Attachment I:

Supplemental Information on Standard Procedures for Threatened and Endangered Species Risk Assessments on San Francisco Bay Species

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List of Commonly Used Abbreviations and Nomenclature

BCF	Bioconcentration Factor
CDPR	California Department of Pesticide Regulation
CDPR PUR	California Department of Pesticide Regulation Pesticide Use Reporting Database
CTS	California Tiger Salamander
DS	Delta Smelt
EC_{50}	50% (or Median) Effect Concentration
ECOTOX	EPA managed database of Ecotoxicology data
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division
ESA	Endangered Species Assessment
e.g.	Latin *exempli gratia* (“for example”)
et al.	Latin *et alii* (“and others”)
etc.	Latin *et cetera* (“and the rest” or “and so forth”)
EXAMS	Exposure Analysis Modeling System
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
ft	Feet
i.e.	Latin for *id est* (“that is”)
KABAM	$\underline{K}_{OW}$ (based) <u>A</u>quatic <u>B</u>io<u>A</u>ccumulation <u>M</u>odel
km	Kilometer(s)
Kd	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
LOC	Level of Concern
MA	May Affect
NASS	National Agricultural Statistics Service
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
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides and Toxic Substances
PCE	Primary Constituent Element
PRZM	Pesticide Root Zone Model
RQ	Risk Quotient
T-HERPS	Terrestrial Herpetofaunal Exposure Residue Program Simulation
T-REX	Terrestrial Residue Exposure Model
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey

1.0 Introduction

The purpose of this Attachment is to provide supplemental information on procedures and methodologies routinely used as part of the litigation-related threatened and endangered species risk assessments (ESAs) for the San Francisco Bay species. This Attachment is intended to reduce the size of the ESA by reducing repetitive information and providing all standard methodologies and language in one document to be used in association with the chemical- and species-specific ESAs. The information included in this Attachment is intended to provide standard procedures and language relative to three subsections of the ESA, including the problem formulation (Section 2), aquatic and terrestrial modeling approaches (Section 3), and generic uncertainties (Section 4).[1] This document is not comprehensive and does not fully describe the Environmental Fate and Effects Division's (EFED's) assessment methods. For a comprehensive discussion of the procedures used to evaluate potential risks to endangered species, see the Overview Document (USEPA, 2004).

2.0 Problem Formulation

Section 2 describes elements of the problem formulation that are common to all ESAs conducted for the San Francisco bay species and includes general descriptions of purpose, designated critical habitat (if applicable for the species being assessed), assessment and measurement endpoints, on overview of common exposure models, and measures to evaluate the risk assessment in Sections 2.1 through 2.4, respectively.

2.1 Purpose

In all assessments, direct and indirect effects to the specified species and potential modification to designated critical habitat are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA, 2004) and the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998). The effects determinations for each listed species assessed is based on a weight-of-evidence method that relies heavily on an evaluation of risks to each taxon relevant to assess both direct and indirect effects to the listed species and the potential for modification of their designated critical habitat (*i.e.*, a taxon-level approach). Screening level methods include use of standard models such as the Pesticide Root Zone Model coupled with the Exposure Analysis Model System (PRZM-EXAM), Terrestrial Residue Exposure Model (T-REX), TerrPlant, AgDRIFT, and AGDISP, all of which are described at length in the Overview Document. Additional refinements are made on a case by case basis as needed. Use of such information is consistent with the methodology described in the Overview Document (USEPA, 2004), which specifies that "the assessment process may, on a case-by-case basis, incorporate additional methods, models, and lines of evidence that EPA finds technically appropriate for risk management objectives" (Section V, page 31 of USEPA 2004).

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[1] The Section numbers used in this document do not correspond to the Section numbers used in the chemical and species specific risk assessments.

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 a specified pesticide is based on an action area. The action area is the area directly or indirectly affected by the federal action, as indicated by the exceedence 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 a specific pesticide may potentially involve numerous areas throughout the United States and its Territories. However, attention will be focused on relevant sections of the action area including those geographic areas associated with locations of the species 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 in the lawsuits regarding the potential use of a specific pesticide in accordance with current labels:

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

Some species have designated critical habitats associated with them. Designated critical habitat identifies specific areas that have the physical and biological features, (known as primary constituent elements or PCEs) essential to the conservation of the listed species. PCEs for each species are described in the main ESA.

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

If a determination is made that use of a specific pesticide "may affect" a listed species or its designated critical habitat, additional information is considered to refine the potential for exposure and for effects to each species and other taxonomic groups upon which these species depend (*e.g*, prey items). Additional information, including spatial analysis (to determine the geographical proximity of the assessed species' habitat and a pesticide's use sites) and further evaluation of the potential impact of a specific pesticide on the PCEs is also used to determine whether modification of designated critical habitat may occur. Based on the refined information, the Agency uses the best available information to distinguish those actions that "may affect, but are not likely to adversely affect" from those actions that "may affect and are likely to adversely affect" the assessed listed species and/or result in "no effect" or potential modification to the PCEs of its designated critical habitat. This information is presented as part of the Risk Characterization of the ESA.

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 use of a specific pesticide is expected to directly impact living organisms within the action area, critical habitat analysis is limited in a practical sense to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes (*i.e.*, the biological resource requirements for the listed species associated with the critical habitat or important physical aspects of the habitat that may be reasonably influenced through biological processes). Activities that may modify critical habitat are those that alter the PCEs and appreciably diminish the value of the habitat. Evaluation of actions related to use of a specific pesticide that may alter the PCEs of the assessed species' critical habitat form the basis of the critical habitat impact analysis. Actions that may affect the assessed species' designated critical habitat have been identified by the Services and are discussed further below.

2.2 Designated Critical Habitat

Critical habitat are designated for the California Alameda Whipsnake, Bay Checkerspot Butterfly, Valley Elderberry Longhorn Beetle, California Tiger Salamander – Central California Distinct Population Segment (DPS), California Tiger Salamander – Santa Barbara County DPS, Delta Smelt, and Tidewater Goby. The California Clapper Rail, California Tiger Salamander Sonoma County DPS, California Freshwater Shrimp, Salt March Harvest Mouse, San Francisco Garter Snake, and the San Joaquin Kit Fox do not have designated critical habitat.

'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 receives protection under Section 7 of the ESA through prohibition against destruction or adverse modification with regard to actions carried out, funded, or authorized by a federal Agency. Section 7 requires consultation on federal actions that are likely to result in the destruction or adverse modification of critical habitat.

To be included in a critical habitat designation, the habitat must be '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)). PCEs include, but are not limited to, 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. Information specific to each species is provided in each ESA.

2.3 Assessment Endpoints and Measures of Ecological Effect

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Selection of the assessment endpoints is based on valued entities (*e.g.,* San Francisco (SF) Bay species being assessed, organisms important in the life cycle of the assessed species, and the PCEs of its designated critical habitat), the ecosystems potentially at risk (*e.g.,* waterbodies, riparian vegetation, and upland and dispersal habitats), the migration pathways of the pesticide (*e.g.*, runoff, spray drift, *etc*.), and the routes by which ecological receptors are exposed to the pesticide (*e.g.,* direct contact, *etc*.).

2.3.1 Assessment Endpoints

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

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

In order to address the risk hypothesis, the potential for direct and indirect effects to the SF Bay species, prey items, and habitat is estimated based on a taxon-level approach. Using a risk quotient (ratio of exposure concentration to effects concentration) approach, the use, environmental fate, and ecological effects of the pesticide are characterized and integrated to assess the risks. 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 the chemical is estimated using the probit dose-response slope and either the level of concern or actual calculated risk quotient value.

2.4 Measures to Evaluate the Risk Hypothesis

2.4.1 Measures of Exposure

Measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) 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 models used to predict terrestrial EECs on food items are the Terrestrial Residue EXposure model (T-REX), Terrestrial Herptafaunal Exposure and Residue Program Simulation (T-HERPS), and K_{OW} (based) Aquatic BioAccumulation Model (KABAM). The model used to derive EECs relevant to terrestrial and wetland plants is TerrPlant. These models, which are discussed in further detail below, are parameterized using relevant reviewed registrant-submitted environmental fate data. Specific inputs used in the exposure models are included in the risk assessment.

2.4.1.1 Aquatic Exposure

PRZM and EXAMS are screening simulation models coupled with the input shell PRZM EXAMS Model Shell, version 5.0 (file name PE5.pl) to generate daily exposures and 1-in-10 year EECs that may occur in surface water bodies adjacent to application sites receiving the pesticide through runoff and spray drift. PRZM simulates pesticide application, movement and transformation on an agricultural field and the resultant pesticide loadings to a receiving water body via runoff, erosion and spray drift. EXAMS simulates the fate of the pesticide and resulting concentrations in the water body. The standard scenario used for ecological pesticide assessments assumes application to a 10-hectare agricultural field that drains into an adjacent 1-hectare water body, 2-meters deep (20,000 m^3 volume) with no outlet. The measure of exposure for aquatic species is the 1-in-10 year return peak or rolling mean concentration. The 1-in-10-year 60-day mean is used for assessing chronic exposure to fish; the 1-in-10-year 21-day mean is used for assessing chronic exposure for aquatic invertebrates.

2.4.1.2 Terrestrial Exposure

Terrestrial exposures are evaluated for both animal and plant taxa. Exposure to animals includes an evaluation of consumption through pesticide contaminated dietary items, whereas the modeled routes of exposure to plants include spray drift and both sheet and channelized run-off. Four models provide estimates of exposure to terrestrial organisms. These models include T-REX, T-HERPS, KABAM, and TerrPlant.

Exposure estimates for birds (surrogates for amphibians and reptiles) and mammals assumed to be in the target area or in an area exposed to spray drift are derived using the T-REX model. T-REX calculates risk quotients in three ways: 1) as exposure to dietary residues of pesticides applied to foliage, 2) LD_{50}/ft^2 analysis[2], and 3) seed treatment analysis.

For foliar applications, T-REX uses application information (application rate, number of applications, method of application) and the dissipation rate of a chemical applied to foliar surfaces to calculate pesticide residues on avian and mammalian food items. Upper-limit EECs and risk quotients are derived using the Kenaga nomograph, as modified by Fletcher *et al.* (1994). The Kenaga nomograph is based on a large set of actual field residue data. The upper limit values from the nomograph represent the 95th percentile of residue values from actual field measurements (Hoerger and Kenaga, 1972).

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[2] The $LD50/ft^2$ is most commonly used to estimate risk for granular formulations and for row, banded, and in-furrow applications. It can also be used to estimate risk to broadcast applications.

For modeling purposes, direct exposures to mammals and birds (also used as a surrogate for amphibians and reptiles) through contaminated food are estimated using the EECs for the most sensitive size class and dietary item for that species. Dietary-based and dose-based exposures of potential prey are assessed using the small mammal (15 g) and small bird (20 g) which consume short grass because these categories represent the highest RQs of the size and dietary categories in T-REX that are appropriate surrogates for the SF Bay species and some of the prey items. Estimated exposures to the pesticide by consumption of terrestrial insects use the dietary based EECs for small insects.

T-REX includes the capability to calculate the LD_{50}/ ft^2 risk index values. Conceptually, an LD_{50}/ft^2 is the amount of a pesticide estimated to kill 50% of exposed animals in each square foot of applied area. Although a square foot does not have defined ecological relevance, and any unit area could be used, risk presumably increases as the number of LD_{50}/ft^2 increases. The LD50/ft^2 is used to estimate risk for granular formulations and row, banded, and in-furrow applications. It may also be used for broadcast applications. For example, it is commonly used to assess exposure to bare ground broadcast applications. For additional information on the LD_{50}/ft^2 risk index, please refer to USEPA (1992). Finally, when pesticides are used as a seed treatment, T-REX uses the seeding rate to estimate exposure and risk.

The T-HERPS model is used as a refinement tool when there are exceedances to the SF Bay species in T-REX for amphibians and for estimated exposure for snakes. Currently, birds are used as surrogates for terrestrial-phase amphibians and reptiles. However, amphibians and reptiles are poikilotherms (body temperature varies with environmental temperature) while birds are homeotherms (temperature is regulated, constant, and largely independent of environmental temperatures). Therefore, amphibians and reptiles 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 and some reptiles 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 and some reptiles is likely to result in an over-estimation of exposure and risk for some reptiles and terrestrial-phase amphibians. Therefore, T-REX has been refined to the T-HERPS model (v. 1.0), which allows for an estimation of food intake for poikilotherms using the same basic procedure as T-REX to estimate avian food intake.

T-REX may underestimate exposure to snakes when birds are used as a surrogate and are assumed to eat similar dietary items because of the large meal size a snake may consume on a single day.[3] That is why birds consuming short grass in T-REX are used as the screen to determine whether further refinement in T-HERPS is needed for snakes. T-HERPS was modified to estimate exposure to snakes based on the maximum size prey item they could consume and is used to refine a risk estimate when LOCs are exceeded for small birds consuming short grass based on RQs estimated in T-REX. The following allometric equation

[3] When examining the same application rates and types, RQs calculated in T-REX for small birds consuming short grass are higher than or equal to the highest RQs estimated in T-HERPs for medium snakes consuming small herbivore mammals. Therefore, RQs calculated in T-REX for the small birds consuming short grass may be used as a screen for examining risk to snakes.

developed by King 2002 was used to estimate the maximum size prey items for snakes (King, 2002).

$$\text{Prey Size} = \text{Snake Mass}^{1.015}$$

The 95% confidence limits on the coefficient are 0.959 and 1.071 (King, 2002). The upper limit was used in T-HERPS to estimate exposure to snakes.

The KABAM model (an aquatic bioaccumulation model) is used to estimate potential bioaccumulation of pesticide residues in a freshwater aquatic food web for chemicals that are non-ionic, organic, have a K_{ow} between 4 and 8, and have the potential to reach aquatic areas. It also evaluates subsequent risks that these residues pose to SF Bay species via consumption of contaminated aquatic prey (*i.e.*, aquatic invertebrates and fish). The bioaccumulation assessment in KABAM is based on an aquatic food web bioaccumulation model published by Arnot and Gobas (2004). The model relies on both a pesticide's octanol-water partition coefficient (K_{OW}) to estimate uptake and elimination constants through the respiration and diet of aquatic organisms and the predicted water and sediment concentrations from PRZM/EXAMS to estimate concentrations of the pesticide in aquatic organisms. These estimated tissue concentrations are compared to toxicity values for various taxonomic groups that may eat aquatic organisms in order to evaluate potential risk. The current version of KABAM estimates risks only to terrestrial birds and mammals consuming aquatic prey.

EECs for terrestrial plants inhabiting dry and wetland areas are derived using TerrPlant. This model uses estimates of pesticides in runoff and in spray drift to calculate EECs from single pesticide applications. EECs are based upon solubility, application rate, and minimum incorporation depth.

2.3.2.3 Spray Drift and Downstream Dilution Exposure

Spray drift models, AGDISP and/or AgDRIFT (if applicable) are used to assess exposures of terrestrial animals to the pesticide deposited on terrestrial habitats by spray drift. AGDISP (Teske and Curbishley, 2003) is used to simulate aerial and ground applications. In addition to the buffered area from the spray drift analysis, the downstream extent of the pesticide that exceeds the LOC for the effects determination is also considered.

2.4.2 Measures of Effect

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

Unless data specific to reptiles and amphibians are available surrogate species are used to assess effects to amphibians and reptiles. The assessment of risk for direct effects to the terrestrial-phase tiger salamander, Alameda whipsnake, and/or San Francisco garter snake makes the assumption that toxicity of the pesticide to birds is similar to or less than the toxicity to terrestrial-phase amphibians and reptiles (this also applies to potential prey items). The same assumption is made for fish and aquatic-phase tiger salamanders, as well as potential prey items.

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

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

2.4.3 Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from agricultural and non-agricultural uses of a pesticide, and the likelihood of direct and indirect effects to SF Bay 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. For an assessment of the risks as a result of the use of a particular pesticide, 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).

Listed species LOCs are used for comparing RQ values for acute and chronic exposures of a pesticide directly to the SF Bay species being assessed. If estimated exposures directly to the assessed species are sufficient to exceed the listed species LOC from a particular use of the pesticide, then the effects determination for that use is “may affect”. When considering indirect effects to the assessed species due to effects to prey, the listed species LOCs are also used. If estimated exposures to the prey of the assessed species exceed the listed species LOC for a particular use, then the effects determination for that use is a "may affect." If the RQ being considered also exceeds the non-listed species acute risk LOC, then the effects determination is a LAA. If the acute RQ is between the listed species LOC and the non-listed acute risk species LOC, then further lines of evidence (*i.e*. probability of individual effects, species sensitivity distributions) are considered in distinguishing between a determination of NLAA and a LAA. If the RQ being considered for a particular use exceeds the non-listed species LOC for plants, the effects determination is "may affect". However, for the Bay Checkerspot Butterfly and the Valley Elderberry Beetle (which are considered obligates with a dicot), any exceedance of the endangered species LOC for dicots would result in an LAA determination.

3.0 Uncertainties

Supplemental information relative to generic uncertainties for the exposure and effects assessments is provided in Sections 3.1 through 3.2, respectively. Additional uncertainties specific to the assessed chemical are described in the risk assessment.

3.1 Exposure Assessment Uncertainties

3.1.1 Maximum Use Scenario

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

3.1.2 Impact of Vegetative Setbacks on Runoff

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.

3.1.3 Aquatic Exposure Modeling of the Pesticide

3.1.3.1 PRZM/EXAMS

The standard ecological water body scenario (EXAMS pond) used to calculate potential aquatic exposure to pesticides is intended to represent conservative estimates, and to avoid underestimations of the actual exposure. The standard scenario consists of application to a 10-hectare field bordering a 1-hectare, 2-meter deep (20,000 m^3) 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 are 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, some organisms may inhabit water bodies of different size and depth and/or are located adjacent to larger or smaller drainage areas than the EXAMS pond. The Services agree that the existing EXAMS pond represents the best currently available approach for estimating aquatic exposure to pesticides (USFWS/NMFS/NOAA, 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. In addition, the model assumption that granular applications have 0% spray drift may result in an underestimation of exposure for pesticides with this type of application.

In order to account for uncertainties associated with modeling, monitoring data (when relevant) may be compared to PRZM/EXAMS estimates of EECs.

3.1.4 Spatial Uncertainties

3.1.4.1 Potential for Effects in the 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 area involved in the action" (50 CFR §402.2). Based on an analysis of the Federal action, the action area is defined by the actual and potential use of the pesticide and areas where that use could result in effects. Specific measures of ecological effect for the assessed species that define the action area include any direct and indirect 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 scope of the SF Bay assessment limits consideration of the overall action area to those portions that may be applicable to the protection of the SF Bay species in question and their designated critical habitat within the state of California. As a result, 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 SF 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 the SF bay species and designated critical habitat may be affected or modified via endpoints associated with reduced survival, growth, or reproduction.

3.1.4.2 Impact of Run-off Assumptions on the Potential Area of LAA Effects

An example of an important simplifying assumption that may require future refinement is the assumption of uniform runoff characteristics throughout a landscape. It is well documented that runoff characteristics are highly non-uniform and anisotropic, and become increasingly so as the area under consideration becomes larger. The assumption made for estimating the aquatic potential area of LAA effects (based on predicted in-stream dilution) was that the entire landscape exhibited runoff properties identical to those commonly found in agricultural lands in this region. However, considering the vastly different runoff characteristics of: a) undeveloped (especially forested) areas, which exhibit the least amount of surface runoff but the greatest amount of groundwater recharge; b) suburban/residential areas, which are dominated by the relationship between impermeable surfaces (roads, lots) and grassed/other areas (lawns) plus local drainage management; c) urban areas, that are dominated by managed storm drainage and impermeable surfaces; and d) agricultural areas dominated by Hortonian and focused runoff (especially with row crops), a refined assessment should incorporate these differences for modeled stream flow generation. As the zone around the immediate (application) target area expands, there will be greater variability in the landscape; in the context of a risk assessment, the runoff potential that is assumed for the expanding area will be a crucial variable (since dilution at the outflow point is determined by the size of the expanding area). Thus, it important to know at least some approximate estimate of types of land use within that region. Runoff from forested areas ranges from 45 – 2,700% less than from agricultural areas; in most studies, runoff was 2.5 to 7 times higher in agricultural areas (*e.g*., Okisaka *et al*., 1997; Karvonen *et al.*, 1999; McDonald *et al*., 2002; Phuong and van Dam 2002). Differences in runoff potential between urban/suburban areas and agricultural areas are generally less than between agricultural and forested areas. In terms of likely runoff potential (other variables – such as topography and rainfall – being equal), the relationship is generally as follows (going from lowest to highest runoff potential):

Three-tiered forest < agroforestry < suburban < row-crop agriculture < urban.

There are, however, other uncertainties that should serve to counteract the effects of the aforementioned issue. For example, the dilution model considers that 100% of the agricultural area has the chemical applied, which is almost certainly a gross over-estimation. Thus, there will be assumed chemical contributions from agricultural areas that will actually be contributing only runoff water (dilutant); so some contributions to total contaminant load will really serve to lessen rather than increase aquatic concentrations. In light of these (and other) confounding factors, the Agency believes that this model gives us the best available estimates under current circumstances.

3.1.5 Usage Uncertainties

3.1.5.1 CDPR PUR Data

When available, county-level usage data are obtained from California’s Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database. Data from 1999 to the most recent complete year available are included in this analysis because methodologies for removing outliers are provided by CDPR for 1999 and earlier pesticide data. 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.

3.1.5.2 Organic Agriculture

In this assessment, the National Land Cover Dataset (NLCD) are used to identify potential areas where the pesticide can be used.[4] The NLCD data do not consider whether organic practices are commonly used in areas where crops are grown, as indicated by the NLCD data, or where endangered species may be found. Therefore, in areas where there is significant organic agriculture, the conclusions arrived at in the risk assessments are expected to be conservative. Significant portions of some counties in California are devoted to organic agriculture where only certain pesticides are allowed[5]. According to the National Agricultural Statistics Service (NASS) 2007 census on National Organic Standards cropland, which includes pasture and grazing land, California ranks at 6th place in states with the most percentage organic cropland, with seven counties having more than 10% of cropland devoted to organic agriculture. Marin County has up to 84% of available cropland devoted to organic, the highest in the state and nation.[6] The trend of increasing organic farming practices both in the number of farms and total acreage has been on the rise for many years. However, it is unknown how many organic farms revert back to regular farming practices and whether regular pesticides are used outside cropland areas under certification, such as for rodent control or rights of way management in peripheral areas.

3.1.6 Terrestrial Exposure Modeling

3.1.6.1 T-REX

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

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

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[4] CA CDPR Usage data are also analyzed to characterize current use practices.
[5] The National Organic Standards only allows certain approved pesticides under the National Organic Program for a minimum of three years before certification. See http://www.ams.usda.gov/AMSv1.0/nop for more information on the organic program and http://attra.ncat.org/pest.html for a summary of pesticide techniques and control methods.
[6] NASS 2007 data summarized at the state and county level using NASS Tables 1, 43 and 48 on total cropland, and total acres used for organic production.

underestimation of field exposure by food consumption by a factor of 1.25 – 2.5 for most food items.

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

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

3.1.6.2 T-HERPS

T-HERPS evaluates potential exposures to terrestrial-phase herpetofaunal species resulting from consumption of terrestrial organisms. Consistent with the standard assessment process for terrestrial organisms, T-HERPS does not evaluate a number of potential exposure routes, including dermal exposures, water intake/submersion, or inhalation. For some pesticides, each of these exposure routes could be significant for terrestrial-phase animals.

In the absence of data on terrestrial herpetofauna, T-HERPS uses avian toxicity data as a surrogate for risk estimation. Although differences in sensitivity may be expected, the lack of available toxicity data on reptiles and amphibians precludes a robust comparison to birds. This represents a source of uncertainty in the estimated risks to amphibians and reptiles.

T-HERPS calculates EECs for terrestrial-phase herptiles that consume mammals and other terrestrial-phase herptiles. The amount of chemical estimated to be in the prey animal, in most cases, is thought to be a conservative estimate of potential dietary exposure because T-HERPS assumes that a small prey animal is consuming its daily intake of contaminated food before being consumed by the assessed species. Depuration of the pesticide from the prey item due to excretion or metabolism has not been included in the estimation. Therefore, the EECs for chemicals that are short-lived in an animal are expected to represent an over-estimate of exposure. However, for chemicals that are bioaccumulative and are not readily degraded or excreted in an animal, the resulting exposure estimates could be low-end estimates because body burdens within the prey species would be expected to increase over time for bioaccumulative chemicals, resulting in potential body burdens that exceed the estimated daily dose calculated by T-HERPS. In addition, potential residues on the surface of potential prey items (*e.g.*, in the fur) were not estimated by T-HERPS. Additional residues would be expected to be on the prey item surface as well as within the prey item. Residues could be on prey items by several pathways, including direct deposition of spray drift or by contact of the prey animal with contaminated soil or foliage.

The daily food intake is estimated in T-HERPS, using an iguanid lizard allometric equation as presented in U.S. EPA (1993). This equation is used in T-HERPS to estimate potential exposures to all herptiles. Allometric equations specific for terrestrial-phase amphibians have not been identified. To test the assumption that use of the iguanid lizard allometric equation results in a reasonable approximation of terrestrial-phase amphibian food intake, measured food intake values reported for juvenile bullfrogs (*Rana catesbeiana*) of various weights reported by Modzelewski and Culley (1974, as cited in USEPA, 1993) were compared to estimates derived using the iguanid food intake allometric equation incorporated into T-HERPS for the same body weight range.

The analysis suggests that food intake values for juvenile bullfrogs in the Modzelewski and Culley (1974) study are reasonably approximated using the allometric equation for iguanid lizards. The data for juvenile bullfrogs reported daily food intake values that ranged from approximately 3% to 7% of their body weight. Estimates of daily food intake using T-HERPS for the same range of body weights (13 grams to 100 grams) ranged from approximately 3% to 5% body weight daily. This analysis suggests that use of the iguanid lizard allometric equation results in a reasonable approximation of food intake reported for terrestrial phase frogs.

An additional uncertainty of T-HERPS is associated with temperature influence on the food intake allometric equation. Given that terrestrial-phase frogs are poikilothermic, temperature may impact feeding rate. Temperature has not specifically been incorporated into the food ingestion allometric equation, and is not directly considered in T-HERPS.

The allometric equation used to estimate daily food intake assumes a typical or constant food intake rate daily. In reality, the amount of food consumed (and, therefore, potential exposures to pesticides) may vary significantly from day to day, depending on a number of factors including availability of particular food items and energy needs.

T-HERPS estimates potential exposures for a number of food items. EECs for a particular food item are calculated with the assumption that one food item is consumed daily. Terrestrial-phase herptiles may receive 100% of their daily diet from one food item for a particular day, especially if larger prey, such as a small mammal, is available. However, many terrestrial-phase herptiles may consume a variety of food items in a given day. T-HERPS estimates potential exposures resulting from consumption of a range of food items for the purpose of giving a high-end and low-end bounding estimate.

3.1.6.3 TerrPlant

TerrPlant's 10 to 1 ratio of target area to semi-aquatic non-target area is based on research indicating a pond located in Georgia with a six to seven foot typical depth requires a two acre drainage area per foot of depth (USDA, 1997). Although the data are derived from observations of aquatic areas (*e.g*., farm ponds), it is assumed that this ratio is relevant to low-lying semi-aquatic areas. There is some uncertainty associated with the depth of the ponds used for modeling purposes and the expected depth of a semi-aquatic area.

Consistent with a screening level approach, the application efficiency, which is the amount of applied pesticide reaching the target area, is assumed to be 100% for all applications. Application efficiency is considered separately from spray drift; where the sum of the two does not necessarily equal 100%.

Spray drift is estimated based on application method alone, without consideration of other potentially influential factors related to application, such as droplet size, wind speed and release height.

The model assumption that granular applications have 0% spray drift may result in an underestimation of exposure for pesticides with this type of application.

TerrPlant assumes that drift and runoff concentrations are uniform over the non-target area. In the field, decreasing concentration gradients are expected for each of these exposure pathways as the distance increases from the application site. If the dimensions (*i.e*., length and width) of the target area and non-target area where defined, the uncertainties associated with these assumptions could be explored.

For pesticides that involve ground incorporation applications with incorporation greater than one inch, less of the pesticide applied is vulnerable to runoff. In TerrPlant, the application rate is divided by the incorporation depth. The basis for calculation of effects of ground incorporation on pesticide runoff also originated from former assumptions related to modeling aquatic EECs. The assumption is that the incorporation depth in inches is directly related to the proportion of runoff. For example, incorporation of a pesticide to a depth of two inches would result in half of the application rate being available for runoff. This proportion is considered relevant up to six inches. Thus, the model assumes that the amount of pesticide in runoff is directly related to the depth to which the pesticide is incorporated into the ground. For further discussion of these procedures, the reader is referred to the TerrPlant User Manual (USEPA, 2006).

There are several assumptions related to temporal factors of exposure and effects. First, the model assumes that a pesticide contained in drift and runoff reaches the non-target area at the same time. This assumption is conservative because it is unlikely that a pesticide would move at equal rates in drift and runoff. Second, the model does not consider the coincidence of drift pesticide and runoff pesticide reaching the non-target area in time to reach the emergence portion of the plant's life cycle. If applied later in the plant's life cycle, it is possible that a pesticide will reach the non-target plants at stages of different sensitivities. It is uncertain whether or not an exposure which occurs at a different life stage of the plant is relevant to the RQ derived based on the early seedling stage of a plant's lifecycle (*i.e.*, this may have greater or lesser effect than indicated by the RQ).

Modeled pesticide concentrations in runoff are dependent solely upon the solubility of a pesticide. The amount of pesticide in runoff does not consider other relevant transport properties of a pesticide (*e.g.*, K_d). In addition, the model does not consider pesticide movement through the soil or contained in eroded soil.

The model does not incorporate parameters that would allow for photolytic, hydrolytic, or microbial degradation. In cases where degradation occurs, this leads to an uncertainty and likely overestimation in the amount of pesticide that would be present in runoff and in drift.

The RQ values which are currently derived by TerrPlant represent the risk of effects for single maximum applications. It is assumed that each single application would expose different plants (*i.e.*, due to different drift patterns). The modeling of EECs from single pesticide applications rather than multiple applications could result in underestimating pesticide exposures to plants.

For defining RQ values for plants exposed to runoff, measures of effect to seedling emergence are used; however, vegetative vigor could also be affected by runoff (*i.e.*, effects to plant roots). Limitations in the testing methods add uncertainty to the effects to vegetative vigor from runoff. For example, vegetative vigor studies employ a foliar spray application that does not evaluate root uptake and consequently effects to plant roots. Therefore, these effects are not measured and cannot be incorporated into RQ development.

There is an absence of data comparing the field concentrations of pesticides to EECs generated by TerrPlant. Therefore, the relevance of TerrPlant predictions to pesticide concentrations in the field is unknown.

3.1.6.4 KABAM

KABAM estimates risks to terrestrial birds and mammals consuming aquatic prey. There are several key assumptions and resulting uncertainties associated with modeling pesticide concentrations in tissues of aquatic organisms. These assumptions include the equations of the model itself and the parameterization of those underlying equations. Appendix A of the KABAM User's Guide (http://www.epa.gov/oppefed1/models/water/, USEPA, 2009) describes the assumptions associated with the equations of the bioaccumulation model, KABAM. A sensitivity analysis, which is included in Appendix A, was completed in order to explore exposure uncertainties associated with specific parameters of the equations and their influences on model outputs. Based on the sensitivity analysis, the parameters that have the greatest influence on model outputs include the K_{OW} value for the chemical of interest as well as water column and pore water estimated environmental concentrations (EECs).

Given the influence of water column and pore water EECs on the model outputs, the use of PRZM/EXAMS for deriving surface and pore water EECs introduces the assumptions and uncertainties associated PRZM and EXAMS to KABAM.

One major assumption of the model is that it assumes steady state, although sporadic peaks to aquatic organisms are expected, given the episodic nature of pesticide applications. For a chemical with a Log K_{OW} of approximately 5, comparison of the fish tissue EECs predicted using the steady state and dynamic bioaccumulation modeling with PRZM/EXAMS and the Arnot and Gobas bioaccumulation model (Arnot and Gobas, 2004) indicates predictions are similar (USEPA, 2008) when a 60-d average is selected for water and sediment concentrations as input to the steady state model. This result suggests that steady-state bioaccumulation modeling can provide useful predictions of bioaccumulation potential even with highly variable exposures, provided proper consideration of the averaging period associated with water and sediment concentrations is considered.

In the KABAM default settings, it is assumed that the elimination of the pesticide from aquatic organisms through metabolism does not occur, *i.e.*, the metabolism rate constant (k_M) is zero. In cases where pesticide metabolism does occur (*e.g.*, where fish rapidly depurate the pesticide in bioconcentration factor-BCF-studies), use of the default metabolism rate constant is likely to overestimate pesticide bioaccumulation. Appendix H of the KABAM User's Guide provides methods for estimating k_M for fish using empirical data provided in chemical-specific BCF studies.

The Arnot and Gobas (2004) model is generally appropriate for chemicals with Log K_{OW} values $\geq$4 to $\leq$8. Uncertainty increases as the value increases above 8 because the model has generally been validated using chemicals with Log K_{OW} values within the range of 4 to 8. Use of the KABAM model for chemicals with Log K_{OW} > 8 increases uncertainty in the model outputs because bioaccumulation predictions are based on extrapolations in its subroutines. For chemicals with Log K_{OW} < 4, exposure from food becomes insignificant because uptake and depuration across the gills controls the residue concentrations in the organism. Therefore, it is not necessary to run a food web model for these chemicals. In these cases, available BCF data are sufficient to predict residues in the aquatic species.

It is assumed that there is no predation within a trophic level of the aquatic food web in KABAM (*e.g.*, medium fish cannot prey upon medium fish). It is also assumed that mammals and birds only consume organisms from the aquatic system.

3.1.7 Spray Drift Modeling

AgDRIFT and AGDISP are used in spatial analysis to evaluate risk to terrestrial and aquatic organisms due to exposure to spray drift. Although there may be multiple chemical applications at a single site, 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 a pesticide from multiple applications, each application of the chemical would have to occur under identical atmospheric conditions (*e.g.*, same wind speed and – for plants – same wind direction) and (if it is an animal) the animal being exposed would have to be present directly downwind at the same distance after each application. Although there may be sites where the dominant wind direction is fairly consistent (at least during the relatively quiescent conditions that are most favorable for aerial spray applications), it is nevertheless highly unlikely that plants in any specific area would receive the maximum amount of spray drift repeatedly. It appears that in most areas (based upon available meteorological data) wind direction is temporally very changeable, even within the same day. Additionally, other factors, including variations in topography, cover, and meteorological conditions over the transport distance are not accounted for by the AgDRIFT/AGDISP model (*i.e.*, it models spray drift from aerial and ground applications in a flat area with little to no ground cover and a steady, constant wind speed and direction). Therefore, in most cases, the drift estimates from AgDRIFT/AGDISP may overestimate exposure even from single applications, especially as the distance increases from the site of application, since the model does not account for potential obstructions (*e.g.*, large hills, berms, buildings, trees, *etc*.). Furthermore, conservative assumptions are often made regarding the droplet size distributions being modeled ('ASAE Very Fine to Fine' for orchard uses and 'ASAE Very Fine' for agricultural uses), the application method (*e*.g., aerial), release heights and wind speeds. Alterations in any of these inputs would change the area of potential effect.

3.2 Effects Assessment Uncertainties

3.2.1 Age Class and Sensitivity of Effects Thresholds

It is generally recognized that test organism age may have a significant impact on the observed sensitivity to a toxicant. The acute toxicity data for fish are collected on juvenile fish between 0.1 and 5 grams. Aquatic invertebrate acute testing is performed on recommended immature age classes (*e.g*., first instar for daphnids, second instar for amphipods, stoneflies, mayflies, and third instar for midges).

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

3.2.2 Impact of Multiple Stressors on the Effects Determination

The influence of length of exposure and concurrent environmental stressors (*i.e.*, construction of dams and locks, fragmentation of habitat, change in flow regimes, increased sedimentation, degradation of quantity and quality of water in the watersheds of the action area, predators, *etc*.) will likely affect the species' response to a pesticide. Additional environmental stressors may increase sensitivity to the herbicide, although there is the possibility of additive/synergistic reactions. Timing, peak concentration, and duration of exposure are critical in terms of evaluating effects, and these factors are expected to vary both temporally and spatially within the action area. Overall, the effect of this variability may result in either an overestimation or underestimation of risk. However, as previously discussed, the Agency's LOCs are set to be protective given the wide range of possible uncertainties.

3.2.3 Exposure to Pesticide Mixtures

In accordance with the Overview Document and the Services Evaluation Memorandum (USEPA, 2004; USFWS/NMFS/NOAA, 2004), the single active ingredient is considered. However, the assessed species and its environments may be exposed to multiple pesticides simultaneously. Interactions of other toxic agents with the specific pesticide could result in additive effects, more than additive effects, or less than additive effects. As previously discussed, evaluation of pesticide mixtures is beyond the scope of ESA assessments because of the myriad of factors that cannot be quantified based on the available data. Those factors include identification of other possible co-contaminants where some of the SF Bay species reside and their concentrations, differences in the pattern and duration of exposure among contaminants, and the differential effects of other physical/chemical characteristics of the receiving waters (*e.g.*, organic matter present in sediment and suspended water). Evaluation of factors that could influence additivity/synergism/antagonism is beyond the nature and quality of the available data to allow for an evaluation. However, it is acknowledged that not considering mixtures could over- or under-estimate risks depending on the type of interaction and factors discussed above.

3.2.4 Uncertainty in the Potential Effect to Riparian Vegetation vs. Water Quality Impacts

Effects to riparian vegetation are evaluated using submitted guideline seedling emergence and vegetative vigor studies. In cases where LOCs are exceeded for seedling emergence endpoints and/or vegetative vigor endpoints, it may be concluded that the chemical use is likely to adversely affect the SF Bay species by potentially impacting grassy/herbaceous riparian vegetation resulting in increased sedimentation. However, the characterization of riparian areas is uncertain due to a lack of readily available information on riparian areas.

In addition, soil retention/sediment loading is dependent on a number of factors including land management and tillage practices. Therefore, although an assessment may conclude that a chemical is likely to adversely affect the assessed listed species and their designated critical habitat by potentially impacting sensitive herbaceous riparian areas, it is possible that adverse impacts on sediment loading may not occur in areas where soil retention strategies are used.

4.0 References

Arnot, J. A., & Gobas, F. A. P. C. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. *Environmental Toxicology and Chemistry, 23*(10), 2343-2355.

Fletcher, J. S., Nellessen, J. E., & Pfleeger, T. G. 1994. Literature review and evaluation of the EPA food-chain (Kenaga) nomogram, an instrument for estimating pesticide residues on plants. *Environmental Toxicology and Chemistry, 13*(9), 1383-1391.

Hoerger, F., & Kenaga, E. E. 1972. Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of their Magnitude in the Environment. In F. Coulston & F. Korte (Eds.), *Environmental Quality and Safety: Chemistry, Toxicology, and Technology* (Vol. 1, pp. 9-28). New York: Academic Press.

Karvonen, T., Koivusalo, H., Jauhiainen, M., Palko, K., & Weppling, K. 1999. A hydrological model for predicting runoff from different land use areas. *Journal of Hydrology, 217*(3-4), 253-265.

King, R. B. 2002. Predicted and observed maximum prey size - snake size allometry. *Functional Ecology, 16*, 766-772.

McDonald, M. A., Healey, J. R., & Stevens, P. A. 2002. The effects of secondary forest clearance and subsequent land-use on erosion losses and soil properties in the Blue Mountains of Jamaica. *Agriculture, Ecosystems & Environment, 92*(1), 1-19.

Modzelewski, E. H., Jr.; Culley, D. D., Jr. (1974.) Growth responses of the bullfrog, Rana catesbeiana fed various live foods. *Herpetologica* 30: 396-405.

NASS. 2007. *Census of Agriculture*. United States Department of Agriculture. National Agricultural Statistics Service. Issued February 4, 2009. Revised December 2009. U.S. Summary and State Reports Volume 1. Available online at: http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_1_State_Level/California/index.asp

Okisaka, S., Murakami, A., Mizukawa, A., Ito, J., Vakulenko, S. A., Molotkov, I. A., et al. 1997. Nonpoint source runoff modeling: A comparison of a forested watershed and an urban watershed on the South Carolina coast. *Journal of Experimental Marine Biology and Ecology, 213*(1), 133-149.

Phuong, V. T., & van Dam, J. 2002. Linkages between forests and water: A review of research evidence in Vietnam. *European Tropical Forest Research Network (ETFRN) News: Forests, Water and Livelihoods 45/46,* 3pp.Available at http://www.etfrn.org/etfrn/newsletter/news4546/nl45_oip_05.htm (Accessed January 27, 2010).

Teske, M. E., & Curbishley, T. B. 2003. *AGDISP Version 8.07 User Manual*. Prepared For United States Department of Agriculture Forest Service. C.D.I. Technical Note No. 02-06. June 2003.

USDA. 1997. *Ponds – Planning, design, construction*. United States Department of Agriculture. Issued June 1992. Revised November 1997. Agriculture Handbook 590. Available online at: http://www.in.nrcs.usda.gov/pdf%20files/PONDS.PDF

USEPA. 1992a. *Comparative analysis of acute avian risk from granular pesticides*. Office of Pesticide Programs. USEPA. March 1992.

USEPA. 1993. *Wildlife Exposure Handbook, United States Environmental Progection Agency*. Washington, D.C.: Government Printing Office. Available at http://www.epa.gov/ncea/pdfs/toc2-37.pdf (Accessed June 19, 2009).

USEPA. 2006. *User's Guide TerrPlant version 1.2.2*. December 2006. United States Environmental Protection Agency. Environmental Fate and Effects Division. Office of Pesticide Programs.

USEPA. 2004. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. United States Environmental Protection Agency (USEPA). Environmental Fate and Effects Division. Office of Pesticide Programs. Available at http://www.epa.gov/espp/consultation/ecorisk-overview.pdf (Accessed June 19, 2009).

USEPA. 2008. *White paper on Methods for Assessing Ecological Risks of Pesticides with Persistent, Bioaccumulative, and Toxic Characteristics*. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment. October 7, 2008. Environmental Fate and Effects Division. Office of Pesticide Programs. Office of Prevention, Pesticides, and Toxic Substances. United States Environmental Protection Agency. Available at http://www.epa.gov/scipoly/SAP/meetings/2008/october/sap_pbt_whitepaper_final_Oct_7_08d.pdf (Accessed January 27, 2010).

USEPA. 2009. *User's Guide and Technical Documentation KABAM version 1.0 (KOW (based) Aquatic BioAccumulation Model).* April 7, 2009. Environmental Fate and Effects Division. Office of Pesticide Programs. Available at http://www.epa.gov/oppefed1/models/water/kabam/kabam_v1_0_users_guide.pdf (Accessed January 27, 2010).

USFWS/NMFS. 1998. *Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act. Final Draft*. United States Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). Available at http://www.fws.gov/endangered/consultations/s7hndbk/s7hndbk.htm (Accessed June 19, 2009).

USFWS/NMFS/NOAA.2004. 50 CFR Part 402. Joint Counterpart Endangered Species Act Section 7 Consultation Regulations; Final Rule. *Federal Register* Volume 69. Number 20.Pages 47731-47762. August 5, 2004.