relevant to the DS and CTS and their designated critical habitat. Further discussion of the action area for the DS and CTS and their critical habitat is provided in Section 2.6.

2.2.1. Evaluation of Degradates

A number of major degradates have been identified for metolachlor/S-metolachlor: CGA-51202 (metolachlor OA), CGA-50720, CGA-41638, CGA-37735, CGA-13656, and CGA-354743 (metolachlor-ESA). Among these major degradates, metolachlor ESA and metolachlor OA have been identified as potentially of toxicological concern. For this reason, both of these degradates (in addition to the parent) are considered in the assessment.

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 active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision 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 (U.S., EPA 2004; USFWS/NMFS 2004).

Metolachlor and S-metolachlor have several registered products in mixtures with other herbicides. Based on the qualitative evaluation of the best available data and the Agency's existing guidance, metolachlor and S-metolachlor formulations are reflecting an independent additive toxicity response and not an interactive effect (**Appendix A**). Given that the active and inert ingredients would not be expected to have similar mechanisms of action, metabolites or toxicokinetic behavior, it is also reasonable to conclude that an assumption of dose-addition would be inappropriate. Consequently, an assessment based on the toxicity of the single active ingredient of metolachlor/S-metolachlor is appropriate.

2.3. Previous Assessments

Metolachlor was first registered with the U.S. Environmental Protection Agency (U.S.EPA) in 1976 by Ciba-Geigy. Until 1999, the chemical was manufactured exclusively by Syngenta Crop Protection (formerly Novartis Crop Protection Inc./Ciba-Geigy Corporation). Syngenta discontinued metolachlor in 1999, and replaced it with S-metolachlor, which was conditionally registered in 1997. Syngenta no longer holds any active registrations for metolachlor or its end-use products. However, metolachlor registrations are currently held by Control Solutions, Inc

(Reg. Number 53883-149), Sipcam Agro USA, Inc., (Reg. Number: 60063-24), and Makhteshim Agan of North America, Inc. (Reg. Number: 66222-131).

The Agency has completed numerous assessments on metolachlor, the major and most recent of which include an assessment supporting the Agency's Re-registration Eligibility Decision (RED) in 1994, an evaluation of the potential effects on 26 ESUs of listed salmonids in the Pacific Northwest (PNW) in 2006, an evaluation of the effects on Barton Springs salamander (Case No: 1:04CV00126-CKK) in 2007, and an evaluation of the effects on California red legged frog [Case No: 02-1580-JSW(JL)] in 2007. Key findings from the above actions are presented below.

The ecological risk assessment for the RED identified an exceedance of the endangered species risk level of concern (LOC) for fish, based on runoff into a shallow (6-inch) water body from roadside use. Since 1994, EFED has incorporated the use of more advanced exposure models into the risk assessment process. The 2006 evaluation concerning the salmonids was more comprehensive than the RED, incorporating newer exposure models and methodologies described in the Overview document (U.S. EPA 2004). The PNW assessment found that use of metolachlor may have no (direct) effect on salmonids' survival, growth or reproduction and is not likely to adversely affect salmonid prey, aquatic plants, and riparian vegetation.

The ecological risk assessment on the Barton Springs salamander (*Eurycea sosorum*) determined that metolachlor use may have no direct effect on the Barton Springs salamander's survival, growth or reproduction and is not likely to adversely affect salamander prey and aquatic plants. In contrast, the assessment on the California red legged frog suggested that the use of metolachlor may affect, and is likely to adversely affect the California red-legged frog, based on indirect effects (habitat modification to terrestrial plants) and that these same effects constitute adverse modification to critical habitat. The assessment on Barton Springs salamander evaluated the use of metolachlor on corn, cotton, legumes, potato, safflower and sorghum at a maximum rate 1.7 lb ai/A whereas the one on California redlegged frog evaluated metolachlor uses on corn, cotton, legumes, potato, safflower, sorghum, and soybean at a maximum rate of 2 lb ai/A. Differences in use rates, crops in which metolachlor is used, and the crop scenarios used in exposure modeling are the reasons for the different conclusions in the assessments on Barton Springs salamander and California red legged frog.

It is important to mention here that the findings from the current assessment may be different from the most recent major assessment on California red-legged frog for numerous reasons. These reasons include: assessment of both metolachlor and S-metolachlor (only metolachlor was assessed on red-legged frog); crops, application rates, and formulations include those for both metolachlor and S-metolachlor; and label changes took place since the California red-legged frog assessment resulting in new uses and use rates. Furthermore, new refinement methodologies such as T-HERPS, which were not available at the time of the CRLF assessment, are also used in the current assessment.

2.4. Environmental Fate Properties

Table 2-1 lists the physical-chemical properties of metolachlor/S-metolachlor, metolachlor-ESA and metolachlor-OA. **Table 2-2** lists the environmental fate properties of metolachlor/S-metolachlor and its major degradation products, metolachlor-ESA and metolachlor-OA.

Table 2-1. Physical and Chemical Properties of Metolachlor/S-Metolachlor, Metolachlor ESA, and Metolachlor OA

Property	Metolachlor/S-Metolachlor		ESA	OA
	Value and units	MRID or Source	Value and units	Value and units
Molecular Weight	283.8 g/mole	Product Chemistry	329.7 g/mole	279.4 g/mole
Chemical Formula	$C_{15}H_{22}ClNO_2$		$C_{15}H_{23}SNO_5$	$C_{12}H_{21}NO_4$
Vapor Pressure	2.85×10^{-5} Torr @ 25°C		NA	NA
Henry's Law Constant	2.2×10^{-8} atm-m ³ /mole	Estimated from water solubility and vapor pressure	NA	NA
Water Solubility	480 mg/L @ 25°C	Product Chemistry		
Octanol – water partition coefficient (log K _{ow})	3.04 @ 25°C		Kd = 0.041 (MRID 44931722)	Kd = 0.079 (MRID 40494605)

Table 2-2. Summary of Metolachlor/S-Metolachlor Environmental Fate Properties

Study	Value and unit	Major and Minor Degradates	MRID # or Citation	Study Classification, Comment
Abiotic Hydrolysis	Stable		40430201	Acceptable
Aqueous Photolysis	Half-life ¹ = 70 days	CGA-51202 CGA-41638 CGA-50270 CGA-46129	40430202	Acceptable
Soil Photolysis	Half-life ¹ = 8 days in silt loam soil	CGA-51202 CGA-41507 CGA-40172 CGA-41638 CGA-50720 CGA-40919 CGA-37913 CGA-37735 CGA-48087 CGA-46129	43928935	Acceptable
Aerobic Soil Metabolism	Half-life ¹ = 66, 37.8, 14.9, 13.9, and 50.3 days Half-life = 162.5 days for ESA (CGA-354743) Half-life = 127.5 days for OA (CGA-51202) (Based on decline portion of formation and	CGA-51202 CGA-354743 CGA-41507 CGA-40172 CGA-41638	41185701 41309801	Acceptable

Study	Value and unit	Major and Minor Degradates	MRID # or Citation	Study Classification, Comment
	decline data - MRID 4392836)	CGA-50720 CGA-40919 CGA-36913 CGA-37735 CGA-48087 CGA-13656 CGA-46129		
Anaerobic Soil Metabolism	Half-life ¹ = 81 days in sandy loam soil	CGA-51202 CGA-40172 CGA-41638 CGA-50720 CGA-40919 CGA-37735 CGA-13656	41185701 41309801	Acceptable
Aerobic Aquatic Metabolism	Half-life ¹ = 47 days in a flooded sandy loam sediment under aerobic conditions	CGA-51202 CGA-40172 CGA-13656 CGA-50720	41185701	Acceptable
Anaerobic Aquatic Metabolism	Half-life ¹ = 78 days in a flooded sandy loam sediment under anaerobic conditions	CGA-51202 CGA-41507 CGA-40172 CGA-41638 CGA-50720 CGA-40919 CGA-37913 CGA-37735	41185701	Acceptable
Mobility, unaged leaching, adsorption/desorption and aged leaching soil column	Four soils (0.3% to 2.2% organic matter), adsorption Kd = 0.3 (sand), 1.4 (sandy loam), 1.1 (silt loam) and 4.7 (clay). Desorption Kd = 1.3 (sand), 4.1 (sandy loam), 3.7 (silt loam), and 8.0 (clay).		40494603 40494604 40494605 43928937 43928938	Acceptable
Volatility from Soil (Laboratory)	Approximately 0.05% of the metolachlor dose volatilizing per day.		40494606	Acceptable
Terrestrial Field Dissipation	the half life ² of metolachlor in the 6-12 inch soil layer ranged from 7 days (Iowa) to 292 days (California) with a range of the total water applied ranging from 16.97 inches to > 40 inches during the study period	CGA-51202 CGA-354743 CGA-37735	41309804 41309805 41335701 41335702 41309802 41309803 45848001	
Bioconcentration Factor (BCF)- Species Name	Mean equilibrium bioconcentration factor (BCF) = 69 X in whole fish 15 X in edible tissue 155 X in nonedible tissue	CGA-41368	41154201	Acceptable

¹Half-lives were calculated using the single-first order equation and nonlinear regression, unless otherwise specified.

²The value may reflect both dissipation and degradation processes.

Hydrolysis

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

Photolysis

The aqueous photolysis half-life was 70 days when exposed to natural sunlight and 0.17 day when exposed to artificial sunlight (450 watt mercury arc lamp with light intensity of 4500-4800 uW/cm²). After 30 days exposure to natural sunlight the degradation products were CGA-41638 (3.63% of applied radiocarbon), CGA-51202 (3.54%), CGA-46129 (3.42%), CGA-50720 (3.20%), and parent metolachlor remaining was 62.92%.

The soil photolysis half-life of metolachlor when exposed to natural sunlight was 8 days, and when exposed to artificial light conditions (mercury arc lamp with intensity of 1600-2400 uW/cm²) the half-life was 37 days. The major degradates reported after 21 days exposure to natural sunlight were CGA-51202 (maximum of 3.4% of applied radiocarbon), CGA-37735 (9.0%), CGA-41638 (5.7%), and CGA-37913 (7.3%).

Microbial Degradation

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

The aerobic aquatic metabolism half-life of metolachlor was 47 days. The major metabolites in the sediment were CGA-41507 (3.34% of applied radiocarbon at 29 days), CGA-50720 (1.17%), CGA-40172 (1.13%), CGA-46127 (1.54%), and parent metolachlor was 34.56%. In the water fraction after 29 days incubation parent metolachlor was 30.90% and the metabolite CGA-41507 was 1.21% and CGA-51202 was 1.9%.

Under anaerobic soil conditions metolachlor degraded with a half-life of 81 days in a sandy loam soil that was incubated under anaerobic conditions for 60 days at 25°C following 30 days of aerobic incubation. The major degradate in both the soil and flood water was CGA-51202 (maximum of 23.33% of applied radiocarbon at 29 days after anaerobic conditions were established); and other reported degradates were CGA-37735 (1.25% at 29 days), CGA-41638 (8.3% at 60 days), CGA-13656 (1.46% at 29 days), and CGA-50720 (maximum of 7.34% at 60 days).

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

at 29 days), and CGA-37913 (maximum of 2.33% at 6 months), and after 12 months the sediment contained 1.47% parent metolachlor.

Mobility

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

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

Field Dissipation

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

Small-Scale Prospective Groundwater Monitoring Study

The residue sample collection for a Georgia groundwater monitoring study was initiated in June 2003, and continuing through 939 days after application. The study results show that metolachlor and two of its degradation products CGA-51202 and CGA-354743 can leach through the vadose zone into groundwater when applied in a vulnerable hydrogeologic setting. The detected peak concentrations of the degradation products CGA-51202 and CGA-354743 are even higher than the detected peak metolachlor concentration.

Volatility

Laboratory volatility studies indicated that volatility is not a significant mode of dissipation for metolachlor from soil. The maximum dissipation was 0.05% of the metolachlor dose volatilizing per day. However, several field scale studies suggested that significant amount can be lost due to

volatilization depending on application methods of metolachlor (Pruger and Hatfield, 1999 and Gish et al, 2009.)

Bioconcentration

The magnitude of the n-octanol/water partition coefficient for S-metolachlor ($\log K_{ow} = 3.05$) indicated a potential for bioaccumulation. However, the study shows a low potential to bioaccumulate in fish with a reported whole body bioconcentration factor of 69X and a whole body elimination of 93% after 14 days depuration.

2.4.1. Environmental Transport Mechanisms

Potential transport mechanisms for metolachlor/S-metolachlor 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 metolachlor/S-metolachlor.

A number of studies have documented atmospheric transport and re-deposition of pesticides from the Central Valley to the Sierra Nevada mountains (Fellers et al., 2004, Sparling et al., 2001, LeNoir et al., 1999, and McConnell et al., 1998). Prevailing winds blow across the Central Valley eastward to the Sierra Nevada mountains, transporting airborne industrial and agricultural pollutants into the Sierra Nevada ecosystems (Fellers *et al.*, 2004, LeNoir *et al.*, 1999, and McConnell *et al.*, 1998). The magnitude of transport via secondary drift depends on the metolachlor's ability to be mobilized into air and its eventual removal through wet and dry deposition of gases/particles and photochemical reactions in the atmosphere. Therefore, physicochemical properties of the metolachlor that describe its potential to enter the air from water or soil (*e.g.*, Henry's Law constant and vapor pressure), pesticide use data, modeled estimated concentrations in water and air, and available air monitoring data are considered in evaluating the potential for atmospheric transport of metolachlor to locations where it could impact DS and CTS (all 3 DPSs).

In general, deposition of drifting or volatilized pesticides is expected to be greatest close to the site of application. Computer models of spray drift (AgDRIFT) are used to determine potential exposures to aquatic and terrestrial organisms. Metolachlor is most toxic to monocotyledon 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 organisms.

2.4.2. Mechanism of Action

Metolachlor and S-metolachlor are broad spectrum herbicides used to control seedling grasses, nutsedges, and certain annual broadleaf weeds such as nightshades, lambsquarter, and pigweeds in both agricultural and non-agricultural settings. Both metolachlor and S-metolachlor are seedling shoot and meristematic growth inhibitors. They are typically applied to soil prior to planting or crop/weed emergence. Germinating weed seedlings come in contact with the soil-applied metolachlor through its movement in xylem along with water. Symptoms include stunting of shoots that result in abnormal seedlings that do not emerge from the soil. Grasses may leaf-out under ground and the shoots may be abnormal when leaves do not properly unfurl.

Broadleaves may have crinkled leaves and a shortened mid-vein which produces a "draw-string effect" or "heart shaped" leaves. The site of action of metolachlor is not completely known, but is speculated to inhibit the synthesis of very long-chain fatty acids (source: <http://ipmworld.umn.edu/chapters/whitacreherb.htm>).

2.4.3. Use Characterization

Analysis of labeled use information is the critical first step in evaluating the federal action. The current labels for metolachlor and S-metolachlor represent the FIFRA regulatory action; therefore, labeled 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.

Both metolachlor and S-metolachlor, members of chloroacetamide herbicide family, are registered nationally for the control of annual grasses and certain broadleaf weeds. Registered formulations include emulsifiable concentrate for metolachlor and emulsifiable concentrate, granules, and ready to use formulations for S-metolachlor. The liquid emulsifiable concentrate is the most commonly used formulation. Ground application is most commonly used, although aerial, irrigation, and chemigation applications are also permitted.

While metolachlor is used for weed control in food crops only, S-metolachlor is used on a wide variety of food and non-food crops nationally. Metolachlor is registered for use in corn (all types), cotton, peanut, potato, safflower, sorghum, soybean, tomato, citrus, grape, and tree nuts. Food crop uses for S-metolachlor include silage corn, corn (all types), silage sorghum, sorghum, legumes (vegetables and dry beans), alfalfa, Swiss chard, rhubarb, radish, soybean, cotton, cabbage, onion, horseradish, peanut, celery, tomato, pepper, (green and tabasco), pumpkin, potato, spinach, sugarbeet, sunflower, safflower, and peach, whereas non-food uses include meadowfoam, sod grasses, and ornamental sod, herbs, shrubs, trees, and turf.

The following labeled uses are considered as part of the federal action evaluated in this assessment: silage corn, corn (all types), silage sorghum, sorghum, legumes (vegetables and dry beans), alfalfa, Swiss chard, rhubarb, radish, soybean, cotton, cabbage, onion, horseradish, peanut, celery, tomato, pepper, (green and tabasco), pumpkin, potato, spinach, sugarbeet, sunflower, safflower, peach, meadowfoam, sod grasses, and ornamental sod, herbs, shrubs, trees, and turf for S-metolachlor and corn (all types), cotton, peanut, potato, safflower, sorghum, soybean, tomato, citrus, grape, and tree nuts for metolachlor.

There are new uses for metolachlor and S-metolachlor which are pending at this time. These include the use of metolachlor on tomato and S-metolachlor on sesame, melon, bushberry, low bushberry, caneberry, sweet sorghum, leafy brassica greens, turnip greens, carrot, cucumber, okra, bulb onion, green onion. The due dates for these actions are 2/27/2011 and 12/1/2010, respectively. Additionally, an amendment is pending to add use on edamame and to add fall applications to corn, cotton, soybean and grain and forage sorghum to S-metolachlor label (EPA Reg No: 100-816), the due date of which is December 2010. These labels have not been approved and EFED does not have enough information regarding the above actions to determine the effects of metolachlor on DS and CTS. However, the above label amendments should not impact the current assessment as the proposed maximum application rates (3.8 lb ai/A) do not

exceed the maximum application rate (4 lb ai/A) evaluated in this assessment and they do not represent new use areas not already assessed through consideration at other use sites. **Table 2-3** and **Table 2-4** present the current uses and corresponding application rates and methods of application derived from labels for metolachlor and S-metolachlor, respectively.

Table 2-3. Metolachlor Use Information Based on Labels

Use	Formulation Code ¹	Application Method ²	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Year (#)	Maximum Seasonal Application Rate (lb ai/A)	Application Interval (days)
Food Uses						
Cotton	EC	Ground Aerial	2.0	2	4.0	NS ³
Citrus Grape	EC	Ground	3.9	1	3.9	- ⁴
Tree nuts	EC	Ground	3.8	1	3.8	-
Legume crops (dried beans, lima bean, snap bean, lupine, grain lupine, cowpea, garbanzo bean, lentils, southern pea, succulent beans, and legume vegetables)	EC	Ground Aerial	3.0	2	3.0	NS
Corn (all types)	EC	Ground Aerial	4.0	2	6.0	NS
Peanut	EC	Ground Aerial	3.0	1	3.0	-
Potato	EC	Ground Aerial	4.0	2	5.5	NS
Safflower	EC	Ground Aerial	3.0	1	3.0	-
Sorghum	EC	Ground Aerial	3.2	NS	NS	NS
Soybean	EC	Ground Aerial	4.0	1	4.0	-
¹ Formulation code: EC - Emulsifiable Concentrate ² Chemigation is included in ground application ³ Not specified on the label; however an interval of 30 to 45 days was assumed based on S-metolachlor labels, an interval of 30 days was used in the modeling as it resulted in the most conservative EECs ⁴ Not applicable due to single application						

Table 2-4. S-Metolachlor Use Information Based on Labels

Use	Formulation ¹	Application Method ²	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Year (#)	Maximum Seasonal Application Rate (lb ai/A)	Application Interval (days)
Food Uses						
Legume crops (dried beans, grain lupine, field/ dried/ southern/succulent pea, lentils, black eyed pea, mung bean, lima bean, snap bean)	EC	Ground	1.9	1	1.9	- ³
Alfalfa	EC	Ground	3.2	1	3.2	-
Swiss chard Radish	EC	Ground	1.3	1	1.3	-
Silage corn	EC	Ground	2.0	1	2.0	-
Corn (all types)	EC	Ground Aerial	2.5	2	3.8	30 - 45 ⁴
	G	Ground	2.4	1	2.4	-
Cotton	EC	Ground Aerial	1.3	2	2.5	30 - 45
Cabbage	EC	Ground	3.8	1	3.8	-
Meadowfoam	EC	Ground	0.6	1	0.6	-
Onion	EC	Ground	1.3	2	2.6	21 – 28 days after first
Horse radish	EC	Ground	1.7	1	1.7	-
Legume vegetables	EC	Ground Aerial	1.9	2	1.9	30 - 45
Peach	EC	Ground	2.5	1	2.5	-
Peanut	G	Ground	1.9	1	1.9	-
	EC	Aerial				
Pepper	EC	Ground	1.6	1	1.6	-
Tabasco pepper	EC	Ground	2.5	1	2.5	-
Pumpkin and Rhubarb	EC	Ground Aerial	1.3	1	1.3	-
Potato	EC	Ground Aerial	2.5	2	3.4	30 - 45
	G	Ground	1.9	NS	2.4	NS
Sorghum	EC	Ground Aerial	1.7	1	1.7	-
Silage sorghum	EC	Aerial Ground	1.6	1	1.6	-
Spinach	EC	Ground	1.0	1	1.0	-
Sugarbeet	EC	Aerial	1.6	NS	2.5	-
Sunflower	EC	Ground Aerial	1.9	NS	NS	NS
Tomato Safflower Celery	EC	Ground	1.9	1	1.9	-
Soybean	EC RTU	Ground Aerial	2.5	1	2.5	-
	G	Ground	1.9	NS	2.4	-

Use	Formulation ¹	Application Method ²	Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications per Year (#)	Maximum Seasonal Application Rate (lb ai/A)	Application Interval (days)
Non-Food Uses						
Grasses for sod	EC	Ground	1.3	NS	NS	NS
Ornamental shade trees and ornamental sod	EC	Ground Aerial	2.5	NS	4.0	42
Ornamental herbs and woody shrubs	EC	Ground	2.5	NS	NS	NS
Ornamental turf	EC	Ground	2.5	1	2.5	-

¹Formulation codes: EC - Emulsifiable Concentrate; G - Granular; RTU – Ready to use

²Chemigation is included in ground application

³Not applicable due to single application

⁴The labels for S-metolachlor specified a 30–45 day intervals for food uses (except onion) with two applications; For food uses with two applications, in the aquatic modeling, the single maximum rate was applied first, and the remaining allowed rate was applied for the second application. The use of 30 day interval will provide the most conservative EECs (compared to 45-day interval) and therefore this interval was used in the modeling

According to the United States Geological Survey's (USGS) national pesticide usage data, an average of 66.38 million pounds of metolachlor was applied nationally to agricultural use sites in the U.S. in 1997 (**Figure 2-1**). Of this, about 75% of the total usage was in corn. Soybean and sorghum represented the second (14%) and third (7%) major uses for metolachlor.

In 2002, an average of 24.50 million pounds of S-metolachlor was applied nationally to agricultural use sites (**Figure 2-2**). About 73% of the total pounds used in the United States were used in corn followed by 10% each in soybean and sorghum.

Figure 2-1. Estimated Agricultural Use of Metolachlor in U.S. in 1997

(Source: http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=97&map=m1011)

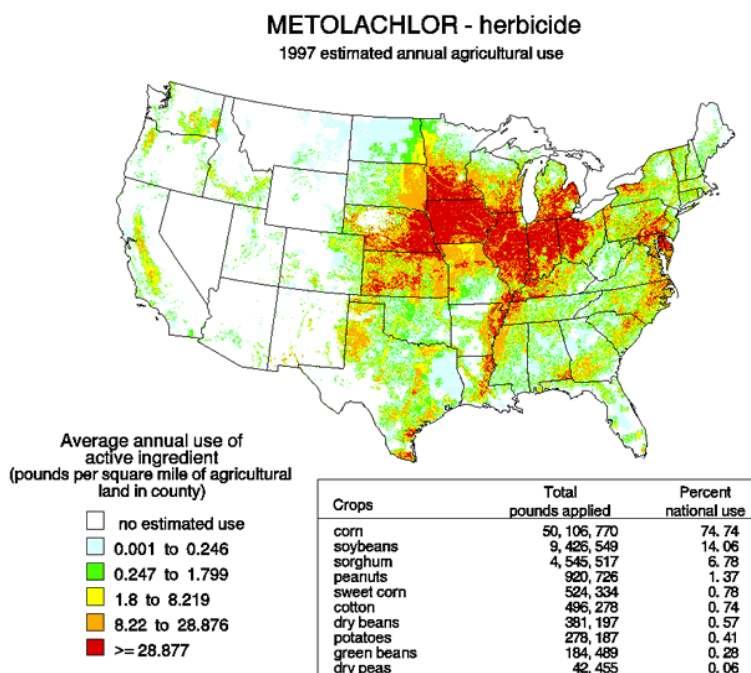
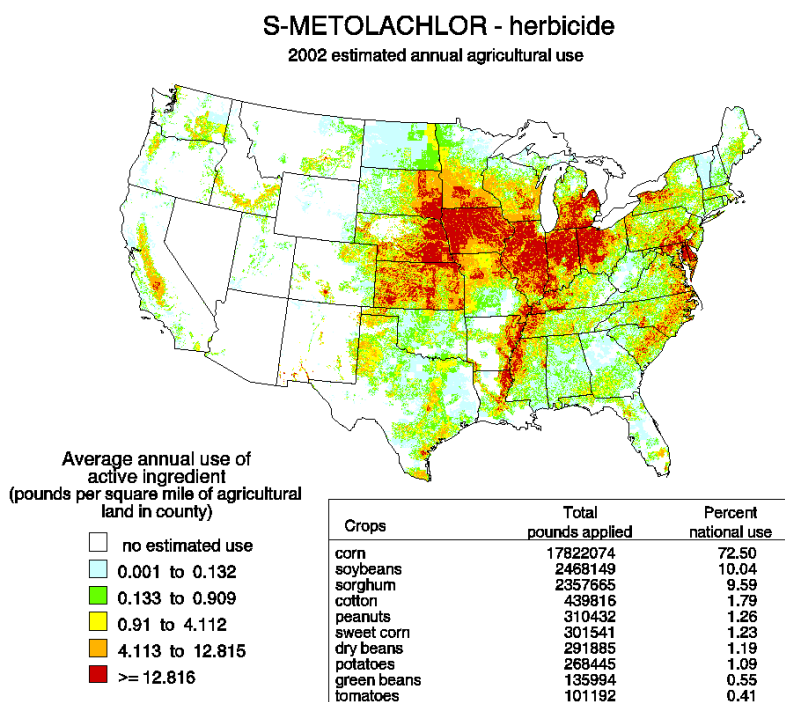


Figure 2-2. Estimated Agricultural Use of S-Metolachlor in U.S. in 2002

(Source: http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=02&map=m9124)



The Agency's Biological and Economic Analysis Division (BEAD) provided an analysis of both national- and county-level usage information (County-Level Usage for Carbaryl, Metolachlor, S-Metolachlor, Naled, Simazine, and Sodium Nitrate in California in Support of a San Francisco Bay Endangered Species Assessment, February 17, 2010) using state-level usage data obtained from USDA-NASS¹, Doane (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) database². CDPR PUR is considered a more comprehensive source of usage data than USDA-NASS or EPA proprietary databases, and thus the usage data reported for metolachlor by county in this California-specific assessment were generated using CDPR PUR data. Nine years (1999-2007) 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 include: average annual pounds applied, average annual area treated, and average and

¹ 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>.

² 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>.

maximum application rate across all eight years. The units of area treated are also provided where available.

The usage data reported by CDPR PUR summarizing metolachlor and S-metolachlor's usage for all California use sites is provided below in **Tables 2-5** and **2-6**, respectively. The uses considered in this risk assessment represent all currently registered uses according to a review of all current labels. No other uses are relevant to this assessment. Any reported use other than currently registered uses represent either historic uses that have been canceled, mis-reported uses, or mis-use. Historical uses, mis-reported uses, and misuse are not considered part of the federal action and, therefore, are not considered in this assessment.

Table 2-5. Summary of California Department of Pesticide Registration (CDPR) Pesticide Use Reporting (PUR) Data from 1999 to 2007 for Metolachlor Uses

Use	Average Application Rate (lb ai/A) ¹	95th Percentile Application Rate (lb ai/A)	99th Percentile Application Rate (lb ai/A)	Maximum Application Rate (lb ai/A) ²
Alfalfa	2.4	5.9	5.9	5.9
Almond	2.9	4.0	4.0	4.0
Avocado	2.0	2.0	2.0	2.0
Barley	2.4	2.5	2.5	2.5
Bean, Dried	2.2	3.0	7.4	23.0
Bean, Succulent	2.1	2.7	5.0	31.7
Bean, Unspecified	2.0	2.5	3.0	3.0
Cantaloupe	0.2	0.2	0.2	0.2
Celery	0.1	0.1	0.1	0.1
Corn (Forage/Fodder)	2.2	3.0	4.9	19.8
Corn, Human Consumption	1.9	3.0	3.6	3.6
Cotton	1.9	2.0	2.2	19.8
Cotton (Forage/Fodder)	0.5	0.7	0.7	0.7
Forage Hay/Silage	2.0	2.0	2.0	2.0
Grape	2.0	2.0	2.0	2.0
Grape, Wine	0.1	0.1	0.1	0.1
Kumquat	1.3	1.3	1.3	1.3
Lettuce, Leaf	0.1	0.1	0.1	0.1
N-Greenhouse Flower	1.1	3.3	4.6	14.7
N- Greenhouse Plants In Containers	6.9	9.8	9.8	9.8
N- Greenhouse Transplants	6.2	7.8	7.8	7.8
N-Outdoor Flower	2.2	5.9	5.9	20.7
N-Outdoor Container Plants	3.0	7.8	9.8	9.8
Oat	2.0	2.0	2.0	2.0

Oat (Forage/Fodder)	2.0	2.0	2.0	2.0
Peas	1.4	2.5	2.5	2.5
Pepper, Fruiting	1.7	2.0	2.0	2.0
Potato	1.8	3.0	3.5	3.5
Research Commodity	2.1	2.1	2.1	2.1
Safflower	2.4	3.0	4.0	4.0
Soil Fumigation/Preplant	1.7	2.0	2.0	2.0
Sorghum/Milo	2.3	2.3	2.3	2.3
Sugarbeet	2.0	2.0	2.0	2.0
Sunflower	2.0	2.0	2.0	2.0
Tomato	1.5	2.0	2.0	2.0
Tomato, Processing	1.6	2.5	2.5	2.5
Turf/Sod	2.0	3.9	3.9	3.9
Uncultivated Ag	1.7	2.1	2.5	2.5
Uncultivated Non-Ag	2.0	3.0	3.0	3.0
Unknown	2.5	2.5	2.5	2.5
Walnut	4.9	8.3	8.3	8.3
Wheat	1.1	2.0	2.0	2.0
Wheat (Forage - Fodder)	1.2	2.0	2.0	2.0

¹The average application rate was calculated as the weighted average of the average application rate for one county; the values reflect the average application rate for that site across all counties

²Based on data supplied by BEAD (source: transmittal memo dated 3/1/2010)

Table 2-6. Summary of California Department of Pesticide Registration (CDPR) Pesticide Use Reporting (PUR) Data from 1999 to 2007 for S-Metolachlor Uses

Use	Average Application Rate (lb ai/A) ¹	95th Percentile Application Rate (lb ai/A)	99th Percentile Application Rate (lb ai/A)	Maximum Application Rate (lb ai/A) ²
Alfalfa	1.9	3.2	3.2	3.2
Almond	0.4	0.4	0.4	0.4
Barley	2.1	4.7	4.7	4.7
Bean, Dried	1.4	1.9	1.9	12.7
Bean, Succulent	1.4	1.9	1.9	12.7
Bean, Unspecified	1.4	1.9	2.1	4.8
Broccoli	0.6	0.6	0.6	0.6
Corn (Forage/ Fodder)	1.5	1.9	2.4	12.8
Corn, Human Consumption	1.4	1.9	2.5	12.6
Cotton	1.3	1.3	1.8	17.7
Cucumber	1.3	1.3	1.3	1.3
Garbanzos	1.3	1.4	1.4	1.4

Melon	1.0	1.9	1.9	1.9
N-Greenhouse Flower	0.6	0.9	0.9	0.9
N- Greenhouse Container Plants	4.6	53.6	53.6	53.6
N-Outdoor Flower	0.0	0.0	0.0	0.0
N-Outdoor Flower	1.4	1.9	2.0	2.9
N-Outdoor Container plants	3.9	5.5	54.6	68.3
N-Outdoor Transplants	2.1	2.5	2.5	2.5
N-Outdoor Transplants	0.0	0.0	0.0	0.0
Oat	0.8	1.6	1.6	1.6
Oat (Forage - Fodder)	1.4	1.6	1.6	1.6
Peas	0.9	1.6	1.9	3.0
Pepper, Fruiting	1.3	1.6	2.4	7.1
Pepper, Spice	1.4	1.4	1.4	1.4
Potato	1.2	1.9	2.8	9.5
Rangeland	0.9	0.9	0.9	0.9
Research Commodity	1.6	2.8	2.8	2.8
Rights Of Way	1.5	1.5	1.5	1.5
Safflower	1.6	1.9	1.9	2.0
Soil Fumigation/Preplant	1.4	1.7	2.2	12.6
Sorghum (Forage/ Fodder)	1.6	1.9	1.9	1.9
Sorghum/Milo	1.4	1.6	1.6	1.6
Soybean	1.0	1.0	1.0	1.0
Sudangrass	1.9	3.8	3.8	3.8
Sugarbeet	1.3	1.6	1.6	1.6
Sunflower	1.6	1.9	5.4	10.1
Swiss Chard	0.5	0.7	1.2	1.2
Tomato	1.3	1.9	2.0	7.8
Tomato, Processing	1.2	1.9	1.9	12.7
Turf/Sod	2.1	1.9	15.2	15.2
Uncultivated Ag	2.6	3.8	9.5	9.5
Walnut	0.9	0.9	0.9	0.9
Wheat	10.6	56.4	56.4	56.4

¹The average application rate was calculated as the weighted average of the average application rate for one county; the values reflect the average application rate for that site across all counties

²Based on data supplied by BEAD (source: transmittal memo dated 3/1/2010)

Table 2-7 depicts the average annual use of metolachlor/S-metolachlor in various counties of California. Metolachlor and S-metolachlor use was highest in Fresno county followed by Kings and San Joaquin counties.

Table 2-7. Average County Use of Metolachlor and S-Metolachlor Based on CDPR- PUR Data from 1999 to 2007

County	Average Annual Usage (lb)	
	S-Metolachlor	Metolachlor
Butte	678	235
Colusa	9,947	292
Contra Costa	1,489	458
Del Norte	5	71
El Dorado	1	
Fresno	95,614	14,511
Glenn	2,589	1,345
Humboldt	6	105
Imperial	90	73
Kern	10,897	1,982
Kings	37,572	13,940
Los Angeles	465	9
Madera	3,626	349
Merced	20,901	3,469
Monterey	3,265	943
Orange	66	47
Placer	228	26
Riverside	486	644
Sacramento	3,757	1,521
San Benito	265	20
San Bernardino	2	85
San Diego	100	92
San Joaquin	24,727	5,271
San Luis Obispo	385	280
San Mateo		1
Santa Barbara	1,329	1,023
Santa Clara	886	24
Solano	5,518	1,132
Stanislaus	16,564	5,999
Sutter	3,720	429
Tehama	169	
Tulane	3,408	3,467
Ventura	457	21
Yolo	19,732	1,253
Yuba	55	34
TOTAL	51,838	4,775

2.5. Assessed Species

Table 2-8 provides a summary of the current distribution, habitat requirements, and life history parameters for the listed species being assessed (DS and CTS). More detailed life-history and distribution information can be found in **Attachment 3**. The distribution of DS and CTS within California is presented in **Figures 2.2 and 2.3**, respectively.

The DS was listed as threatened on March 5, 1993 (58 FR 12854) by the USFWS (USFWS, 2007a). DS are mainly found in the Suisun Bay and the Sacramento-San Joaquin estuary near San Francisco Bay. During spawning DS move into freshwater.

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.

Table 2-8. Summary of Current Distribution, Habitat Requirements, and Life History Information for the CTS and DS¹

Assessed Species	Size	Current Range	Habitat Type	Designated Critical Habitat?	Reproductive Cycle	Diet
California Tiger Salamander (CTS) (Ambystoma californiense)	50 g	<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	<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><u>Aquatic Phase:</u> algae, snails, zooplankton, small crustaceans, and aquatic larvae and invertebrates, smaller tadpoles of Pacific tree frogs, CRLF, toads;</p> <p><u>Terrestrial Phase:</u> terrestrial invertebrates, insects, frogs, and worms</p>
Delta Smelt (DS) (Hypomesus transpacificus)	Up to 120 mm in length	Suisun Bay and the Sacramento-San Joaquin estuary (known as the Delta) near San Francisco Bay, CA	The species is adapted to living in fresh and brackish water. They typically occupy estuarine areas with salinities below 2 parts per thousand (although they have been found in areas up to 18ppt). They live along the freshwater edge of the mixing zone (saltwater-freshwater interface).	Yes	They spawn in fresh or slightly brackish water upstream of the mixing zone. Spawning season usually takes place from late March through mid-May, although it may occur from late winter (Dec.) to early summer (July-August). Eggs hatch in 9 – 14 days.	They primarily eat planktonic copepods, cladocerans, amphipods, and insect larvae. Larvae feed on phytoplankton; juveniles feed on zooplankton.

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

Figure 2-3. Delta Smelt Critical Habitat and Occurrence Sections Identified in Case No. 07-2794-JCS

Delta Smelt Habitat

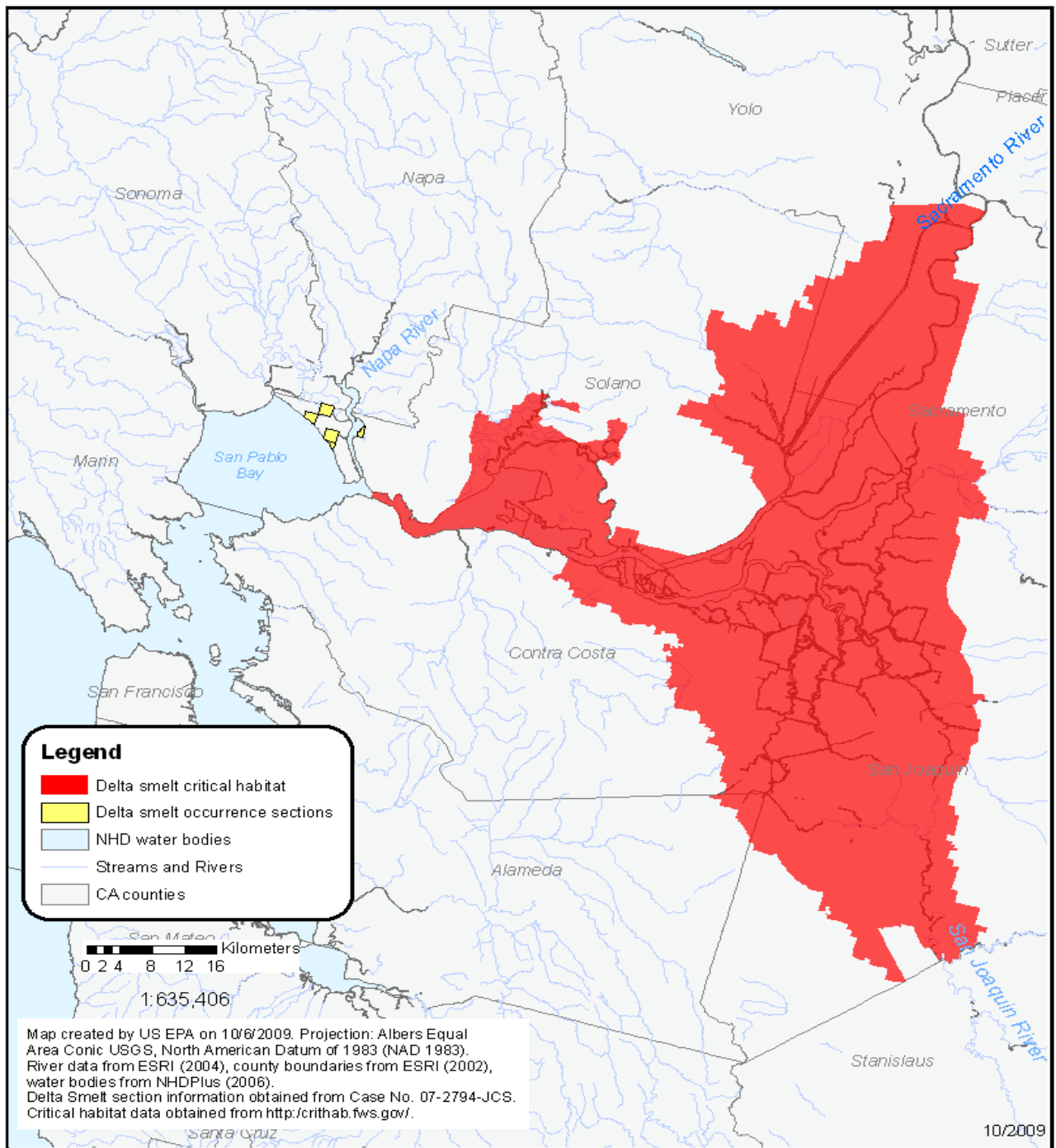
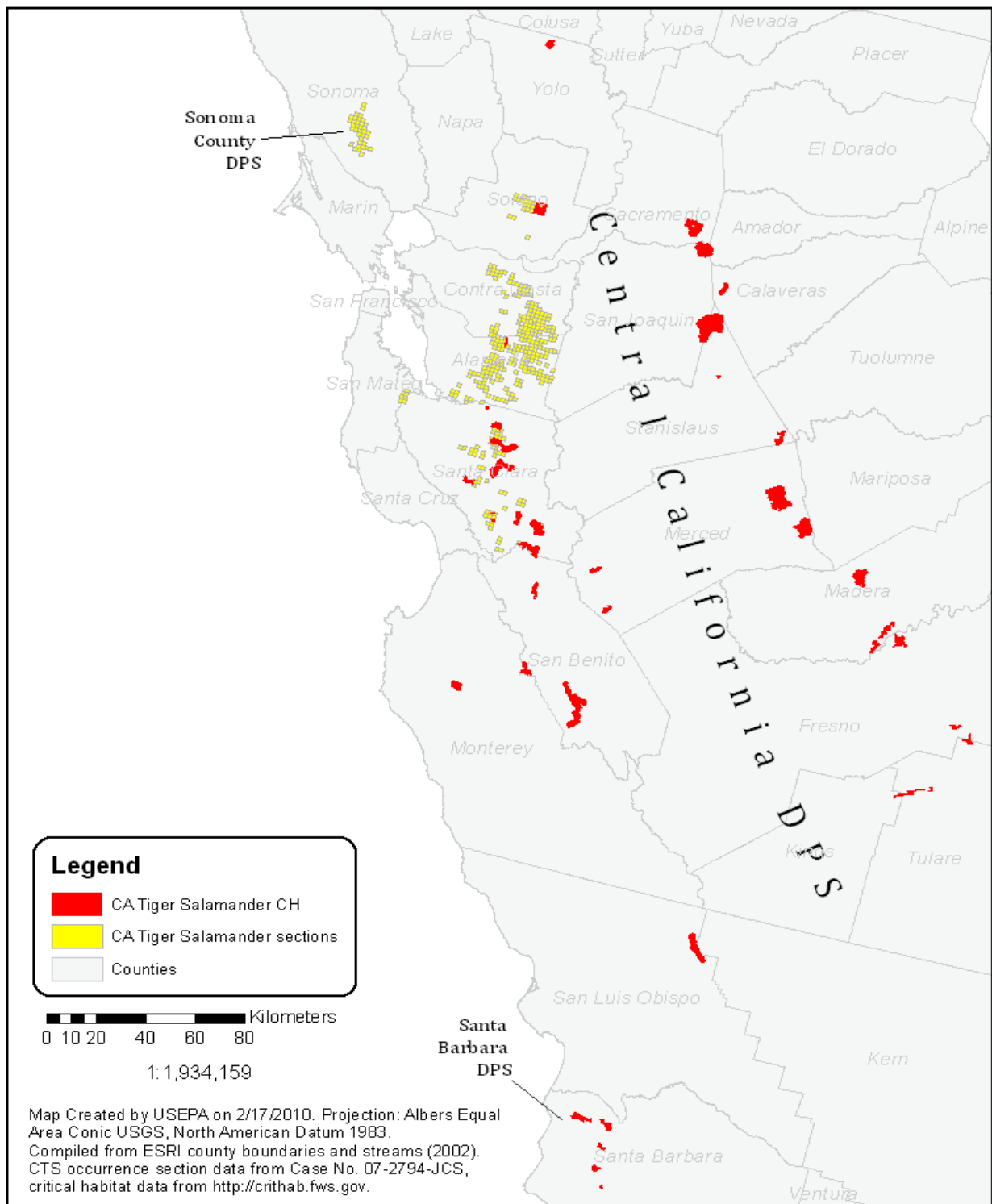


Figure 2-4. California Tiger Salamander Critical Habitat and Occurrence Sections Identified in Case No. 07-2794-JCS



2.6. Designated Critical Habitat

Critical habitat has been designated for the DS and CTS. Risk to 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 there is a need for special management to protect the listed species. It may also 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 2-9** describes the PCEs for the critical habitats designated for the DS and CTS.

Table 2-9. Designated Critical Habitat PCEs for the DS and CTS¹

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 ²	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	
Delta Smelt	Spawning Habitat—shallow, fresh or slightly brackish backwater sloughs and edgewaters to ensure egg hatching and larval viability. Spawning areas also must provide suitable water quality (<i>i.e.</i> , low “concentrations of pollutants) and substrates for egg attachment (<i>e.g.</i> , submerged tree roots and branches and emergent vegetation).	59 FR 65256 65279, 1994
	Larval and Juvenile Transport—Sacramento and San Joaquin Rivers and their tributary channels must be protected from physical disturbance and flow disruption. Adequate river flow is necessary to transport larvae from upstream spawning areas to rearing habitat in Suisun Bay. Suitable water quality must be provided so that maturation is not impaired by pollutant concentrations.	
	Rearing Habitat—Maintenance of the 2 ppt isohaline and suitable water quality (low concentrations of pollutants) within the Estuary is necessary to provide delta smelt larvae and juveniles a shallow protective, food-rich environment in which to mature to adulthood.	
	Adult Migration— Unrestricted access to suitable spawning habitat in a period that may extend from December to July. Adequate flow and suitable water quality may need to be maintained to attract migrating adults in the Sacramento and San Joaquin River channels and their associated tributaries. These areas also should be protected from physical disturbance and flow disruption during migratory periods.	

¹These 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.

²PCEs 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.

More detail on the designated critical habitat applicable to this assessment can be found in **Attachment 2**. Activities that may destroy or adversely modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the species. Evaluation of actions related to use of metolachlor and S-metolachlor that may alter the PCEs of the designated critical habitat for the DS and CTS form the basis of the critical habitat impact analysis.

As previously noted in Section 2.1, 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 metolachlor and S-metolachlor is expected to directly impact living organisms within the action area, critical habitat analysis for metolachlor and S-metolachlor 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.

2.6. Action Area and LAA Effects Determination Area

2.6.1. Action Area

The action area is used to identify areas 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 are 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 toxic effect to the assessed species and any potential modification of its critical habitat, including reduction in survival, growth, and fecundity as well as the full suite of sublethal effects available in the effects literature. It is recognized that the overall action area for the national registration of metolachlor is likely to encompass considerable portions of the United States based on the large array of agricultural and 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 the DS and 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 San Francisco Bay Species. Additionally, the concept of a state-wide action area takes into account the potential for direct and indirect effects and any potential modification to critical habitat based on ecological effect measures associated with reduction in survival, growth, and reproduction, as well as the full suite of sublethal effects available in the effects 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 to 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 DS and CTS and

designated critical habitat may be affected or modified via endpoints associated with reduced survival, growth, or reproduction.

2.6.2. LAA Effects Determination Area

A stepwise approach is used to define the Likely to Adversely Affect (LAA) Effects Determination Area. An LAA effects determination applies to those areas where it is expected that the pesticide's use will directly or indirectly affect the species and/or modify its designated critical habitat using EFED's standard assessment procedures (see **Attachment 1**) and effects endpoints related to survival, growth, and reproduction. This is the area where the "Potential Area of LAA Effects" (initial area of concern + drift distance or downstream dilution distance) overlaps with the range and/or designated critical habitat for the species being assessed. If there is no overlap between the potential area of LAA effects and the habitat or occurrence areas, a no effect determination is made. The first step in defining the LAA Effects Determination Area is to understand the federal action. The federal action is defined by the currently labeled uses for metolachlor and S-metolachlor. An analysis of labeled uses and review of available product labels was completed. Some of the currently labeled uses are special local needs (SLN) uses not specified for use in California or are restricted to specific states and are excluded from this assessment. In addition, a distinction has been made between food use crops and those that are non-food/non-agricultural uses. For those uses relevant to the assessed species, the analysis indicates that, for metolachlor/S-metolachlor, the following agricultural uses are considered as part of the federal action evaluated in this assessment:

- Alfalfa
- Cabbage
- Celery
- Citrus
- Corn (all types)
- Cotton
- Horse radish
- Legume crops
- Onion
- Peach
- Peanut
- Pepper
- Potato
- Pumpkin
- Radish
- Rhubarb
- Safflower
- Sorghum
- Soybean
- Spinach
- Sugar beet
- Sunflower

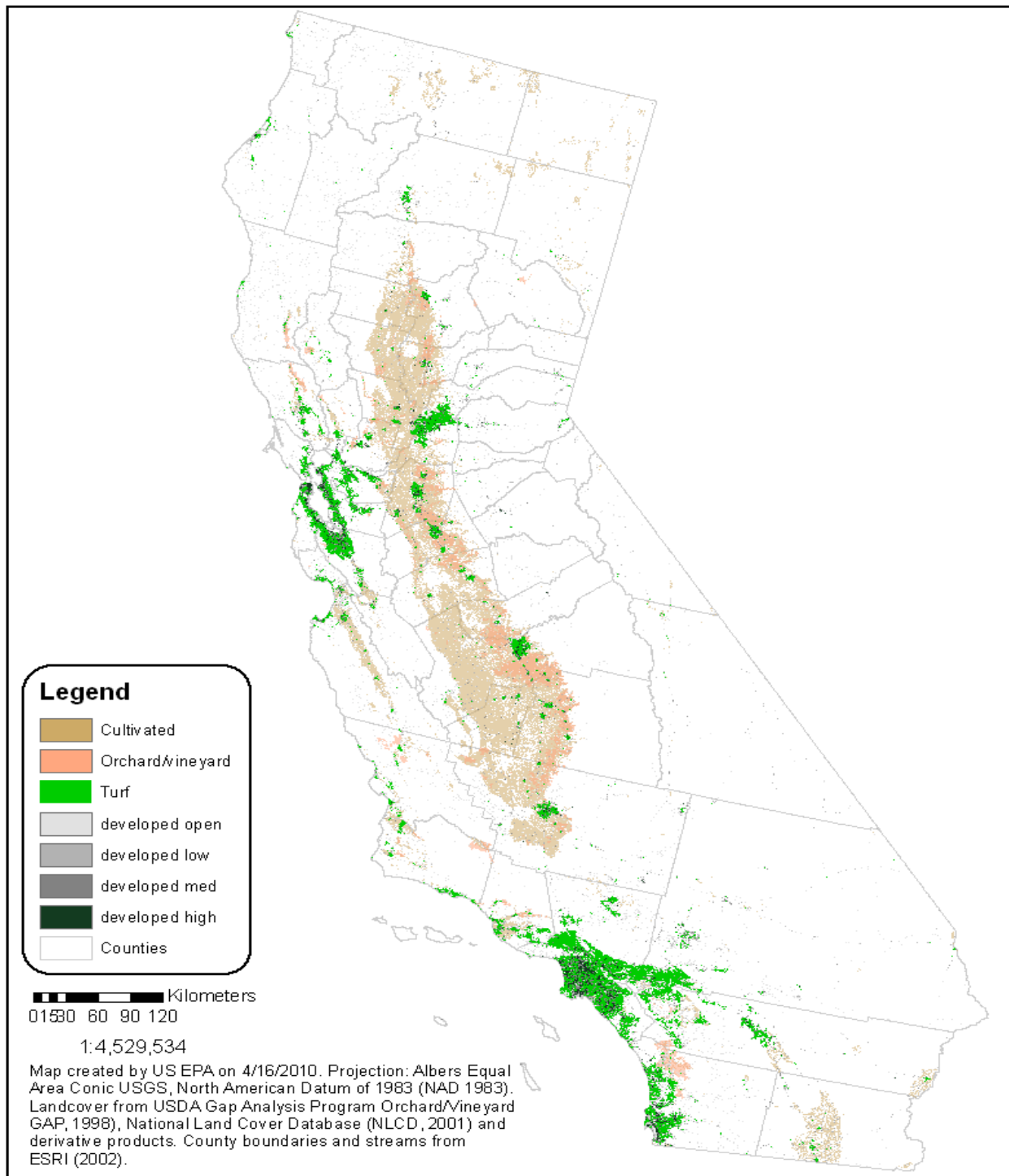
- Swiss chard
- Tabasco pepper
- Tomato
- Tree nuts

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

- Meadowfoam
- Grasses for sod
- Ornamental shade trees, herbs and shrubs
- Ornamental sod and turf

Following a determination of the assessed uses, an evaluation of the potential “footprint” of metolachlor and S-metolachlor use patterns (*i.e.*, the area where pesticide application may 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. For metolachlor and S-metolachlor, these land cover types include cultivated, orchard/vineyard, developed open/developed low/developed medium/developed high, and turf. A map representing all the land cover types that make up the initial area of concern for metolachlor and S-metolachlor is presented in **Figure 2-5**.

Figure 2-5. Initial Area of Concern, or “Footprint” of Potential Use, for Metolachlor/S-Metolachlor



Once the initial area of concern is defined, the next step is to define the potential boundaries of the Potential Area of LAA Effects by determining the extent of offsite transport via spray drift and runoff where exposure of one or more taxonomic groups to the pesticide will result in exceedances of the listed species LOCs.

The AgDRIFT model (Version 2.01) is used to define how far from the initial area of concern an effect to a given species may be expected via spray drift (*e.g.*, the drift distance). The spray drift analysis for metolachlor/S-metolachlor uses the most sensitive endpoint of monocot plants (EC₂₅ = 0.0048 lb ai/A for ryegrass) from the seedling emergence study. Further details on the spray drift analysis is provided in Section 5.2.3.a.

In addition to the buffered area from the spray drift analysis, the Potential Area of LAA Effects also considers the downstream extent of metolachlor/S-metolachlor that exceeds the LOC based on downstream dilution analysis (discussed in Section 5.2.3.b).

An evaluation of usage information was conducted to determine the area where use of metolachlor and S-metolachlor may impact the assessed species. This analysis is used to characterize where predicted exposures are most likely to occur, but does not preclude use in other portions of the action area. A more detailed review of the county-level use information was also completed. These data suggest that metolachlor and S-metolachlor have historically been used on a wide variety of agricultural and non-agricultural uses.

2.7. Assessment Endpoints and Measures of Ecological Effect

2.7.1. Assessment Endpoints

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. **Table 2-10** identifies the taxa used to assess the potential for direct and indirect effects of metolachlor/S-metolachlor on the DS and CTS. The specific assessment endpoints used to assess the potential direct and indirect effects to DS and CTS are provided in **Table 2-11**. For more information on the assessment endpoints, see **Attachment 1**.

Table 2-10. Taxa Used in the Analyses of Direct and Indirect Effects for the CTS and DS

Listed Species	Birds	Mammals	Terr. Plants	Terr. Inverts.	FW Fish	FW Inverts.	Estuarine /Marine Fish	Estuarine /Marine Inverts.	Aquatic Plants
California tiger salamander	Direct	Indirect (prey/habitat)	Indirect (habitat)	Indirect (prey)	Direct Indirect (prey)	Indirect (prey)	n/a	n/a	Indirect (food/habitat)
Delta smelt	n/a	n/a	Indirect (habitat)	n/a	Direct***	Indirect (prey)	Direct	Indirect (prey)	Indirect (food/habitat)

Abbreviations: n/a = Not applicable; Terr. = Terrestrial; Invert. = Invertebrate; FW = Freshwater

***The most sensitive fish species across freshwater and estuarine/marine environments is used to assess effects for these species because they may be found in freshwater or estuarine/marine environments.

Table 2-11. Taxa and Assessment Endpoints Used to Evaluate the Potential for Metolachlor/S-Metolachlor to Result in Direct and Indirect Effects to the DS and CTS or Modification of their Critical Habitat

Taxa Used to Assess Direct and Indirect Effects to DS and CTS and/or Modification to Critical Habitat	Assessed Listed Species	Assessment Endpoints	Measures of Ecological Effects
1. Freshwater Fish and Aquatic-Phase Amphibians	<u>Direct Effect</u> – - Delta Smelt* - California Tiger Salamander	Survival, growth, and reproduction of individuals via direct effects	1a. Most sensitive fish acute LC ₅₀ (MRID 43928910): Bluegill sunfish LC₅₀ = 3.2 mg ai/L 1b. Most sensitive fish chronic NOAEC (MRID 44995903): Fathead minnow NOAEC = 0.03 mg ai/L 1c. Most sensitive fish early-life stage NOAEC (guideline or ECOTOX): None available
2. Freshwater Invertebrates	<u>Indirect Effect (prey)</u> - CA Tiger Salamander - Delta Smelt	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on aquatic prey food supply (i.e., freshwater invertebrates)	2a. Most sensitive freshwater invertebrate EC ₅₀ (ECOTOX Ref# 67777): Water flea EC₅₀ = 1.1 mg ai/L 2b. Most sensitive freshwater invertebrate chronic NOAEC (ECOTOX Ref# 83887): Water flea NOAEC = 0.001 mg ai/L
3. Estuarine/Marine Fish	<u>Direct Effect</u> – - Delta Smelt*	Survival, growth, and reproduction of individuals via direct effects Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on aquatic prey food supply (i.e., estuarine/marine fish)	3a. Most sensitive estuarine/marine fish EC ₅₀ (MRID 43928910): Sheepshead minnow LC₅₀ = 7.9 mg ai/L 3b. Most sensitive estuarine/marine fish chronic NOAEC (MRID 44995903): Sheepshead minnow NOAEC = 1mg ai/L
4. Estuarine/Marine Invertebrates	<u>Indirect Effect (prey)</u> - Delta Smelt	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on aquatic prey food supply (i.e., estuarine/marine invertebrates)	4a. Most sensitive estuarine/marine invertebrate EC ₅₀ (MRID 43487102): Eastern oyster EC₅₀ = 1.6 mg ai/L 4b. Most sensitive estuarine/marine invertebrate chronic NOAEC (MRID 44995902): Mysid shrimp NOAEC = 0.13 mg ai/L
5. Aquatic Plants (freshwater/marine)	<u>Indirect Effect (food/habitat)</u> - CA Tiger Salamander - Delta Smelt	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on habitat, cover, food supply, and/or primary productivity (i.e., aquatic plant community)	5a. Vascular plant acute EC ₅₀ (MRID 43928931): Duckweed EC₅₀ = 0.021 mg ai/L 5b. Non-vascular plant acute EC ₅₀ (MRID 43928929): Green algae EC₅₀ = 0.008 mg ai/L
6. Birds	<u>Direct Effect</u> - CA Tiger Salamander	Survival, growth, and reproduction of individuals via direct effects Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect	6a. Most sensitive bird or terrestrial-phase amphibian acute LC ₅₀ or LD ₅₀ (MRID 43928907): Bobwhite quail LD₅₀ = >2194 mg ai/kg bw; LC₅₀ = >4912 mg ai/kg diet

Taxa Used to Assess Direct and Indirect Effects to DS and CTS and/or Modification to Critical Habitat	Assessed Listed Species	Assessment Endpoints	Measures of Ecological Effects
		effects on terrestrial prey (birds)	6b. Most sensitive bird or terrestrial-phase amphibian chronic NOAEC (MRID 44995901): Bobwhite quail NOAEC = 1000¹ mg ai/kg diet
7. Mammals	<u>Indirect Effect (prey/habitat from burrows/rearing sites)</u> - CA Tiger Salamander	Survival, growth, and reproduction of individuals via direct effects Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey (mammals) and/or burrows/rearing sites	7a. Most sensitive laboratory mammalian acute LC ₅₀ or LD ₅₀ (MRID 0015523): Rat LD₅₀ = 2780 mg ai/kg bw 7b. Most sensitive laboratory mammalian chronic NOAEC (MRID 00080897): Rat NOAEL = 24 mg ai/kg bw/day or 300 mg/kg diet
8. Terrestrial Invertebrates	<u>Indirect Effect (prey)</u> - CA Tiger Salamander	Survival, growth, and reproduction of individuals via direct effects Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey (terrestrial invertebrates)	8a. Most sensitive terrestrial invertebrate acute EC ₅₀ or LC ₅₀ (MRID 44718401): Honey bee oral/contact LD₅₀ = >85/>200 µg ai/bee 8b. Most sensitive terrestrial invertebrate chronic NOAEC (guideline or ECOTOX): None available
9. Terrestrial Plants	<u>Indirect Effect (food/habitat) (non-obligate relationship)</u> - CA Tiger Salamander - Delta Smelt	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on food and habitat (<i>i.e.</i> , riparian and upland vegetation)	9a. Distribution of seedling emergence EC ₂₅ for monocots (MRIDs 43928932 and 43928933): Monocot EC₂₅ = 0.0048 – 0.021 lb ai/A 9b. Distribution of seedling emergence EC ₂₅ for dicots (MRIDs 43928932 and 43928933) Dicot EC₂₅ = 0.0057 – 0.27 lb ai/A

¹The most sensitive avian chronic NOAEC of 403 mg/kg diet (MRID 46508901) was not used for this assessment as this endpoint was based on reduction in eggshell thickness and increase in cracked eggs, neither of which are relevant to CTS (all 3 DPSs)

Abbreviations: SF=San Francisco

*The most sensitive fish species across freshwater and estuarine/marine environments is used to assess effects for these species because they may be found in freshwater or estuarine/marine environments.

**Birds are used as a surrogate for terrestrial-phase amphibians and reptiles.

2.7.2. Assessment Endpoints for Designated Critical Habitat

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of metolachlor and S-metolachlor 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 metolachlor and S-metolachlor 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.

2.8. Conceptual Model

2.8.1. 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 metolachlor/S-metolachlor to the environment. The following risk hypotheses are presumed in this assessment:

The labeled use of metolachlor and S-metolachlor within the action area may:

- directly affect DS and CTS by causing mortality or by adversely affecting growth or fecundity;
- indirectly affect DS and CTS and/or modify their designated critical habitat by reducing or changing the composition of food supply;
- indirectly affect DS and 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 DS and 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 DS and 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).

2.8.2. Diagram

The conceptual model is a graphic representation of the structure of the risk assessment. It specifies the metolachlor and S-metolachlor release mechanisms, biological receptor types, and effects endpoints of potential concern. The conceptual models for DS and CTS and the conceptual models for the aquatic and terrestrial PCE components of critical habitat are shown in **Figure 2-6 and Figure 2-7**, respectively. Although the conceptual models for direct/indirect effects and modification of designated critical habitat PCEs are shown on the same diagrams, the potential for direct/indirect effects and modification of PCEs will be evaluated separately in this assessment. Exposure routes shown in dashed lines are not quantitatively considered because the

contribution of those potential exposure routes to potential risks to DS and CTS and modification to designated critical habitat is expected to be negligible. Metolachlor/S-metolachlor concentrations in ground and irrigation water are expected to be lower than those in surface water, therefore only surface water concentrations were modeled for this assessment.

Figure 2-6. Conceptual Model Depicting Stressors, Exposure Pathways, and Potential Effects to Aquatic Organisms from the Use of Metolachlor/S-Metolachlor
(Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk)

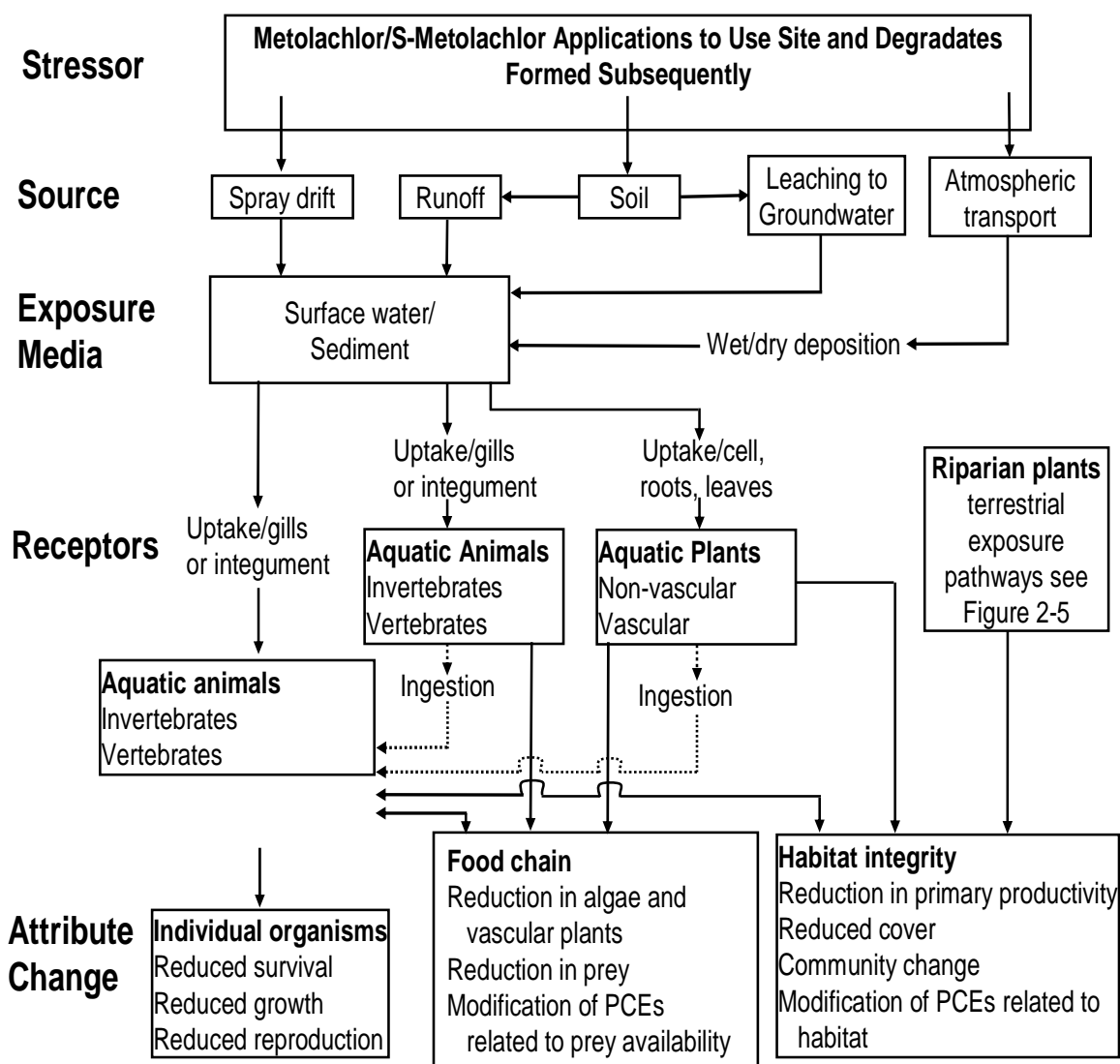
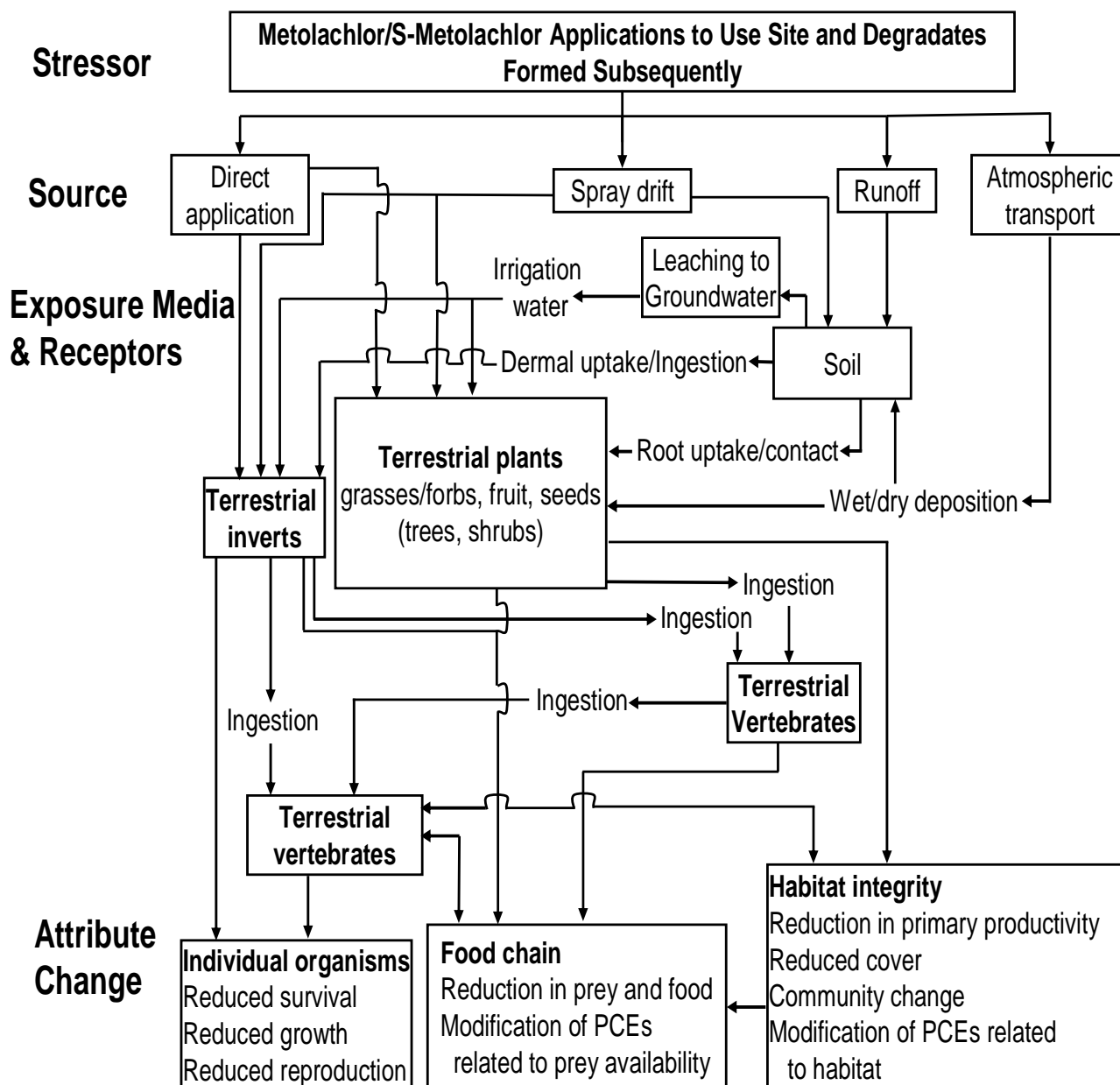


Figure 2-7. Conceptual Model Depicting Stressors, Exposure Pathways, and Potential Effects to Terrestrial Organisms from the Use of Metolachlor/S-Metolachlor

(Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk)



2.9. Analysis Plan

In order to address the risk hypothesis, the potential for direct and indirect effects to the assessed species, prey items, and habitat is estimated based on a taxon-level approach. In the following sections, the use, environmental fate, and ecological effects of metolachlor/S-metolachlor 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 metolachlor/S-metolachlor is estimated using the probit dose-response slope and either the level of concern (discussed below) or actual calculated risk quotient value.

Descriptions of routine procedures for evaluating risk to the San Francisco Bay Species are provided in **Attachment 1**.

2.9.1. Measures of Exposure

The environmental fate properties of metolachlor/S-metolachlor along with available monitoring data indicate that water and sediment runoff and spray drift are the principle potential transport mechanisms of metolachlor and S-metolachlor to the aquatic and terrestrial habitats. Based on the physical, chemical, and environmental fate properties, metolachlor and its degradates have potential to leach into groundwater. In this assessment, transport of metolachlor/S-metolachlor through runoff and spray drift is considered in deriving quantitative estimates of metolachlor exposure to DS and CTS and their prey and habitats. For addressing groundwater leaching potential and possibly irrigation with groundwater, the monitoring data were assessed. The potential contribution of atmospheric transport of volatile metolachlor was evaluated based on metolachlor concentrations in air and in rainfall samples from California monitoring results.

Measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) of metolachlor/S-metolachlor 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 Terrestrial Residue Exposure (T-REX) model. 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.

2.9.1.a. Estimating Exposure in the Aquatic Environment

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 (Aug 2007) to generate daily exposures and 1-in-10 year EECs of metolachlor/S-metolachlor that may occur in surface water bodies adjacent to application sites receiving metolachlor/S-metolachlor 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 m³ volume) with no outlet. PRZM/EXAMS was used to estimate screening-level exposure of aquatic organisms to metolachlor/s-metolachlor. 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 DS and the aquatic-phase CTS, as well as indirect effects to the DS and CTS through effects to potential prey items and the food chain, including: algae and aquatic invertebrates. The 1-in-10-year 60-day mean is used for assessing chronic exposure to the DS and the aquatic-phase CTS; the 1-in-10-year 21-day mean is used for assessing chronic exposure for aquatic invertebrates, which are the chief prey items of the DS and the aquatic-phase CTS.

The standard scenario used in this assessment assumes standardized “geometry” (field size, pond depth and size, etc), and the soil, hydrogeologic, meteorological conditions, and agronomic practices utilized data specific to the crop and location being modeled. Therefore the scenarios for use in this assessment may not represent the highest exposure sites for metolachlor/S-metolachlor outside of California.

2.9.1.b. Estimating Exposure in the Terrestrial Environment

Exposure estimates for the terrestrial-phase CTS and its prey items (terrestrial invertebrates and mammals) 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, 10/09/2008). 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 metolachlor/S-metolachlor through contaminated food are estimated using the EECs for the small bird (20 g), which consumes short grass. 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 short grass 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 metolachlor/S-metolachlor 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. 1.0, 5/15/2007), (in

Risk Characterization) 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 upon solubility, application rate and minimum incorporation depth.

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

2.9.2. Measures of Effect

Data identified in Section 2.7 are used as measures of effect for direct and indirect effects. Data were obtained from registrant submitted studies or from literature studies identified by ECOTOX. More information on the ECOTOXicology (ECOTOX) database and how toxicological data are used in assessments is available in **Attachment 1**.

2.9.2.a. 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 metolachlor/S-metolachlor, and the likelihood of direct and indirect effects to the assessed species 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. 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**). More information on standard assessment procedures is available in **Attachment 1**.

2.9.3. Data Gaps

No data gaps were identified for metolachlor/S-metolachlor in this assessment. Though studies were identified in the open literature that documented the acute and chronic exposure effects of S-metolachlor and metolachlor on amphibians (various frog species), a technical evaluation of the data from these studies requires it be used only qualitatively. Therefore, toxicity data on fish and birds (which serve as surrogate species for aquatic and terrestrial phase amphibians, respectively) were used to estimate direct and indirect effects to CTS (all 3 DPSs).

3. Exposure Assessment

Registered formulations include emulsifiable concentrate for metolachlor and emulsifiable concentrate, granules, and ready to use formulations for S-metolachlor. The liquid emulsifiable concentrate is the most commonly used formulation. Ground application is most commonly used, although aerial, irrigation, and chemigation applications are also permitted for both metolachlor and S-metolachlor.

3.1. Label Application Rates and Intervals

Metolachlor and S-metolachlor labels may be categorized into two types: labels for manufacturing uses (including technical grade metolachlor and S-metolachlor and its formulated products) and end-use products. While technical products, which contain metolachlor and S-metolachlor 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 in both agricultural and non-agricultural settings. The formulated product labels legally limit metolachlor and S-metolachlor's potential use to only those sites that are specified on the labels.

Various label amendments and mitigations took place for metolachlor/S-metolachlor as a result of the reregistration process. Several environmental hazard statements and statements including spray drift language were added to labels as part of this and are considered in this assessment. No known future label changes that could affect the effects determination in this assessment were identified for metolachlor/S-metolachlor.

Information on application rates, methods, intervals, and times were compiled from all registered labels. Currently registered agricultural and non-agricultural uses of metolachlor and S-metolachlor within California and modeled scenarios are summarized in **Table 3-1**. Rates used in modeling are the maximum allowed rates for that specific crop group. Lower rates may exist, and/or growers may choose to apply lower concentrations than permitted by the label.

Table 3-1. Metolachlor/S-Metolachlor Uses, Scenarios, and Application Information Used in Aquatic Exposure Modeling

PRZM Scenario	Uses Represented	Application Method	Maximum Single Application Rate (lb ai/A)	Maximum Annual Application Rate (lb ai/A)	Number of Applications/ First Applied Date (mm-dd)/ Interval in Days, (if more than 1 application)
CA alfalfa OP	Alfalfa	Ground	3.2	3.2	1 / 03-01
CA row crop RLF	Peanut	Air and ground	3.0	3.0	1 / 03-01

	Soybean	Air and ground	4.0	4.0	1 / 03-01
	Celery	Ground	1.9	1.9	1 / 03-01
	Pepper	Ground	1.6	1.6	1 / 03-01
	Tabasco pepper	Ground	2.5	2.5	1 / 03-01
	Rhubarb	Air and ground	1.3	1.3	1 / 03-01
	Legume crops	Air and ground	3.0	3.0	1 / 03-01
CA citrus STD	Citrus	Ground	3.9	3.9	1 / 06-01
CA cole crop RLF	Cabbage	Ground	3.8	3.8	1 / 02-01
CA melons RLF	Pumpkin	Air and ground	1.3	1.3	1 / 05-01
CA corn OP	Corn (all types)	Air and ground	4.0	6.0	2 ² / 05-01/21
CA cotton STD	Cotton	Air and ground	2.0	4.0	2 / 06-01/21
CA grape STD	Grapes	Ground	3.9	3.9	1 / 03-01
CA onion STD	Onion	Ground	1.3	2.6	2 / 03-01/21
	Radish	Ground	1.3	1.3	1 / 03-01
	Horse radish	Ground	1.3	1.3	1 / 03-01
CA lettuce STD	Swiss chard	Ground	1.3	1.3	1 / 02-01
	Spinach	Ground	1.0	1.0	1 / 02-01
CA almond STD	Tree nuts	Ground	3.8	3.8	1 / 02-01
CA tomato STD	Tomato	Ground	1.9	1.9	1 / 02-01
CA fruit STD	Peach	Ground	2.5	2.5	1 / 03-01
CA wheat RLF	Sunflower	Air and ground	1.9	1.9	1 / 02-01
	Safflower	Air and ground	3.0	3.0	1 / 02-01
	Sorghum	Air and ground	3.2	3.2	1 / 02-01
CA sugarbeet OP	Sugarbeet	Air	1.6	2.5	2 / 02-01/21
CA potato RLF	Potato	Air and ground	4.0	5.5	2 / 02-01/21
CA rangeland hay RLF	Meadowfoam	Ground	0.6	0.6	1 / 05-01
CA nursery	Ornamental shade trees & ornamental sod	Air and ground	2.5	4.0	2 / 03-01/42
CA turf RLF	Grasses for Sod	Ground	1.3	2.5	2 / 05-01/42
	Ornamental turf	Ground	2.5	2.5	1 / 05-01

¹Uses assessed based on memorandum from Pesticide Re-evaluation Division (PRD) dated 3/1/2010 and EFED Label Data report and associated Label Use Information Reports

²For site uses that allow two applications, in the aquatic modeling, the single maximum rate was applied first, and the remaining allowed rate was applied for the second application.

3.2. Aquatic Exposure Assessment

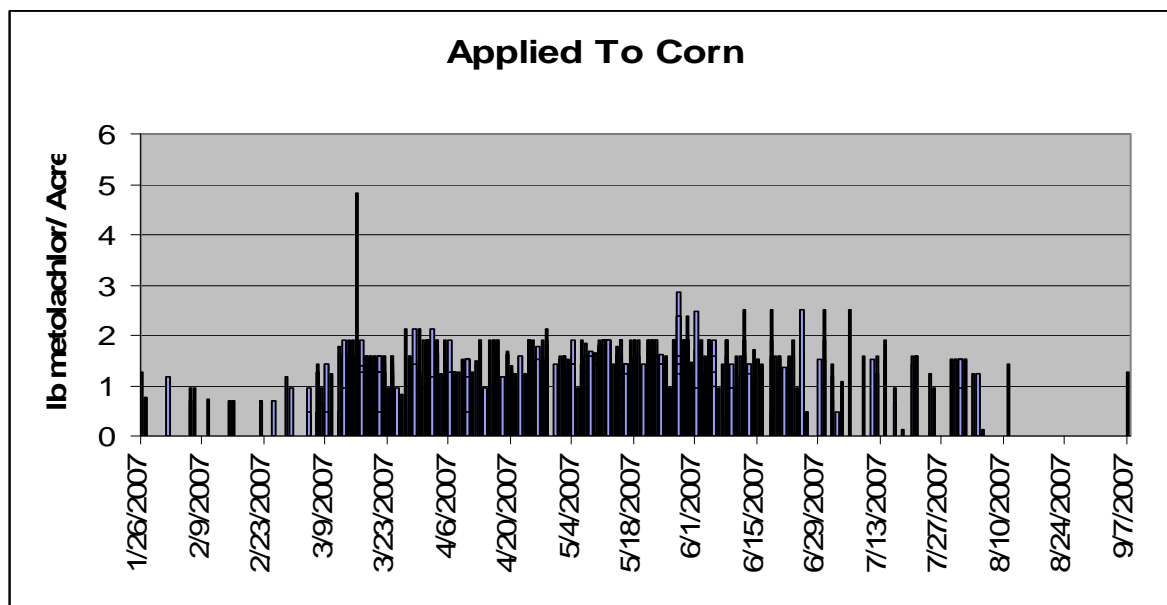
3.2.1. Modeling Approach

The EECs (Estimated Environmental Concentrations) are calculated using the EPA Tier II PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) with the EFED Standard Pond environment. PRZM is used to simulate pesticide transport as a result of runoff and erosion from an agricultural field, and EXAMS estimates environmental fate and transport of pesticides in surface water. Aquatic exposure is modeled for the parent alone and degradates metolachlor-ESA and OA separately.

The most recent PRZM/EXAMS linkage program (PE5, PE Version 5, dated Nov. 15, 2006) was used for all surface water simulations. Linked crop-specific scenarios and meteorological data were used to estimate exposure resulting from use on crops and turf.

Use-specific management practices for all of the assessed uses of metolachlor/S-metolachlor were used for modeling, including application rates, number of applications per year, application intervals, and the first application date for each use. The date of first application was developed based on several sources of information including data provided by BEAD, a summary of individual applications from the CDPR PUR data, and Crop Profiles maintained by the USDA. A sample of the distribution of metolachlor/S-metolachlor applications to corn from the CDPR PUR data for 2007 used to pick application dates is shown in **Figure 3-1**. The figure indicates that metolachlor/S-metolachlor could be applied to corn from January to September. Therefore, application dates were chosen to coincide with the time of year with the highest rainfall. More details on the crop profiles and the previous assessments may be found at <http://www.ipmcenters.org/CropProfiles/>.

Figure 3-1. Applications of Metolachlor/S-Metolachlor to Corn during 2007 Based on CDPR PUR data



3.2.2. Model Inputs

The appropriate PRZM and EXAMS input parameters for metolachlor/S-metolachlor were selected from the environmental fate data submitted by the registrant and in accordance with US EPA-OPP EFED water model parameter selection guidelines, *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides. Version 2.1*, October 22, 2009 and *PE5 User's Manual, (P)RZM (E)XAMS Model Shell, Version (5)*, November 15, 2006. Input parameters can be grouped by physical-chemical properties and other environmental fate data application information, and use scenarios. Physical and chemical properties relevant to assess the behavior of metolachlor/S-metolachlor and its degradates ESA and OA in the environment are presented in **Table 2-1** and **Table 2-2** and application information from the labels in **Table 2-3** and **Table 2-4**. The input parameters for PRZM and EXAMS are in **Table 3-2** and **3-3** for metolachlor/S-metolachlor and metolachlor ESA and metolachlor OA, respectively. **Appendix D** contains example model output files used to calculate input values.

Although a complete fate data set was not available for the degradates metolachlor-ESA and metolachlor-OA, EFED used the PRZM-EXAMS to estimate aquatic concentrations. Data available included the soil adsorption/desorption studies for both ESA (MRID 44931722) and OA (MRID 40494605), as well as the conversion efficiency of metolachlor to the two degradates (MRIDs 43928936, 41309801). Application rates for the two degradates were determined by multiplying the metolachlor application rate by the maximum fraction of the relevant degradate detected in the environmental fate studies and molecular weight correction factors. Half-lives for the two compounds were estimated using the decline portion of the formation and decline data contained in the Comparative Aerobic Soil Metabolism Study (MRID 43928936). For other parameters where data were not available, the compounds were conservatively assumed to be stable. It should be noted that because of the assumptions of stability and the fact there is no outflow from the EXAMS pond, the equations in the models cause the degradates to appear to accumulate in the pond. The 1-in-10-year values used as concentration estimates are higher than they actually would be in the environment.

Table 3-2. Summary of PRZM/EZAMS Environmental Fate Data Used for Aquatic Exposure Estimation for Metolachlor/S-Metolachlor¹

Parameter	Value	Comments	Source
Molecular Weight (grams/mole)	283.8		product chemistry
Solubility (mg/L)	480		
Vapor Pressure (torr)	2.8E ⁻⁵		
Henry's Constant (atm m ³ /mol)	2.2E ⁻⁸	Calculated	
K _d (L/kg)	181	Average K _{oc} ²	MRID00078291 MRID43928937 MRID40494602 MRID40494603 MRID40494604
Aerobic Soil Metabolism Half-life (days)	48.9	Estimated upper ³ 90 th percentile	MRID41309801 MRID43928936

			MRID45499606
Aerobic Aquatic Metabolism Half-life (days)	141	Based on 3X single aerobic aquatic metabolism linear first order half-life	MRID41185701
Anaerobic Aquatic Metabolism Half-life (days)	234	Based on 3X single anaerobic aquatic metabolism linear first order half-life	MRID41185701
Photodegradation in Water (days)	70		MRID40430202
Hydrolysis Half-life (days)	Stable		MRID40430201
Spray Drift Fraction	5% 1%	Aerial Ground	Default value

¹Application rate given in input units for PRZM-EXAMS. Conversion is kg/ha = 1.12 * lb/A

²Average K_{oc} using values 118.5, 303.0, 151.4, 241.4, 66.8, 21.6, 110.4, 74.4, 175.0, 333.3, 230.0, 244.7, 226.3, 367.2, 176.5, 120.7, 111.1 as per “Guidance for Chemistry and Management Practice Input Parameters for Use in Modeling the Environmental Fate and Transport of Pesticides” Version 2.1, dated October 2009.

³Upper 90th Percentile based on acceptable aerobic metabolism half-lives of 66, 37.8, 37.8, 14.9, 13.9, and 50.3 days.

Table 3-3. Summary of PRZM/EZAMS Environmental Fate Data Used for Aquatic Exposure Estimation for Metolachlor-ESA and OA

Parameter	Value	Comments	Source
Application Rate ESA (kg a.i./ha)	0.445	metolachlor kg ai/ha * 1.16 ¹ *0.12	label rate for sorghum ³
Application Rate OA (kg a.i./ha)	0.878	metolachlor kg ai/ha * 0.98 ² * 0.28	label rate for sorghum
Molecular Weight ESA (g/mole)	329.7		
Molecular Weight OA (g/mole)	279.4		
K _d ESA (L/kg)	0.041	Lowest non-sandy soil, Maryland clay	MRID44931722
K _d OA (L/kg)	0.079		MRID40494605
Solubility (mg/L)	480		product chemistry
Aerobic Soil Metabolism Half-life ESA (days)	162.5	Based on decline portion of formation and decline data	MRID4392836
Aerobic Soil Metabolism Half-life OA (days)	127.5		
Aerobic Aquatic Metabolism Half-life (days) ESA	325	2 X aerobic soil half-life value	
Aerobic Aquatic Metabolism Half-life (days) OA	255	2 X aerobic soil half-life value	
Anaerobic Aquatic Metabolism Half-life(days)	0	Assume stable	
Photodegradation in Water (days)	0	stable	MRID40430202
Hydrolysis Half-life (days)	0	stable	MRID40430201

¹Molecular weight correction factor= MW ESA (329.7 g/mol)/MW Metolachlor (283.8 g/mol) =1.16
0.12 (12%) is the maximum concentration observed in the aerobic soil metabolism study for ESA.

²Molecular weight correction factor= MW OA (279.4 g/mol)/ MW Metolachlor (283.8 g/mol) = 0.98
0.28 (28%) is the maximum concentration observed in the aerobic soil metabolism study for OA.

³Example - Application Rate of Degradate (metolachlor OA)= (max. application rate of parent) x (fraction of maximum detected degradate) x (molecular weight of degradate/ molecular weight of parent); sorghum (aerial) = (3.2 lb ai/acre) x (0.28) x (279.4/283.8) = 0.878 lb ai/acre

3.2.3. Results

The aquatic EECs for the various metolachlor/S-metolachlor use scenarios are listed in **Table 3-4**. Aerial applications typically resulted in higher aquatic EECs (due to greater spray drift). Thus, the aerial EECs are used as risk quotient bounding estimates for each crop group.

Peak metolachlor concentrations ranged from 1.29 µg/L (meadowfoam, ground applied) to 50.66 µg/L (Swiss chard, ground applied). The 21-day average concentrations ranged from 1.26 µg/L (meadowfoam, ground applied) to 49.0 µg/L (Swiss chard, ground applied). The 60-day average concentrations ranged from 1.18 µg/L (meadowfoam, ground applied) to 46.12 µg/L (Swiss chard, ground applied).

Table 3-4. Estimated Aquatic Concentrations for Metolachlor/S-Metolachlor Uses in California

Uses Represented	Application Method	1 in 10 year EECs (µg/L)		
		peak	21-Day Average	60-Day Average
Food Uses				
Alfalfa	Ground	18.29	17.82	17.00
Peanut, Legume vegetables	Air	22.82	22.07	21.11
	Ground	12.56	12.01	11.74
Soybean	Air	30.44	29.42	28.16
	Ground	16.74	16.02	15.65
Celery	Ground	8.28	7.93	7.75
Pepper	Ground	6.69	6.41	6.26
Tabasco pepper	Ground	10.46	10.01	9.78
Rhubarb	Air	9.89	9.56	9.15
	Ground	5.44	5.21	5.09
Citrus	Ground	16.26	15.26	13.16
Cabbage	Ground	44.12	42.50	40.07
Pumpkin	Air	6.64	6.25	5.81
	Ground	3.30	3.10	2.75
Corn (all types)	Air	30.10	28.65	26.73
	Ground	16.32	15.95	15.27
Cotton	Air	28.70	27.39	24.27
	Ground	18.29	17.40	15.48
Grapes	Ground	13.09	12.52	11.67
Onion	Ground	4.53	4.32	4.02
Radish	Ground	2.24	2.13	1.95

Horse radish	Ground	4.30	4.10	3.76
Swiss chard	Ground	50.66	49.00	46.12
Spinach	Ground	38.97	37.68	35.47
Tree nuts	Ground	18.76	17.94	16.69
Tomato	Ground	26.51	25.48	23.41
Peach	Ground	8.57	8.10	7.57
Sunflower	Air	28.97	28.02	26.09
	Ground	24.13	23.37	21.76
Safflower	Air	45.73	44.25	41.21
	Ground	38.10	36.90	34.36
Sorghum	Air	48.78	47.20	43.95
	Ground	40.64	39.37	36.65
Sugarbeet	Air	17.15	16.46	15.75
Potato	Air	28.82	27.50	26.26
	Ground	15.41	14.61	13.86
Non-Food Uses				
Meadowfoam	Ground	1.29	1.26	1.18
Ornamental shade trees and ornamental sod	Air	28.05	26.89	25.78
	Ground	18.64	17.92	17.16
Grasses for Sod	Ground	11.06	10.63	9.93
Ornamental turf	Ground	11.89	11.39	10.71

The EECs for metolachlor-ESA and metolachlor-OA are presented in **Tables 3-5 and 3-6**, respectively. Concentrations of the degradates were not adjusted for spray drift fraction (i.e., no drift) because they are assumed to form when metolachlor is in contact with soil and/or water. Estimated concentrations are higher than would actually occur in the environment because a compound that is stable to degradation “accumulates” in the modeled pond due to lack of outflow. Therefore, reported concentrations are a highly conservative estimate. Because of the “accumulation,” peak concentrations, 21-day and 60-day mean concentrations were approximately the same for most crops.

Concentrations for metolachlor-ESA ranged from 0.16 µg /L (meadowfoam) to 10.26 µg/L (Swiss chard). Metolachlor-OA concentrations ranged from 0.26 µg/L (meadowfoam) to 17.05 µg/L (Swiss chard).

Table 3-5. Estimated Aquatic Concentrations for the Degradate Metolachlor-ESA

Crop	1 in 10 year EEC (µg/L)		
	Peak	21-Day Average	60-Day Average
Based on Food Uses			
Swiss chard	10.26	10.16	9.99
Pumpkin	1.03	1.02	1.01
Based on Non-Food Uses			
Ornamental sod and shade trees	4.70	4.66	4.57
Meadowfoam	0.16	0.16	0.16

Table 3-6. Estimated Aquatic Concentrations for the Degradate Metolachlor-OA

Crop	1 in 10 year EEC (µg/L)		
	Peak	21-Day Average	60-Day Average
Based on Food Uses			
Swiss chard	17.05	16.85	16.50
Pumpkin	1.74	1.73	1.70
Based on Non-Food Uses			
Ornamental sod and shade trees	7.85	7.75	7.56
Meadowfoam	0.26	0.26	0.25

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. An evaluation of the surface water monitoring data was conducted to assess the occurrence of metolachlor/S-metolachlor, metolachlor-OA, and metolachlor-ESA. Surface water data were obtained from the California Department of Pesticide Regulation (<http://www.cdpr.ca.gov/docs/sw/surfddata.htm>) and United States Geological Survey (USGS) NAWQA program data warehouse. Since the sampling program was not targeted to the metolachlor use areas, the monitoring data may not represent the most conservative occurrence data for metolachlor/S-metolachlor and its degradation products in California.

3.2.4.a. USGS NAWQA Surface Water Data

Surface water monitoring data from the USGS NAWQA program were obtained on March 30, 2010. A total of 29,838 water samples across various sites throughout the US were analyzed for metolachlor. A total of 2,274 water samples were analyzed for metolachlor in CA at 82 sites located in twenty counties between August 1993 and June 2009. The maximum reported concentration of metolachlor is 3.88 µg/L in the Orestimba Creek at the River Road near Crows Landing in Stanislaus County with agricultural land use type. The 90th percentile metolachlor concentration at this location is 0.096 µg/L in USGS NAWQA surface water data.

3.2.4.b. USGS NAWQA Groundwater Data

Groundwater monitoring data from the USGS NAWQA program were obtained on March 30, 2010. A total of 11,746 water samples across various sites throughout the US were analyzed for metolachlor. A total of 864 water samples were analyzed for metolachlor in CA at 466 sites located in twenty counties between August 1993 and June 2009. A total of 851 samples showed below detection limit of 0.014 µg/L. Only one sample showed detection value higher than 0.2 µg/L, which is 1.3 µg/L in Stanislaus County with land use type under orchard or vineyard.

A total of 110 water samples were analyzed for metolachlor ESA in CA at 79 sites located in twenty counties between August 1993 and June 2009. Only five samples showed metolachlor-ESA concentrations greater than 1 µg/L. They were 2.65, 1.67, 1.48, 1.31, and 1.06 µg/L, respectively, and were detected in Merced County. A total of 93 samples showed below detection limit of 0.05 µg/L.

A total of 110 water samples were analyzed for metolachlor-OA in CA at 79 sites located in twenty counties between August 1993 and June 2009. Only three samples showed metolachlor-OA at concentrations greater than 0.50 µg/L. They were 0.64, 0.58, and 0.57 µg/L, respectively, and were detected in Merced County. A total of 103 samples showed below detection limit of 0.05 µg/L.

The groundwater concentrations detected are less than the surface water monitoring data or even an order of magnitude less than the surface water modeling estimated exposure concentrations, therefore, the impact of exposure from groundwater for irrigation purpose should be less than the impact of surface water exposure.

3.2.4.c. California Department of Pesticide Regulation (CDPR) Data

Surface water monitoring data from the California Department of Pesticide Regulation (CDPR) were assessed on March 30, 2010, and all data with analysis for metolachlor, metolachlor ESA or metolachlor-OA were extracted. The CDPR data were dated June 2008. A total of 1,492 water samples were analyzed for metolachlor, 28 samples analyzed for metolachlor-ESA and metolachlor-OA.

The maximum reported concentration of metolachlor in CADPR monitoring data was 1.77 µg/L in Del Puerto Creek at Vineyard Avenue (a tributary to San Joaquin River). The 90th percentile metolachlor concentration is 0.11 µg/L in CADPR data.

The maximum reported concentration for metolachlor-OA and ESA was 0.50 and 0.11 µg/L, respectively. A distributional analysis of metolachlor degradation product was not conducted because there was limited data on the metolachlor degradation products.

3.2.4.d. Atmospheric Monitoring Data

Atmospheric impacts were evaluated in two parts: dry and wet deposition. For dry deposition, air monitoring data was evaluated to assess the occurrence of metolachlor. Air monitoring data were obtained from the California Department of Pesticide Regulation (Segawa, *et al*, 2003 and Kollman 2002). A review of the air monitoring data indicates that metolachlor was detected in trace quantities in an air monitoring study in Lompoc City, Santa Barbara County (Segawa, *et al*, 2003). Air concentrations of metolachlor were 1.7 ng/m³ for the highest one-day average, 1.01 ng/m³ for the highest 3-day average, 0.54 ng/m³ for the highest 18-day average concentration. No air monitoring data is available on the metolachlor degradation products.

For wet deposition, the rain water monitoring data was evaluated to assess the occurrence of metolachlor. The metolachlor concentrations measured in rain water samples taken in San Joaquin Valley, California were considered (<http://pubs.usgs.gov/of/2005/1307/>, Majewski, *et al*. 2005). The monitoring study period covers from 2001 to 2004. The total maximum detection of metolachlor in rain water is 0.19 µg/L. The maximum rain water residue value was considered in combination with California specific precipitation data and runoff estimates from PRZM. Precipitation and runoff data associated with the PRZM scenarios used to model aquatic EECs were used to determine relevant 1-in-10 year peak runoff and rain events. The scenarios included were: CA almond, CA cole crop, CA grape, CA row crop, CA tomato, CA melon, CA nursery, CA onion and CA potato.

To estimate concentrations of metolachlor in the aquatic habitat resulting from wet deposition, the daily PRZM-simulated volume of runoff from a 10 ha field is combined with an estimate of daily precipitation volumes over the 1 ha farm pond relevant to the EXAMS environment. This volume is multiplied by the maximum concentration of metolachlor in precipitation reported in monitoring data, which is 0.19 µg/L. The result is a daily mass load of metolachlor into the farm pond. This mass is then divided by the volume of water in the farm pond (2.0×10^7 L) to achieve a daily estimate of metolachlor concentration in the farm pond, which represents the aquatic habitat. From the daily values, the 1-in-10 year peak estimate of the concentration of metolachlor in the aquatic habitat is determined for each PRZM scenario (**Table 3-7**). There are several assumptions associated with this approach, including: 1) the concentration of metolachlor in the rain event is spatially and temporally homogeneous (e.g. constant over the 10 ha field and 1 ha pond for the entire rain event); 2) the entire mass of metolachlor contained in the precipitation runs off of the pond or is deposited directly into the pond; 3) there is no degradation of metolachlor between the time it leaves the air and the time it reaches the pond.

Table 3-7. 1-in-10 Year Peak Estimates of Metolachlor Concentrations in Aquatic and Terrestrial Habitats Resulting from Wet Deposition

Met Station	Scenario(s)	Concentration in aquatic habitat (µg/L)	Deposition on terrestrial habitat (lbs ai/A)
Sacramento	CA almond	0.035	0.0001
Santa Maria	CA cole crop	0.038	0.0001
San Francisco	CA grape	0.033	0.0001
Monterey Co.	CA row crop	0.031	0.0001
Fresno	CA wheat	0.023	0.0001
San Diego	CA nursery	0.026	0.0001
Bakersfield	CA onion and CA potato	0.010	0.0000

To estimate deposition of metolachlor on the terrestrial habitat resulting from wet deposition, the daily volume of water deposited in precipitation on 1 acre of land is estimated. This volume is multiplied by the maximum concentration of metolachlor in precipitation reported in monitoring data, which is 0.19 µg/L. The result is a mass load of metolachlor per acre (converted to units of lbs a.i./A). From the daily values, the 1-in-10 year peak estimate of the deposition of metolachlor on the terrestrial habitat is estimated for each PRZM scenario (**Table 3-7**). In this approach, it is assumed that the concentration of metolachlor in the rain event is spatially and temporally homogeneous (e.g. constant over the 1 acre of terrestrial habitat for the entire rain event).

3.3. Terrestrial Animal Exposure Assessment

3.3.1. Exposure to Residues in Terrestrial Food Items Based on Foliar Applications

T-REX is used to calculate dietary and dose-based EECs of metolachlor/S-metolachlor for birds (including terrestrial-phase amphibians), mammals, and terrestrial invertebrates. T-REX simulates a 1-year time period. For this assessment, spray and granular applications of metolachlor/S-metolachlor are considered. Terrestrial EECs were derived for the uses previously summarized in **Table 2-3 and 2-4**. Exposure estimates generated using T-REX are for the parent alone.

Terrestrial EECs for foliar formulations of metolachlor/S-metolachlor were derived for all the uses summarized in **Tables 2-3 and 2-4**. However, in view of numerous uses associated with metolachlor/S-metolachlor, EECs were presented for the highest (corn) and lowest (spinach) food uses and highest (ornamental sod and shade trees) and lowest (meadowfoam) non-food uses to represent the range of exposure concentrations resulting from various metolachlor/S-metolachlor uses.

Given that no data on interception and subsequent dissipation from foliar surfaces is available for metolachlor/S-metolachlor, a default foliar dissipation half-life of 35 days is used based on the

work of Willis and McDowell (1987). Use specific input values, including number of applications, application rate, foliar half-life and application interval are provided in **Table 3-8**. For food uses with more than one application, the label specified an interval of 30 – 45 days. The 30-day interval was used in the exposure modeling as it provided the most conservative EECs. An example output from T-REX is available in **Appendix E**.

Table 3-8. Input Parameters Used to Derive Terrestrial EECs for Liquid Formulations of Metolachlor/S-Metolachlor with T-REX

Use	Application Rate (lb ai/A)	Number of Applications	Application Interval	Foliar Dissipation Half-Life (days)	Comment
Food Uses					
Corn	4	2	30 – 45 days ¹	35	Represents the highest use rate for foliar food uses
Spinach	1	1	n/a	35	Represents the lowest use rate for foliar food uses
Non-Food uses					
Ornamental sod and shade trees	2.5	Not specified; assumed 2 applications	42 days	35	Represents the highest use rate for foliar non-food uses
Meadowfoam	0.6	1	n/a	35	Represents the lowest use rate for foliar non-food uses

n/a = Not applicable as single application

¹An interval of 30 days was used to represent the most conservative EEC

Organisms consume a variety of dietary items and may exist in a variety of sizes at different life stages. T-REX estimates exposure for the following dietary items: short grass, tall grass, broadleaf plants/small insects, and fruits/pods/seeds/large insects, and seeds for granivores. Birds and mammals consume all of these items. The size classes of birds represented in T-REX are small (20 g), medium (100 g), and large (1000 g). The size classes for mammals are small (15 g), medium (35 g), and large (1000 g). EECs are calculated for the most sensitive dietary item and size class for birds (surrogate for amphibians) and mammals. For mammals and birds, the most sensitive EECs are for the smallest size class consuming short grass.

3.3.1.a. Dietary Exposure to Birds, Mammals, and Amphibians from Foliar Applications of Metolachlor/S-Metolachlor

Upper-bound Kenaga nomogram values reported by T-REX are used for derivation of dietary EECs for the CTS. EECs in T-REX that are applicable to assess direct effect to the terrestrial-phase CTS are for small birds (20g) consuming short grass³. For birds (surrogates for terrestrial-

³The short grass EECs and RQs are used for reptiles and amphibians to represent a conservative screen. It is not being assumed that amphibians and snakes eat short grass, the result of modeling the 20 gram bird consuming short grass is more conservative than modeling an alternative diet for amphibians and snakes and is therefore, a valid conservative screen and is protective of these species. If the short grass assessment does not result in LOC exceedances, there is a high confidence that effects are unlikely to occur.

phase CTS), EECs and RQs for acute dose based and chronic dietary based exposure are calculated as these are the most sensitive values. If the LC₅₀ is lower than the LD₅₀, the highest acute dietary EEC and RQ are shown as well. For mammals, EECs and RQs for acute dose based and chronic dose based exposure are calculated as these are typically the most sensitive values. If the dietary assessment results in higher RQs than the dose-based assessment, the highest dietary RQs are shown as well.

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 corn (**Table 3-9**). Dietary-based EECs ranged from 144 - 1490 mg ai/kg diet from various uses of metolachlor/S-metolachlor. Dose-based EECs ranged from 164 - 1697 mg ai/kg bw for birds and 137 - 1421 mg ai/kg bw for mammals. Terrestrial EECs were lowest for meadowfoam, which is a non-food use.

Table 3-9. T-REX Derived Upper-bound Kenaga Nomogram EECs for Dietary- and Dose-based Exposures to Birds and Mammals from Applications of Liquid Formulations of Metolachlor/S-Metolachlor

Use	Application Rate (lb ai/A/# of Applications/Interval in days	EECs for CTS (all DPSs) (small birds consuming short grass)		EECs for CTS Prey (small mammals consuming short grass)	
		Dietary-based EEC (mg/kg-diet)	Dose-based EEC (mg/kg-bw)	Dietary-based EEC (mg/kg-diet)	Dose-based EEC (mg/kg-bw)
Food Uses					
Corn	4/2/30	1490	1697	1490	1421
Spinach	1/1/n/a	240	273	240	229
Non-Food Uses					
Ornamental sod and shade trees	2.5/2/42	861	981	861	821
Meadowfoam	0.6/1/n/a	144	164	144	137

n/a = not applicable as single application

3.3.2. Exposure to Terrestrial Invertebrates Derived Using T-REX

T-REX is also used to calculate EECs for terrestrial invertebrates exposed to metolachlor/S-metolachlor. Available acute contact toxicity data for bees exposed to metolachlor/S-metolachlor (in units of µg a.i./bee), are converted to µg a.i./g (of bee) by multiplying by 1 bee/0.128 g. Dietary-based EECs calculated by T-REX for small insects (units of a.i./g) are used to estimate exposure to terrestrial invertebrates. The EECs are later compared to the adjusted acute contact toxicity data for bees in order to derive RQs.

Both small and large insects are applicable for estimating indirect effects based on reduction in prey to the CTS. The most sensitive insect is the small insect. Small insect EECs ranged from 81 – 838 ppm for various metolachlor/S-metolachlor uses (**Table 3-10**). Highest and lowest small insect EECs were noted for corn and meadowfoam, respectively. An example output from T-REX is available in **Appendix E**.

Table 3-10. Summary of EECs Used for Estimating Risk to Terrestrial Invertebrates from Foliar Applications of Metolachlor/S-Metolachlor

Use	Application Rate (lb ai/A)/# of Applications/Interval (days)	Small Insect EEC (ppm)
Food Uses		
Corn	4/2/21	838
Spinach	1/1/n/a	135
Non-Food Uses		
Ornamental sod and shade trees	2.5/2/42	484
Meadowfoam	0.6/1/n/a	81

n/a = not applicable as single application

3.3.3. Exposure to Residues in Terrestrial Food Items Based on Granular Applications

Estimated environmental concentrations from granular applications (mg ai/square foot) of S-metolachlor (metolachlor does not have any granular formulations) are also estimated using T-REX. T-REX assumes that 100% of the applied S-metolachlor 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 single application of S-metolachlor.

Risk to terrestrial animals from ingesting granules is based on LD_{50}/ft^2 values. Although the habitat of the CTS and its prey items are not limited to a square foot, there is presumably a direct correlation between the concentration of a pesticide in the environment (mg/ft^2) and the chance that an animal will be exposed to a concentration that could adversely affect its survival. Further description of the mg/ft^2 index is provided in U.S. EPA (1992 and 2004).

In order to derive an estimate of the granular exposure per square foot, the granular application rates for S-metolachlor were converted from lb ai/A to mg/ft^2 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 or mammalian 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/ft^2) with adjusted avian or mammalian toxicity values.

Estimated environmental concentrations from granular uses of S-metolachlor are calculated for corn, peanut, soybean, and potato only as these are the crops where granular applications of S-metolachlor are labeled (**Table 3-11**). Of all the uses, S-metolachlor use in corn resulted in the highest EEC of 25 mg/ft^2 . EECs from granular applications are lowest for potato, peanut and soybean (19.8 mg/ft^2).

Table 3-11. Summary of EECs Used for Estimating Risk to Terrestrial Animals from Granular Applications of S-Metolachlor

Use	Application Rate (lb ai/A)	EEC (mg/ft ²)
Corn	2.4	25
Peanut/soybean/potato	1.9	19.8

3.4. Terrestrial Plant Exposure Assessment

TerrPlant 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 related application method. A runoff value of 0.05 is utilized based on metolachlor/S-metolachlor's solubility, which is classified by TerrPlant as 480 mg/L. For aerial and ground application methods, drift is assumed to be 5% and 1%, respectively. EECs relevant to terrestrial plants consider pesticide concentrations in drift and in runoff. These EECs are listed by use in **Table 3-11**. An example output from TerrPlant v.1.2.2 is available in **Appendix F**.

Spray drift EECs are calculated for liquid formulations of metolachlor/S-metolachlor only as no drift is associated with granular formulations. Spray drift EECs were highest for corn (0.04 lb ai/A) and lowest for meadowfoam (0.06 lb ai/A) (**Table 3-12**). Runoff EECs, in general, were greater for semi-aquatic areas compared to dry areas. Also, runoff EECs were lower for granular applications compared to liquid formulations.

Table 3-12. TerrPlant Inputs and Resulting EECs for Plants Inhabiting Dry and Semi-aquatic Areas Exposed to Metolachlor/S-Metolachlor via Runoff and Drift

Use (Formulation)	Application rate (lb ai/A)	Application method	Drift Value (%)	Spray drift EEC (lb ai/A)	Dry area EEC (lb ai/A)	Semi-aquatic area EEC (lb ai/A)
Food Uses/Liquid Formulations						
Corn	4	Ground spray	1	0.04	0.2	2
Corn	4	Aerial spray	5	0.2	0.2	2
Spinach	1	Ground spray	1	0.01	0.05	0.5
Food Uses/Granular Formulations						
Corn	2.4	Ground	0	0	0.12	1.2
Potato/peanut/soybean	1.3	Ground	0	0	0.07	0.65
Non-Food Uses/Liquid Formulations						
Ornamental sod and shade trees	2.5	Ground spray	1	0.03	0.13	1.25
Ornamental sod and shade trees	2.5	Aerial spray	5	0.13	0.13	1.25
Meadowfoam	0.6	Ground spray	1	0.06	0.03	0.3

4. Effects Assessment

This assessment evaluates the potential for metolachlor/S-metolachlor to directly or indirectly affect DS and CTS or modify their designated critical habitat. Assessment endpoints for the effects determination for each assessed species include direct toxic effects on the survival, reproduction, and growth, 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 each assessed species. Direct effects to the aquatic-phase CTS are based on toxicity information for freshwater fish, while terrestrial-phase amphibian effects are based on avian toxicity data, given that birds are generally used as a surrogate for terrestrial-phase amphibians and reptiles.

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 freshwater fish for direct effects on DS and aquatic-phase CTS and birds for direct effects to terrestrial-phase CTS. Indirect effects were based on freshwater and estuarine/marine invertebrates, aquatic plants, and terrestrial plants for DS and freshwater invertebrates and vertebrates, aquatic plants, terrestrial plants, and mammals for CTS. Acute (short-term) and chronic (long-term) toxicity information is characterized based on registrant-submitted studies and a comprehensive review of the open literature on metolachlor/S-metolachlor.

4.1. Ecotoxicity Study Data Sources

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 registrant-submitted studies as well as ECOTOX information obtained on 3 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.

Open literature toxicity data for 'target' terrestrial plant species, which include efficacy studies, are not currently considered in deriving the most sensitive endpoint for terrestrial plants. Efficacy studies do not typically provide endpoint values that are useful for risk assessment (*e.g.*, NOAEC, EC50, etc.), but rather are intended to identify a dose that maximizes a particular effect (*e.g.*, EC₁₀₀). Therefore, efficacy data and non-efficacy toxicological target data are not included in the ECOTOX open literature summary table provided in Appendix I. The list of citations including toxicological and/or efficacy data on target plant species not considered in this assessment is provided in **Appendix H**.

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.*, survival, reproduction, and growth) identified in Section 2.7. For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, because quantitative relationships between modifications and reduction in species survival, reproduction, and/or growth are not available. Although the effects determination relies on endpoints that are relevant to the assessment endpoints of survival, growth, or reproduction, it is important to note that the full suite of sublethal endpoints potentially available in the effects literature (regardless of their significance to the assessment endpoints) are considered, as they are relevant to the understanding of the area with potential effects, as defined for the action area.

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.

A detailed spreadsheet of the available ECOTOX open literature data, including the full suite of lethal and sublethal endpoints is presented in **Appendix I**. **Appendix J-1 and J-2** include a summary of the human health effects data for S-metolachlor and metolachlor, respectively.

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 ecological incident data, are considered to further refine the characterization of potential ecological effects associated with exposure to metolachlor/S-metolachlor. A summary of the available aquatic and terrestrial ecotoxicity information and the incident information for metolachlor/S-metolachlor are provided in Sections 4.1 through 4.4.

Available toxicity of degradates and other stressors of concern are summarized for each taxa in the appropriate Sections for the taxa. A detailed summary of the available ecotoxicity information for all metolachlor/S-metolachlor degradates and formulated products can be found Appendix G.

4.2. Toxicity of metolachlor/S-metolachlor to Aquatic Organisms

Table 4-1 summarizes the most sensitive aquatic toxicity endpoints, based on an evaluation of both the submitted studies and the open literature, as previously discussed. A brief summary of submitted and open literature data considered relevant to this ecological risk assessment for the DS and CTS is presented below. Additional information is provided in **Appendix G**. All endpoints are expressed in terms of the active ingredient (a.i.) unless otherwise specified.

Table 4-1. Aquatic Toxicity Profile for Metolachlor/S-Metolachlor

Assessment Endpoint	Acute/ Chronic	Species TGAI/TEP % a.i.	Toxicity Value Used in Risk Assessment	Citation or MRID # (Author, Date) ¹	Comment
Freshwater fish (surrogate for aquatic-phase amphibians)	Acute	Bluegill sunfish <i>Lepomis macrochirus</i> TGAI	96-hr LC ₅₀ = 3.2 mg ai/L ² 95% CI = 2.8 – 4.6 mg ai/L Slope = 14.8	MRID 43928910 (Spare 1983)	Acceptable Moderately toxic Sub-lethal effects (loss of equilibrium) at and above 3.3 ppm; NOAEL = 1.5 mg ai/L
	Chronic	Fathead minnow <i>Pimephales promelas</i> TGAI	NOAEC/ LOAEC = 0.03/0.056 mg/L (reduced growth of fish larvae)	44995903 (Sousa, 1999)	Supplemental
Freshwater invertebrates	Acute	Water flea <i>Daphnia magna</i>	48 hr EC ₅₀ = 1.1mg ai/L (based on immobilization)	E67777 (Foster et al., 1998)	Quantitative/Acceptable Moderately toxic
	Chronic	Water flea <i>Daphnia magna</i>	NOAEC/ LOAEC = 0.001/0.01 mg ai/L (based on number of young per female)	E83887 (Liu et al., 2006)	Quantitative/Acceptable
Estuarine/ marine fish ²	Acute	Sheepshead minnow <i>Cyprinodon variegatus</i> TGAI 97%	96-hr LC ₅₀ = 7.9 mg ai/L MATC = 1.5 mg ai/L Slope = 4.4 - infinity	43044602 (Ward, 1980)	Supplemental Moderately toxic
	Chronic	Sheepshead minnow <i>Cyprinodon variegatus</i> TGAI 97%	NOAEC/ LOAEC = 1/2.2 mg ai/L (based on fish length)	43044602 (Ward, 1980)	Supplemental
Estuarine/ marine invertebrates	Acute	Eastern oyster <i>Crassostrea virginica</i> TGAI 97.3%	96 hr EC ₅₀ = 1.6 mg ai/L (based on shell deposition) 95% CI = 1.4 – 1.9 Slope = 5	43487102 (Dionne, 1994)	Acceptable Moderately toxic Sub-lethal effects (reduced feeding and digestive activity) at 4.5 mg ai/L
	Chronic	Mysid shrimp <i>Mysidopsis bahia</i> TGAI 98.6%	NOAEC/ LOAEC = 0.13/0.25 mg ai/L (based on female length)	44995902 (Lima, 1999)	Acceptable
Aquatic plants	Vascular	Duckweed <i>Lemna gibba</i> TGAI 97.6%	14 day EC ₅₀ = 0.021 mg ai/L 95% CI = 0.019 – 0.023	43928931 (Hoberg, 1995)	Acceptable Reduction in frond density and biomass is the affected endpoint
	Non-vascular	Green alga <i>Pseudokirchneriella subcapitata</i> TGAI 97.6%	5 day EC ₅₀ = 0.008 mg ai/L 95% CI = 0.0026 – 0.025 Slope = 3	43928929 (Hoberg, 1995)	Acceptable Reduction in cell growth is the affected endpoint

¹ECOTOX references are designated with an E followed by the ECOTOX reference number

²The most sensitive freshwater fish LC₅₀ and NOAEC values will be used to determine the direct and indirect effects to DS as these values are more sensitive than those for estuarine/marine species

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

Table 4-2. Categories of Acute Toxicity for Fish and Aquatic Invertebrates

LC ₅₀ (mg/L)	Toxicity Category
< 0.1	Very highly toxic
> 0.1 - 1	Highly toxic
> 1 - 10	Moderately toxic
> 10 - 100	Slightly toxic
> 100	Practically nontoxic

4.2.1. Toxicity to Freshwater Fish

A summary of acute and chronic freshwater fish data, including data from the open literature, is provided below in Sections 4.2.1.a through 4.2.1.c. Freshwater fish toxicity data were used to assess potential direct effects of metolachlor/S-metolachlor to DS and aquatic-phase CTS and indirect effects to the CTS via reduction in available vertebrate food/prey items. Given that no acceptable toxicity data are available for aquatic-phase amphibians, freshwater fish data will be used as a surrogate to estimate direct acute and chronic risks to the CTS.

4.2.1.a. Freshwater Fish: Acute Exposure (Mortality) Studies

Eight (six on metolachlor and two on S-metolachlor) freshwater fish studies (two on rainbow trout (*Onchorynchus mykiss*), one on crucian carp (*Carassius carassius*), one on channel catfish (*Ictalurus punctatus*), one on guppy (*Poecilia reticulata*), and three on bluegill sunfish (*Lepomis macrochirus*), as shown in **Appendix G, Table G-1**, are available to document the acute exposure effects of metolachlor/S-metolachlor on freshwater fish. Based on these studies, the acute 96-hour median lethal toxicity thresholds (*i.e.*, LC_{50s}) for metolachlor/S-metolachlor ranged from 3.2 (bluegill sunfish) to 15 (bluegill sunfish) mg ai/L. Reported median lethal concentrations for rainbow trout, crucian carp, channel catfish, and guppy were 3.8, 4.9, 4.9, and 8.6 mg ai/L, respectively. Therefore, metolachlor/S-metolachlor is classified as slightly to moderately toxic to freshwater fish on an acute exposure basis. As shown in **Table 4-1**, the bluegill sunfish 96-hour LC₅₀ of 3.2 mg ai/L will be used to calculate RQs that determine direct effects to DS and CTS and indirect effects to aquatic-phase CTS.

A total of three acute toxicity studies are available to document the toxicity effects of the two metolachlor degradates (ESA and OA) to freshwater fish. A study assessing the effects of metolachlor-ESA on rainbow trout showed that the degradate is less toxic than the parent. The LC₅₀ was 48 mg/L, classifying metolachlor ESA as slightly toxic to fish. In concentrations where mortality occurred, sub-lethal effects noted included erratic swimming, loss of equilibrium, and pigmentation changes. Acute toxicity studies are available on metolachlor-OA for two fish species, crucian carp and rainbow trout. Metolachlor-OA is practically non-toxic to fish on an acute basis with LC_{50s} of >93.1 mg/L and >96.3 mg/L, respectively.

4.2.1.b. Freshwater Fish: Chronic Exposure (Growth/Reproduction) Studies

Only one scientifically sound freshwater fish (fathead minnow, *Pimephales promelas*) study was available to evaluate chronic exposure effects from S-metolachlor (**Appendix G, Table G-2**). The reported NOAEC/ LOAEC values from this study were 0.03/0.056 mg ai/L, based on reduced dry weight of larval fish. The NOAEC value of 0.03 mg ai/L was used to calculate chronic RQs.

No studies are available to document the chronic exposure effects of metolachlor/S-metolachlor major degradates, metolachlor-ESA and OA, on freshwater fish.

4.2.1.c. Freshwater Fish: Sublethal Effects and Additional Open Literature Information

Sublethal effects reported in acute fish toxicity studies for metolachlor/S-metolachlor are summarized above in **Table 4-1** and in **Appendix G**. Sub-lethal effects noted in acute exposure tests include lethargy, loss of equilibrium, hypersensitivity, apathy, and extended abdomen. The above effects generally occurred at levels close to (i.e., within an order of magnitude) the reported 96-hour LC₅₀ values.

No valid studies were located in the open literature that reported endpoints on 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 metolachlor/S-metolachlor and/or its formulated products were located in the open literature.

4.2.2. Toxicity to Freshwater Invertebrates

A summary of acute and chronic freshwater invertebrate data, including data published in the open literature, is provided below in Sections 4.2.2.a through 4.2.2.c. Freshwater aquatic invertebrate toxicity data were used to assess potential indirect effects of metolachlor/S-metolachlor to the DS and CTS via reduction in available food/prey items.

4.2.2.a. Freshwater Invertebrates: Acute Exposure Studies

Registrant-submitted toxicity tests show that both metolachlor (LC₅₀ = 25 mg ai/L) and S-metolachlor (LC₅₀ = 26 mg ai/L) are slightly toxic to daphnids (*Daphnia magna*) on an acute basis (**Appendix G, Table G-3**). Reported NOAECs were 5.6 mg/L and 4.8 mg/L for metolachlor and S-metolachlor, respectively. Sublethal effects included lethargy.

Studies on *Daphnia magna* were submitted for both major degradates (**Appendix G, Table G-3**). The LC₅₀ for metolachlor-OA is 15.4 mg/L, classifying it as slightly toxic to aquatic invertebrates. For metolachlor-ESA, the LC₅₀ was >108 mg/L, classifying it as practically non-toxic to aquatic invertebrates.

4.2.2.b. Freshwater Invertebrates: Chronic Exposure Studies

The registrant submitted a study each on metolachlor and S-metolachlor to document the chronic exposure effects to *Daphnia magna* (**Appendix G, Table G-4**). Based on growth and reproduction, the NOAEC and LOAEC were 3.2 and 6.9 mg/L, respectively for metolachlor and 1.9 and 9.4 mg ai/L, respectively for S-metolachlor. An ECOTOX study discussed below reported a NOAEC value that is 2 orders of magnitude lower than the above endpoint and is used in RQ calculations.

No studies are available to document the chronic exposure effects of metolachlor/S-metolachlor major degradates, metolachlor-ESA and OA, on freshwater invertebrates.

4.2.2.c. Freshwater Invertebrates: Open Literature Data

Several open literature studies that documented toxicity effects from metolachlor/S-metolachlor are available in ECOTOX for aquatic invertebrates (**Appendix G, Table G-8**). Some produced EC₅₀s in the same range (~25 mg/L) as registrant-submitted data. However, several studies contained EC₅₀s that were lower, in the 1.1-4.4 mg/L range. The lowest endpoint from these studies (48-hr EC₅₀ of 1.1 mg/L for *Ceriodaphnia dubia*, E# 67777) was used to calculate RQs for this assessment. The next lowest endpoint from these studies was for *Chironomus plumosus* (midge fly larvae). In the midge fly study (E# 6797), both technical grade metolachlor and an emulsifiable concentrate were used in 48-hour static tests. The LC₅₀s for the tests were 3.8 and 4.4 mg/L, respectively.

ECOTOX located a chronic study on *Ceriodaphnia dubia* which reported a NOAEC value that is three orders of magnitude lower than the one from the registrant-submitted study (**Appendix G, Table G-8**). The 21-day study compared the responses of *Ceriodaphnia dubia* to metolachlor and S-metolachlor and established the most sensitive endpoint for metolachlor (NOAEC/LOAEC = 0.001/0.01 mg/L, E# 83887). Parameters evaluated included length, longevity, days to first brood, broods per female, and number of young per female. The most sensitive parameter was number of young per female.

4.2.3. Toxicity to Estuarine/Marine Fish

A summary of acute and chronic estuarine/marine fish data, including data published in the open literature is provided below in Sections 4.2.3.a through 4.2.3.b.

4.2.3.a. Estuarine/Marine Fish: Acute Exposure Studies

Two sheepshead minnow (*Cyprinodon variegates*) studies submitted by the registrant suggest that metolachlor's toxicity to fish in a brackish water environment is similar to freshwater (**Appendix G, Table G-1**). Reported LC₅₀ values (7.9 and 9.8 mg ai/L) from these two studies were similar classifying metolachlor as moderately toxic to estuarine/marine fish. Similar to those in the freshwater fish studies, sublethal effects noted in estuarine/marine fish also include lethargy and loss of equilibrium. As the freshwater fish LC₅₀s are more sensitive than the

estuarine/marine fish, the bluegill sunfish LC₅₀ of 3.2 mg ai/L will be used to determine direct acute effects to DS.

No studies are available that demonstrated the acute exposure effects of metolachlor/S-metolachlor degradates on estuarine/marine fish.

4.2.3.b. Estuarine/Marine Fish: Chronic Exposure Studies

A single study is available on sheepshead minnow that documented the toxicity effects of metolachlor to estuarine/marine fish (**Appendix G, Table G-2**). The NOAEC/LOAEC values, based on reduction in larval fish dry weight, are 1.0/2.2 mg ai/L. As the freshwater fish NOAEC is more sensitive than the estuarine/marine fish, the fathead minnow NOAEC/LOAEC of 0.03/0.056 mg ai/L will be used to determine direct long-term effects to DS.

No studies are available to document the chronic exposure effects of metolachlor/S-metolachlor major degradates, metolachlor-ESA and OA, on freshwater fish.

4.2.3.c. Estuarine/Marine Fish: Open Literature Studies

No acute exposure studies were located in the open literature that reported endpoints on estuarine/marine fish that are less sensitive than the selected measures of effect summarized in **Table 4-1**.

4.2.4. Toxicity to Estuarine/Marine Invertebrates

A summary of acute and chronic estuarine/marine invertebrate data, including data published in the open literature, is provided below in Sections 4.2.4.a through 4.2.4.b.

4.2.4.a. Estuarine/Marine Invertebrates: Acute Exposure Studies

Two registrant-submitted studies, one each on mysid shrimp (*Americamysis bahia*) and eastern oyster (*Crassostrea virginica*), reported median lethal and effect concentrations of 4.9 and 1.6 mg ai/L, respectively (**Appendix G, Table G-3**). Based on this, metolachlor is classified as moderately toxic to estuarine/marine invertebrates. The above endpoints will be used to determine indirect effects to DS, through prey reduction, in estuarine/marine environment.

No studies are available to document the acute exposure effects of metolachlor/S-metolachlor major degradates, metolachlor-ESA and OA, on estuarine/marine invertebrates.

4.2.4.b. Estuarine/Marine Invertebrates: Chronic Exposure Studies

Only one study (registrant-submitted) is available to document chronic exposure effects of metolachlor/S-metolachlor to estuarine/marine invertebrates. The study-reported

NOAEC/LOAEC values of 0.13/0.25 mg ai/L, based on mysid shrimp female growth (**Appendix G, Table G-3**), will be used to determine estuarine/marine prey effects to DS.

No studies are available to document the chronic exposure effects of metolachlor/S-metolachlor major degradates, metolachlor-ESA and OA, on estuarine/marine invertebrates.

4.2.4.c. Estuarine/Marine Invertebrates: Open Literature Studies

No estuarine/marine invertebrate studies, based on acute or chronic exposure, were located for metolachlor/S-metolachlor from the open literature.

4.2.4.d. Amphibians: Open Literature Studies

Two studies (E#s 66376 and 20274; **Appendix G, Table G-8**) located in ECOTOX for two species, the African clawed frog (*Xenopus laevis*, LC₅₀ 13.6 mg/L) and American bullfrog (*Rana catesbeiana*, EC₅₀ 17.4 mg/L), indicated that mortality effects for amphibians occur at concentrations similar to lethal endpoints for fish, which serve as a surrogate for aquatic phase amphibians. Species sensitivity distributions for amphibians are not well understood at this point, thus the more protective toxicity value from the fish data (3.2 mg ai/L for bluegill sunfish) was opted to determine direct effects to aquatic-phase CTS.

A study each was identified for metolachlor [E# 114296 using gray tree frogs (*Hyla versicolor*) and leopard frogs (*Rana pipens*)] and S-metolachlor (E# 85815 using leopard frog and African clawed frog) in open literature that reported effects on growth, development, and reproduction based on chronic exposure (**Appendix G, Table G-8**). Both studies evaluated a single dose of metolachlor and S-metolachlor in addition to their combinations with other pesticides. Endpoints reported from both studies will be used qualitatively only in view of numerous limitations associated with the studies, which are discussed in detail in **Appendix G**.

The study on metolachlor tested a single dose of 7.4 ppb in comparison with other pesticides, both single and mixture products. The study reported that metolachlor alone did not result in any sublethal effects (effects on survival, time to metamorphosis, and mass at metamorphosis) in both leopard and gray tree frogs. Mixtures of herbicides (acetochlor + metolachlor + glyphosate + 2,4-D + atrazine at 10 + 7.4 + 6.9 + 16.0 + 6.4 ppb, respectively) also had no negative effects on the survival and metamorphosis of both frog species.

Contrary to the above study, the study on S-metolachlor showed that exposure to S-metolachlor alone (0.1 and 10 ppb) and in combination with atrazine (0.1 and 10 ppb each) resulted in damage to the thymus as measured by thymic plaques, resulting in immunosuppression and contraction of flavobacterial meningitis. The frequency of thymus damage was higher with Bicep (a commercial formulation of a mixture of metolachlor and atrazine) compared to metolachlor alone. Though larval growth and development was not affected by S-metolachlor alone, prepared mixtures of atrazine + S-metolachlor impacted larval development greater than Bicep, suggesting that the surfactant in Bicep reduced the effect of mixtures.

4.2.5. Toxicity to Aquatic Plants

Aquatic plant toxicity studies are used as one of the measures of effect to evaluate whether metolachlor/S-metolachlor may affect primary production. Aquatic plants may also serve as dietary items of DS and CTS. In addition, freshwater vascular and non-vascular plant data are used to evaluate a number of the PCEs associated with the critical habitat impact analysis.

Based on a review of the registrant-submitted and open literature studies, guideline studies provided more sensitive endpoints, and these were used in the assessment. Furthermore, effects on aquatic plants occurred at lower concentrations than for aquatic animals. For metolachlor, EC₅₀ values for non-vascular plants ranged from 0.010 mg/L (green algae, *Pseudokirchneriella subcapitata*) to 1.2 mg/L (blue-green algae, *Anabaena flos-aquae*) (**Appendix G, Table G-5**). For S-metolachlor, EC₅₀s ranged from 0.008 mg/L (green algae) to 0.11 mg/L (marine diatom, *Skeletonema costatum*). Based on the available data, green algae appear to be most sensitive to the effects of metolachlor and S-metolachlor. Diatoms seem to be less sensitive, and blue-green algae, along with some other vascular plant species are the least sensitive of the aquatic plants.

The toxicity of metolachlor (LC₅₀ = 0.02 mg ai/L) and S-metolachlor (LC₅₀ = 0.05 mg ai/L) was similar to the vascular plant duckweed (*Lemna gibba*) (**Appendix G, Table G-5**). The LC₅₀ value for S-metolachlor of 0.02 mg ai/L was used in this assessment to document indirect effects to both DS and CTS.

Each of the two major degradates was tested with both a non-vascular (green alga) and a vascular (duckweed) plant. Both degradates are less toxic to aquatic plants than the parent compounds (**Appendix G, Table G-5**). Of the two plants tested, duckweed is more sensitive to metolachlor-ESA, with an EC₅₀ of 43 mg ai/L and a NOAEC of 4 mg ai/L. Green alga is more sensitive to metolachlor-OA, with an EC₅₀ of 57 mg ai/L and a NOAEC of 29 mg/L.

Eight studies were located in open literature that reported acute exposure effects of metolachlor/S-metolachlor on non-vascular plants. However, none of these studies reported endpoints that were more sensitive than those reported in the registrant-submitted guideline studies.

4.3. Toxicity of Metolachlor/S-Metolachlor to Terrestrial Organisms

Table 4-3 summarizes the most sensitive terrestrial toxicity endpoints, based on an evaluation of both the submitted studies and the open literature. A brief summary of submitted and open literature data considered relevant to this ecological risk assessment is presented below. Additional information is provided in **Appendix G**.

Avian toxicity data is used to assess potential direct effects of metolachlor/S-metolachlor to the terrestrial-phase CTS. Terrestrial plant toxicity data is used to assess potential indirect (habitat) effects to DS whereas terrestrial invertebrate (prey), vertebrate (mammalian prey), and plant (habitat) data is used to assess indirect effects to the terrestrial-phase CTS. Given that no acceptable toxicity data are available for aquatic-phase amphibians, toxicity data on birds will be used as a surrogate to estimate direct acute and chronic risks to the terrestrial-phase CTS.

Table 4-3. Terrestrial Toxicity Profile for Metolachlor/S-Metolachlor

Endpoint	Acute/ Chronic	Species	Toxicity Value Used in Risk Assessment	Citation MRID/ ECOTOX reference No.	Comment
Birds (also a surrogate for terrestrial- phase CTS)	Acute	Bobwhite quail <i>Colinus virginianus</i> TGAI 87.4%	LD ₅₀ = >2194 mg ai/kg bw	43928907 (Beavers, 1983)	Acceptable No treatment related mortality NOAEL (based on body weight loss) = 874 mg/kg bw
	Acute	Bobwhite quail <i>Colinus virginianus</i> TGAI 87.4%	LC ₅₀ = >4912 mg ai/kg diet	43928908 (Beavers, 1983)	Acceptable No treatment related mortality NOAEC (based on reduction in body weight gain) = 2762 mg ai/kg diet
	Chronic	Bobwhite quail <i>Colinus virginianus</i> TGAI 98.6%	NOAEC/LOAEC = 1000/>1000 mg ai/kg diet	44995901 (Kaczor and Miller, 1999)	Acceptable No significant treatment- related effects on any of the reproductive parameters
Mammals	Acute	Norway rat <i>Rattus norvegicus</i>	LD ₅₀ = 2780 mg/kg bw	0015523 (Bathe 1973)	Treatment-related mortality at all doses (1670 – 4640 mg ai/kg bw) tested
	Chronic	Norway rat <i>Rattus norvegicus</i>	Reproductive NOEL = 300 mg ai/kg diet or 24 mg/kg bw/day	00080897 (Smith 1981)	Reduced pup weights in F ₁ and F ₂ litters; parental NOAEL = 1000 ppm or 76 – 86 mg/kg bw/day
Terrestrial invertebrates	Acute Contact	Honey bee <i>Apis mellifera</i> TGAI 98.5%	72 hr oral LD ₅₀ = >85 µg ai/bee NOAEL = 85 µg ai/bee 72 hr contact LD ₅₀ = >200 µg ai/bee NOAEL = 85 µg ai/bee	44718402 (Candolfi, 1997)	Acceptable
Terrestrial plants	n/a	<u>Seedling Emergence</u> Monocots TGAI 97.6%	Ryegrass (<i>Lolium perenne</i>) EC ₂₅ /NOAEC = 0.0048/0.001lb ai/A	43928932 (Chetram and Shuster, 1995)	Supplemental (as tests were conducted on only six species rather than ten)
	n/a	<u>Seedling Emergence</u> Dicots TGAI 97.6%	Lettuce (<i>Lactuca sativa</i>) EC ₂₅ /NOAEC = 0.0057/0.0003 lb ai/A	43928932 (Chetram and Shuster, 1995)	
	n/a	<u>Vegetative Vigor</u> Monocots TGAI 97.3%	Ryegrass EC ₂₅ /NOAEC = 0.016/0.003 lb ai/A	43487108 (Chetram, 1994)	Acceptable
	n/a	<u>Vegetative Vigor</u> Dicots TGAI 97.3%	Cucumber (<i>Cucumis sativus</i>) EC ₂₅ /NOAEC = 0.03/0.025 lb ai/A	43487108 (Chetram, 1994)	Acceptable

n/a: not applicable; bw = body weight; ¹The most sensitive avian chronic NOAEC of 403 mg/kg diet (MRID 46508901) was not used for this assessment as this endpoint was based on reduction in eggshell thickness and increase in cracked eggs, neither of which are relevant to CTS (all 3 DPSs)

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.

Table 4-4. Categories of Acute Toxicity for Avian and Mammalian Studies

Toxicity Category	Oral LD ₅₀	Dietary LC ₅₀
Very highly toxic	< 10 mg/kg	< 50 mg/kg-diet
Highly toxic	10 - 50 mg/kg	50 - 500 mg/kg-diet
Moderately toxic	51 - 500 mg/kg	501 - 1000 mg/kg-diet
Slightly toxic	501 - 2000 mg/kg	1001 - 5000 mg/kg-diet
Practically non-toxic	> 2000 mg/kg	> 5000 mg/kg-diet

4.3.1. Toxicity to Birds and Terrestrial-Phase Amphibians

A summary of acute and chronic bird data, including data published in the open literature is provided below in Sections 4.3.1.a and 4.3.1.b.

4.3.1.a. Birds: Acute Exposure (Mortality) Studies

On an acute exposure basis (both oral and dietary), metolachlor/S-metolachlor is practically non-toxic to birds. Acute LD₅₀ and sub-acute LC₅₀ values were >2194 mg ai/kg bw and >4912 mg ai/kg diet, respectively, for both bobwhite quail and mallard duck (**Appendix G; Table G-6**). No treatment-related mortalities were noted in either study. The NOAEC values reported in both the studies, 874 and 1556 ppm, were based on reduction in body weight gain.

No data regarding avian toxicity effects, based on acute exposure, of metolachlor/S-metolachlor degradates is currently available in registrant-submitted studies or ECOTOX.

4.3.1.b. Birds: Chronic Exposure (Growth, Reproduction) Studies

Two registrant-submitted studies are available to document reproductive effects resulting from chronic exposure to S-metolachlor in bobwhite quail (**Appendix G; Table G-6**). Significant treatment-related effects were noted from only one study (MRID 46508901) which reported NOAEC/LOAEC values of 403/1010 mg ai/kg diet. Reported reproductive effects include a reduction in eggshell thickness and increased number of cracked eggs. However, the endpoints from this study were not used as CTS does not produce hard-shelled eggs similar to birds. Therefore, endpoints (NOAEC/LOAEC = 1000/>1000 mg/kg bw) from the study (MRID 44995901) where significant treatment-related effects were not noted were used.

No data regarding avian toxicity effects, based on chronic exposure, of metolachlor/S-metolachlor degradates is currently available in registrant-submitted studies or ECOTOX.

4.3.2. Toxicity to Mammals

A summary of acute and chronic mammalian data, including data published in the open literature, is provided below in Sections 4.3.2.a and 4.3.2.b. A more complete analysis of

toxicity data to mammals is available in **Appendix J**, which is a copy of the Health Effects Division (HED) chapter prepared in support of the reregistration eligibility decision completed in 1997.

4.3.2.a. Mammals: Acute Exposure (Mortality) Studies

Studies on mammals suggest that both metolachlor ($LD_{50} = 2780$ mg ai/kg bw) and S-metolachlor ($LD_{50} = 3267$ mg ai/kg bw) are similar in their toxicity on acute exposure basis (**Appendix G; Table G-6**). Based on the above data, both metolachlor and S-metolachlor are classified as practically non-toxic to mammals. In this assessment, the rat LD_{50} of 2780 mg /kg bw is used in RQ calculations to determine indirect prey effects to CTS.

No data regarding mammalian toxicity effects, based on acute exposure, of metolachlor/S-metolachlor degradates is currently available in registrant-submitted studies or ECOTOX.

4.3.2.b. Mammals: Chronic Exposure (Growth, Reproduction) Studies

A two-generation reproduction study in albino CD rats, with doses of 0, 30, 300 or 1000 ppm in the diet, revealed a reproductive NOEL of 300 mg ai/kg diet (23.5-26.0 mg/kg/day) for metolachlor (**Appendix G; Table G-6**). This NOEL was derived from reduced pup weights in the F_1 and F_2 litters at the tested highest dose tested of 1000 mg ai/kg diet (75.8-85.7 mg/kg/day). The NOEL for parental toxicity was 1000 mg ai/kg diet.

No data regarding mammalian toxicity effects, based on chronic exposure, of metolachlor/S-metolachlor degradates is currently available in registrant-submitted studies or ECOTOX.

4.3.3. Toxicity to Terrestrial-Phase Amphibians

No terrestrial-phase amphibian studies, based on acute or chronic exposure, were located for metolachlor/S-metolachlor from the open literature.

4.3.4. Toxicity to Terrestrial Invertebrates

A summary of acute terrestrial invertebrate data, including data published in the open literature, is provided below in Sections 4.3.3.a. and 4.3.3.b.

4.3.4.a. Terrestrial Invertebrates: Acute Exposure (Mortality) Studies

The only guideline insect tests on metolachlor/S-metolachlor are on honeybees. Registrant-submitted studies include acute contact and acute oral toxicity studies for S-metolachlor. The acute contact LD_{50} is >200 μ g a.i./bee and the oral LD_{50} is >85 μ g a.i./bee. NOAELS are 200 and 85 μ g a.i./bee for acute contact and oral doses, respectively. Based on the above information, metolachlor/S-metolachlor is classified as practically non-toxic to honey bees.

No open literature studies are available on metolachlor/S-metolachlor which reported endpoints that were more sensitive than those reported in the registrant-submitted guideline studies.

4.3.4.b. Terrestrial Invertebrates: Chronic Exposure Studies

No information is available in the registrant-submitted or open literature studies data regarding the chronic exposure effects of metolachlor/S-metolachlor on terrestrial invertebrates.

4.3.5. Toxicity to Terrestrial Plants

Terrestrial plant data were used to calculate RQs for indirect effects to DS and CTS through habitat modification since riparian vegetation provides shade and cover for both species. Impacts to riparian and upland (i.e., grassland, woodland) vegetation may result in indirect effects to DS and CTS, as well as modification to designated critical habitat PCEs via increased sedimentation, alteration in water quality, and reduction in of riparian habitat that provides shade and predator avoidance.

Plant toxicity data from both registrant-submitted studies and studies in the scientific literature were reviewed for this assessment. Registrant-submitted studies are conducted under conditions and with species defined in EPA toxicity test guidelines. Sublethal 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. These tests 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 metolachlor and S-metolachlor, 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.

Table 4-1 summarizes the most sensitive terrestrial plant toxicity endpoints, based on an evaluation of both the submitted studies (**Appendix G; Table G-8**) and the open literature (**Appendix G; Table G-9**). Both monocots and dicots were more sensitive in the seedling emergence tests, which was not unexpected given metolachlor's mode of action. The seedling emergence (based on S-metolachlor) EC₂₅ for the most sensitive monocot (ryegrass) was 0.0048 lb ai/A, and the EC₂₅ for the most sensitive dicot (lettuce) was 0.0057 lb ai/A (**Appendix G; Table G-8**). The seedling emergence NOAEC for the most sensitive monocot (ryegrass) and dicot (lettuce) species were 0.001 and 0.0003 lb ai/A, respectively. In terms of vegetative vigor (based on metolachlor), monocots appeared to be more sensitive than dicots, with a monocot (ryegrass) EC₂₅ of 0.016 lb ai/A, and dicot (cucumber) EC₂₅ of 0.03 lb ai/A.

Vegetative vigor and seedling emergence guideline tests were also available for both the ESA degradate and the OA degradate. Both are less toxic than the parent compound. With the exception of the monocot seedling emergence endpoint for ESA, the EC₂₅s for all endpoints were greater than 0.5 lb ai/A. For ESA, no definitive endpoint was established for monocot seedling emergence as the NOAEC was below the concentration tested.

Three plant studies evaluating effects of metolachlor and S-metolachlor on non-crop plant species were available in ECOTOX. Generally, these studies were conducted on mature and/or growing plants, rather than pre-emergence, thus they are more comparable to the vegetative vigor endpoints than the seedling emergence endpoints from the guideline studies. Open literature studies on crop species produced less sensitive endpoints than the registrant-submitted studies. Plants have been grouped into two classes: herbaceous (grasses and forbs) and woody (trees and shrubs). This classification is intended to reflect both a difference in ecological function, and expected differences in sensitivity to the herbicide. In order to establish upper and lower bounds, the most sensitive and the least sensitive endpoints for each group are included in the table. For the grasses and forbs, a test concentration of 0.11 lb ai/A was applied (E# 73233). At this concentration, results ranged from no observed effect (broomcorn, *Panicum miliaceum*) to a 90% reduction in height (barnyard grass, *Echinocloa crusgalli*). The most sensitive species tested in the trees and shrubs class was the Tatarian maple (*Acer tataricum*), which exhibited reduced growth at an application of 3.0 lb ai/A (E# 73251). The least sensitive species tested was the European white birch (*Betula pendula*), which had no observable effects at an application rate of 9.1 lb ai/A.

In a natural landscape, plants most at risk from use of metolachlor would be newly emerging plants located near the use site. Based on available studies, metolachlor is absorbed by plants mostly at the roots and shoots, thus the most effective route of exposure is when metolachlor is incorporated into or deposited onto bare soil, where it may be taken up by the growing plant (represented by the seedling emergence guideline tests). However, it is also effective against mature and growing herbaceous plants (represented by the guideline vegetative vigor tests, and most of the open literature studies) at environmentally relevant concentrations (EC₂₅ from 0.02-0.11 lb ai/A).

4.4. Toxicity of Mixtures

An open literature study (E# 85815) is available that estimated the impacts of S-metolachlor (0.1 ppb) alone and in mixtures with atrazine [commercial formulation of Bicep (0.1 or 10 ppb) and prepared mixtures (0.1 or 10 ppb of metolachlor + atrazine each)] on growth and development of amphibian [leopard frog (*Rana pipens*) and African clawed frog (*Xenopus laevis*) larvae]. The study showed that exposure to S-metolachlor alone and in combination with atrazine resulted in damage to the thymus as measured by thymic plaques, resulting in immunosuppression and contraction of flavobacterial meningitis. The frequency of thymus damage was higher with Bicep compared to metolachlor alone. Though larval growth and development was not affected by S-metolachlor alone, prepared mixtures of atrazine + S-metolachlor impacted larval development greater than Bicep, suggesting that the surfactant in Bicep reduced the toxic effect of mixtures.

Numerous issues have been noted with this study, the details of which are presented in **Appendix A**. Therefore, this study will be used for qualitative purposes only in this assessment.

4.5. Incident Database Review

A review of the Ecological Incident Information System (EIIS, version 2.1), the Aggregate Summary Module (ASM) (v.1.0) of Office of Pesticide Program's Incident database maintained by the Information Technology and Resource Management Division, and the Avian Monitoring Information System (AIMS) for ecological incidents involving metolachlor/S-metolachlor was completed on 10 March 2010. The results of this review for terrestrial, plant, and aquatic incidents are discussed below. A complete list of the incidents involving metolachlor and S-metolachlor including associated uncertainties is included as **Appendix L**, respectively.

Incidents from the EIIS Database:

Incidents are reported separately for S-metolachlor and metolachlor in the EIIS database. A total of 274 and 157 incidents were reported on metolachlor and S-metolachlor, respectively. The types of reported incidents (plant incidents being the dominant) were similar for both metolachlor and S-metolachlor.

Of the 274 incidents reported on metolachlor, there were 18 reported incidents of effects on aquatic animals, primarily fish. Generally, these occurred under registered use conditions, and were rated as possible or unlikely to be associated with the application of metolachlor. One incident, a fish kill in Minnesota, has a certainty rating of highly probable, but was also listed as accidental misuse. There were two reported bird kills from metolachlor use in corn and potato. The certainty of bird kill incidents based on metolachlor use in corn and potato were categorized as possible and unlikely, respectively. A bulk of the incidents, 254 to be specific, was reported in agricultural crops under registered use conditions. The most commonly reported crop damage was to corn, peanut, and soybean.

Of the 157 incidents on S-metolachlor, only two reports are for organisms other than plants. In one case, there is a report of three birds dying as a result of S-metolachlor use. The certainty of this incident was unrated, and legality was designated as unknown. The second case was a reported fish kill of an unspecified magnitude. The legality of the use was designated unknown, and the incident was designated unlikely to be the result of the pesticide use. The remainder of the incidents pertain to damage to agricultural crops. Based on the data, it appears that most of the incidents are undesired effects at the treatment site, when applied in accordance with registered use. The most commonly reported damaged crops were corn, cotton, and soybean. The certainty that these incidents were related to metolachlor use was generally rated as either possible or probable. Fewer incidents were also reported on crops such as alfalfa, pea, peanut, legumes, potato, sorghum, and sugarbeet.

Incidents from the ASM Database:

A total of 606 and 51 incidents were reported in the AMS database for S-metolachlor and metolachlor, respectively. Except for 5 fish incidents each for S-metolachlor and metolachlor, the rest of the reported incidents pertain to plants. Other than the date range during which the incident occurred, no other information on the incident (including the species affected) was reported in this database limiting the utility of the results.

Incidents from the AIMS Database:

Three avian incidents for metolachlor and a single incident for S-metolachlor were reported in the AIMS database. Based on these 3 incidents, about 34 birds were reported killed due to metolachlor and 3 due to S-metolachlor. In the 1991 incident from North Carolina on metolachlor, about 33 birds comprising of blackbird, eastern bluebird, finch, gull, and wren were reported killed. The other incidents, both on metolachlor and S-metolachlor, were minor with less than 3 bird kills.

4.6. 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 and aquatic animals that may indirectly affect the listed species of concern (USEPA, 2004). As part of the risk characterization, an interpretation of acute RQs 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 metolachlor/S-metolachlor 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.

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

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 DS and CTS or for modification to their designated critical habitat from the use of metolachlor/S-metolachlor 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 assessed species or their designated critical habitat (*i.e.*, “no effect,” “likely to adversely affect,” or “may affect, but not likely to adversely affect”). In the risk estimation section, risk quotients are calculated using standard EFED procedures and models. In the risk description section, additional analyses may be conducted to help characterize the potential for risk.

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 listed aquatic animals, as well as terrestrial invertebrates, the LOC is 0.05. For acute exposures to the listed birds (and, thus, terrestrial-phase amphibians) and mammals, the LOC is 0.1. The LOC for chronic exposures to animals, as well as acute exposures to plants is 1.0.

Acute and chronic risks to aquatic organisms are estimated by calculating the ratio of exposure to toxicity using 1-in-10 year EECs in **Table 3-4** (parent) and **Tables 3-5 and 3-6** (degradates) based on the label-recommended metolachlor/S-metolachlor usage and the appropriate aquatic toxicity endpoint from **Table 4-1**. Acute and chronic risks to terrestrial animals are estimated based on exposures resulting from applications of metolachlor/S-metolachlor (**Tables 3-8, 3-9, and 3-10**) and appropriate toxicity endpoint from **Table 4-3**. Exposures are also derived for terrestrial plants, as discussed in Section 3.4, based on the highest and lowest application rates of metolachlor/S-metolachlor use within the action area.

In view of the numerous uses associated with metolachlor/S-metolachlor, RQs for aquatic organisms are presented for only the uses that resulted in highest and lowest EECs based on aerial and ground applications for both food and non-food uses of metolachlor/S-metolachlor (to represent the range of RQs for various uses). Based on aquatic modeling, pumpkin and radish represented lowest EECs from aerial and ground applications, respectively, whereas sorghum and Swiss chard represented highest EECs from aerial and ground applications, respectively for food uses. Meadowfoam (applied by ground) and ornamental sod and shade trees (applied by air) represented the lowest and highest EECs for non-food uses. For terrestrial organisms, risk quotients are presented for only the uses that represented the highest (corn for food uses and ornamental sod and shade trees for non-food uses) and lowest (spinach for food uses and meadowfoam for non-food uses) application rates.

5.1.1. Exposures in the Aquatic Habitat

5.1.1.a. Freshwater Fish and Aquatic-phase Amphibians

Acute risk to DS and aquatic-phase CTS is based on 1 in 10 year peak EECs in the standard pond and the lowest acute toxicity value for freshwater fish. Chronic risk is based on the 1 in 10 year 60-day EECs and the lowest chronic toxicity value for freshwater fish. Risk quotients for freshwater fish based on the parent metolachlor/S-metolachlor and degradates are shown in **Tables 5-1 and 5-2**. Freshwater fish RQs will be used to estimate direct acute and chronic risks to the DS and aquatic-phase CTS (all 3 DPSs). Freshwater fish RQs will also be used to assess potential indirect effects of metolachlor/S-metolachlor to the aquatic-phase CTS via reduction in available prey items.

Table 5-1. Acute and Chronic RQs for Freshwater Fish Based on Parent Metolachlor/S-Metolachlor Uses

Uses (Application Method)	Species for Acute Toxicity	Species for Chronic Toxicity	Peak EEC (µg/L)	60-day Average EEC (µg/L)	Acute RQ*	Chronic RQ*
Food Uses						
Pumpkin (Aerial)	Bluegill sunfish	Fathead minnow	6.6	5.8	<0.05	<1.0
Sorghum (Aerial)	Bluegill sunfish	Fathead minnow	48.8	44.0	<0.05	1.5
Radish (Ground)	Bluegill sunfish	Fathead minnow	2.2	2.0	<0.05	<1.0
Swiss chard (Ground)	Bluegill sunfish	Fathead minnow	50.7	46.1	<0.05	1.5
Non-Food Uses						
Meadowfoam (Ground)	Bluegill sunfish	Fathead minnow	1.3	1.2	<0.05	<1.0
Ornamental sod and shade trees (Aerial)	Bluegill sunfish	Fathead minnow	28.1	25.8	<0.05	<1.0
* = LOC exceedances (acute RQ ≥ 0.05; chronic RQ ≥ 1.0) are bolded and shaded; Acute RQ = use-specific peak EEC / 3200 µg/L; Chronic RQ = use-specific 60-day EEC / 30 µg/L						

Table 5-2. Acute RQs for Freshwater Fish Based on Metolachlor/S-Metolachlor Degradates Metolachlor-ESA and OA

Uses (Application Method)	Species for Acute Toxicity	Peak EEC for Metolachlor-ESA (µg/L)	Peak EEC for Metolachlor-OA (µg/L)	Acute RQ for Metolachlor-ESA*	Acute RQ for Metolachlor-OA*
Food Uses					
Pumpkin	Rainbow trout	1.0	1.7	<0.05	<0.05
Swiss Chard		10.3	17.1	<0.05	<0.05
Non-Food Uses					
Meadowfoam	Rainbow trout	0.2	0.3	<0.05	<0.05
Ornamental sod and shade trees		4.7	7.9	<0.05	<0.05
* = LOC exceedances (acute RQ ≥ 0.05) are bolded and shaded; Acute RQ for Metolachlor-ESA = use-specific peak EEC /48,000 µg/L; Acute RQ for Metolachlor-OA = use-specific peak EEC / 93,100 µg/L					

Acute RQs did not exceed the listed or non-listed (including restricted use) species LOC for any of the food or non-food uses of parent metolachlor/S-metolachlor (**Table 5-1**) or its degradates ESA and OA (**Table 5-2**). However, chronic RQs are above the Agency's LOC of 1.0 for 5 uses (cabbage, Swiss chard, sorghum, safflower, and spinach) of parent metolachlor/S-metolachlor. Therefore, parent metolachlor/S-metolachlor has the potential to directly affect the DS and aquatic-phase CTS (all 3 DPSs) or indirectly affect CTS (all 3 DPSs) through prey reduction.

5.1.1.b. Freshwater Invertebrates

Acute risk to freshwater invertebrates is based on 1 in 10 year peak EECs in the standard pond and the lowest acute toxicity value for freshwater invertebrates. Chronic risk is based on 1 in 10 year 21-day EECs and the lowest chronic toxicity value for freshwater invertebrates.

Risk quotients for freshwater invertebrates based on parent metolachlor/S-metolachlor and its degradates ESA and OA are shown in **Table 5-3** and **Table 5-4**. Freshwater invertebrate RQs will be used to assess potential indirect effects of metolachlor/S-metolachlor to the DS and aquatic-phase CTS (all 3 DPSs) via reduction in available prey items.

Table 5-3. Summary of Acute and Chronic RQs for Freshwater Invertebrates Based on Parent Metolachlor/S-Metolachlor

Uses (Application Method)	Species for Acute Toxicity	Species for Chronic Toxicity	Peak EEC (µg/L)	21-day Average EEC (µg/L)	Acute RQ*	Chronic RQ*
Food Uses						
Pumpkin (Aerial)	Daphnid		6.6	6.3	<0.05	6.3
Sorghum (Aerial)			48.8	47.2	<0.05	47.2
Radish (Ground)			2.2	2.1	<0.05	2.1
Swiss chard (Ground)			50.7	49	<0.05	49
Non-Food Uses						
Meadowfoam (Ground)	Daphnid		1.3	1.3	<0.05	1.3
Ornamental sod and shade trees (Aerial)			28.1	26.9	<0.05	26.9
* = LOC exceedances (acute RQ ≥ 0.05; chronic RQ ≥ 1.0) are bolded and shaded; Acute RQ = use-specific peak EEC / 1100 µg/L; Chronic RQ = use-specific 21-day EEC / 1 µg/L						

Table 5-4. Acute RQs for Freshwater Invertebrates Based on Metolachlor/S-Metolachlor Degradates Metolachlor-ESA and OA

Uses (Application Method)	Species for Acute Toxicity	Peak EEC for Metolachlor- ESA (µg/L)	Peak EEC for Metolachlor- OA (µg/L)	Acute RQ for Metolachlor- ESA*	Acute RQ for Metolachlor- OA*
Food Uses					
Pumpkin	Daphnid	1.0	1.7	<0.05	<0.05
Swiss chard		10.3	17.1	<0.05	<0.05
Non-Food Uses					
Meadowfoam	Daphnid	0.2	0.3	<0.05	<0.05
Ornamental sod and shade trees		4.7	7.9	<0.05	<0.05
* = LOC exceedances (acute RQ ≥ 0.05) are bolded and shaded; Acute RQ for Metolachlor-ESA = use-specific peak EEC /108,000 µg/L; Acute RQ for Metolachlor-OA = use-specific peak EEC / 15,400 µg/L					

Regardless the method of application, acute RQs did not exceed the listed or non-listed (including restricted use) species LOC for any of the food or non-food uses of metolachlor/S-metolachlor and its degradates (**Tables 5-3 and 5-4**). Chronic RQs, however, exceeded the LOC ($RQ > 1.0$) for aquatic invertebrates for all modeled uses (**Table 5-3**). Since the chronic RQs are exceeded, there is potential for indirect effects to DS and aquatic-phase CTS (all 3 DPSs) that rely on freshwater invertebrates as prey items during at least some portion of their life-cycle.

5.1.1.c. Estuarine/Marine Fish

Acute risk to estuarine/marine fish is based on 1 in 10 year peak EECs in the standard pond and the lowest acute toxicity value for estuarine/marine fish. Chronic risk is based on 1 in 10 year 60-day EECs and the lowest chronic toxicity value for estuarine/marine fish is used. Risk quotients are shown in **Table 5-5**. Estuarine/marine fish RQs will be used to estimate direct acute and chronic risks to the DS.

Table 5-5. Summary of RQs for Estuarine/Marine Fish Based on Parent Metolachlor

Uses (Application Method)	Species for Acute Toxicity	Species for Chronic Toxicity	Peak EEC (µg/L)	60-day EEC (µg/L)	Acute RQ*	Chronic RQ*
Food Uses						
Pumpkin (Aerial)	Sheepshead minnow		6.6	5.8	<0.05	<1.0
Sorghum (Aerial)			48.8	44.0	<0.05	1.5
Radish (Ground)			2.2	2.0	<0.05	<1.0
Swiss chard (Ground)			50.7	46.1	<0.05	1.5
Non-Food Uses						
Meadowfoam (Ground)	Sheepshead minnow		1.3	1.2	<0.05	<1.0
Ornamental sod and shade trees (Aerial)			28.1	25.8	<0.05	<1.0
* = LOC exceedances (acute RQ ≥ 0.05; chronic RQ ≥ 1.0) are bolded and shaded; Acute RQ = use-specific peak EEC /3200 µg/L; Chronic RQ = use-specific 60-day EEC / 30 µg/L						

Acute RQs did not exceed the listed or non-listed species LOC for any food or non-food uses of metolachlor/S-metolachlor (**Table 5-5**). However, chronic RQs are above the Agency's LOC of 1.0 for some uses (cabbage, Swiss chard, spinach, safflower, sorghum, and sugarbeet) (**Table 5-5**). Therefore, metolachlor/S-metolachlor may have the potential to directly affect the DS.

5.1.1.d. Estuarine/Marine Invertebrates

Acute risk to estuarine/marine invertebrates is based on peak EECs in the standard pond and the lowest acute toxicity value for estuarine/marine invertebrates. Chronic risk is based on 21-day average EECs and the lowest chronic toxicity value for estuarine/marine invertebrates. Risk quotients are shown in **Table 5-6**. Estuarine/marine invertebrate RQs will be used to assess potential indirect effects of metolachlor/S-metolachlor to the DS via reduction in available prey items.

Table 5-6. Summary of Acute and Chronic RQs for Estuarine/Marine Invertebrates Based on Parent Metolachlor

Uses (Application Method)	Species for Acute Toxicity	Species for Chronic Toxicity	Peak EEC (µg/L)	21-day Average EEC (µg/L)	Acute RQ*	Chronic RQ*
Food Uses						
Pumpkin (Aerial)	Eastern oyster	Mysid shrimp	6.6	6.3	<0.05	<1.0
Sorghum (Aerial)			48.8	47.2	<0.05	<1.0
Radish (Ground)			2.2	2.1	<0.05	<1.0
Swiss chard (Ground)			50.7	49	<0.05	<1.0
Non-Food Uses						
Meadowfoam (Ground)	Eastern oyster	Mysid shrimp	1.3	1.3	<0.05	<1.0
Ornamental sod and shade trees (Aerial)			28.1	26.9	<0.05	<1.0
* = LOC exceedances (acute RQ ≥ 0.05; chronic RQ ≥ 1.0) are bolded and shaded; Acute RQ = use-specific peak EEC / 1600 µg/L and chronic RQ = use-specific 21-day EEC / 130 µg/L						

Regardless the method of application, acute RQs did not exceed the listed or non-listed (including restricted use) species LOC for any of the food or non-food uses of metolachlor/S-metolachlor (**Table 5-6**). Chronic RQs, similar to acute RQs, did not exceed the aquatic invertebrate LOC (RQ > 1.0) for any modeled use (**Table 5-6**). Based on the above, metolachlor/S-metolachlor does not have the potential to indirectly affect the DS via estuarine/marine invertebrate prey reduction.

5.1.1.e. Non-vascular Aquatic Plants

Risk to aquatic non-vascular plants is based on 1 in 10 year peak EECs in the standard pond and the lowest acute toxicity value. Risk quotients for non-vascular plants based on the parent metolachlor/S-metolachlor and the degradates ESA and OA are shown in **Tables 5-7** and **5-8**, respectively. Aquatic non-vascular plant RQs will be used to assess potential indirect effects of metolachlor/S-metolachlor to the DS and CTS (all 3 DPSs) via reduction in available prey items or habitat modification.

Table 5-7. Summary of Acute RQs for Non-Vascular Aquatic Plants Based on Parent Metolachlor/S-Metolachlor

Uses (Application Method)	Peak EEC (µg/L)	RQ*
Food Uses		
Pumpkin (Aerial)	6.6	0.8
Sorghum (Aerial)	48.8	6.1
Radish (Ground)	2.2	0.3
Swiss chard (Ground)	50.7	6.3
Non-Food Uses		
Meadowfoam (Ground)	1.3	0.2
Ornamental sod and shade trees (Aerial)	28.1	3.6

*LOC exceedances (RQ ≥ 1) are bolded; RQ = use-specific peak EEC/ 8 µg/L

Table 5-8. Summary of Acute RQs for Non-Vascular Plants Based on Metolachlor/S-Metolachlor Degradates Metolachlor-ESA and OA

Uses (Application Method)	Species for Acute Toxicity	Peak EEC for Metolachlor- ESA (µg/L)	Peak EEC for Metolachlor- OA (µg/L)	Acute RQ for Metolachlor- ESA*	Acute RQ for Metolachlor- OA*
Food Uses					
Pumpkin	Green algae	1.0	1.7	<1.0	<1.0
Swiss chard		10.3	17.1	<1.0	<1.0
Non-Food Uses					
Meadowfoam	Green algae	0.2	0.3	<1.0	<1.0
Ornamental sod and shade trees		4.7	7.9	<1.0	<1.0
* = LOC exceedances (acute RQ ≥ 1) are bolded and shaded; Acute RQ for Metolachlor-ESA = use-specific peak EEC /99,500 µg/L ; Acute RO for Metolachlor-OA = use-specific peak EEC / 57,100 µg/L					

Risk quotients exceeded the aquatic non-vascular listed and non-listed plant LOC (RQ >1.0) for most metolachlor/S-metolachlor food uses except legume vegetables, celery, pepper, tabasco pepper, rhubarb, pumpkin, onion, radish, and horse radish (**Table 5-7**). Regarding non-food uses, acute risk quotients exceeded the Agency's LOC (listed and non-listed) from aerial and ground applications of metolachlor/S-metolachlor to ornamental sod and shade trees. Risk quotients for the metolachlor degradates ESA and OA, on the other hand, did not exceed the listed or non-listed species LOC for any of the uses (**Table 5-8**). Since the aquatic non-vascular plant risk quotients are exceeded for parent metolachlor/S-metolachlor, there is a potential for indirect effects to DS and CTS (all 3 DPSs) that rely on non-vascular aquatic plants for food and habitat during at least some portion of their life-cycle.

5.1.1.f. Aquatic Vascular Plants

Risk to aquatic vascular plants is based on 1 in 10 year peak EECs in the standard pond and the lowest acute toxicity value. Risk quotients for the parent metolachlor/S-metolachlor and the degradates ESA and OA are shown in **Table 5-9 and Table 5-10**, respectively. Aquatic vascular plant RQs will be used to assess potential indirect effects of metolachlor/S-metolachlor to the DS and CTS (all 3 DPSs) via reduction in available prey items or habitat modification.

Table 5-9. Summary of Acute RQs for Vascular Aquatic Plants Based on Parent Metolachlor/S-Metolachlor

Uses (Application Method)	Peak EEC (µg/L)	RQ*
Food Uses		
Pumpkin (Aerial)	6.6	0.3
Sorghum (Aerial)	48.8	2.3
Radish (Ground)	2.2	0.1
Swiss chard (Ground)	50.7	2.4
Non-Food Uses		
Meadowfoam (Ground)	1.3	0.06
Ornamental sod and shade trees (Aerial)	28.1	1.3

*LOC exceedances (RQ ≥ 1) are bolded; RQ = use-specific peak EEC / 21 µg/L

Table 5-10. Summary of Acute RQs for Vascular Plants Based on Metolachlor/S-Metolachlor Degradates Metolachlor-ESA and OA

Uses (Application Method)	Species for Acute Toxicity	Peak EEC for Metolachlor- ESA (µg/L)	Peak EEC for Metolachlor- OA (µg/L)	Acute RQ for Metolachlor- ESA*	Acute RQ for Metolachlor- OA*
Food Uses					
Pumpkin	Duckweed	1.0	1.7	<1.0	<1.0
Swiss chard		10.3	17.1	<1.0	<1.0
Non-Food Uses					
Meadowfoam	Duckweed	0.2	0.3	<1.0	<1.0
Ornamental sod and shade trees		4.7	7.9	<1.0	<1.0
* = LOC exceedances (acute RQ ≥ 1) are bolded and shaded; Acute RQ for Metolachlor-ESA = use-specific peak EEC /1600 µg/L; Acute RO for Metolachlor-OA = use-specific peak EEC / 95,100 µg/L					

Risk quotients exceeded the aquatic vascular plant listed and non-listed species LOC (RQ >1.0) for parent metolachlor/S-metolachlor food uses that included cabbage, Swiss chard, spinach, tomato, sunflower, safflower, and sorghum (**Table 5-9**). Vascular plant RQs exceeded the aquatic plant LOC for only ornamental sod and shade trees for the non-food uses. Vascular plant

RQs did not exceed the aquatic plant LOCs for any food or non-food uses based on the two metolachlor degradates (**Table 5-10**). Based on the LOC exceedances noted with parent metolachlor/S-metolachlor, there is a potential for indirect effects to the DS and CTS (all 3 DPSs) from loss of vascular aquatic plants which provide primary production needed for their food source, as well as habitat.

5.1.2. Exposures in the Terrestrial Habitat

5.1.2.a. Birds (Surrogate for Terrestrial-phase CTS)

As previously discussed in Section 3.3, potential for direct effects to the terrestrial-phase CTS are assessed based on direct acute effects to birds (as surrogate) as amphibian toxicity data is not available. Potential direct risks to the terrestrial-phase CTS are evaluated using T-REX, acute and chronic toxicity data for the most sensitive bird species for which data are available, and the most sensitive dietary item and size class for that species. For terrestrial-phase amphibians, the most sensitive RQ in T-REX is for the small bird consuming small insects.

Spray Applications: Avian RQs, based on acute exposure to metolachlor/S-metolachlor, could not be calculated because no definitive acute toxicity endpoints are available. Direct risk to CTS from acute exposure will be further characterized in the risk description section.

Potential direct chronic effects of metolachlor/S-metolachlor to the terrestrial-phase CTS are derived by considering dietary-based exposures modeled in T-REX for a small bird (20g) consuming short grass. Chronic effects are estimated using the lowest available toxicity data for birds. EECs are divided by toxicity values to estimate chronic dietary-based RQs.

Chronic RQs for the terrestrial-phase CTS are shown in **Table 5-11**. Chronic RQs ranged from 0.2 – 1.5 for food uses and 0.1 – 0.9 for non-food uses. Chronic RQs exceeded LOCs for only corn and potato. Therefore, metolachlor/S-metolachlor may have the potential to directly affect terrestrial-phase CTS (all 3 DPSs).

Granular Applications: Direct acute effects to CTS (all 3 DPSs) from granular applications of S-metolachlor could not be determined as definitive toxicity data is not available for birds. Direct risk to terrestrial-phase CTS from acute exposure to granular applications will be discussed further in the risk description section.

Table 5-11. Summary of Chronic RQs Used to Estimate Direct Effects to the Terrestrial-Phase CTS from Broadcast Spray Applications of Metolachlor/S-Metolachlor

Use	Avian RQs*	
	Dietary Based EEC	Chronic RQ ¹
Food Uses		
Corn	1490	1.5
Spinach	240	0.2
Non-Food Uses		
Ornamental sod and shade trees	861	0.9
Meadowfoam	144	0.1

*LOC exceedances (RQ \geq 1); ¹Based on Northern bobwhite quail NOAEC = 1000 mg/kg-diet

5.1.2.b. Mammals

Potential for indirect effects to the terrestrial-phase CTS may result from direct effects to mammals, which serve as prey to the terrestrial-phase CTS. Potential indirect effects to the CTS may also result from direct effects to mammals due to effects on habitat or a reduction in rearing sites. RQs for indirect effects are calculated in the same manner as those for direct effects.

Potential risks to mammals are evaluated using T-REX, acute and chronic mammalian toxicity data, and a variety of body-size and dietary categories. Indirect 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.

Potential direct chronic effects to the mammals are evaluated by considering dietary-based EECs modeled in T-REX consuming a variety of dietary items. The specific EECs for each species are for the same size mammals and same dietary items as those considered for acute exposure. Chronic effects are estimated using the lowest available NOAEC from a chronic reproductive study for mammals. Dietary-based EECs are divided by toxicity values to estimate chronic dietary-based RQs.

Table 5-12. Summary of Acute and Chronic RQs Used to Estimate Indirect Effects to the Terrestrial-Phase CTS Via Habitat and Prey Effects on Small Mammals from Broadcast Spray Applications of Metolachlor/S-Metolachlor

Use	Mammalian RQ*s			
	Dose-Based EEC	Dose-Based RQ ¹	Dietary-Based EEC	Chronic RQ ²
Food Uses				
Corn	1421	0.5	1490	5.0
Spinach	229	0.04	240	0.8
Non-Food Uses				
Ornamental sod and shade trees	821	0.13	861	2.9
Meadowfoam	137	0.02	144	0.5

*LOC exceedances (acute RQ ≥ 0.1 and chronic RQ ≥ 1.0) are bolded.

¹Based on dose-based rat oral LD₅₀ = 2780 mg/kg-bw

³Based on dietary-based rat NOAEC = 300 mg/kg-diet or 24 mg/kg bw/day

Spray Applications: The mammalian acute RQs ranged between 0.04 – 0.5 for food uses and 0.02 – 0.13 for non-food uses from spray applications of metolachlor/S-metolachlor (**Table 5-12**). Mammalian RQs did not exceed the acute non-listed species LOC for any metolachlor/S-metolachlor use. However, acute RQs exceeded endangered species LOC for almost all uses. Chronic RQs for mammals ranged between 0.8 – 5.0 for food uses and 0.5 – 2.9 for non-food uses. Except for spinach and meadowfoam, mammalian RQs exceeded chronic risk for all metolachlor/S-metolachlor food and non-food uses. Since the acute and chronic RQs are exceeded for most uses, there is a potential for indirect effects to the terrestrial-phase CTS (all 3 DPSs) that rely on mammals for prey and habitat during its life-cycle.

Granular Applications: Indirect acute effects to terrestrial-phase CTS via ingestion of small mammals that may consume S-metolachlor granules are based on LD₅₀/ft² values. Based on the mammalian acute toxicity value of 2780 mg ai/kg bw (LD₅₀), adjusted mammalian LD₅₀ value was calculated to be 1710 mg ai/kg bw [adjusted mammalian LD₅₀ = LD₅₀ (TW/AW)^{0.25} = 2780 (50/350)^{0.25} = 1710 mg ai/kg bw, where TW = weight of tested species and AW= weight of assessed species]. Comparison of granular EECs (25 and 19.8 mg/ft² for corn and potato/peanut/soybean, respectively) with the adjusted mammalian LD₅₀ value for the smallest weight class of 15g (representative of a small mammal that an adult terrestrial-phase CTS could consume) suggest that risk quotients (0.01 regardless of the crop) did not exceed acute endangered species risk LOCs. Therefore, there is no likelihood of acute mortality to mammals consuming S-metolachlor granules and potential for indirect effects to terrestrial-phase CTS (all 3 DPSs) via a reduction of mammalian prey items.

5.1.2.c. Terrestrial Invertebrates

Potential for indirect effects to the terrestrial-phase CTS may result from direct acute effects to terrestrial invertebrates due to a reduction in prey. RQs for indirect effects are calculated in the same manner as those for direct effects. In order to assess the risks of metolachlor/S-metolachlor to terrestrial invertebrates, the honey bee is used as a surrogate for terrestrial invertebrates. Typically, the toxicity value for terrestrial invertebrates is calculated by multiplying the lowest

available acute contact LD₅₀ by 1 bee/0.128g, which is based on the weight of an adult honey bee. EECs (µg ai/g of bee) calculated by T-REX for small and large insects are divided by the calculated toxicity value for terrestrial invertebrates. Since the available acute oral and contact toxicity data on honey bee is not definitive (>85 and >200 µg ai/bee, respectively), risk quotients could not be calculated. However, risk will further be refined in the risk description section.

5.1.2.d. Terrestrial Plants

Potential indirect effects are expected to occur on DS and CTS (all 3 DPSs) due to direct effects from metolachlor/S-metolachlor uses on terrestrial plants as these plants provide habitat to both the species. Generally, for indirect effects, potential effects on terrestrial vegetation are assessed using RQs from terrestrial plant seedling emergence and vegetative vigor EC₂₅ data as a screen. Risk quotients are shown in **Table 5-13** and **Table 5-14**.

Table 5-13. RQs* for Monocots Inhabiting Dry and Semi-Aquatic Areas Exposed to Metolachlor/S-Metolachlor via Runoff and Drift

Use	Application rate (lb ai/A)	Application method	Drift Value (%)	Spray drift RQ	Dry area RQ	Semi-aquatic area RQ
Food Uses/Liquid Formulations						
Corn	4	Ground	1	8	50	425
Corn	4	Aerial	5	42	83	458
Spinach	1	Ground	1	2	13	106
Food Uses/Granular Formulations						
Corn	2.4	Ground	0	<0.1	25	250
Potato/peanut/ Soybean	1.3	Ground	0	<0.1	14	135
Non-Food Uses/Liquid Formulations						
Ornamentals	2.5	Ground	1	5	31	266
Ornamentals	2.5	Aerial	5	26	52	286
Ornamentals	1.3	Ground	1	3	16	138

*LOC exceedances (RQ ≥ 1) are bolded.

Table 5-14. RQs* for Dicots Inhabiting Dry and Semi-Aquatic Areas Exposed to Metolachlor/S-Metolachlor via Runoff and Drift

Use	Application rate (lb ai/A)	Application method	Drift Value (%)	Spray drift RQ	Dry area RQ	Semi-aquatic area RQ
Food Uses/Liquid Formulations						
Corn	4	Ground	1	7	42	358
Corn	4	Aerial	5	35	70	389
Spinach	1	Ground	1	2	11	89
Food Uses/Granular Formulations						
Corn	2.4	Ground	0	<0.1	25	250
Potato/peanut/ Soybean	1.3	Ground	0	<0.1	14	135
Non-Food Uses/Liquid Formulations						
Ornamentals	2.5	Ground	1	22	44	241
Ornamentals	2.5	Aerial	5	4	26	224
Ornamentals	1.3	Ground	1	2	14	116

*LOC exceedances (RQ \geq 1) are bolded

Terrestrial plant LOC (RQ > 1.0) is exceeded for exposures resulting from single applications of all liquid and granular uses of metolachlor/S-metolachlor for both listed and non-listed monocot and dicot plants inhabiting semi-aquatic and dry areas (**Tables 5-13 and 5-14**). In general, spray drift, dry area, and semi-aquatic area RQs are higher for monocots than dicots, indicating greater effects of metolachlor/S-metolachlor on grasses compared to broadleaf plants. Based on these results, there is a potential for indirect effects to the DS and CTS based on effects to habitat. Example output from TerrPlant v.1.2.2 is provided in **Appendix F**.

5.1.3. Primary Constituent Elements of Designated Critical Habitat

For metolachlor/S-metolachlor uses, the assessment endpoints for designated critical habitat PCEs involve the same endpoints as those being assessed relative to the potential for direct and indirect effects to the listed species assessed here. Therefore, the effects determinations for direct and indirect effects are used as the basis of the effects determination for potential modification to designated critical habitat.

5.2. Risk Description

The risk description synthesizes overall conclusions regarding the likelihood of adverse impacts leading to a preliminary effects determination (*i.e.*, “no effect,” “may affect, but not likely to adversely affect,” or “likely to adversely affect”) for the assessed species and the potential for modification of their designated critical habitat based on analysis of risk quotients and a comparison to the Level of Concern. The final No Effect/May Affect determination is made after the spatial analysis is completed at the end of the risk description, Section 5.2. In Section 5.2.4.c, a discussion of any potential overlap between areas where potential usage may result in

LAA effects and areas where species are expected to occur (including any designated critical habitat) is presented. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a No Effect determination is made.

If the RQs presented in the Risk Estimation (Section 5.1) show no direct or indirect effects for the assessed species, and no modification to PCEs of the designated critical habitat, a preliminary “no effect” determination is made, based on metolachlor/S-metolachlor’s use within the action area. However, if LOCs for direct or indirect effect are exceeded or effects may modify the PCEs of the critical habitat, the Agency concludes a preliminary “may affect” determination for the FIFRA regulatory action regarding metolachlor/S-metolachlor. A summary of the risk estimation results are provided in **Table 5-15** for direct and indirect effects to the listed species assessed here and in **Table 5-16** for the PCEs of their designated critical habitat.

Table 5-15. Risk Estimation Summary for Metolachlor/S-Metolachlor - Direct and Indirect Effects to the Delta Smelt and California Tiger Salamander

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
Freshwater Fish and Aquatic-phase Amphibians	Non-listed Species (Yes: chronic)	Acute (both parent and degradates) risk quotients exceeded LOC for none of the registered metolachlor/S-metolachlor uses. However, chronic RQs exceeded for 5 uses that included cabbage, Swiss chard, spinach, sorghum, and safflower.	<u>Indirect Effects</u> : CTS (all 3 DPSs) (prey)
	Listed Species (Yes: chronic)		<u>Direct Effects</u> : DS and CTS (all 3 DPSs)
Freshwater Invertebrates	Non-listed Species (Yes: chronic)	Acute RQs (both parent and the degradates) did not exceed non-listed species LOC for any metolachlor/S-metolachlor uses; however, chronic (parent) RQs exceeded levels of concern for almost all uses except meadow foam	<u>Indirect Effects</u> : DS (prey) and CTS (all 3 DPSs) (prey)
Estuarine/Marine Fish	Non-listed Species (Yes: chronic)	Risk quotients, based on acute exposure, did not exceed listed and non-listed species LOC for any of the registered metolachlor/S-metolachlor (both parent and degradates) uses; However, chronic RQs exceeded LOCs for few metolachlor/S-metolachlor uses for both listed and non-listed species	<u>Indirect Effects</u> : None
	Listed Species (Yes: chronic)		<u>Direct Effects</u> : DS
Estuarine/Marine Invertebrates	Non-listed Species (No)	Neither acute nor chronic risk quotients exceeded non-listed species LOC for any of the registered metolachlor/S-metolachlor uses	<u>Indirect Effects</u> : DS (prey)
Vascular Aquatic Plants	Non-listed Species (Yes)	Aquatic vascular plant RQs exceeded LOC for one non-food use of parent metolachlor/S-metolachlor. RQs exceeded LOC for most food uses.	<u>Indirect Effects</u> : DS and CTS (all 3 DPSs) (food/habitat for both)

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
		None of the LOCs exceeded risk LOCs for the degradates	
Non-Vascular Aquatic Plants	Non-listed Species (Yes)	Aquatic non-vascular plant RQs exceeded LOC for most of the parent metolachlor/S-metolachlor food uses and 1 non-food use; however, none of the acute RQs exceeded risk LOCs for the degradates	<u>Indirect Effects</u> : DS and CTS (all 3 DPSs) (food/habitat for both)
Birds, Reptiles, and Terrestrial-Phase Amphibians	Listed Species (Yes: chronic)	Except for corn and potato, chronic RQs did not exceed LOC for any of the metolachlor/S-metolachlor uses	<u>Direct Effects</u> : CTS (all 3 DPSs)
Mammals	Non-listed Species (Yes: chronic)	Acute RQs did not exceed non-listed mammalian LOCs for any uses of metolachlor/S-metolachlor; however, chronic RQs exceeded mammalian LOCs for almost all uses except spinach and meadowfoam	<u>Indirect Effects</u> : CTS (all 3 DPSs) (prey/habitat)
Terrestrial Invertebrates	Listed Species (No)	Risk could not be calculated as the endpoints were non-definitive; Based on acute oral and contact studies which suggest that metolachlor/S- metolachlor is practically non-toxic to honey bees, risk is not predicted	<u>Indirect Effects</u> : CTS (all 3 DPSs) (prey)
Terrestrial Plants - Monocots	Non-listed Species (Yes) - Only non-listed LOCs were evaluated because DS and CTS do not have an obligate relationship with terrestrial monocots and dicots	Terrestrial plant LOC is exceeded for all uses of metolachlor/S-metolachlor for both monocot and dicot plants in semi-aquatic and dry areas	<u>Indirect Effects</u> : DS and CTS (all 3 DPSs) (habitat for both)
Terrestrial Plants - Dicots			

Table 5-16. Risk Estimation Summary for Metolachlor/S-Metolachlor – Effects to Designated Critical Habitat (PCEs) of Delta Smelt and California Tiger Salamander

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
Freshwater Fish and Aquatic-phase Amphibians	Non-listed Species (Yes: chronic)	Acute (both parent and degradates) risk quotients exceeded LOC for none of the registered metolachlor/S-metolachlor uses. However, chronic RQs exceeded for 5 uses that included cabbage, Swiss chard, spinach, sorghum, and safflower.	DS and CTS (all 3 DPSs)
	Listed Species (Yes: chronic)		DS and CTS (all 3 DPSs)
Freshwater Invertebrates	Non-listed Species (Yes: chronic)	Acute RQs (both parent and the degradates) did not exceed non-listed species LOC for any metolachlor/S-metolachlor uses; however, chronic (parent) RQs exceeded levels of concern for almost all uses except meadow foam	DS and CTS (all 3 DPSs)
Estuarine/Marine Fish	Non-listed Species (Yes: chronic)	Risk quotients, based on acute exposure, did not exceed listed and non-listed species LOC for any of the registered metolachlor/S-metolachlor (both parent and degradates) uses; However, chronic RQs exceeded LOCs for few metolachlor/S-metolachlor uses for both listed and non-listed species	DS
	Listed Species (Yes: chronic)		DS
Estuarine/Marine Invertebrates	Non-listed Species (No)	Neither acute nor chronic risk quotients exceeded non-listed species LOC for any of the registered metolachlor/S-metolachlor uses	DS
Vascular Aquatic Plants	Non-listed Species (Yes)	Aquatic vascular plant RQs exceeded LOC for one non-food use of parent metolachlor/S-metolachlor. RQs exceeded LOC for most food uses. None of the LOCs exceeded risk LOCs for the degradates	DS and CTS (all 3 DPSs)
Non-Vascular Aquatic Plants	Non-listed Species (Yes)	Aquatic non-vascular plant RQs exceeded LOC for most of the parent metolachlor/S-metolachlor food uses and 1 non-food use; however, none of the acute RQs exceeded risk LOCs for the degradates	DS and CTS (all 3 DPSs)
Birds, Reptiles, and Terrestrial-Phase Amphibians	Listed Species (Yes: chronic)	Except for corn and potato, chronic RQs did not exceed LOC for any of the metolachlor/S-metolachlor uses	CTS (all 3 DPSs)
Mammals	Non-listed Species (Yes: chronic)	Acute RQs did not exceed non-listed mammalian LOCs for any uses of metolachlor/S-metolachlor; however, chronic RQs exceeded mammalian LOCs for almost all uses except	CTS (all 3 DPSs)

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
		spinach and meadowfoam	
Terrestrial Invertebrates	Listed Species (No)	Risk could not be calculated as the endpoints were non-definitive; Based on acute oral and contact studies which suggest that metolachlor/S-metolachlor is practically non-toxic to honey bees, risk is not predicted	CTS (all 3 DPSs)
Terrestrial Plants - Monocots	Non-listed Species (Yes) - Only non-listed LOCs were evaluated because DS and CTS do not have an obligate relationship with terrestrial monocots and dicots	Terrestrial plant LOC is exceeded for all uses of metolachlor/S-metolachlor for both monocot and dicot plants in semi-aquatic and dry areas	DS and CTS (all 3 DPSs)
Terrestrial Plants - Dicots			

Following a preliminary “may affect” 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 assessed species. 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 are “likely to adversely affect” the assessed species and its designated critical habitat.

The criteria used to make determinations that the effects of an action are “not likely to adversely affect” the assessed species or modify 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 assessed species and their designated critical habitat is provided in Sections 5.2.1 through 5.2.3. The effects determination section for each listed species assessed will follow a similar pattern. Each will start with a discussion of the potential for direct effects,

followed by a discussion of the potential for indirect effects. These discussions do not consider the spatial analysis. For those listed species that have designated critical habitat, the section will end with a discussion on the potential for modification to the critical habitat from the use of metolachlor/S-metolachlor. Finally, in Section 5.2.4, a discussion of any potential overlap between areas of concern and the species (including any designated critical habitat) is presented. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a No Effect determination is made.

5.2.1.a. Direct Effects to the DS

Delta smelt is adapted to living in both fresh and brackish water. The DS typically occupies estuarine areas with salinity below 2 parts per thousand and the freshwater edge of the saltwater-freshwater interface and spawns in fresh or slightly brackish water upstream of the mixing zone. Direct effects, both acute and chronic, to DS in freshwater and estuarine/marine environment are estimated based on freshwater fish toxicity data as this is more sensitive than the estuarine/marine fish toxicity data.

Model-estimated peak environmental concentrations resulting from different metolachlor/S-metolachlor (parent) uses ranged from 1.3 (meadowfoam) to 50.7 (Swiss chard) $\mu\text{g/L}$. Monitoring data suggest that the maximum reported concentrations of metolachlor were 3.9 $\mu\text{g/L}$ in the Orestimba Creek at the River Road near Crows Landing in Stanislaus County based on USGS NAWQA data and 1.8 $\mu\text{g/L}$ in Del Puerto Creek at Vineyard Avenue (a tributary to San Joaquin River) based on CADPR data. Comparison of the highest modeled surface water EEC for parent metolachlor/S-metolachlor (peak = 50.7 $\mu\text{g/L}$) with available surface water monitoring data from California indicates that the peak modeled EEC is approximately 13 (NAWQA) – 28 (CADPR) times higher than the maximum concentration of metolachlor detected in surface water. Therefore, use of modeled EECs is assumed to provide a conservative measure of metolachlor/S-metolachlor exposures for DS.

Based on the highest modeled EECs for parent metolachlor/S-metolachlor for Swiss chard [EEC = 50.7 (peak) and 46.1 (60-day average) $\mu\text{g/L}$ for liquid formulation applied by ground] and the most sensitive fish endpoints [bluegill sunfish for acute toxicity (LC_{50} = 3200 $\mu\text{g/L}$), calculated acute RQs are below the Agency's risk LOCs for freshwater fish for all metolachlor/S-metolachlor uses (for both liquid and granular formulations). Similarly, RQs calculated for metolachlor degradates ESA and OA did not exceed risk LOCs for any uses. Unlike acute RQs, chronic RQs exceeded LOCs for estuarine/marine fish (using the fathead minnow NOAEC of 30 $\mu\text{g/L}$). These chronic exceedances are based on only few metolachlor/S-metolachlor uses (cabbage, Swiss chard, spinach, safflower, sorghum, and sugarbeet). Therefore, direct effects, both in freshwater and estuarine habitat, are not expected on DS from any metolachlor/S-metolachlor uses.

In addition to no exceedances for acute (listed and non-listed) RQs for any food or non-food uses of metolachlor/S-metolachlor, the probability of individual effects was low enough that the likelihood of measuring such an effect was considered improbable. Based on the reported slopes of 14.8 and 4.4 in the bluegill sunfish and sheepshead minnow acute studies, respectively, the estimated chance of an individual acute mortality to the DS is calculated to be very low (1 in

1.57E+82 at LOC and 1.34E+192 at RQ for freshwater fish and 4.18E+08 at LOC and 5.02E+24 at RQ for estuarine/marine fish).

A total of 19 aquatic incidents (1 on S-metolachlor and 18 on metolachlor) in EHS database and 5 incidents in ASM database involving fish kills were reported for metolachlor/S-metolachlor. Except for 1 metolachlor incident that was listed as accidental misuse, all the other incidents from EHS database were reported to be unlikely from the use of metolachlor/S-metolachlor. More details on the fish incidents can be found in **Appendix L and Appendix M**.

Overall, in view of acute (all uses, listed and nonlisted) and chronic (most uses) RQs that are well below LOCs for both freshwater and estuarine/marine fish species, low probability of an individual mortality occurrence based on acute exposure, and reports of fish incidents for which the certainty is rated as unlikely, there is not a potential for metolachlor/S-metolachlor to cause direct adverse effects to the DS.

5.2.1.b. Direct Effects to the Aquatic-Phase CTS

The aquatic-phase CTS inhabits freshwater pools or ponds. Direct effects to the aquatic-phase CTS are estimated based on acute and chronic toxicity data from freshwater fish. The aquatic-phase considers life stages of the CTS 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 metolachlor/S-metolachlor.

Model-estimated peak environmental concentrations resulting from different metolachlor/S-metolachlor uses ranged from 1.3 to 50.7 µg/L. The maximum reported monitoring concentrations of metolachlor were 3.9 µg/L in the Orestimba Creek at the River Road near Crows Landing in Stanislaus County based on USGS NAWQA surface water monitoring data and 1.8 µg/L in Del Puerto Creek at Vineyard Avenue (tributary to San Joaquin River) based on CADPR monitoring data. Comparison of the highest modeled surface water EEC (peak = 38.6 µg/L) with available surface water monitoring data from California indicates that the peak modeled EEC is approximately 13 (NAWQA) – 28 (CADPR) times higher than the maximum concentration of metolachlor detected in surface water. Therefore, use of modeled EECs is assumed to provide a conservative measure of metolachlor/S-metolachlor exposures for DS.

Based on the registrant-submitted and open literature studies, the median lethal concentration for freshwater fish ranged from 3.2 (bluegill sunfish) to 14 (bluegill sunfish) mg ai/L. Reported acute toxicity values for crucian carp, channel catfish, guppy, and fathead minnow were 4.9, 4.9, 8.6, and 8 mg ai/L, respectively. Lethargy and loss of equilibrium were the most commonly noted sub-lethal effects in most of the acute exposure studies.

Based on the highest modeled peak aquatic EEC that resulted from metolachlor/S-metolachlor uses in Swiss chard (50.7 µg/L) and acute toxicity data from the bluegill sunfish study (LC_{50} = 3200 ppb), the calculated acute RQ is <0.05, which is less than the LOC for listed species (0.05). However, based on the highest modeled 60-day EEC from metolachlor/S-metolachlor uses in Swiss chard (46.1 µg/L) and chronic toxicity data from the fathead minnow study (NOAEC = 30 µg/L), calculated chronic RQ is >1.0 for some uses. Similar to parent metolachlor/S-

metolachlor, RQs calculated for metolachlor degradates ESA and OA did not exceed risk LOCs for any uses. As RQs did not exceed acute (all uses) or chronic (most uses) risk LOCs for any food or non-food metolachlor/S-metolachlor uses (for both parent and degradates), direct effects to aquatic-phase CTS (all 3 DPSs) are not expected.

Based on the reported slope of 14.8 in the bluegill sunfish study, the estimated chance of an individual acute mortality for the aquatic-phase CTS is calculated to be 1 in $1.57\text{E}+82$ with listed species LOC as the threshold and 1 in $1.34\text{E}+192$ at RQ level. Given the low probability of an individual mortality occurrence based on acute exposure and in view of acute and chronic RQs that are well below LOCs for freshwater fish, metolachlor/S-metolachlor is not likely to cause direct adverse effects to the aquatic-phase CTS (all 3 DPSs).

Open literature studies documented that acute toxicity endpoints for amphibians ranged between 13.6 (African clawed frog) to 76 (American bullfrog) mg ai/L (**Appendix G, Table G-8**). Comparison of the highest model-derived EECs to the above endpoints indicate that direct effects to the aquatic-phase CTS (all 3 DPSs) is unlikely. Sub-lethal effects noted in acute exposure studies included cellular damage and reduced length.

Two open literature studies [ECOTOX# 85815 using S-metolachlor on leopard frog (*Rana pipens*) and ECOTOX# 114296 using metolachlor on leopard frog and gray tree frog (*Hyla versicolor*)] tested chronic exposure effects of metolachlor/S-metolachlor either alone or in mixture with other pesticides. ECOTOX# 114296, which tested metolachlor at 7.4 µg/L, reported that metolachlor alone did not result in any sublethal effects (effects on time to metamorphosis, mass at metamorphosis, and survival to metamorphosis) in both leopard and gray tree frogs. ECOTOX# 85815, which tested S-metolachlor at 0.22 µg/L, reported sub-lethal effects such as reduced growth and development, changes in thymus histology, and increased thymus plaques leading to increased disease incidence. Both studies reported detrimental effects to frogs when metolachlor was mixed with nine other pesticides. Based on the model-derived chronic EEC of 13.5 µg/L for sorghum (scenario that resulted in highest 60-day average EEC), sublethal effects such as those reported in ECOTOX# 85815 may occur in frogs due to metolachlor/S-metolachlor uses. However, use of only one exposure concentration and non-reproducible nature of the results in the above study leads to some uncertainty about the sublethal effects in amphibians due to metolachlor/S-metolachlor uses.

A total of 19 fish incidents (1 on S-metolachlor and 18 on metolachlor) were reported for metolachlor/S-metolachlor in the EIIS database. Except for 1 metolachlor incident that was listed as accidental misuse, all the other incidents were reported to be unlikely from the use of metolachlor/S-metolachlor. More details on the fish incidents can be found in **Appendix L and Appendix M**.

In summary, as the listed and non-listed species LOCS were not exceeded for both parent and degradates of metolachlor/S-metolachlor, the probability of an individual mortality is low, and fish incidents are not likely due to labeled uses, there is not a potential for metolachlor/S-metolachlor to cause direct effects to the aquatic-phase CTS (all 3 DPSs).

5.2.1.c. Direct Effects to the Terrestrial-Phase CTS

Potential for direct effects to the terrestrial-phase CTS are assessed based on direct acute and chronic toxicity effects to birds as surrogate. In lieu of definitive endpoints on acute toxicity of metolachlor/S-metolachlor to birds, risk quotients were not calculated.

A comparison of the estimated highest terrestrial exposure concentrations for liquid formulations of metolachlor/S-metolachlor (1697 mg/kg bw on dose basis for small birds consuming short grass for corn which represents the highest application scenario) with the most sensitive acute oral avian LD₅₀ value (>2194 mg/kg bw) was made as if the endpoint was definitive. Using this approach, dose-based RQ was calculated to be <0.8 for corn scenario. RQ calculated based on this approach is an upper bound estimate; RQ for a definitive endpoint would be lower, but how much lower cannot be determined using this approach. Chronic RQs, calculated based a definitive avian endpoint, suggested that risk quotients exceeded listed species LOC for only 2 uses (corn and potato).

On the other hand, comparison of granular EECs (25 and 19.8 mg/ft² for corn and potato/peanut/soybean, respectively) with the adjusted avian LD₅₀ value of >1865 mg/kg bw [$LD_{50} (TW/AW)^{1.15-1} = >2194 (50/150)^{0.15} = >1865 \text{ mg ai/kg bw}$] indicates that likelihood of acute risk to terrestrial-phase CTS (all 3 DPSs) from granular applications of metolachlor/S-metolachlor is unlikely.

A refinement of the acute (dose-based) risks posed to the terrestrial-phase CTS from ingestion of residues on short grass was performed. This refinement was performed because the avian acute (only acute dose-based risks are refined by T-HERPS but not dietary-based acute or chronic risks) RQ values 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 EEC and RQ values based on dietary intake rate of an amphibian, rather than a dietary intake rate of an avian. Dose-based acute risk quotients for all the modeled use scenarios (based on broadcast spray applications) dropped below acute endangered species LOCs (0.1) using T-HERPS. Dose-based RQ for corn, which represents the highest application rate scenario, is <0.03. However, based on chronic risk quotients which exceeded listed species LOCs, risk to terrestrial-phase CTS (all 3 DPSs) are expected from metolachlor/S-metolachlor uses.

An additional refinement was conducted to evaluate how far away from the use site the terrestrial-phase CTS might be able to consume contaminated food items to determine if direct effects to CTS are likely. To evaluate this, T-REX was first used to determine the application rate at which the LOC was cleared for all food items. The clearance application rate was 1.0 lb ai/A. To determine how far away from the use site this “application rate” could occur for each crop, AgDrift was used to estimate the deposition. The AgDrift model was parameterized using fractions of the application collected on deposition cards, which would most closely approximate the “short grass” category. For the highest application rate of 4.0 lb ai/A (corn), off-site

deposition dropped below 1.0 lb ai/A at a distance of 23 feet from the use site. When estimating clearance distance, an important consideration is the foraging distance of the organism (T-REX is based on the assumption that the animal evaluated forages exclusively in the treated area). Thus, terrestrial-phase CTS foraging exclusively within 23 feet of the treatment site would be at risk. It is recognized that there is potential for off-site movement of the pesticide via biological vectors (*i.e.*, the residue deposited on or accumulated in the body of an animal leaving the field that is then consumed by the CTS), however at this time there is no standard method to evaluate it. It is anticipated biological vectors will not be an important exposure pathway for metolachlor/S-metolachlor because it is not bioaccumulative, a slow-acting poison, or potentially more toxic to a predator consuming the contaminated organism. On the other hand, based on refinement with T-HERPS, LOC was cleared for all food items for all uses. This means that terrestrial-phase CTS foraging in the application site will only be at risk from metolachlor/S-metolachlor applications.

The habitat for the terrestrial-phase CTS is mainly grasslands, oak Savannahs, and small mammal burrows. Since the predominant use of metolachlor/S-metolachlor in California is in agricultural crops, it is unlikely that CTS inhabits areas within 23 feet of agricultural fields.

Considering the facts that the toxicity endpoints are an upper bound estimate, no treatment related mortality was reported in any of the acute exposure studies, LOCs were not exceeded for dose-based RQs based on T-HERPS refinement, and effects would likely be confined to the use site, direct effects from metolachlor/S-metolachlor to the terrestrial phase CTS (all 3 DPSs) appear unlikely. Incidents on birds, the certainty of which is rated unlikely, provides an additional line of evidence that direct effects to terrestrial-phase CTS (all 3 DPSs) from metolachlor/S-metolachlor uses are unlikely.

5.2.1.d. Indirect Effects

i.a. Potential Loss of Prey to DS

The Delta smelt's diet consists primarily of planktonic copepods, cladocerans, amphipods, and insect larvae. Larvae feed on phytoplankton; juveniles feed on zooplankton. They live along the freshwater edge of the mixing zone (saltwater-freshwater interface), typically occupying estuarine areas with salinities below 2 parts per thousand, however, they have been found in areas up to 18 ppt. Therefore, their food source consists of both freshwater and saltwater invertebrates during most of their life, and brackish water plants as larvae.

Freshwater and Estuarine/Marine Invertebrates:

No acute RQs exceeded the LOCs for either listed (LOC = 0.05) or non-listed (LOC = 0.5) freshwater (for both parent and degradates) or estuarine/marine invertebrate (for parent metolachlor/S-metolachlor) species due to broadcast spray and granular applications of metolachlor/S-metolachlor. Based on the default slope of 4.5, the estimated chance of an individual acute mortality is calculated to be 1 in 4.18E+08 at the LOC level and 6.33E+09 at the RQ level for freshwater invertebrates. For estuarine/marine invertebrates, the estimated chance of an individual acute mortality, based on a reported slope of 4.4, is 1 in 2.92E+01 at the LOC level and 1 in 1.15E+02 at the RQ level.

While none of the estuarine/marine invertebrate chronic RQs exceeded LOCs, chronic risk LOCs were exceeded for freshwater invertebrates for all uses. Chronic toxicity to freshwater invertebrates was evaluated using an open literature study that used *Ceriodaphnia dubia*, one of the most sensitive aquatic invertebrate species, as the test organism. The lowest test concentration in this study was 0.001mg/L (the NOAEC) and the next test concentration (the LOAEC) was 0.010 mg/L, thus effects would be expected to occur somewhere within this range. Based on this particular study, it cannot be determined if the effects occur closer to the NOAEC or the LOAEC. Data from other studies generally showed effects at higher concentrations. For example, ECOTOX# 13689 determined a chronic reproductive NOAEC of 6.3 mg/L for *Ceriodaphnia dubia*, the endpoint of which is 3 orders of magnitude higher than the study used to calculate the risk quotients. The registrant-submitted guideline study for *Daphnia magna* resulted in a chronic reproductive NOAEC of 3.2 mg/L (MRID 43802601). Behavioral studies regarding the olfaction and fight response of the rusty crayfish produced a LOAEL of 25 µg/L (ECOTOX# 68515) and NOAEC/LOAEC of 67/80 µg/L, respectively (ECOTOX# 109340). Comparison of 21-day average EECs (49 µg/L for Swiss chard) with NOAEC values reported from other reproduction and behavioral studies suggest that effects to invertebrates are unlikely.

Based on the modeled peak concentrations of parent metolachlor, which ranged from 1.3 – 50.7 µg/L, and maximum reported concentrations for monitoring sites in California, which ranged from 1.9 to 3.9 µg/L, acute RQs that did not exceed LOCs for freshwater invertebrates, acute and chronic RQs that did not exceed LOCs for estuarine/marine invertebrates, freshwater invertebrate studies that documented chronic effects at levels higher than that used in RQ calculation for the same species (*Ceriodaphnia dubia*) and at concentrations 2 -3 orders of magnitude higher, measurable effects on aquatic invertebrates are not predicted due to metolachlor/S-metolachlor uses. Furthermore, the lack of aquatic invertebrate incidents and predicted lower chance of an individual mortality suggests that aquatic invertebrates, both freshwater and estuarine/marine, may not be affected by the currently registered uses of metolachlor/S-metolachlor. Therefore, indirect effects to DS through reduction of aquatic invertebrate prey items is unlikely.

i.b. Potential Loss of Prey to CTS

The diet of the aquatic-phase California tiger salamander is comprised of algae, snails, zooplankton, small crustaceans, and aquatic larvae and invertebrates, smaller tadpoles of Pacific tree frogs, CRLF, toads. The terrestrial-phase CTS feeds on terrestrial invertebrates, insects, frogs, and worms.

Aquatic Vertebrates:

There is no evidence in the literature that the aquatic-phase CTS consumes fish. However, indirect effects to CTS through direct effects to fish (prey items) were considered in this assessment as CTS eats other aquatic vertebrates such as frogs and fish serve as surrogates for frogs.

No listed or non-listed species acute (for both the parent and the degradates) LOCs were exceeded for freshwater fish. However, chronic RQs exceeded for only 5 uses (cabbage, Swiss chard, sorghum, safflower, and spinach) and these uses are the ones with lowest annual use rates.

Therefore, no indirect effects are anticipated to CTS based on this food component. In addition to no exceedances for acute RQs for any food or non-food uses of metolachlor/S-metolachlor, the probability of individual effects was low enough that the likelihood of measuring such an effect was considered improbable. Based on the reported slope of 14.8 in the bluegill sunfish acute study, the estimated chance of an individual acute mortality to fish is calculated to be 1 in $1.57\text{E}+82$. Given the low probability of an individual mortality occurrence based on acute exposure and in view of acute and chronic RQs that are well below LOCs, metolachlor/S-metolachlor is not likely to cause indirect adverse effects to the CTS (all 3 DPSs) through reduction of aquatic vertebrates prey items such as frogs.

Aquatic Invertebrates:

No acute (for both the parent and the degradates) RQs exceeded the LOCs for either listed (LOC = 0.05) or non-listed (LOC = 0.5) freshwater species due to broadcast spray and granular applications of metolachlor/S-metolachlor. Based on the default slope of 4.5, the estimated chance of an individual acute mortality is calculated to be very low (1 in $4.18\text{E}+08$ at the LOC level and 1 in $6.33\text{E}+09$ at the RQ level for freshwater invertebrates).

Chronic (for parent metolachlor/S-metolachlor) risk LOCs were exceeded for freshwater invertebrates for all uses. Chronic toxicity to freshwater invertebrates was evaluated using an open literature study that used *Ceriodaphnia dubia*, one of the most sensitive aquatic invertebrate species, as the test organism. The lowest test concentration in this study was 0.001 mg/L (the NOAEC) and the next test concentration (the LOAEC) was 0.010 mg/L; thus effects would be expected to occur somewhere within this range. Based on this particular study, it cannot be determined if the effects occur closer to the NOAEC or the LOAEC. Data from other studies generally showed effects at higher concentrations. For example, ECOTOX# 13689 determined a chronic reproductive NOAEC of 6.3 mg/L for *Ceriodaphnia dubia*, the endpoint of which is 3 orders of magnitude higher than the study used to calculate the risk quotients in this assessment. The registrant-submitted guideline study for *Daphnia magna* resulted in a chronic reproductive NOAEC of 3.2 mg/L (MRID 43802601). Behavioral studies regarding the olfaction and fight response of the rusty crayfish produced a LOAEL of 25 µg/L (ECOTOX# 68515) and NOAEC/LOAEC of 67/80 µg/L, respectively (ECOTOX# 109340). Comparison of 21-day average EECs (49 µg/L for Swiss chard) with NOAEC values reported from other reproduction and behavioral studies suggest that effects to invertebrates are unlikely.

Based on the modeled peak concentrations of metolachlor, which ranged from 1.3 – 50.7 µg/L, and maximum reported concentrations for monitoring sites in California, which ranged from 1.9 to 3.9 ppb, acute RQs that did not exceed LOCs for freshwater invertebrates, freshwater invertebrate studies that documented chronic effects at levels higher than that used in RQ calculation for the same species (*Ceriodaphnia dubia*) and at concentrations 2 -3 orders of magnitude higher, measurable effects on aquatic invertebrates are not predicted due to metolachlor/S-metolachlor uses. Furthermore, the lack of aquatic invertebrate incidents and predicted lower chance of an individual mortality suggests that aquatic invertebrates, both freshwater and estuarine/marine, may not be affected by the currently registered uses of metolachlor/S-metolachlor. Therefore, indirect effects to CTS (all 3 DPSs) through reduction of aquatic invertebrate prey items is unlikely.

Terrestrial Invertebrates:

Risk quotients were not calculated for terrestrial invertebrates as the available toxicity endpoints were non-definitive. The most sensitive test established that the acute contact and oral LD₅₀s were greater than the highest concentrations tested (200 and 85 µg ai/bee, respectively). How much higher the endpoint is cannot be determined from the studies. No other terrestrial invertebrate data were available on metolachlor/S-metolachlor.

A comparison of the estimated highest exposure concentrations for terrestrial invertebrates from liquid formulations of metolachlor/S-metolachlor (838 ppm for corn which represents the highest application scenario) with the most sensitive acute contact honey bee adjusted LD₅₀ value (1563 ppm) was made as if the endpoint was definitive. Using this approach, RQ was calculated to be 0.54 for corn scenario. This is above the LOC for terrestrial invertebrates (0.05) and therefore there is uncertainty regarding the risk to this taxa.

Based on the data from guideline studies, risk to terrestrial invertebrates appears unlikely as metolachlor/S-metolachlor is practically nontoxic to bees on acute oral and contact basis. However, this conclusion must be considered in light of the fact that very little data are available to represent a vast, diverse, and ecologically important taxa. The conclusion is consistent with other toxicity data that shows metolachlor to be primarily toxic to plants. While future ecotoxicity studies could affect the conclusion, based on the best available information at the time of the assessment no effects on terrestrial invertebrates are expected.

Mammals:

None of the acute RQs exceeded the non-listed species LOC for mammals. Chronic RQs, which ranged from 0.5 to 6, exceeded LOCs for all uses except spinach and meadowfoam. However, as the habitat for terrestrial-phase CTS is mainly grasslands, oak Savannahs, and small mammal burrows and since the predominant use of metolachlor/S-metolachlor in California is in agricultural crops, it is unlikely that mammals could be affected by metolachlor/S-metolachlor applications to agricultural crops such as corn, cotton, tomato, legume vegetables, and ornamental crops.

As a refinement, indirect effects to terrestrial-phase CTS through reduction of mammalian prey items was evaluated based on how far away from the use site terrestrial-phase CTS might be able to consume contaminated food items. To evaluate this, T-REX was first used to determine the application rate at which the LOC was cleared for all food items for CTS. The clearance application rate was 1.0 lb ai/A. To determine how far away from the use site this “application rate” could occur for each crop, AgDrift was used to estimate the deposition. The AgDrift model was parameterized using fractions of the application collected on deposition cards, which would most closely approximate the “short grass” category. For the highest application rate of 4 lb ai/A (corn), off-site deposition dropped below 1.0 lb ai/A at a distance of 23 ft from the use site. When estimating clearance distance, an important consideration is the foraging distance of the organism (T-REX is based on the assumption that the animal evaluated forages exclusively in the treated area). Thus, mammalian prey items and CTS foraging exclusively within 23 feet of the treatment site would be at risk. The Agency recognizes the potential for off-site movement of the

pesticide via biological vectors (*i.e.*, the residue deposited on or accumulated in the body of an animal leaving the field that is then consumed by the CTS), however at this time there is no standard method to evaluate it. It is anticipated that biological vectors will not be an important exposure pathway for metolachlor/S-metolachlor because it is not bio-accumulative, a slow-acting poison, or potentially more toxic to a predator consuming the contaminated organism.

Chronic effects could occur on mammals exposed to metolachlor/S-metolachlor applications. However, based on the facts that 1) metolachlor/S-metolachlor is not toxic to mammals on acute exposure basis 2) terrestrial-phase CTS habitat (rodent burrows in grasslands and oak Savannahs) is spatially distant from where metolachlor/S-metolachlor applications are typically made (agricultural fields) 3) metolachlor/S-metolachlor application and effects to mammals would likely be confined to the use site plus a 23 foot drift zone, indirect effects from metolachlor/S-metolachlor to the terrestrial phase CTS (all 3 DPSs) through mammalian prey reduction appears unlikely.

i. Potential Modification of Habitat

Aquatic Plants:

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 frogs. 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 aquatic species.

Potential indirect effects to the DS and CTS based on impacts to habitat and/or primary production are assessed using RQs from freshwater aquatic vascular and non-vascular plant data. Acute risk LOCs for vascular plants exceeded for most metolachlor/S-metolachlor (for parent) uses, except legume vegetables, celery, pepper, tabasco pepper, rhubarb, pumpkin, onion, radish, horse radish, peach, and ornamentals other than sod and shade trees. Acute risk LOCs for non-vascular plants were exceeded for seven crops, Swiss chard, cabbage, spinach, tomato, sunflower, safflower, and sorghum. On the other hand, vascular and non-vascular plant acute risk LOCs were not exceeded for either degradate for any food or non-food uses. Since acute risk LOCs exceeded from metolachlor/S-metolachlor uses in crops where reported annual use is the highest (example: corn), indirect effects (food and habitat modification) to DS and CTS (all 3 DPSs) are possible through effects to aquatic vascular and non-vascular plants.

Even though the DS and CTS depend on a wide range of non-vascular and vascular plants, it is expected that metolachlor/S-metolachlor, being a herbicide, would elicit adverse impacts on other vascular and non-vascular plants resulting in indirect effects to DS and CTS via direct habitat-related impacts to non-vascular and vascular plants. Therefore, there is a potential for metolachlor/S-metolachlor to cause indirect effects to DS and CTS (all 3 DPSs).

Presence of herbicides in the water bodies supporting the DS and CTS (all 3 DPSs) could reduce populations of sensitive vascular and non-vascular plants, and/or cause a shift in phytoplankton

community dynamics. Typically, aquatic plant populations are relatively dynamic, and the presence of herbicides in the water may result in an overall reduction of biomass, and/or a shift in community composition as more sensitive species are eliminated. Herbicides may also modify timing of maximum plant growth.

Terrestrial Plants:

Terrestrial plants serve several important habitat-related functions for the DS and CTS. In addition to providing habitat and cover for invertebrate and vertebrate prey items of the listed assessed species, terrestrial vegetation also provides shelter 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.

Terrestrial plant acute species risk LOCs were exceeded for all metolachlor/S-metolachlor uses, regardless the formulation type or application method (aerial versus ground). Acute RQs for monocot plants ranged from 106 – 425 and 135 – 250 for liquid and granular formulations, respectively. Acute RQs for dicot plants ranged from 89 – 358 for liquid applications and 114 – 210 for granular applications. This suggests that monocot plants are more sensitive to metolachlor/S-metolachlor compared to dicots.

Furthermore, terrestrial plant acute RQs calculated based on endpoints derived from seedling emergence studies were higher compared to those derived from vegetative vigor studies. Metolachlor is absorbed through the roots and the shoot of the plant, and is most efficacious when applied to the soil from which the plant absorbs it. This is also demonstrated by the difference in response in the two guideline studies. The EC₂₅ for seedling emergence test is 0.005 lb ai/A for monocots and 0.006 lb ai/A for dicots. For the vegetative vigor tests (more correlative to what would occur if metolachlor was deposited on a plant that was actively growing, as opposed to one that had just emerged) the EC₂₅ is 0.02 lb ai/A for monocots and 0.27 lb ai/A for dicots, a difference of an order of magnitude.

In a healthy riparian system, there is often a three-tier vegetation system, with trees as an overstory, shrubs as an understory, and grasses and forbs forming the ground cover. DS and aquatic-phase CTS may occupy waterbodies with dense riparian vegetation. Upland habitat for the terrestrial-phase CTS includes shrubs. While no guideline data are available for trees and shrubs, open literature data in ECOTOX indicates these woody species are far less sensitive to metolachlor, with effects noted in the 3.0 - 9.1 lb ai/A range. It is reasonable to presume that the shrub species in both types of habitats will intercept some of the metolachlor which might otherwise be deposited on the more sensitive herbaceous species. Additionally, in a natural system, senescent plants, fallen leaves, and other debris often provide a litter layer which might also serve to protect newly emerging herbaceous plants. Areas of bare soil in the CTS habitat are expected to be relatively small in comparison to the total habitat area. Thus, effects in a natural system are likely to be more closely approximated by the vegetative vigor endpoints than the seedling emergence endpoints.

In summary, based on exceedance of the terrestrial plant LOCs for all metolachlor/S-metolachlor uses 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:

- Metolachlor/S-metolachlor 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 metolachlor/S-metolachlor's mode of action and a comparison of seedling emergence EC₂₅ values to EECs estimated using TerrPlant, emerging or developing seedlings may be affected. Furthermore, based on the residual nature of metolachlor/S-metolachlor, 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 most species tested in 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 metolachlor/S-metolachlor via runoff and spray drift

A review of the EIIS database revealed 256 terrestrial plant incidents for metolachlor and 155 for S-metolachlor (**Appendix L and Appendix M**). Most of these reported plant incidents occurred under registered use conditions and were rated as either possible or probable. The most commonly reported damage was on corn, cotton, and soybean for S-metolachlor and corn, peanut and soybean for metolachlor.

In summary, terrestrial plant RQs are above LOCs; therefore, upland and riparian vegetation may be affected. However, woody plants are generally not sensitive to environmentally relevant metolachlor/S-metolachlor concentrations; therefore, effects on shading, bank stabilization, structural diversity (height classes) of vegetation, and woodlands are not expected. 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, DS and CTS may be indirectly affected by adverse effects to herbaceous vegetation which provides habitat and cover for the DS and CTS and its prey. Therefore, metolachlor/S-metolachlor has the potential to indirectly affect DS and CTS (all 3 DPSs).

5.2.2. Modification of Designated Critical Habitat

Based on the weight-of-evidence, there is a potential for the modification of designated critical habitat for DS and CTS based on freshwater invertebrate prey loss to both species due to changes in the composition of food supply. Aquatic and terrestrial plants are also at risk from metolachlor/S-metolachlor uses. However, risk to terrestrial plants is much higher compared to aquatic plants. As a result of risk to plants, both aquatic, and terrestrial, both DS and CTS (all 3 DPSs) will be impacted due to effects such as changes in primary productivity, modification of water quality parameters, habitat morphology, and/or sedimentation.

5.2.3. Spatial Extent of Potential Effects

Since LOCs are exceeded, analysis of the spatial extent of potential LAA effects is needed to determine where effects may occur in relation to the treated site. If the potential area of usage and subsequent Potential Area of LAA Effects overlaps with DS and CTS habitat or areas of occurrence and/or critical habitat, a likely to adversely affect determination is made. If the Potential Area of LAA Effects and the DS and CTS habitat and areas of occurrence and/or critical habitat do not overlap, a no effect determination is made.

To determine this area, the footprint of metolachlor/S-metolachlor's use pattern is identified, using corresponding land cover data. For metolachlor and S-metolachlor, these land cover types include cultivated, orchard/vineyard, developed open/developed low/developed medium/developed high, and turf. Actual usage is expected to occur in a smaller area as the chemical is only expected to be used on a portion of the identified area. The spatial extent of the effects determination also includes areas beyond the initial area of concern that may be impacted by runoff and/or spray drift (Use Footprint + distance down stream or down wind from use sites where organisms relevant to the assessed species may be affected). The determination of the buffer distance and downstream dilution for spatial extent of the effects determination is described below.

5.2.3.a. Spray Drift

In order to determine terrestrial and aquatic habitats of concern due to metolachlor/S-metolachlor exposures through spray drift, it is necessary to estimate the distance that spray applications can drift from the treated area and still be present at concentrations that exceed levels of concern. Ground applications of metolachlor/S-metolachlor granular formulations are not expected to result in any spray drift. For the flowable (liquid formulation) uses, a quantitative analysis of spray drift distances was completed using AgDRIFT (v. 2.01) using default inputs for ground applications (*i.e.*, high boom, ASAE droplet size distribution = Very Fine to Fine, 90th data percentile) and aerial applications (*i.e.*, ASAE Very Fine to Fine).

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 metolachlor/S-metolachlor. However, because no obligate relationship exists between the DS/CTS and terrestrial plants, the portion of the action area that is relevant to the DS and CTS is defined by the dissipation distance to the EC₂₅ level (*i.e.*, the potential buffer distance required to protect non-endangered terrestrial plant species).

Since the seedling emergence endpoint (EC₂₅ for ryegrass and lettuce = 0.0048 and 0.0057 lb ai/A, respectively) is more sensitive than the vegetative vigor endpoint (EC₂₅ for ryegrass and cucumber = 0.016 and 0.03 lb ai/A, respectively) and as metolachlor/S-metolachlor is a preemergence herbicide that inhibits roots of emerging/developing plants with no significant activity against existing vegetation, spray drift distances are derived using the seedling emergence endpoint for both monocots and dicots. For comparison purposes, spray drift

dissipation distances were also calculated using the vegetative vigor endpoint for monocots and dicots.

Spray drift dissipation distances for typical metolachlor/S-metolachlor use rates are presented in **Table 5-17**. Based on the endpoints derived for seedling emergence, adverse effects to terrestrial plants might reasonably be expected to occur at distances greater than 1000 feet for monocots and up to 991 feet for dicots from the use site for ground applications of metolachlor/S-metolachlor. For aerial applications, adverse effects to terrestrial plants might reasonably be expected to occur at distances greater than 1000 feet for both monocots and dicots. Vegetative vigor-based dissipation distances were lower than those calculated based on seedling emergence endpoints. 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 DS and CTS habitat) could affect the estimates presented in **Table 5-17**.

Table 5-17. Spray Drift Dissipation Distances for Metolachlor/S-Metolachlor

Use Scenario	Metolachlor/ S-Metolachlor Application Rate	Spray Drift Dissipation Distance (ft)			
		Seedling Emergence		Vegetative Vigor	
	(lb ai/A)	Monocots	Dicots	Monocots	Dicots
Ground Applications					
Corn	4	>1000	991	492	302
Spinach	1	430	377	154	85
Ornamental sod/shade trees	2.5	820	732	345	200
Meadowfoam	0.6	285	250	95	52
Aerial Applications					
Corn	4	>1000	>1000	>1000	>1000
Ornamental sod/shade trees	2.5	>1000	>1000	>1000	>1000

5.2.3.b. Downstream Dilution Analysis

The downstream extent of exposure in streams and rivers where the EEC could potentially be above levels that would exceed the most sensitive LOC is calculated using the downstream dilution model. To complete this assessment, the greatest ratio of aquatic RQ to LOC was estimated. Using an assumption of uniform runoff across the landscape, it is assumed that streams flowing through treated areas (*i.e.*, the Initial Area of Concern) are represented by the modeled EECs; as those waters move downstream, it is assumed that the influx of non-impacted water will dilute the concentrations of metolachlor/S-metolachlor present. The highest RQ/LOC ratio and the land cover class (cultivated crop) are used as inputs into the downstream dilution model.

The downstream dilution analysis is based on the greatest ratio of aquatic RQ to LOC, which was calculated to be 49 for metolachlor/S-metolachlor based on direct chronic effects. This value

was estimated using the NOAEC value for the most sensitive aquatic invertebrate species (*Daphnia magna*) of 1 ppb and 21-day average EEC from metolachlor/S-metolachlor applications to Swiss chard of 49 ppb. The downstream dilution approach is described in more detail in **Appendix K**. This value has been input into the downstream dilution model and results in a distance of 285 kilometers which represents the maximum continuous distance of downstream dilution from the edge of the Initial Area of Concern where LOCs may be exceeded in the aquatic environment.

5.2.3.c. Overlap of Potential Areas of LAA Effect and Habitat and Occurrence of DS and CTS

The spray drift and downstream dilution analyses help to identify areas of potential effect to the DS and CTS from registered uses of metolachlor/S-metolachlor. The Potential Area of LAA Effects on survival, growth, and reproduction for the DS and CTS from metolachlor/S-metolachlor spray drift extend from the site of application to >1000 feet from the site of application. For exposure to runoff and spray drift, the area of potential LAA effects extends up to 285 km downstream from the site of application. When these distances are added to the footprint of the Initial Area of Concern (which represents potential metolachlor/S-metolachlor use sites) and compared to DS and CTS habitat, there are several areas of overlap (**Figures 5-1 and 5-2**). The overlap between the areas of LAA effect and DS and CTS habitat, including designated critical habitat, indicates that metolachlor/S-metolachlor use in California has the potential to affect the DS and CTS (all 3 DPSs). More information on the spatial analysis is available in **Appendix K**.

Figure 5-1. Map Showing the Metolachlor/S-Metolachlor Use Overlap with the DS Critical Habitat and Occurrence Sections Identified by Case No. 07-2794-JCS

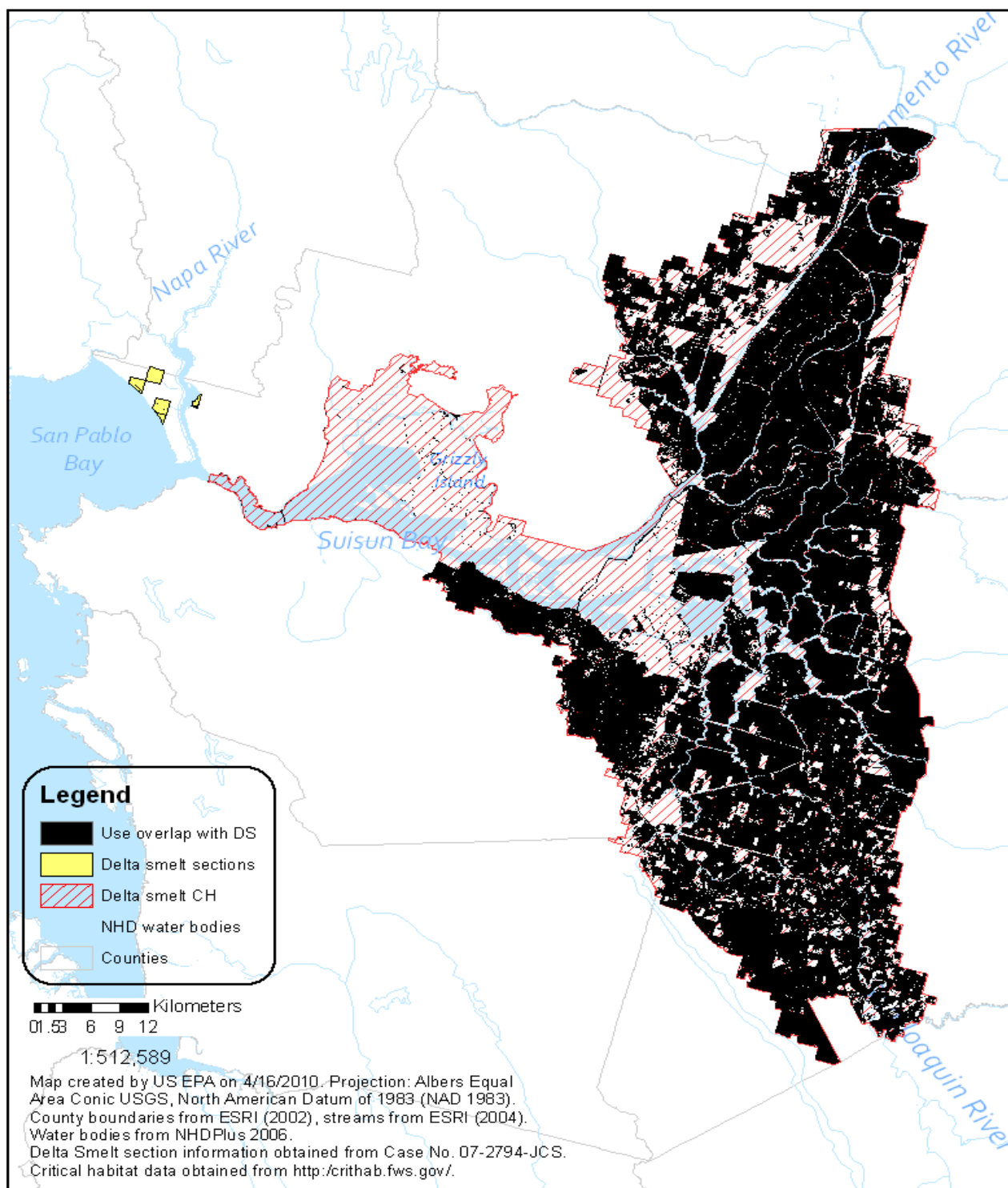
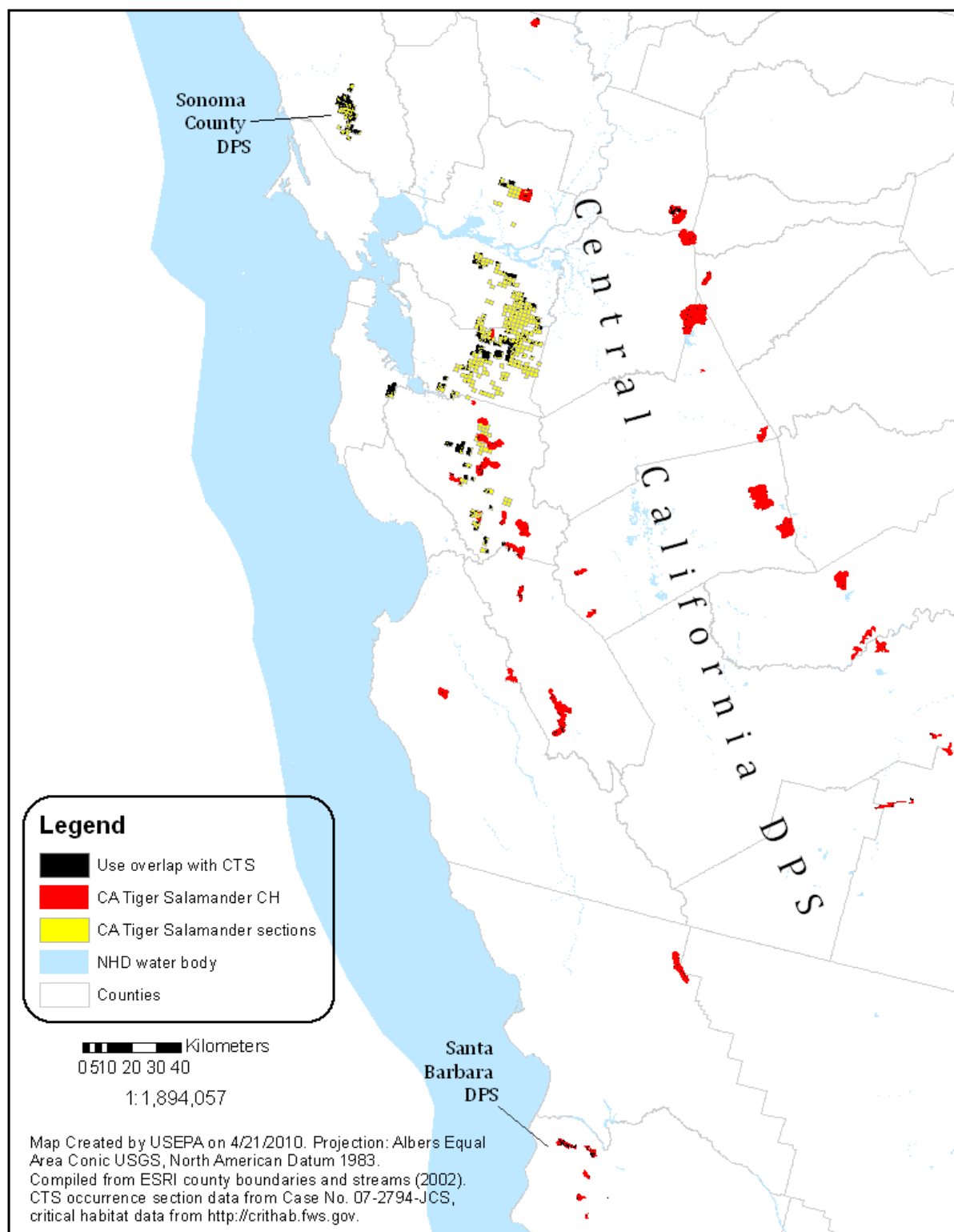


Figure 5-2. Map Showing the Metolachlor/S-Metolachlor Use Overlap with the DS Critical Habitat and Occurrence Sections Identified by Case No. 07-2794-JCS



5.3. Effects Determinations

5.2.1. DS and CTS

A comprehensive look at the available evidence suggests that direct effects to DS and CTS (both aquatic and terrestrial phases) are unlikely. However, indirect effects to DS and CTS are possible due to adverse effects on aquatic and terrestrial plants which may provide food and habitat for both the species. Therefore, the Agency makes a **may affect, and likely to adversely affect** determination for the DS and CTS (all 3 DPSs) and a **habitat modification determination** for their designated critical habitat based on the potential for direct and indirect effects and effects to the PCEs of critical habitat.

5.2.2. Addressing the Risk Hypotheses

In order to conclude this risk assessment, it is necessary to address the risk hypotheses defined in Section 2.8.1. Based on the conclusions of this assessment, two of the hypotheses that metolachlor/S-metolachlor may directly affect DS and CTS (all 3 DPSs) (both aquatic and terrestrial-phase) and indirectly affect their designated critical habitat by reducing or changing the composition of the food supply can be rejected. However, the other hypotheses listed below cannot be rejected:

- Metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and/or affect 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
- Metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and affect their designated critical habitat by reducing or changing the composition of the terrestrial plant community in the species' current range
- Metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and affect 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)

6. Uncertainties

Uncertainties that apply to most assessments completed for the San Francisco Bay Species Litigation are discussed in **Attachment 1**. This section describes additional uncertainties specific to this assessment.

6.1. Exposure Assessment Uncertainties

Overall, the uncertainties inherent in the exposure assessment tend to result in over-estimation of exposures. This is apparent when comparing modeling results with monitoring data. In particular, estimated peak exposures are generally an order of magnitude above 90th percentile site concentrations in the surface water monitoring data. In general, the monitoring data should be considered a lower bound on exposure, while modeling represents an upper bound.

6.1.1. Uncertainty Associated with 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 dependant on pest resistance, timing of applications, cultural practices, and market forces.

6.1.2. Aquatic Exposure Modeling of Metolachlor and S-Metolachlor

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 m³) 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, smelts travel from estuarine to lotic habitats and the exposure may not be accurately reflected by 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 DS. The EXAMS pond is assumed to be representative of exposure to the DS. 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 for metolachlor/S-metolachlor 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 metolachlor/S-metolachlor use areas.

6.1.3. Exposure in Estuarine/marine Environments

PRZM-EXAMS modeled EECs are intended to represent exposure of aquatic organisms in relatively small ponds and low-order streams. Therefore it is likely that EECs generated from the PRZM-EXAMS model will over-estimate potential concentrations in larger receiving water bodies such as estuaries, embayments, and coastal marine areas because chemicals in runoff water (or spray drift, etc.) should be diluted by a much larger volume of water than would be found in the 'typical' EXAMS pond. However, as chemical constituents in water draining from freshwater streams encounter brackish or other near-marine-associated conditions, there is potential for important chemical transformations to occur. Many chemical compounds can undergo changes in mobility, toxicity, or persistence when changes in pH, Eh (redox potential), salinity, dissolved oxygen (DO) content, or temperature are encountered. For example, desorption and re-mobilization of some chemicals from sediments can occur with changes in salinity (Jordan *et al.*, 2008; Means, 1995; Swarzenski *et al.*, 2003), changes in pH (*e.g.*, Wood

and Baptista 1993; Parikh et al. 2004; Fernandez et al. 2005), Eh changes (Velde and Church, 1999; Wood and Baptista, 1993), and other factors. Thus, although chemicals in discharging rivers may be diluted by large volumes of water within receiving estuaries and embayments, the hydrochemistry of the marine-influenced water may negate some of the attenuating impact of the greater water volume; for example, the effect of dilution may be confounded by changes in chemical mobility (and/or bioavailability) in brackish water. In addition, freshwater contributions from discharging streams and rivers do not instantaneously mix with more saline water bodies. In these settings, water will commonly remain highly stratified, with fresh water lying atop denser, heavier saline water – meaning that exposure to concentrations found in discharging stream water may propagate some distance beyond the outflow point of the stream (especially near the water surface). Therefore, it is not assumed that discharging water will be rapidly diluted by the entire water volume within an estuary, embayment, or other coastal aquatic environment. PRZM-EXAMS model results should be considered consistent with concentrations that might be found near the head of an estuary unless there is specific information – such as monitoring data – to indicate otherwise. Conditions nearer to the mouth of a bay or estuary, however, may be closer to a marine-type system, and thus more subject to the notable buffering, mixing, and diluting capacities of an open marine environment. Conversely, tidal effects (pressure waves) can propagate much further upstream than the actual estuarine water, so discharging river water may become temporarily partially impounded near the mouth (discharge point) of a channel, and resistant to mixing until tidal forces are reversed.

The Agency does not currently have sufficient information regarding the hydrology and hydrochemistry of estuarine aquatic habitats to develop alternate scenarios for assessed listed species that inhabit these types of ecosystems. The Agency acknowledges that there are unique brackish and estuarine habitats that may not be accurately captured by PRZM-EXAMS modeling results, and may, therefore, under- or over-estimate exposure, depending on the aforementioned variables.

6.1.4. Water Monitoring Data Limitations

The surface water monitoring data were derived from non-targeted monitoring programs. Therefore, the monitoring data may not represent the highest concentrations in drinking water source water. Furthermore, the sampling frequency for the monitoring data was not designed to capture peak concentrations. Therefore, the maximum concentrations in the monitoring data may underestimate the actual peak concentration.

6.1.5. Usage Uncertainties

County-level usage data were obtained from California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR-PUR) database. Eight years of data (1999 – 2007) 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. No methodology for removing outliers was provided by CDPR for 2001 and earlier pesticide data; therefore, this information was not included in the analysis because it may misrepresent actual usage patterns. 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 home owner 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.

6.1.6. Terrestrial Exposure Models

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.

Organisms consume a variety of dietary items and may exist in a variety of sizes at different life stages. For foliar applications of liquid formulations, T-REX estimates exposure for the following dietary items: short grass, tall grass, broadleaf plants/small insects, fruits/pods/seeds/large insects, and seeds for granivores. Birds (used as a surrogate for amphibians and reptiles) consume all of these items. The size classes of birds represented in T-REX are the small (20 g), medium (100 g), and large (1000 g). The size classes for mammals are small (15 g), medium (35 g), and large (1000 g). EECs are calculated for the most sensitive dietary item and size class for birds (surrogate for amphibians and reptiles) and mammals. **Table 6-1** shows the percentages of the EECs and RQs of the various dietary classes for each size class as compared to the most sensitive dietary class (short grass) and size class (small mammal or bird). This information could be used to further characterize potential risk that is specific to the diet of birds and mammals. For example, if a mammal only consumes broadleaf plants and small insects and the RQ was 100 for small mammals consuming short grass, the RQ for small mammals that only consumed broadleaf plants and small insects would be 56 (100 x 0.56).

Table 6-1. Percentage of EEC or RQ for the Specified Dietary Items and Size Classes as Compared to the EEC or RQ for The Most Sensitive Dietary Items (Short Grass) and Size Class (Small Bird or Small Mammal)

Dietary Items	Percentage of EECs or RQs for the Specified Dietary Items and Size Class as compared to the EEC or RQ for Small Birds ¹ or Small Mammals Consuming Short Grass					
	Birds: Dose Based EECs and RQs					
Size Class	Small, 20 g		Mid, 100 g		Large, 1000 g	
	EEC	RQ	EEC	RQ	EEC	RQ
Short Grass	100%	100%	57%	45%	26%	14%
Tall Grass	46%	46%	26%	21%	12%	7%
Broadleaf plants/small Insects	56%	56%	32%	25%	14%	8%
Fruits/pods/seeds/large insects	6%	6%	4%	3%	2%	1%
Granivores	1%	1%	1%	1%	0.4%	0.2%
Mammals: Dose-Based EECs and RQs						

Dietary Items	Percentage of EECs or RQs for the Specified Dietary Items and Size Class as compared to the EEC or RQ for Small Birds ¹ or Small Mammals Consuming Short Grass					
	Small, 15 g		Mid, 35 g		Large, 1000 g	
Size Class	EEC	RQ	EEC	RQ	EEC	RQ
Short Grass	100%	100%	69%	85%	16%	46%
Tall Grass	46%	46%	32%	39%	7%	21%
Broadleaf plants/small Insects	56%	56%	39%	48%	9%	26%
Fruits/pods/seeds/large insects	6%	6%	4%	5%	1%	3%
Granivores	1%	1%	1%	1%	0.2%	0.6%
Mammals and Birds: Dietary-based EECs and RQs for all Size Classes ²						
Short Grass	100%					
Tall Grass	46%					
Broadleaf plants/sm Insects	56%					
Fruits/pods/seeds/lg insects	6%					

¹ The percents of the maximum RQ shown here for birds are based on the Agency's default avian scaling factor of 1.15 (Mineau *et al.* 1996).

² Percentages for dose-based chronic EECs and RQs for mammals are equivalent to the acute dose-based EECs and RQs.

In the risk assessment, RQs were only calculated for the most sensitive dietary class relevant to the organisms assessed. For most organisms, not enough data is available to conclude that birds or mammals may not exclusively feed on a dietary class for at least some time period. However, most birds and mammals consume a variety of dietary items and thus the RQ will overestimate risk to those organisms. For example, the CCR is estimated to consume only 15% plant material (USFWS, 2003). Additionally, some organisms will not feed on all of the dietary classes. For example, many amphibians would only consume insects and not any plant material.

6.1.7. 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 METOLACHLOR/S-METOLACHLOR from multiple applications, each application of metolachlor/S-metolachlor 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 models spray drift from 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.*).

6.1.8. Modeled Versus Monitoring Concentrations

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 for metolachlor 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 metolachlor/S-metolachlor use areas. In this case, PRZM/EXAMS model-derived EECs were an order of magnitude more conservative than actual measured concentrations.

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 available as measures of effect for fish and aquatic invertebrates.

6.2.2. Use of Surrogate Species Effects Data

Guideline toxicity tests on metolachlor/S-metolachlor are not available for aquatic-phase amphibian; therefore, freshwater fish are used as surrogate species for aquatic-phase CTS. The available open literature information on metolachlor/S-metolachlor toxicity to aquatic-phase amphibians shows that acute and chronic ecotoxicity endpoints for aquatic-phase amphibians are generally less sensitive than freshwater fish. Therefore, endpoints based on freshwater fish ecotoxicity data are assumed to be protective of potential direct effects to aquatic-phase CTS. An extrapolation of the risk conclusions from the most sensitive tested species to the aquatic-phase 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 phyla. 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 characterization purposes.

Sublethal effects, including behavioral effects, have been linked to metolachlor/S-metolachlor. Where quantitative data existed, these effects were considered in the assessment, and appear to occur at concentrations higher than the frank effects used as assessment endpoints. Thus, based on data available at the time of this assessment, risk conclusions in the assessment are anticipated to be adequately protective in regards to sublethal effects.

6.2.4. Acute LOC Assumptions

The risk characterization section of this assessment includes an evaluation of the potential for individual effects. The individual effects probability associated with the acute RQ is based on the assumption that the dose-response curve fits a probit model. It uses the mean estimate of the slope and the LC_{50} to estimate the probability of individual effects.

6.2.5. Residue Levels Selection

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.

6.2.6. Extrapolation of Effects

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% (U.S. Environmental Protection Agency, 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.

6.2.7. Mixtures

The Delta smelt and the California tiger salamander and various components of their ecosystem may be exposed to multiple pesticides, introduced into its environment either via a multiple active ingredient formulated product, a tank mixture, or transport from independently applied active ingredients. Multiple pesticides may act in an additive, synergistic, or antagonistic fashion. Quantifying reasonable environmental exposures and establishing reasonable corresponding toxicological endpoints for the myriad of possible situations is beyond the scope of this document, and in some cases, beyond the current state of ecotoxicological practice. Mixtures could affect the DS and CTS in ways not addressed in this assessment. Exposure to multiple contaminants could make organisms more or less sensitive to the effects of metolachlor/S-metolachlor, thus the directional bias associated with environmental mixtures is unknown, and may vary on a case-by-case basis.

6.2.8. Non-Definitive Endpoints

The current assessment on metolachlor/S-metolachlor utilized avian and terrestrial invertebrate (honey bee) endpoints that were non-definitive as a result of which there is uncertainty regarding risk conclusions.. Guidance is currently being developed on how to address the uncertainty related to non-definitive endpoints.

The Agency's pesticide ecological testing guidelines allow for 'limit tests' for acute and sub-acute exposures (e.g., testing a chemical up to 2,000 mg a.i./kg-bw for birds and 25 µg a.i./bee for honey bees). Because only one concentration is typically tested in a limit test, an LC₅₀/EC₅₀/LD₅₀ value cannot be calculated from these studies. Additionally, some acute and/or sub-acute studies fail to demonstrate a definitive endpoint because an LC₅₀/EC₅₀/LD₅₀ value cannot be calculated based on the effects observed at the concentrations tested. If mortality does not reach 50% at the highest concentration tested, the resulting LC₅₀/EC₅₀/LD₅₀ is a 'greater than' value (e.g., LD₅₀ > 2,000 mg a.i./kg-bw), and the concentration that would result in 50% mortality is unknown. In some cases, relevant estimated environmental concentrations (EECs) for a pesticide with a non-definitive acute and/or sub-acute toxicity endpoint are higher than the highest concentrations tested.

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 metolachlor/S-metolachlor to DS and CTS and their designated critical habitat.

Based on the best available information, the Agency makes a “May Affect” determination for the DS and CTS. Additionally, the Agency has determined that there is the potential for modification of the designated critical habitat for the DS and CTS from the use of the chemical.

A summary of the risk conclusions and effects determinations for the DS and CTS and their critical habitat, given the uncertainties discussed in Section 6 and **Attachment 1**, is presented in **Table 7-1 and 7-2**. Use specific effects determinations are provided in **Tables 7-3 and 7-4**.

Table 7-1. Effects Determination Summary for Effects of Metolachlor/S-Metolachlor on the DS and CTS (all 3 DPSs)

Species	Effects Determination	Basis for Determination
California Tiger Salamander (<i>Ambystoma californiense</i>)	May Affect and Likely to Adversely Affect (LAA)	Potential for Direct Effects
		<i>Aquatic-phase (Eggs, Larvae, and Adults):</i> Based on freshwater fish endpoints as surrogate for the aquatic-phase CTS, acute (for both the parent and the degradates) RQs did not exceed the listed or non-listed species risk LOC for any metolachlor/S-metolachlor use. However, chronic RQs exceeded for 5 (Swiss chard, spinach, sorghum, safflower, and cabbage) metolachlor /S-metolachlor uses. Probit analysis, which suggested that the probability of an individual effect is low (1 in 1.57E+82 at LOC) and fish incident data which indicated that the certainty is unlikely, confirm that direct effects to aquatic-phase CTS (all 3 DPSs) are unlikely.
		<i>Terrestrial-phase (Juveniles and Adults):</i> Avian data were used as a surrogate to estimate direct effects to the terrestrial-phase CTS. In the absence of definitive acute toxicity endpoints, acute risk quotients were not calculated. Comparison of EECs with the acute endpoints (as if they were definitive) suggested that resulting RQs were an upper bound estimate (acute dose-based and dietary-based RQs were <0.6 and <0.2, respectively) and how much lower cannot be determined. A refinement of the above RQs based on THERPS suggested that acute RQs dropped below endangered species LOCs for all uses. Chronic RQs, on the other hand, exceeded endangered species LOC for all metolachlor/S-metolachlor uses. Based on the above, direct effects to all 3 DPSs of CTS are likely.
		Potential for Indirect Effects
		<i>Aquatic prey items, aquatic habitat, cover and/or primary productivity</i> Except for chronic risk LOC exceedances for aquatic invertebrates, no other LOC exceedances were noted for any other aquatic prey items. Based on an analysis of full toxicity data set, monitoring data, modeled EECs, incident data, and chance of an individual effect, indirect effects on aquatic prey items for CTS (all 3 DPSs) appear unlikely. Acute risk LOCS exceeded for aquatic vascular and nonvascular plants for most metolachlor/S-metolachlor (parent only) uses. However, acute risk LOCS were not exceeded for either metolachlor-OA or metolachlor-ESA for any use. As acute risk LOCs exceeded for uses in crops where the reported annual use is highest (example: corn), indirect effects to CTS (all 3 DPSs) are likely.
		<i>Terrestrial prey items, riparian habitat</i>

Species	Effects Determination	Basis for Determination
		<p>Risk to terrestrial invertebrates could not be calculated as the available acute toxicity endpoints were non-definitive. However, calculated acute and chronic mammalian RQs suggest that endangered species LOC was exceeded for almost all uses.</p> <p>Terrestrial plant risk LOC exceedances were noted for both monocots and dicots in wetlands and uplands adjacent to use sites for all crops in which metolachlor/S-metolachlor is registered. Therefore, indirect effects to CTS through habitat modification are likely.</p>
Delta smelt (<i>Hypomesus transpacificus</i>)	May Affect and Likely to Adversely Affect (LAA)	<p>Potential for Direct Effects</p> <p><i>Freshwater Life Stages (Eggs, Larvae, and Breeding Adults) and Saltwater Life Stages (Juveniles and Adults):</i> Acute (for both the parent and the degradates) RQs did not exceed the listed or non-listed species risk LOC for any metolachlor/S-metolachlor use. However, chronic RQs exceeded for only 5 (Swiss chard, spinach, sorghum, safflower, and cabbage) metolachlor /S-metolachlor uses. The above metolachlor/S-metolachlor uses are associated with low annual application rates. Probit analysis, which suggested that the probability of an individual effect is low (1 in 1.57E+82 and 1 in 4.18 E+08 at LOC for freshwater and estuarine/marine fish, respectively), and fish incident data which indicated that the certainty is unlikely, confirm that direct effects to freshwater and estuarine/marine fish are unlikely.</p>
		<p>Potential for Indirect Effects:</p> <p><i>Aquatic prey items, aquatic habitat, cover and/or primary productivity</i></p> <p>No acute RQs exceeded the listed or non-listed species LOCs for freshwater or estuarine/marine invertebrate species due to liquid or granular applications of metolachlor/S-metolachlor. No freshwater invertebrate acute risk LOC exceedances were noted with either metolachlor degradates for any of the uses. While none of the estuarine/marine invertebrate chronic RQs exceeded LOCs for parent metolachlor/S-metolachlor, chronic risk LOCs were exceeded for freshwater invertebrates for all uses. However, based on the analysis of full toxicity data set for invertebrate prey items, monitoring data, modeled EECs, incident data, and chance of an individual effect, indirect effects on aquatic prey items for DS appear unlikely.</p> <p>Acute risk LOCs exceeded for aquatic vascular and nonvascular plants for most parent metolachlor/S-metolachlor uses. However, acute risk LOCs were not exceeded for metolachlor degradates. As acute risk LOCs exceeded for parent metolachlor/S-metolachlor uses in crops where the reported annual use is highest (example: corn), indirect effects to DS are likely.</p> <p><i>Terrestrial prey items, riparian habitat</i> Terrestrial plant risk LOC exceedances were noted for both monocots and dicots in wetlands and uplands adjacent to use site for all crops in which metolachlor/S-metolachlor is registered. Therefore, indirect effects to DS through habitat modification are likely.</p>

Table 7-2. Effects Determination Summary for the Critical Habitat Impact Analysis

Designated Critical Habitat for:	Effects Determination	Basis for Determination
DS and CTS (all 3 DPSs)	May Affect and Likely to Adversely Affect (LAA)	<p>As summarized in Table 7-1, chronic risk LOCs were exceeded for freshwater invertebrate prey items of DS and aquatic-phase CTS (all 3 DPSs). Both acute and chronic risk LOCs were exceeded for terrestrial vertebrate prey items of the aquatic-phase CTS. Based on the above, metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and/or affect their designated critical habitat by reducing or changing the composition of the food supply.</p> <p>Data analysis suggests that both aquatic and terrestrial plants are at risk from metolachlor/S-metolachlor uses. Acute risk LOCS exceeded for aquatic vascular and nonvascular plants for most metolachlor/S-metolachlor uses. Terrestrial plant risk LOC exceedances were noted for both monocots and dicots in wetlands and uplands adjacent to use site for all crops in which metolachlor/S-metolachlor is registered. Overall, risk to terrestrial plants is significantly higher compared to the aquatic plants. Even though the DS and CTS depend on a wide range of aquatic and terrestrial plants, it is expected that metolachlor/S-metolachlor, being an herbicide, would elicit adverse impacts on plant communities. Based on the above, metolachlor/S-metolachlor may indirectly affect the DS and CTS (all 3 DPSs) and/or affect 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, the terrestrial plant community in the species' current range, and aquatic habitat in their current range via modification of water quality parameters, habitat morphology, and/or sedimentation.</p>

Table 7-3. Use Specific Summary of the Potential for Adverse Effects to Aquatic Taxa

Uses	Potential for Effects to Identified Taxa Found in the Aquatic Environment									
	Freshwater Vertebrates ¹		Estuarine/Marine Vertebrates ²		Freshwater Invertebrates ³		Estuarine/Marine Invertebrates ⁴		Vascular Plants ⁵	Non-vascular Plants ⁵
	Acute	Chronic ⁶	Acute	Chronic ⁶	Acute	Chronic	Acute	Chronic		
All Uses	No	Yes	No	Yes	No	Yes ⁷	No	No	Yes ⁸	Yes ⁹

¹A yes in this column indicates a potential for direct and indirect effects to DS

²A yes in this column indicates a potential for direct and indirect effects to DS. A yes also indicates a potential for direct and indirect effects for the CTS-CC, CTS-SC, and CTS-SB

³A yes in this column indicates a potential for CTS-CC, CTS-SB, CTS-SC, and DS

⁴A yes in this column indicates a potential for indirect effects to DS

⁵A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, CTS-SB, and DS

⁶All uses except cabbage, Swiss chard, spinach, sorghum, and safflower

⁷All uses except meadowfoam

⁸Except legume vegetables, celery, pepper, Tabasco pepper, rhubarb, pumpkin, onion, radish, horse radish, peach, meadowfoam and ornamental turf, herbs, and shrubs

⁹LOC exceeded for cabbage, Swiss chard, spinach, tomato, sunflower, safflower, and sorghum

Table 7-4. Use Specific Summary of the Potential for Adverse Effects to Terrestrial Taxa

Uses	Potential for Effects to Identified Taxa Found in the Terrestrial Environment						
	Small Mammals ¹		Small Birds ²		Invertebrates ³	Dicots ⁴	Monocots ⁴
	Acute ⁵	Chronic ⁶	Acute	Chronic ⁷	Acute ⁸		
All Uses	Yes	Yes	No	Yes	No	Yes	Yes

¹A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, and CTS-SB

²A yes in this column indicates a potential for direct and indirect effects to the, CTS-CC, CTS-SC, and CTS-SB

³A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, and CTS-SB

⁴A yes in this column indicates a potential for indirect effects to CTS-CC, CTS-SC, CTS-SB, and DS; LOC exceedances are evaluated based on the non-listed species

⁵All uses except alfalfa, cabbage and potato

⁶All uses except meadowfoam and spinach

⁷LOC exceeded for corn and potato only

⁸Risk is not assumed based on data generated from toxicity studies

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 to seek concurrence with the LAA determinations and to determine whether there are reasonable and prudent alternatives and/or measures to reduce and/or eliminate potential incidental take.

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 listed 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.

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- Enhanced information on the density and distribution of DS and CTS life stages within the action area and/or applicable designated critical habitat. 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 assessed species.
- Quantitative information on prey base requirements for the assessed species. While existing information provides a preliminary picture of the types of food sources utilized by the assessed species, 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 species and potential modification to critical habitat.

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