Risks of Oxydemeton Methyl Use to Federally Listed California Red Legged Frog

(*Rana aurora draytonii*)

Pesticide Effects Determination

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1. Executive Summary

Background

This assessment evaluates the potential for oxydemeton-methyl (ODM) to adversely affect the California Red Legged Frog (CRLF). ODM is an organophosphate insecticide. The mode of action for this class of chemicals is the inhibition of acetylcholinesterase, which is necessary for completion of neurotransmission. Inhibition of acetylcholinesterase results in disruption to the central and peripheral nervous system, and can result in mortality as well as sublethal effects.

ODM is currently registered for use on a variety of field, fruit, and vegetable crops as well as on Christmas trees, ornamental trees, and in forestry. ODM applications to Christmas, ornamental, and forestry trees are made by tree injection, while ODM applications for other uses in California are made via spray applications (ground and aerial) and chemigation. Application rates vary between each use, with one-time application rates ranging from 0.375 – 0.75 lbs ai/acre, number of applications ranging from 1 to 3, and intervals ranging 7-14 days. Exposure can occur at the application site; however, ODM is also expected to move through the environment and be transported away from the site of application by run-off or spray drift.

Tree injection methods are expected to confine ODM within tissues of treated trees. The potential for seepage of ODM from plant roots as a result of this method of treatment is unknown, but is not expected to result in exposure at the soil surface. Therefore, terrestrial organisms are not expected to be exposed, including the CRLF. The potential for runoff is also expected to be very low, so aquatic organisms are unlikely to be affected. Therefore, uses requiring this application method are considered to have "no effect" on the CRLF and are not analyzed further in this assessment. Uses that were included are: alfalfa grown for seed, lima beans, sugar beets, broccoli, broccoli raab, brussel sprouts, cabbage, cauliflower, clover grown for seed, sweet corn, cotton, cucurbits (cucumbers, pumpkins, summer squash, winter squash, watermelons, musk melons [cantaloupes], other melons), non-bearing fruit trees (apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces), non-bearing grapes, head lettuce, Spanish onions, peppermint, spearmint, safflower, walnuts, and ornamental plants grown for cut flowers.

There were insufficient monitoring data to support an aquatic evaluation based on concentrations found in water samples. Therefore, it was necessary to estimate aquatic exposure based on modeled results. Terrestrial exposure was also estimated through the use of models.

Aquatic Phase

Direct, acute effects to the aquatic phase CRLF are not expected as there are no acute listed LOC exceedences for freshwater fish, the surrogate test species for the aquatic phase CRLF. Chronic data for freshwater fish are available; however, the NOAEC calculated for this test is greater than the LC_{50}. Therefore, an acute-to-chronic ratio determined from other organophosphorus insecticides was used to estimate chronic toxicity. Based on this value, the RQ for chronic reproductive effects exceeds the LOC for cole crops, indicating risk to the aquatic-phase CRLF resulting from chronic exposure. Indirect effects to the CRLF and its critical habitat due to effects on aquatic plants are not expected, since ODM was not shown to be toxic to aquatic plants in Tier I tests. Although acute RQs for aquatic invertebrates exceed the LOC, indirect effects to CRLF, based on invertebrate food availability are not expected because the effect on invertebrate food sources is determined to be insignificant. Thus it was determined that ODM use is likely to adversely affect the aquatic phase CRLF through direct chronic effects and indirect effects due to chronic effects to fish and amphibian food resources and critical habitat (fish and invertebrate prey base).

Terrestrial Phase

ODM use is likely to adversely affect the terrestrial phase of the CRLF directly, as determined by acute and chronic LOC exceedences for birds, the surrogate test species for terrestrial phase CRLF. Avian reproductive effects indicate direct chronic fecundity effects to CRLF as well. Toxic effects on the CRLF prey base are likely to adversely affect the terrestrial phase CRLF as several taxa from the CRLF diet exceed the acute and chronic LOCs. Birds, mammals, insects, and small amphibians are all part of the terrestrial CRLF diet. Because multiple components of the diet are expected to be affected, including mammals, birds and insects, a determination of likely to adversely affect is also made for indirect effects. Plant LOCs were not exceeded, thus plant-related indirect effects and effects to critical habitat are not expected.

Based on LOC exceedences, the overlap of use sites with frog habitat and core areas, and other factors, the following table summarizes the effects determination for the CRLF from ODM use.

Table 1-1: Effects Determination Summary for ODM Use and the California Red-Legged Frog.

Assessment Endpoint	Effects determination	Basis for Determination
Aquatic Phase (Eggs, larvae, tadpoles, juveniles, and adults)		
Direct Effects and Critical Habitat Effects		
1. Survival, growth, and reproduction of CRLF	May Affect, Likely to Adversely Affect	Chronic RQs exceed LOC for surrogate species (rainbow trout) for 3 cole crops (broccoli, cauliflower, brussel sprouts)
	May Affect, Not Likely to Adversely Affect	No chronic exceedance for aquatic vertebrates for lettuce. No chronic exceedance for aquatic vertebrates for lettuce, since aquatic EEC is essentially equal to the no effect level
	No Effect	Exposure not expected from all non-food uses applied via tree injection due to lack of exposure. Acute and chronic RQs do not exceed LOCs for food uses other than cole crops.
Indirect Effects		
2. Reduction or modification of aquatic prey base	May Affect, Likely to Adversely Affect	Chronic RQs exceed LOC for fish (rainbow trout) for 3 cole crops, resulting in impacts to fish and amphibian prey base
	May Affect, Not Likely to Adversely Affect	Acute LOC is exceeded for aquatic invertebrates for 3 cole crops, however effect is considered insignificant based on low likelihood of individual effect. No chronic exceedance for

Assessment Endpoint	Effects determination	Basis for Determination
		aquatic vertebrates for lettuce, since aquatic EEC is essentially equal to the no effect level
	No Effect	Exposure to aquatic organisms not expected from all non-food uses applied via tree injection. Acute and chronic RQs do not exceed LOCs for invertebrates with food uses other than cole crops.
3. Reduction or modification of aquatic plant community	No Effect	No LOC exceedences for any plant species
4. Degradation of riparian vegetation	No Effect	No LOC exceedences for any plant species.
Terrestrial Phase (Juveniles and Adults)		
Direct Effects		
5. Survival, growth, and reproduction of CRLF	May Affect, Likely to Adversely Affect	Acute and Chronic LOC exceedences for birds, the surrogate species for direct effects to frogs, at lowest use rate. Probability of effect approaches 100% at calculated RQs.
	No Effect	Exposure to terrestrial organisms not expected from all non-food uses applied via tree injection.
Indirect Effects and Critical Habitat Effects		
6. Reduction or modification of terrestrial prey base	May Affect, Likely to Adversely Affect	Acute and Chronic LOC exceedences for multiple components of CRLF prey base (mammals, birds, and terrestrial invertebrates) at lowest use rate. LAA to terrestrial phase CRLF and its critical habitat based on acute RQs exceeding 0.5 and chronic RQs over LOC for mammals, insects, birds. Adverse terrestrial critical habitat modification is expected.
	No Effect	Exposure to terrestrial organisms not expected from all non-food uses applied via tree injection.
7. Degradation of riparian vegetation	No Effect	No plant LOC exceedences.

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

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

- Quantitative information on prey base requirements for individual aquatic- and terrestrial-phase frogs. While existing information provides a preliminary picture of the types of food sources utilized by the frog, 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 frogs and potential modification to critical habitat.

Effects on Primary Constituent Elements of the Critical Habitat

Aquatic Breeding and Non-breeding Habitat

Adverse effects on the aquatic critical habitat are not expected, as there is No Effect via aquatic plants, and the effect on invertebrates is insignificant.

Upland and Dispersal Habitat

There may be effects on these habitats through reduction in prey base (invertebrates, and small mammals, birds, and amphibians). However, effects are not expected to result from reduction in plant populations.

Action Area

Based on chronic effects to mammals, a terrestrial buffer zone of 11,338 feet is needed to delineate the Action Area. This is the distance from the edge of the use site needed to reduce exposure to below the Level of Concern for all taxa considered. The aquatic Action Area is based on direct effects to the CRLF as a result of exposure to ODM. Nevertheless, based on the RQs, terrestrial effects are expected to dominate the Action Area.

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* (U.S. EPA 1998), the Services' *Endangered Species Consultation Handbook* (USFWS/NMFS 1998) and is consistent with procedures and methodology outlined in the Overview Document (U.S. EPA 2004) and reviewed by the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (USFWS/NMFS 2004).

2.1 Purpose

The purpose of this endangered species assessment is to evaluate potential direct and indirect effects on individuals of the federally threatened California red-legged frog *(Rana aurora draytonii*) (CRLF) arising from FIFRA regulatory actions regarding use of Oxydemeton methyl (ODM). This ecological risk assessment has been prepared as part of the *Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 02-1580-JSW(JL)) settlement entered in the Federal District Court for the Northern District of California on October 20, 2006.

This assessment covers ODM uses on alfalfa grown for seed, lima beans, sugar beets, broccoli, broccoli raab, brussel sprouts, cabbage, cauliflower, clover grown for seed, sweet corn, cotton, cucurbits (cucumbers, pumpkins, summer squash, winter squash, watermelons, musk melons [cantaloupes], other melons), non-bearing fruit trees (apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces), non-bearing grapes, head lettuce, Spanish onions, peppermint, spearmint, safflower, walnuts, and ornamental plants grown for cut flowers. ODM is also registered for use in treating ornamental, forest, non-bearing and Christmas trees via injection. However, these uses are expected to pose little chance of exposure outside of the treated trees due to the nature of the treatment method, so they are not included in this risk assessment. In addition, this assessment evaluates whether these actions can be expected to result in the modification of the species' critical habitat. Key biological information for the CRLF is included in Section 2.5, and designated critical habitat information for the species is provided in Section 2.6 of this assessment.

In this endangered species assessment, direct and indirect effects to the CRLF and potential modification to its critical habitat are evaluated in accordance with the methods (both screening level and species-specific refinements, when appropriate) described in the Agency's Overview Document (U.S. EPA 2004).

In accordance with the Overview Document, provisions of the ESA, and the Services' *Endangered Species Consultation Handbook,* the assessment of effects associated with registrations of ODM are based on an action area. The action area is considered to be the area directly or indirectly affected by the federal action, as indicated by the exceedance of Agency Levels of Concern (LOCs) used to evaluate direct or indirect effects. It is acknowledged that the action area for a national-level FIFRA regulatory decision associated with a use of ODM 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 CRLF and its designated critical habitat within the state of California.

As part of the "effects determination," one of the following three conclusions will be reached regarding the potential for registration of ODM at the use sites described in this document to affect CRLF individuals and/or result in modification of designated CRLF critical habitat:

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

Critical habitat identifies specific areas that have the physical and biological features, (known as primary constituent elements or PCEs) essential to the conservation of listed species. The PCEs for CRLFs are aquatic and upland areas where suitable breeding and non-breeding aquatic habitat is located, interspersed with upland foraging and dispersal habitat (Section 2.6).

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

If a determination is made that use of ODM within the action area(s) associated with the CRLF "may affect" this species and/or its designated critical habitat, additional information is considered to refine the potential for exposure and for effects to the CRLF and other taxonomic groups upon which these species depend (e.g.., aquatic and terrestrial vertebrates and invertebrates, aquatic plants, riparian vegetation, etc.). Additional information, including spatial analysis (to determine the geographical proximity of CRLF habitat and ODM use sites) and further evaluation of the potential impact of ODM on the PCEs is also used to determine whether modification to 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 CRLF and/or the PCEs of its designated critical habitat. This information is presented as part of the Risk Characterization in Section 5 of this document.

The Agency believes that the analysis of direct and indirect effects to listed species provides the basis for an analysis of potential effects on the designated critical habitat. Because ODM is expected to directly impact living organisms within the action area (defined in Section 2.7), critical habitat analysis for ODM 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 destroy or adversely modify critical habitat are those that alter the PCEs and appreciably diminish the value of the habitat. Evaluation of actions related to use of ODM that may alter the PCEs of the CRLF's critical habitat form the basis of the critical habitat impact analysis. Actions that may affect the CRLF's designated critical habitat have been identified by the Services and are discussed further in Section 2.6.

2.2 Scope

ODM is registered for use on a variety of agricultural crops in California, including alfalfa grown for seed, lima beans, sugar beets, broccoli, broccoli raab, brussel sprouts, cabbage, cauliflower, clover grown for seed, sweet corn, cotton, cucurbits (cucumbers, pumpkins, summer squash, winter squash, watermelons, musk melons [cantaloupes], other melons), non-bearing fruit trees (apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces), non-bearing grapes, head lettuce, Spanish onions, peppermint, spearmint, safflower, walnuts, and ornamental plants grown for cut flowers. Applications made to these crops via aerial or ground spray are the focus of this risk assessment. The product registered for these uses may also be applied via chemigation; however, the range of exposures resulting from this method of application is expected to be accounted for by the aerial and ground spray applications. Therefore, the focus of this assessment will be the ground and aerial applications for the above uses, and additional analyses will not be conducted for chemigation. ODM is also registered for use in treating ornamental, forest, non-bearing and Christmas trees via tree injection methods. Because these uses are expected to pose little opportunity for exposure to terrestrial or aquatic organisms, they are not included in this risk assessment.

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 other reported use, such as may be seen in the California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database[1], 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.

The end result of the EPA pesticide registration process (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 ODM in accordance with the approved product labels for California is "the action" being assessed.

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

[1] 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.

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).

Oxydemeton-methyl does not have any registered products that contain multiple active ingredients.

2.2.1 Degradates

ODM has two degradates which two are sufficiently similar to the parent to possibly have similar toxicity (i.e., both are phosphate esters and have the entire basic structure of ODM). These are the sulfone (MSRO), an oxidation product containing one extra oxygen atom on sulfur, and the sulfide (MSI) a reduction product containing one less oxygen atom on sulfur than the parent. ODM does not form an oxon degradate. The sulfide (MSI) forms only under anaerobic conditions, and neither compound is a major degradate. It is not believed that addition of either of these degradates to the exposure assessment will change the outcome of the assessment.

2.3 Previous Assessments

The Agency published an Interim Reregistration Eligibility Decision in August 2002 and identified numerous human health and ecological risks associated with the labeled uses of ODM. Upon completion of the assessment, the Agency decided on a number of label amendments to address the occupational worker and ecological concerns. ODM is highly toxic to honey bees on an acute contact and acute oral basis. Acute and chronic risks to birds and mammals were also identified as concerns. The document is available on the web, at: http://www.epa.gov/oppsrrd1/REDs/oxydemeton_ired_amend_and_ired.pdf. Numerous mitigation measures resulted from the IRED assessment, including cancellation of some uses, precautionary labeling, and the use of buffer zones around areas managed for wildlife or as wildlife habitat. Currently, new labels reflecting these changes are being reviewed and are expected to be finalized by August 2007. As a result, this assessment will only incorporate uses and restrictions confirmed by OPP's Registration Division as of the date of this assessment.

2.4 Stressor Source and Distribution

2.4.1 Environmental Fate and Transport Assessment

Based on acceptable and supplemental data, parent ODM (S-[2-(ethylsulfinyl)ethyl]-O,O-dimethyl phosphorothioate) degrades rapidly in alkaline (pH 9) aqueous solutions and by microbial-mediated metabolism. Volatility is not a significant route of dissipation, based on the Henry's Law Constant of 1.5×10^{-11} atm m^3 /mol.

The metabolites formed in the submitted laboratory studies were desmethyl ODM (S-[2-(ethylsulfinyl)ethyl]-O-methyl phosphorothioate), ODM Thiol (2-(ethylsulfinyl) ethane sulfonic acid), 2-(ethylsulfonyl) ethane sulfonic acid, ODM-sulfide [MSI: (S-[2-(ethylthio)ethyl]O,O-dimethyl phosphorothioate)], ESMSE (1-(ethylsulfinyl)-2-(methylsulfinyl)ethane), and ODM sulfone (S-[2-(ethylsulfonyl)ethyl] O,O-dimethylphosphorothioate). These metabolites are dephosphorylated and/or demethylated ODM. The metabolites ODM Thiol (2-(ethylsulfinyl) ethane sulfonic acid) and 2-(ethylsulfonyl) ethane sulfonic acid are formed under aerobic conditions, and are persistent and mobile and are likely to reach water resources where they would persist and accumulate. The ESMSE metabolite that was formed under anaerobic aquatic conditions also did not appear to degrade, however, it is not expected to persist in water because it is not formed under aerobic conditions. All other detected ODM metabolites were non-persistent in the submitted studies, and are not likely to persist and accumulate in water even if they reached water resources.

Under anaerobic aquatic conditions, parent ODM degraded rapidly to form S-[2-(ethylthio)ethyl]O,O-dimethyl phosphorothioate (ODM-sulfide; MSI). MSI in water increased from 0.1 % of applied at day zero to 53.9 % at 7 days, followed by a decline to non-detectable levels by six months. The other major metabolite reached a maximum of 17.6 % by 9 months, and was 12.9 % of applied by 12 months in water. MSI and EMSME were almost exclusively associated with water in the study. The calculated half-life for MSI in water was 9 days.
The degradation of parent ODM is dependent on alkaline-induced hydrolysis and microbial-mediated metabolism. Parent ODM hydrolyzed with half-lives of 93 days, 40 days, and 2.5 days in pH 5, 7, and 9 buffer solutions, respectively. Photodegradation in water or on soil is not an important route of dissipation, with calculated half-lives of 137 days (194 days in dark control pH buffer solutions) and 63 days (53 days in dark control soil). The only major photolytic transformation product was 2-(ethylsulfonyl) ethane sulfonic acid at a maximum concentration of 18.4 % of applied by 30 days of irradiation in soil.

ODM is not persistent in aerobic soil and anaerobic aquatic environments. The aerobic soil metabolism half-life was 3.2 days in sandy loam soil. The major metabolites were ODM Thiol and 2-(ethylsulfonyl) ethane sulfonic acid at maximum concentrations of 27-31 % of applied. Both of these metabolites are dephosphorylated and demethylated ODM and both kept increasing or reached consistent concentrations in laboratory studies. The minor metabolite ODM sulfone (S-[2-(ethylsulfonyl)ethyl] O,O-dimethylphosphorothioate) did not exceed 6.3 % of applied by 3 days. Parent ODM also degraded rapidly ($t_{1/2}$=3.5 days) under anaerobic aquatic sediment/water conditions (Eh range of -65 to -2 mV for the 0-21 days used for half-life calculations). The major metabolites in the study were ODM sulfide (S-[2-(ethylthio)ethyl]O,O-dimethyl phosphorothioate) and ESMSE (1-(ethylsulfinyl)-2-methylsulfinyl) ethane. ODM sulfide was almost exclusively associated with water in the study, and degraded with a calculated half-life of 9 days. Non-extractable sediment residues increased to 25.5-26.7 % of applied by 2-3 months, and then declined to 18.3 % by 12 months.

Batch equilibrium data indicate that parent ODM partitions primarily to the liquid phase and is potentially very mobile in all tested soils. Parent ODM had Freundlich adsorption coefficients (K_d's) of 0.01 to 0.89 ml/g in sand, sandy loam, silt loam, and clay loam soils. No desorption coefficients could be calculated for parent ODM and no adsorption or desorption coefficients could be calculated for ODM sulfone and ODM sulfide due to limited adsorption.

Volatility of parent ODM or any organic metabolite is not expected to be a significant route of dissipation since no loss of material was observed in a laboratory volatility study. ODM has a vapor pressure of 2.85×10^{-5} Torr, a Henry's Law Constant of 1.5×10^{-11} atm m^3 /mol, and is miscible in water.

Based on supplemental data, ODM applied at 1 and 4.5 lbs ai/A rapidly dissipated ($t_{1/2}$'s=1.6 to 2.2 days) in field dissipation studies in California that were irrigated and planted to sugar beets. The short half-lives are consistent with the aerobic soil metabolism half-life of 3.2 days. The short half-lives and the lack of observed leaching would indicate that degradation was the primary route of dissipation. Neither ODM nor ODM sulfone were detected past 14 days or below 6 inches of soil depth.

Potential transport mechanisms include pesticide surface water runoff, spray drift, and secondary drift of volatilized or soil-bound residues leading to deposition onto nearby or more distant ecosystems. The magnitude of pesticide transport via secondary drift depends on the pesticide'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. A number of studies have documented atmospheric transport and redeposition 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 Sierra Nevada ecosystems (Fellers et al., 2004, LeNoir et al., 1999, and McConnell et al., 1998). Therefore, physicochemical properties of the pesticide that describe its potential to enter the air from water or soil (e.g., Henry's Law constant and vapor pressure), pesticide use, modeled estimated concentrations in water and air, and available air monitoring data from the Central Valley and the Sierra Nevadas are considered in evaluating the potential for atmospheric transport of ODM to habitat for the CRLF.

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 or AGDISP) are used to determine if the exposures to aquatic and terrestrial organisms are below the Agency's Levels of Concern (LOCs). If the limit of exposure that is below the LOC can be determined using AgDRIFT or AGDISP, longer-range transport is not considered in defining the action area. For example, if a buffer zone <1,000 feet (the optimal range for AgDRIFT and AGDISP models) results in terrestrial and aquatic exposures that are below LOCs, no further drift analysis is required. If exposures exceeding LOCs are expected beyond the standard modeling range of AgDRIFT or AGDISP, the Gaussian extension feature of AGDISP may be used. In addition to the use of spray drift models to determine potential off-site transport of pesticides, other factors such as available air monitoring data and the physicochemical properties of the chemical are also considered.

2.4.2 Mechanism of Action

ODM is an organophosphorus (OP) compound belonging to a class known as the anti-cholinesterases. These chemicals act upon target pests through neurotoxic action, in which the enzyme, acetylcholinesterase (AChE), is inhibited within the central and peripheral nervous system. The transmission of nerve impulses across nerve synapses and the junctions between nerves and other tissues is accomplished by the release of a chemical agent, acetylcholine, which binds to receptors on the post-synaptic membrane. When transmission is complete, acetylcholine must be removed from its receptors. AChE hydrolyzes acetylcholine, thereby releasing it from its receptor and allowing the nerve to cease transmission. OPs disrupt this process by competitively binding to AChE, thereby preventing it from hydrolyzing acetylcholine. The result is continuous firing of the nerve impulse, which can lead to pulmonary paralysis and death by asphyxiation. Since the OP-AChE bond can "age" and become irreversible, recovery only occurs with regeneration of new AChE.

2.4.3 Use and Usage Characterization

Analysis of labeled use information is the critical first step in evaluating the federal action. The current label for ODM represents 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.

ODM is nationally registered for use in a variety of agricultural crops including alfalfa grown for seed, lima beans, sugar beets, broccoli, broccoli raab, brussel sprouts, cabbage, cauliflower, clover grown for seed, Christmas trees, sweet corn, cotton, cucurbits (cucumbers, pumpkins, summer squash, winter squash, watermelons, musk melons [cantaloupes], other melons), filberts, non-bearing fruit trees (apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces), non-bearing grapes, head lettuce, Spanish onions, peppermint, sorghum, spearmint, safflower, walnuts, and field grown ornamentals and nursery stock, ornamental plants grown for cut flowers. Applications are made to these crops via aerial or ground spray or chemigation. Details of the labeled uses are provided in Table 2-1. ODM is also registered for use in treating ornamental, forest, non-bearing and Christmas trees via tree injection. It is not registered for use in California on Christmas trees, field grown ornamentals and nursery stock except by tree injection, and it is not registered for use on filberts or sorghum in California by any application method.

Table 2-1. Labeled ODM Uses Assessed in this Document.

Registration Number, Product Name, % AI, Formulations	Crop	Max. One-time Appl. Rate	Max. No. Appl. per Crop Cycle	Max. Quantity Applied per Crop Cycle	Min. Appl. Interval	Application method
10163-220, MSR Spray Concentrate, 25%, Liquid	Alfalfa (grown for seed)	0.5 lbs ai/A	2	1.0 lbs ai/A	14 days	Aerial, chemigation, groundboom
	Beans, lima	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Beets, sugar	0.5 lbs ai/A	1	0.5 lbs ai/A	NA	Aerial, chemigation, groundboom
	Broccoli	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Brussel sprouts	0.5 lbs ai/A	3	1.5 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Cabbage	0.75 lbs ai/A	3	2.25 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Cauliflower	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Clover grown for seed	0.5 lbs ai/A	2	1.0 lbs ai/A	14 days	Aerial, chemigation, groundboom
	Corn, sweet	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Cotton	0.5 lbs ai/A	1	0.5 lbs ai/A	NA	Chemigation and groundboom
	Curcurbits: cucumbers, pumpkins, summer squash, winter squash, watermelons, muskmelons (canteloupes), other melons	0.5 lbs ai/A	1	0.5 lbs ai/A	NA	Aerial, chemigation, groundboom
	Fruit trees, non-bearing: apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces	0.375 lbs ai/A	2	0.75 lbs ai/A	7 days	Airblast
	Grapes, non-bearing	0.375 lbs ai/A	2	0.75 lbs ai/A	7 days	Airblast
	Lettuce, head	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, chemigation, and groundboom
	Onions, Spanish (bulb)	0.5 lbs ai/A	2	1.0 lbs ai/A	14 days	Aerial, chemigation, and groundboom
	Peppermint and spearment	0.75 lbs ai/A	2	1.5 lbs ai/A	10 days	Chemigation and groundboom.
	Safflower	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, chemigation, groundboom
	Walnuts	0.375 lbs ai/A	1	0.375 lbs ai/A	NA	Airblast.

Registration Number, Product Name, % AI, Formulations	Crop	Max. One-time Appl. Rate	Max. No. Appl. per Crop Cycle	Max. Quantity Applied per Crop Cycle	Min. Appl. Interval	Application method
CA010003, MSR Spray Concentrate, 25%, Liquid	Ornamental plants grown for cut flowers	0.375 lbs ai/A	2	0.75 lbs ai/A	7 days	Groundboom, Airblast
CA950002, MSR Spray Concentrate, 25%, Liquid	Broccoli raab	0.5 lbs ai/A	2	1.0 lbs ai/A	7 days	Aerial, Chemigation, Groundboom

The Agency's Biological and Economic Analysis Division (BEAD) provides an analysis of both national- and county-level usage information using state-level usage data obtained from USDA-NASS[2], Doane (www.doane.com; the full dataset is not provided due to its proprietary nature), and the CDPR PUR database. 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 ODM by county in this California-specific assessment were generated using CDPR PUR data. Usage data are averaged together over the years 2000 to 2005 to calculate average annual usage statistics by county and crop for ODM, including pounds of active ingredient applied and base acres treated. California State law requires that every pesticide application be reported to the state and made available to the public. The summary of ODM usage for all use sites, including both agricultural and non-agricultural, is provided below.

California PUR Usage Data

The state of California requires that all pesticide applications (excluding private homeowner uses) be reported. This data is collected in the PUR (pesticide use reporting) database. The Office of Pesticide Programs' (OPP) Biological and Economic Analysis Division (BEAD) performed an analysis (S. Semenova, July 19, 2007) of the PUR data for the years 2002 to 2005, including data for ODM. Use of ODM was reported in a total of 37 California counties over that time.

According to the PUR database, a total of 96,005.7 lb of ODM were used in California in 2002, 93,744.7 lb in 2003, 102,554.4 lb. in 2004, and 121,500.3 lb. in 2005. The average annual number of pounds applied over that four-year period was 103,451.3. Table 2-2a below gives the reported usages that accounted for 95% of the annual average pounds applied, or about 98,279 lb.

[2] United States Depart 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.

According to this analysis, the heaviest usage is on head lettuce and broccoli in Monterey County (over 53,000 lb.). The next highest usage was in Santa Barbra County on broccoli, followed by broccoli in San Luis Obispo County. Ten different use sites are represented in the top 95% of pounds applied.

Tables 2-2b to 2-2h below give the complete summaries for seven of the ten uses represented in Table 2-2a (all, or nearly all, of the cotton, rappini, and sugarbeet usage is already reported in Table 2-2a).

There are twenty counties represented in Tables 2-2b to 2-2h. The agricultural uses on lettuce and cole crops (broccoli, cabbage, cauliflower, brussel sprouts) are concentrated in 12 counties: Monterey, Santa Barbara, San Luis Obispo, San Benito, Santa Cruz, Santa Clara, Ventura, Fresno, Kern, Imperial, Stanislaus, and San Joaquin. The corn use is limited to Contra Costa, Riverside, and Solano counties. Landscape maintenance includes many counties not included in the major agricultural uses, such as Los Angeles, Orange, San Diego, Butte, and San Mateo. The number of pounds applied to corn and landscapes is small compared to the major uses (lettuce and cole crops).

The information presented in Tables 2-2b to 2-2h show where the heaviest use of ODM occurs in California, and on which crops or use sites.

Table 2-2a. Reported Applications of ODM that account for 95% of Average Annual Use in California.

County	Site Name	Total Pounds 2002	Total Pounds 2003	Total Pounds 2004	Total Pounds 2005	AVG Annual Pounds Applied
CONTRA COSTA	CORN, HUMAN CONSUMPTION	943.0	780.8	1335.7	1805.3	1216.2
FRESNO	CORN, HUMAN CONSUMPTION	1921.2	696.0	2565.5	5424.5	2651.8
FRESNO	BROCCOLI	230.7	1942.8	2168.4	1959.6	1575.4
FRESNO	COTTON	644.4	956.5	0.0	0.0	400.2
LOS ANGELES	LANDSCAPE MAINTENANCE	172.5	325.7	790.3	228.4	379.2
MERCED	SUGARBEET	75.5	144.9	1345.3	719.6	571.3
MONTEREY	LETTUCE, HEAD	29928.0	27373.5	31772.4	34310.3	30846.0
MONTEREY	BROCCOLI	20278.5	21155.4	22043.7	26471.8	22487.3
MONTEREY	CAULIFLOWER	6615.6	6699.3	7031.6	8426.0	7193.1
MONTEREY	CABBAGE	2042.7	2929.9	2090.2	2737.3	2450.0
MONTEREY	RAPPINI	981.4	683.7	1036.8	876.0	894.5
SAN BENITO	LETTUCE, HEAD	1569.4	827.7	888.6	696.8	995.6
SAN LUIS OBISPO	BROCCOLI	5349.0	6105.8	4737.9	7646.7	5959.9
SAN LUIS OBISPO	LETTUCE, HEAD	949.7	904.7	1582.6	1860.7	1324.4
SAN MATEO	BRUSSEL SPROUT	370.7	442.2	253.9	482.6	387.4
SANTA BARBARA	BROCCOLI	11989.5	11282.5	11700.0	16553.5	12881.4

County	Site Name	Total Pounds 2002	Total Pounds 2003	Total Pounds 2004	Total Pounds 2005	AVG Annual Pounds Applied
SANTA BARBARA	LETTUCE, HEAD	1936.9	1542.2	2618.5	3204.7	2325.6
SANTA BARBARA	CAULIFLOWER	1942.8	1341.7	1765.7	1755.4	1701.4
SANTA CRUZ	BRUSSEL SPROUT	750.9	850.7	623.7	947.8	793.3
SANTA CRUZ	LETTUCE, HEAD	832.4	744.6	1002.0	422.9	750.5
VENTURA	CABBAGE	608.8	563.4	715.5	354.0	560.5

Table 2-2b. Usage of ODM on Head Lettuce, 2002 to 2005

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
MONTEREY	29928.0	27373.5	31772.4	34310.3	30846.0
SANTA BARBARA	1936.9	1542.2	2618.5	3204.7	2325.6
SAN LUIS OBISPO	949.7	904.7	1582.6	1860.7	1324.4
SAN BENITO	1569.4	827.7	888.6	696.8	995.6
SANTA CRUZ	832.4	744.6	1002.0	422.9	750.5
SANTA CLARA	209.3	357.0	398.5	267.8	308.1
VENTURA	225.6	135.9	127.9	117.4	151.7
FRESNO	0.0	55.5	0.0	0.0	13.9

Table 2-2c. Usage of ODM on Broccoli, 2002 to 2005

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
MONTEREY	20278.5	21155.4	22043.7	26471.8	22487.3
SANTA BARBARA	11989.5	11282.5	11700.0	16553.5	12881.4
SAN LUIS OBISPO	5349.0	6105.8	4737.9	7646.7	5959.9
FRESNO	230.7	1942.8	2168.4	1959.6	1575.4
SANTA CLARA	141.3	290.2	292.6	276.1	250.0
SAN BENITO	283.9	291.3	182.2	167.9	231.3
VENTURA	288.0	208.3	137.1	71.2	176.2
SANTA CRUZ	136.5	110.5	178.4	101.9	131.8
KERN	67.3	31.8	138.0	157.7	98.7
IMPERIAL	26.8	225.3	0.0	0.0	63.0
STANISLAUS	0.0	25.0	0.0	93.2	29.6
SAN JOAQUIN	0.0	0.0	1.9	87.5	22.3

Table 2-2d. Usage of ODM on Cabbage, 2002 to 2005

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
MONTEREY	2042.7	2929.9	2090.2	2737.3	2450.0
VENTURA	608.8	563.4	715.5	354.0	560.5
SAN BENITO	595.9	378.7	175.0	251.2	350.2
SANTA CRUZ	62.8	82.8	118.4	135.1	99.8

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
SANTA BARBARA	113.8	109.6	61.2	73.2	89.4
SAN LUIS OBISPO	36.6	134.6	80.2	76.1	81.9
KERN	24.1	18.6	21.6	92.7	39.2
SANTA CLARA	1.5	69.0	0.0	0.0	17.6
SAN JOAQUIN	11.1	16.7	0.0	6.9	8.7
IMPERIAL	0.0	15.0	0.0	0.0	3.7

Table 2-2e. Usage of ODM on Cauliflower, 2002 to 2005

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
MONTEREY	6615.6	6699.3	7031.6	8426.0	7193.1
SANTA BARBARA	1942.8	1341.7	1765.7	1755.4	1701.4
SAN LUIS OBISPO	344.6	171.2	92.7	107.5	179.0
SANTA CRUZ	153.2	134.2	70.0	39.1	99.2
VENTURA	147.4	96.3	25.7	0.0	67.4
SAN BENITO	86.8	84.6	21.0	24.1	54.1
SANTA CLARA	13.4	0.0	0.0	48.7	15.5
KERN	41.9	0.0	1.5	4.9	12.1
SAN JOAQUIN	4.5	3.0	6.4	0.0	3.5

Table 2-2f. Usage of ODM on Corn for Human consumption, 2002 to 2005

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
FRESNO	1921.2	696.0	2565.5	5424.5	2651.8
CONTRA COSTA	943.0	780.8	1335.7	1805.3	1216.2
RIVERSIDE	19.5	10.6	78.8	209.5	79.6
SAN JOAQUIN	69.2	99.9	0.0	118.7	72.0
SOLANO	0.0	14.6	54.4	0.0	17.2
VENTURA	5.9	31.2	0.0	0.0	9.3
SANTA BARBARA	33.6	0.0	0.0	0.0	8.4
SANTA CLARA	4.9	0.0	0.0	0.0	1.2

Table 2-2g. Usage of ODM for Landscape Maintenance, 2002 to 2005 (Annual Average 10 lb. or more)

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
LOS ANGELES	172.5	325.7	790.3	228.4	379.2
ORANGE	139.4	139.1	177.0	212.3	167.0
SAN DIEGO	249.0	38.3	32.6	16.4	84.1
BUTTE	59.7	54.7	22.1	8.6	36.3
RIVERSIDE	30.2	50.6	18.2	6.3	26.3
VENTURA	26.5	22.0	0.0	0.0	12.1

Table 2-2h. Usage of ODM on Brussel Sprouts, 2002 to 2005

County	Total lb. applied 2002	Total lb. applied 2003	Total lb. applied 2004	Total lb. applied 2005	Annual Avg. lb. applied
SANTA CRUZ	750.9	850.7	623.7	947.8	793.3
SAN MATEO	370.7	442.2	253.9	482.6	387.4
MONTEREY	323.9	208.8	59.4	224.5	204.1
SANTA BARBARA	69.4	46.7	64.5	73.7	63.6
SAN LUIS OBISPO	14.1	40.0	15.4	74.8	36.1

2.5 Assessed Species

The CRLF was federally listed as a threatened species by USFWS effective June 24, 1996 (USFWS 1996). It is one of two subspecies of the red-legged frog and is the largest native frog in the western United States (USFWS 2002). A brief summary of information regarding CRLF distribution, reproduction, diet, and habitat requirements is provided in Sections 2.5.1 through 2.5.4, respectively. Further information on the status, distribution, and life history of and specific threats to the CRLF is provided in Attachment 1.

Final critical habitat for the CRLF was designated by USFWS on April 13, 2006 (USFWS 2006; 71 FR 19244-19346). Further information on designated critical habitat for the CRLF is provided in Section 2.6.

2.5.1 Distribution

The CRLF is endemic to California and Baja California (Mexico) and historically inhabited 46 counties in California including the Central Valley and both coastal and interior mountain ranges (USFWS 1996). Its range has been reduced by about 70%, and the species currently resides in 22 counties in California (USFWS 1996). The species has an elevational range of near sea level to 1,500 meters (5,200 feet) (Jennings and Hayes 1994); however, nearly all of the known CRLF populations have been documented below 1,050 meters (3,500 feet) (USFWS 2002).

Populations currently exist along the northern California coast, northern Transverse Ranges (USFWS 2002), foothills of the Sierra Nevada (5-6 populations), and in southern California south of Santa Barbara (two populations) (Fellers 2005a). Relatively larger numbers of CRLFs are located between Marin and Santa Barbara Counties (Jennings and Hayes 1994). A total of 243 streams or drainages are believed to be currently occupied by the species, with the greatest numbers in Monterey, San Luis Obispo, and Santa Barbara counties (USFWS 1996). Occupied drainages or watersheds include all bodies of water that support CRLFs (i.e., streams, creeks, tributaries, associated natural and artificial ponds, and adjacent drainages), and habitats through which CRLFs can move (i.e., riparian vegetation, uplands) (USFWS 2002).

The distribution of CRLFs within California is addressed in this assessment using four categories of location including recovery units, core areas, designated critical habitat, and known occurrences of the CRLF reported in the California Natural Diversity Database (CNDDB) that are not included within core areas and/or designated critical habitat (see Figure 2.a). Recovery units, core areas, and other known occurrences of the CRLF from the CNDDB are described in further detail in this section, and designated critical habitat is addressed in Section 2.6. Recovery units are large areas defined at the watershed level that have similar conservation needs and management strategies. The recovery unit is primarily an administrative designation, and land area within the recovery unit boundary is not exclusively CRLF habitat. Core areas are smaller areas within the recovery units that comprise portions of the species' historic and current range and have been determined by USFWS to be important in the preservation of the species. Designated critical habitat is generally contained within the core areas, although a number of critical habitat units are outside the boundaries of core areas, but within the boundaries of the recovery units. Additional information on CRLF occurrences from the CNDDB is used to cover the current range of the species not included in core areas and/or designated critical habitat, but within the recovery units.

Recovery Units

Eight recovery units have been established by USFWS for the CRLF. These areas are considered essential to the recovery of the species, and the status of the CRLF "may be considered within the smaller scale of the recovery units, as opposed to the statewide range" (USFWS 2002). Recovery units reflect areas with similar conservation needs and population statuses, and therefore, similar recovery goals. The eight units described for the CRLF are delineated by watershed boundaries defined by US Geological Survey hydrologic units and are limited to the elevational maximum for the species of 1,500 m above sea level. The eight recovery units for the CRLF are listed in Table 2-3 and shown in Figure 2.a.

Core Areas

USFWS has designated 35 core areas across the eight recovery units to focus their recovery efforts for the CRLF (see Figure 2.a). Table 2-3 summarizes the geographical relationship among recovery units, core areas, and designated critical habitat. The core areas, which are distributed throughout portions of the historic and current range of the species, represent areas that allow for long-term viability of existing populations and reestablishment of populations within historic range. These areas were selected because they: 1) contain existing viable populations; or 2) they contribute to the connectivity of other habitat areas (USFWS 2002). Core area protection and enhancement are vital for maintenance and expansion of the CRLF's distribution and population throughout its range.

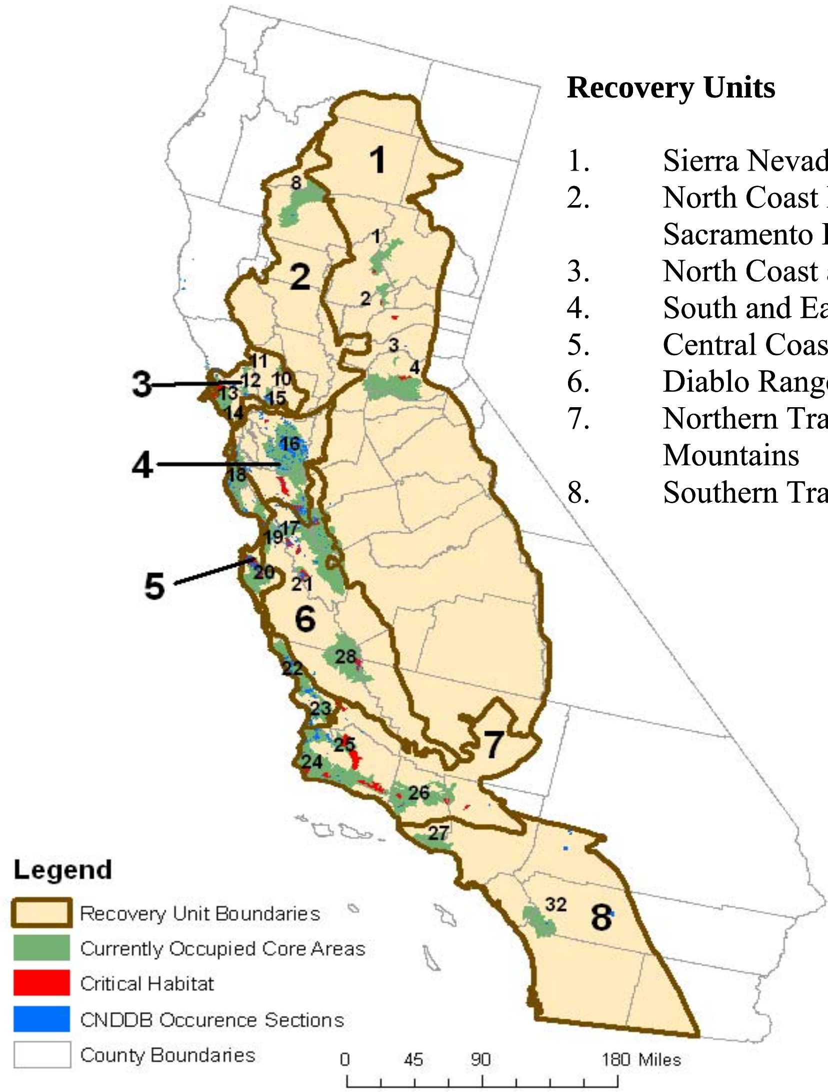
For purposes of this assessment, designated critical habitat, currently occupied (post-1985) core areas, and additional known occurrences of the CRLF from the CNDDB are considered. Each type of locational information is evaluated within the broader context of recovery units. For example, if no labeled uses of ODM occur (or if labeled uses occur at predicted exposures less than the Agency's LOCs) within an entire recovery unit, a "no effect" determination would be made for all designated critical habitat, currently occupied core areas, and other known CNDDB occurrences within that recovery unit. Historically occupied sections of the core areas are not evaluated as part of this assessment because the USFWS Recovery Plan (USFWS 2002) indicates that CRLFs are extirpated from these areas. A summary of currently and historically occupied core areas is provided in Table 2-3 (currently occupied core areas are bolded). While core areas are considered essential for recovery of the CRLF, core areas are not federally-designated critical habitat, although designated critical habitat is generally contained within these core recovery areas. It should be noted, however, that several critical habitat units are located outside of the core areas, but within the recovery units. The focus of this assessment is currently occupied core areas, designated critical habitat, and other known CNDDB CRLF occurrences within the recovery units. Federally-designated critical habitat for the CRLF is further explained in Section 2.6.

Table 2-3. California Red-legged Frog Recovery Units with Overlapping Core Areas and Designated Critical Habitat

Recovery Unit [1] (Figure 2.a)	Core Areas [2,7] (Figure 2.a)	Critical Habitat Units [3]	Currently Occupied (post-1985) [4]	Historically Occupied [4]
Sierra Nevada Foothills and Central Valley (1) (eastern boundary is the 1,500m elevation line)	**Cottonwood Creek (partial) (8)**	--	✓	
	Feather River (1)	BUT-1A-B	✓	
	Yuba River-S. Fork Feather River (2)	YUB-1	✓	
	--	NEV-1[6]		
	Traverse Creek/Middle Fork American River/Rubicon (3)	--	✓	
	Consumnes River (4)	ELD-1	✓	
	S. Fork Calaveras River (5)	--		✓
	Tuolumne River (6)	--		✓
	Piney Creek (7)	--		✓
	East San Francisco Bay (partial)(16)	--	✓	
North Coast Range Foothills and Western Sacramento River Valley (2)	**Cottonwood Creek (8)**	--	✓	
	Putah Creek-Cache Creek (9)	--		✓
	Jameson Canyon – Lower Napa Valley (partial) (15)	--	✓	
	Belvedere Lagoon (partial) (14)	--	✓	
	Pt. Reyes Peninsula (partial) (13)	--	✓	
North Coast and North San Francisco Bay (3)	Putah Creek-Cache Creek (partial) (9)	--		✓
	Lake Berryessa Tributaries (10)	NAP-1	✓	
	Upper Sonoma Creek (11)	--	✓	
	Petaluma Creek-Sonoma Creek (12)	--	✓	
	Pt. Reyes Peninsula (13)	MRN-1, MRN-2	✓	
	Belvedere Lagoon (14)	--	✓	
	Jameson Canyon-Lower Napa River (15)	SOL-1	✓	
South and East San Francisco Bay (4)	--	CCS-1A[6]		
	East San Francisco Bay (partial) (16)	ALA-1A, ALA-1B, STC-1B	✓	
	--	STC-1A[6]		
	South San Francisco Bay (partial) (18)	SNM-1A	✓	

Central Coast (5)	**South San Francisco Bay (partial) (18)**	SNM-1A, SNM-2C, SCZ-1	✓	
	Watsonville Slough- Elkhorn Slough (partial) (19)	SCZ-2 [5]	✓	
	Carmel River-Santa Lucia (20)	MNT-2	✓	
	Estero Bay (22)	--	✓	
	--	SLO-8[6]		
	Arroyo Grande Creek (23)	--	✓	
	Santa Maria River-Santa Ynez River (24)	--	✓	
Diablo Range and Salinas Valley (6)	**East San Francisco Bay (partial) (16)**	MER-1A-B, STC-1B	✓	
	--	SNB-1[6], SNB-2[6]		
	Santa Clara Valley (17)	--	✓	
	Watsonville Slough- Elkhorn Slough (partial)(19)	MNT-1	✓	
	Carmel River-Santa Lucia (partial)(20)	--	✓	
	Gablan Range (21)	SNB-3	✓	
	Estrella River (28)	SLO-1A-B	✓	
Northern Transverse Ranges and Tehachapi Mountains (7)	--	SLO-8[6]		
	Santa Maria River-Santa Ynez River (24)	STB-4, STB-5, STB-7	✓	
	Sisquoc River (25)	STB-1, STB-3	✓	
	Ventura River-Santa Clara River (26)	VEN-1, VEN-2, VEN-3	✓	
	--	LOS-1[6]		
Southern Transverse and Peninsular Ranges (8)	**Santa Monica Bay-Ventura Coastal Streams (27)**	--	✓	
	San Gabriel Mountain (29)	--		✓
	Forks of the Mojave (30)	--		✓
	Santa Ana Mountain (31)	--		✓
	Santa Rosa Plateau (32)	--	✓	
	San Luis Rey (33)	--		✓
	Sweetwater (34)	--		✓
	Laguna Mountain (35)	--		✓

[1] Recovery units designated by the USFWS (USFWS 2000, pg 49).
[2] Core areas designated by the USFWS (USFWS 2000, pg 51).
[3] Critical habitat units designated by the USFWS on April 13, 2006 (USFWS 2006, 71 FR 19244-19346).
[4] Currently occupied (post-1985) and historically occupied core areas as designated by the USFWS (USFWS 2002, pg 54).
[5] Critical habitat unit where identified threats specifically included pesticides or agricultural runoff (USFWS 2002).
[6] Critical habitat units that are outside of core areas, but within recovery units.
[7] Currently occupied core areas that are included in this effects determination are bolded.



Recovery Units

1. Sierra Nevada Foothills and Central Valley
2. North Coast Range Foothills and Western Sacramento River Valley
3. North Coast and North San Francisco Bay
4. South and East San Francisco Bay
5. Central Coast
6. Diablo Range and Salinas Valley
7. Northern Transverse Ranges and Tehachapi Mountains
8. Southern Transverse and Peninsular Ranges

Core Areas

1. Feather River
2. Yuba River- S. Fork Feather River
3. Traverse Creek/ Middle Fork/ American R. Rubicon
4. Cosumnes River
5. South Fork Calaveras River*
6. Tuolumne River*
7. Piney Creek*
8. Cottonwood Creek
9. Putah Creek – Cache Creek*
10. Lake Berryessa Tributaries
11. Upper Sonoma Creek
12. Petaluma Creek – Sonoma Creek
13. Pt. Reyes Peninsula
14. Belvedere Lagoon
15. Jameson Canyon – Lower Napa River
16. East San Francisco Bay
17. Santa Clara Valley
18. South San Francisco Bay
19. Watsonville Slough-Elkhorn Slough
20. Carmel River – Santa Lucia
21. Gablan Range
22. Estero Bay
23. Arroyo Grange River
24. Santa Maria River – Santa Ynez River
25. Sisquoc River
26. Ventura River – Santa Clara River
27. Santa Monica Bay – Venura Coastal Streams
28. Estrella River
29. San Gabriel Mountain*
30. Forks of the Mojave*
31. Santa Ana Mountain*
32. Santa Rosa Plateau
33. San Luis Ray*
34. Sweetwater*
35. Laguna Mountain*

* Core areas that were historically occupied by the California red-legged frog are not included in the map

Figure 2a. Recovery Unit, Core Area, Critical Habitat, and Occurrence Designations for CRLF

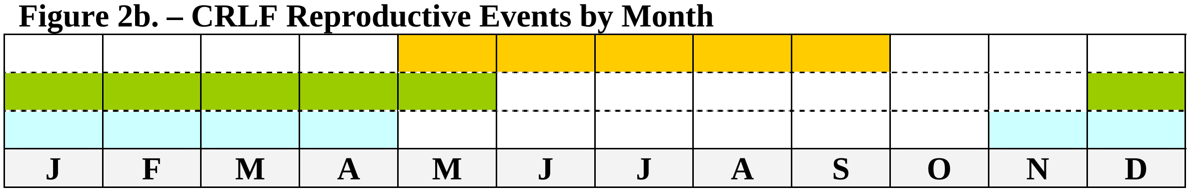
Other Known Occurrences from the CNDBB

The CNDDB provides location and natural history information on species found in California. The CNDDB serves as a repository for historical and current species location sightings. Information regarding known occurrences of CRLFs outside of the currently occupied core areas and designated critical habitat is considered in defining the current range of the CRLF. See: http://www.dfg.ca.gov/bdb/html/cnddb_info.html for additional information on the CNDDB.

2.5.2 Reproduction

CRLFs breed primarily in ponds; however, they may also breed in quiescent streams, marshes, and lagoons (Fellers 2005a). According to the Recovery Plan (USFWS 2002), CRLFs breed from November through late April. Peaks in spawning activity vary geographically; Fellers (2005b) reports peak spawning as early as January in parts of coastal central California. Eggs are fertilized as they are being laid. Egg masses are typically attached to emergent vegetation, such as bulrushes (*Scirpus* spp.) and cattails (*Typha* spp.) or roots and twigs, and float on or near the surface of the water (Hayes and Miyamoto 1984). Egg masses contain approximately 2000 to 6000 eggs ranging in size between 2 and 2.8 mm (Jennings and Hayes 1994). Embryos hatch 10 to 14 days after fertilization (Fellers 2005a) depending on water temperature. Egg predation is reported to be infrequent and most mortality is associated with the larval stage (particularly through predation by fish); however, predation on eggs by newts has also been reported (Rathburn 1998). Tadpoles require 11 to 28 weeks to metamorphose into juveniles (terrestrial-phase), typically between May and September (Jennings and Hayes 1994, USFWS 2002); tadpoles have been observed to over-winter (delay metamorphosis until the following year) (Fellers 2005b, USFWS 2002). Males reach sexual maturity at 2 years, and females reach sexual maturity at 3 years of age; adults have been reported to live 8 to 10 years (USFWS 2002). Figure 2b depicts CRLF annual reproductive timing.

Figure 2b. – CRLF Reproductive Events by Month



Light Blue = **Breeding/Egg Masses**
Green = **Tadpoles (except those that over-winter)**
Orange = **Young Juveniles**
Adults and juveniles can be present all year

2.5.3 Diet

Although the diet of CRLF aquatic-phase larvae (tadpoles) has not been studied specifically, it is assumed that their diet is similar to that of other frog species, with the aquatic phase feeding exclusively in water and consuming diatoms, algae, and detritus (USFWS 2002). Tadpoles filter and entrap suspended algae (Seale and Beckvar, 1980) via mouthparts designed for effective grazing of periphyton (Wassersug, 1984, Kupferberg *et al.*; 1994; Kupferberg, 1997; Altig and McDiarmid, 1999).

Juvenile and adult CRLFs forage in aquatic and terrestrial habitats, and their diet differs greatly from that of larvae. The main food source for juvenile aquatic- and terrestrial-phase CRLFs is thought to be aquatic and terrestrial invertebrates found along the shoreline and on the water surface. Hayes and Tennant (1985) report, based on a study examining the gut content of 35 juvenile and adult CRLFs, that the species feeds on as many as 42 different invertebrate taxa, including Arachnida, Amphipoda, Isopoda, Insecta, and Mollusca. The most commonly observed prey species were larval alderflies (*Sialis* cf. *californica*), pillbugs (*Armadilliadrium vulgare*), and water striders (*Gerris* sp). The preferred prey species, however, was the sowbug (Hayes and Tennant, 1985). This study suggests that CRLFs forage primarily above water, although the authors note other data reporting that adults also feed under water, are cannibalistic, and consume fish. For larger CRLFs, over 50% of the prey mass may consists of vertebrates such as mice, frogs, and fish, although aquatic and terrestrial invertebrates were the most numerous food items (Hayes and Tennant 1985). For adults, feeding activity takes place primarily at night; for juveniles feeding occurs during the day and at night (Hayes and Tennant 1985).

2.5.4 Habitat

CRLFs require aquatic habitat for breeding, but also use other habitat types including riparian and upland areas throughout their life cycle. CRLF use of their environment varies; they may complete their entire life cycle in a particular habitat or they may utilize multiple habitat types. Overall, populations are most likely to exist where multiple breeding areas are embedded within varying habitats used for dispersal (USFWS 2002). Generally, CRLFs utilize habitat with perennial or near-perennial water (Jennings et al. 1997). Dense vegetation close to water, shading, and water of moderate depth are habitat features that appear especially important for CRLF (Hayes and Jennings 1988).

Breeding sites include streams, deep pools, backwaters within streams and creeks, ponds, marshes, sag ponds (land depressions between fault zones that have filled with water), dune ponds, and lagoons. Breeding adults have been found near deep (0.7 m) still or slow moving water surrounded by dense vegetation (USFWS 2002); however, the largest number of tadpoles have been found in shallower pools (0.26 – 0.5 m) (Reis, 1999). Data indicate that CRLFs do not frequently inhabit vernal pools, as conditions in these habitats generally are not suitable (Hayes and Jennings 1988).

CRLFs also frequently breed in artificial impoundments such as stock ponds, although additional research is needed to identify habitat requirements within artificial ponds (USFWS 2002). Adult CRLFs use dense, shrubby, or emergent vegetation closely associated with deep-water pools bordered with cattails and dense stands of overhanging vegetation (http://www.fws.gov/endangered/features/rl_frog/rlfrog.html#where).

In general, dispersal and habitat use depends on climatic conditions, habitat suitability, and life stage. Adults rely on riparian vegetation for resting, feeding, and dispersal. The foraging quality of the riparian habitat depends on moisture, composition of the plant community, and presence of pools and backwater aquatic areas for breeding. CRLFs can be found living within streams at distances up to 3 km (2 miles) from their breeding site and have been found up to 30 m (100 feet) from water in dense riparian vegetation for up to 77 days (USFWS 2002).

During dry periods, the CRLF is rarely found far from water, although it will sometimes disperse from its breeding habitat to forage and seek other suitable habitat under downed trees or logs, industrial debris, and agricultural features (UWFWS 2002). According to Jennings and Hayes (1994), CRLFs also use small mammal burrows and moist leaf litter as habitat. In addition, CRLFs may also use large cracks in the bottom of dried ponds as refugia; these cracks may provide moisture for individuals avoiding predation and solar exposure (Alvarez 2000).

2.6 Designated Critical Habitat

In a final rule published on April 13, 2006, 34 separate units of critical habitat were designated for the CRLF by USFWS (USFWS 2006; FR 51 19244-19346). A summary of the 34 critical habitat units relative to USFWS-designated recovery units and core areas (previously discussed in Section 2.5.1) is provided in Table 2-3.

'Critical habitat' is defined in the Endangered Species Act (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.' All designated critical habitat for the CRLF was occupied at the time of listing. Critical habitat receives protection under Section 7 of the ESA through prohibition against 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 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. The designated critical habitat areas for the CRLF are considered to have the following PCEs that justify critical habitat designation:

- Breeding aquatic habitat;
- Non-breeding aquatic habitat;
- Upland habitat; and
- Dispersal habitat.

Please note that a more complete description of these habitat types is provided in Attachment 1.

Occupied habitat may be included in the critical habitat only if essential features within the habitat may require special management or protection. Therefore, USFWS does not include areas where existing management is sufficient to conserve the species. Critical habitat is designated outside the geographic area presently occupied by the species only when a designation limited to its present range would be inadequate to ensure the conservation of the species. For the CRLF, all designated critical habitat units contain all four of the PCEs, and were occupied by the CRLF at the time of FR listing notice in April 2006. The FR notice designating critical habitat for the CRLF includes a special rule exempting routine ranching activities associated with livestock ranching from incidental take prohibitions. The purpose of this exemption is to promote the conservation of rangelands, which could be beneficial to the CRLF, and to reduce the rate of conversion to other land uses that are incompatible with CRLF conservation. Please see Attachment 1 for a full explanation on this special rule.

USFWS has established adverse modification standards for designated critical habitat (USFWS 2006). 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 ODM that may alter the PCEs of the CRLF's critical habitat form the basis of the critical habitat impact analysis. According to USFWS (2006), activities that may affect critical habitat and therefore result in adverse effects to the CRLF include, but are not limited to the following:

(1) Significant alteration of water chemistry or temperature to levels beyond the tolerances of the CRLF that result in direct or cumulative adverse effects to individuals and their life-cycles.
(2) Significant increase in sediment deposition within the stream channel or pond or disturbance of upland foraging and dispersal habitat that could result in elimination or reduction of habitat necessary for the growth and reproduction of the CRLF by increasing the sediment deposition to levels that would adversely affect their ability to complete their life cycles.
(3) Significant alteration of channel/pond morphology or geometry that may lead to changes to the hydrologic functioning of the stream or pond and alter the timing, duration, water flows, and levels that would degrade or eliminate the CRLF and/or its habitat. Such an effect could also lead to increased sedimentation and degradation in water quality to levels that are beyond the CRLF's tolerances.
(4) Elimination of upland foraging and/or aestivating habitat or dispersal habitat.
(5) Introduction, spread, or augmentation of non-native aquatic species in stream segments or ponds used by the CRLF.
(6) Alteration or elimination of the CRLF's food sources or prey base (also evaluated as indirect effects to the CRLF).

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 ODM is expected to directly impact living organisms within the action area, critical habitat analysis for ODM 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.

2.6.1 Special Rule Exemption for Routine Ranching Activities

As part of the critical habitat designation, the Service promulgated a special rule exemption regarding routine ranching activities where there is no Federal nexus from take prohibitions under Section 9 of the ESA. (USFWS 2006, 71 FR 19285-19290). The Service's reasoning behind this exemption is that managed livestock activities, especially the creation of stock ponds, provide habitat for the CRLF. Maintenance of these areas as rangelands, rather than conversion to other uses should ranching prove to be economically infeasible is, overall, of net benefit to the species.

Several of the specific activities exempted include situations where pesticides may be used in accordance with labeled instructions. In this risk assessment, the Agency has assessed the risk associated with these practices using the standard assessment methodologies. Specific exemptions, and the reasoning behind each of the exemptions is provided below. The rule provides recommended best management practices, but does not require adherence to these practices by the landowner.

1. Stock Pond Management and Maintenance
    a. Chemical control of aquatic vegetation. These applications are allowed primarily because the Service felt "it is unlikely that vegetation control would be needed during the breeding period, as the primary time for explosive vegetation control is during the warm summer months." The Service recommends chemical control measures be used only "outside of the general breeding season (November through April) and juvenile stage (April through September) of the CRLF." Mechanical means are the preferred method of control.
    b. Pesticide applications for mosquito control. These applications are allowed because of concerns associated with human and livestock health. Alternative mosquito control methods, primarily introduction of nonnative fish species, are deemed potentially more detrimental to the CRLF than chemical or bacterial larvicides. The Service believes "it unlikely that [mosquito] control would be necessary during much of the CRLF breeding season," and that a combination of management methods, such as manipulation of water levels, and/or use of a bacterial larvicide will prevent or minimize incidental take.

2. Rodent Control. The Service notes "we believe the use of rodenticides present a low risk to CRLF conservation." In large part, this is due to the fact that "it is unknown the extent to which small mammal burrows are essential for the conservation of CRLF."

    a. Toxicant-treated grains. No data were available to evaluate the potential effects of these compounds (primarily anti-coagulants) on the CRLF. Grain is not a typical food item for the frog, but individuals may be indirectly exposed by consuming invertebrates which have ingested treated grain. There is a possibility of dermal contact, especially when the grain is placed in the burrows. Placing treated grain into the burrows is not prohibited, but should this method of rodent control be used, the Service recommends bait-station or broadcast application methods to reduce the probability of exposure.

b. Burrow fumigants. Use of burrow fumigants is not prohibited, but the Service recommends "not using burrow fumigants within 0.7 mi (1.2 km) in any direction from a water body" suitable as CRLF habitat.

2.7 Action Area

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the federal action and not merely the immediate area involved in the action (50 CFR 402.02). It is recognized that the overall action area for the national registration of ODM is likely to encompass considerable portions of the United States based on the large array of agricultural uses for which it is registered. 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 CRLF and its designated critical habitat within the state of California. Deriving the geographical extent of this portion of the action area is the product of consideration of the types of effects that ODM may be expected to have on the environment, the exposure levels to ODM that are associated with those effects, and the best available information concerning the use of ODM and its fate and transport within the state of California.

The definition of action area requires a stepwise approach that begins with an understanding of the federal action. The federal action is defined by the currently labeled uses for ODM. An analysis of labeled uses and review of available product labels was completed. This analysis indicates that, for ODM, the following uses are considered as part of the federal action evaluated in this assessment:

Alfalfa grown for seed	Beans (lima)	Sugar beets	Broccoli
Broccoli raab	Brussel sprouts	Cabbage	Cauliflower
Clover grown for seed	Sweet corn	Cotton	Cucumbers
Pumpkins	Summer squash	Winter squash	Watermelons
Musk melons (cantaloupes)	Other melons	Apples	Apricots
Cherries	Crab apples	Nectarines	Peaches
Plums	Prunes	Quinces	Grapes
Head lettuce	Spanish onions	Peppermint	Spearmint
Safflower	Walnuts	Ornamental plants grown for cut flowers.	

The analysis indicates that the following uses: ornamental, forest, non-bearing tree, and Christmas tree uses for which applications are made by injection do not need to be considered in this assessment. Tree injection methods of application are expected to pose little opportunity for exposure to the CRLF and other organisms upon which it depends. Tree injection methods are expected to confine ODM within tissues of treated trees. The potential for passive export of ODM from plant roots as a result of this method of treatment is unknown, but is not expected to result in exposure at the soil surface. ODM residues will be available to insects that consume leaves or sap; however, most of these are expected to be present on the trees while they are alive. Further, California PUR database usage data between 2002 and 2005 indicate that tree injection applications of ODM are minor compared to other types of applications. Most applications of this type were made to trees in landscape maintenance and rights of way. In most instances fewer than four instances of application occurred, and less than one pound was applied per year.

These applications are expected to occur in urban and suburban areas, which is reflected in the fact that usage is highest in San Diego, Orange, and Los Angeles Counties, which have large urban areas. Therefore, exposure to terrestrial organisms is not expected to be significant. The potential for runoff is also expected to be very low, so aquatic organisms are unlikely to be affected. Thus, tree injection uses are concluded to have "No Effect" on the CRLF and are not analyzed further in this assessment.

After determination of which uses will be assessed, an evaluation of the potential "footprint" of the use pattern should be determined. This "footprint" represents the initial area of concern and is typically based on available land cover data. Local land cover data available for the state of California were analyzed to refine the understanding of potential ODM use. The overall conclusion of this analysis is that all uses listed above have the potential to overlap with CRLF habitat. The initial area of concern is defined as all land cover types that represent the labeled uses described above. A map representing all the land cover types that make up the initial area of concern is presented in Figure 2c.

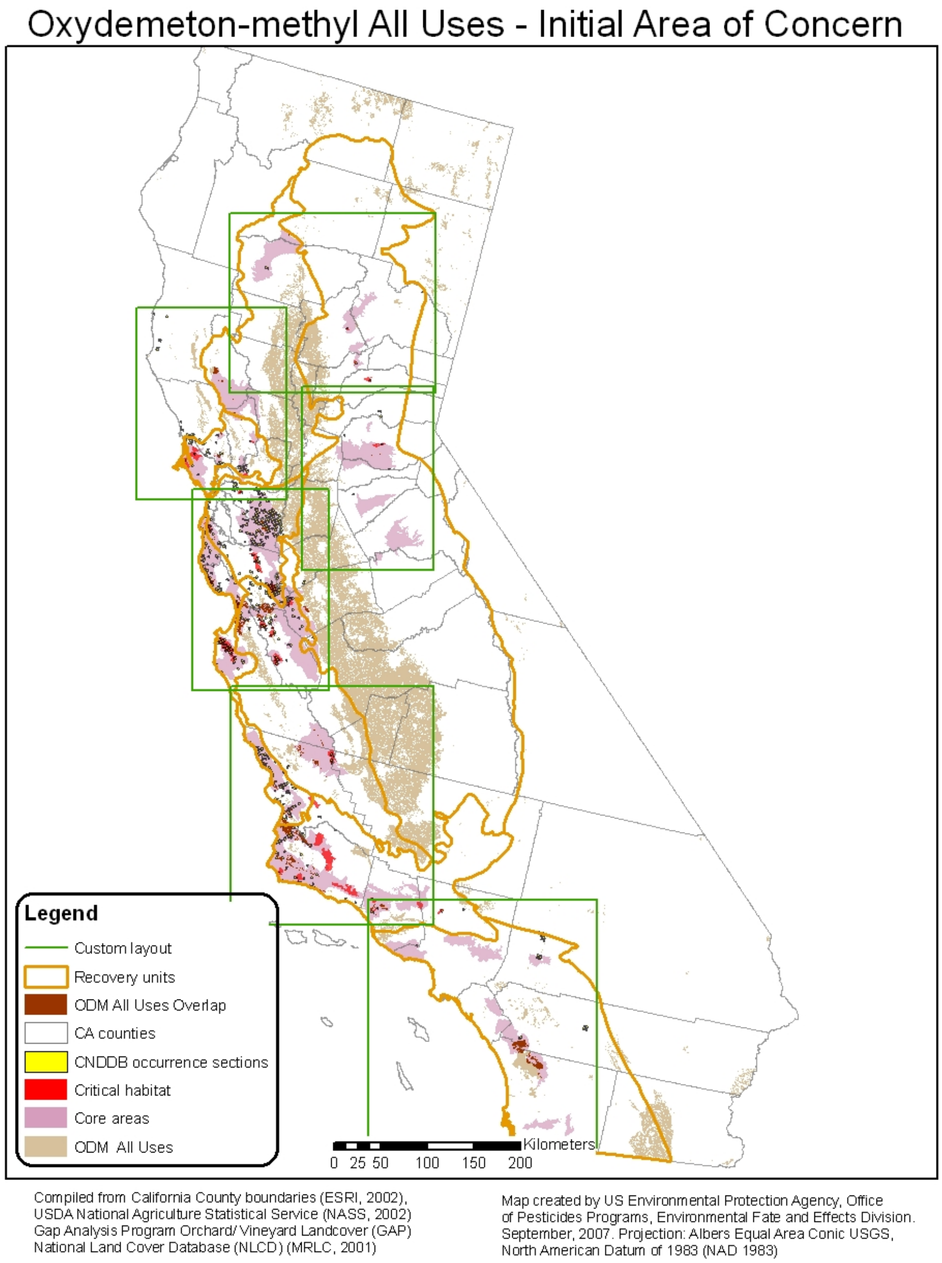


Figure 2c. Initial Area of Concern Map for ODM Uses in Proximity to the CRLF.

Once the initial area of concern is defined, the next step is to compare the extent of that area with the results of the screening level risk assessment. The screening level risk assessment will define which taxa, if any, are predicted to be exposed at concentrations above the Agency's Levels of Concern (LOC). The screening level assessment includes an evaluation of the environmental fate properties of ODM to determine which routes of transport are likely to have an impact on the CRLF.

Based on the low sorption potential and low volatility of ODM and its degradates, exposure in water bodies will be primarily in the water column. Exposure may occur in the soil at sites of application, through run-off to water bodies, and through spray drift to terrestrial environments.

LOC exceedances are used to describe how far effects may be seen from the initial area of concern. Factors considered include: spray drift, downstream run-off, atmospheric transport, etc. This information is incorporated into GIS and a map of the action area is created.

For ODM and the CRLF, the screening-level assessment indicated that exceedances are expected for birds (surrogate for the CRLF), mammals, and terrestrial invertebrates as a result of all uses. Further refinement of this assessment using the spreadsheet model, T-HERPS, which is more specific to analyses for CRLF exposure, resulted in the same findings. Fish and aquatic invertebrates also demonstrate RQs that exceed aquatic LOCs as a result of ODM aerial and ground applications to cole crops (broccoli, cauliflower, cabbage), and aerial applications to lettuce. Plants in terrestrial and riparian areas and aquatic plants are excluded from this assessment because toxicity tests available in guideline and ECOTOX studies demonstrated that ODM is not toxic to plants. Furthermore, no incidents involving plants have been reported in OPPs Ecological Incident Information System (EIIS). Based on this information, we believe that plants can be safely excluded from consideration in this risk assessment. Therefore, it is concluded that there is "No Effect" on the CRLF via plant-related endpoints. Discussion of plant effects is discussed further in Section 4: Effects Assessment.

Based on the RQ determined for all uses (i.e., RQs exceed for all terrestrial taxa under all uses analyzed in this risk assessment), and the extent of spray drift expected as a result of the highest application rate to cabbage, the initial area of concern is expected to be expanded beyond its perimeter by the addition of a 11,338-ft zone. It is also expanded due to runoff into moving water from areas of which at least 27% of cropped land contains ODM-treated crops. As a result the action area is larger than the initial area of concern. This area encompasses between 22.1% and 62.8% of CRLF habitat within the eight recovery units. The action area and analyses used to derive this area is given in the Risk Estimation Section, where the action area is depicted in Figure 5a. Detailed GIS results and maps are provided in Appendix G.

2.8 Assessment Endpoints and Measures of Ecological Effect

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected."[3] Selection of the assessment endpoints is based on valued entities (e.g., CRLF, organisms important in the life cycle of the CRLF, 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 ODM (e.g., runoff, spray drift, etc.), and the routes by which ecological receptors are exposed to ODM-related contamination (e.g., direct contact, etc).

[3] From U.S. EPA (1992). *Framework for Ecological Risk Assessment.* EPA/630/R-92/001.

2.8.1 Assessment Endpoints for the CRLF

Assessment endpoints for the CRLF include direct toxic effects on the survival, reproduction, and growth of the CRLF, as well as indirect effects, such as reduction of the prey base and/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 CRLF. 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.

A complete discussion of all the toxicity data available for this risk assessment, including resulting measures of ecological effect selected for each taxonomic group of concern, is included in Section 4 of this document. A summary of the assessment endpoints and measures of ecological effect selected to characterize potential assessed direct and indirect CRLF risks associated with exposure to ODM is provided in Table 2-4. At this time, data on the toxicity of ODM to amphibians are not available; therefore, data for other taxa will be used as a surrogate for the CRLF.

Table 2-4 Summary of Assessment Endpoints and Measures of Ecological Effects for Direct and Indirect Effects of Oxydemeton Methyl on the California Red-legged Frog

Assessment Endpoint	Measures of Ecological Effects[4]
Aquatic Phase (eggs, larvae, tadpoles, juveniles, and adults)[a]	
1. Survival, growth, and reproduction of CRLF individuals via direct effects on aquatic phases	1a. Most sensitive fish acute LC_{50} (guideline) 1b. Most sensitive fish early-life stage NOAEC (guideline or ECOTOX)
2. Survival, growth, and reproduction of CRLF individuals via effects to food supply (*i.e.*, freshwater invertebrates, non-vascular plants)	2a. Most sensitive fish and aquatic invertebrate EC_{50} or LC_{50} (guideline) (see below about aquatic plants) 2b. Most sensitive aquatic invertebrate (guideline)and fish chronic NOAEC (determined with ACR)
3. Survival, growth, and reproduction of CRLF individuals via indirect effects on habitat, cover, and/or primary productivity (*i.e.*, aquatic plant community)	3. Non-vascular plant EC_{50} (freshwater algae, guideline) (Resulted in No-Effect determination, so aquatic plants are excluded from further analysis)
4. Survival, growth, and reproduction of CRLF individuals via effects to riparian vegetation, required to maintain acceptable water quality and habitat in ponds and streams comprising the species' current range.	4. Distribution of EC_{25} values for monocots (ECOTOX) (Resulted in No-Effect determination, so terrestrial plants are excluded from further analysis)
Terrestrial Phase (Juveniles and adults)	
5. Survival, growth, and reproduction of CRLF individuals via direct effects on terrestrial phase adults and juveniles	5a. Most sensitive bird[b] acute LC_{50} or LD_{50} (guideline) 5b. Most sensitive bird[b] chronic NOAEC (guideline)
6. Survival, growth, and reproduction of CRLF individuals via effects on prey (*i.e.*, terrestrial invertebrates, small terrestrial vertebrates, including	6a. Most sensitive terrestrial invertebrate and vertebrate acute EC_{50} or LC_{50} (guideline)[c] 6b. Most sensitive terrestrial invertebrate and vertebrate

[4] All registrant-submitted and open literature toxicity data reviewed for this assessment are included in Section 4.

mammals and terrestrial phase amphibians)	chronic NOAEC (guideline)
7. Survival, growth, and reproduction of CRLF individuals via indirect effects on habitat (*i.e.,* riparian vegetation)	7a. Distribution of EC_{25} values for monocots (ECOTOX) (Resulted in No-Effect determination, so terrestrial plants are excluded from further analysis)
[a] Adult frogs are no longer in the "aquatic phase" of the amphibian life cycle; however, submerged adult frogs are considered "aquatic" for the purposes of this assessment because exposure pathways in the water are considerably different that exposure pathways on land. [b] Birds are used as surrogates for terrestrial phase amphibians. [c] Although the most sensitive toxicity value is initially used to evaluate potential indirect effects, sensitivity distribution is used (if sufficient data are available) to evaluate the potential impact to food items of the CRLF.	

2.8.2 Assessment Endpoints for Designated Critical Habitat

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of ODM that may alter the PCEs of the CRLF's critical habitat. PCEs for the CRLF were previously described in Section 2.6. Actions that may destroy or adversely modify critical habitat are those that alter the PCEs. 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 ODM effects data are available.

Assessment endpoints and measures of ecological effect selected to characterize potential modification to designated critical habitat associated with exposure to ODM are provided in Table 2-7. Adverse modification to the critical habitat of the CRLF includes the following, as specified by USFWS (2006) and previously discussed in Section 2.6:

1. Alteration of water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs.
2. Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs.
3. Significant increase in sediment deposition within the stream channel or pond or disturbance of upland foraging and dispersal habitat.
4. Significant alteration of channel/pond morphology or geometry.
5. Elimination of upland foraging and/or aestivating habitat, as well as dispersal habitat.
6. Introduction, spread, or augmentation of non-native aquatic species in stream segments or ponds used by the CRLF.
7. Alteration or elimination of the CRLF's food sources or prey base.

Measures of such possible effects by labeled use of ODM on critical habitat of the CRLF are described in Table 2-5. 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. Assessment endpoints used for the analysis of designated critical habitat are based on the adverse modification standard established by USFWS (2006).

Table 2-5. Summary of Assessment Endpoints and Measures of Ecological Effect for Primary Constituent Elements of Designated Critical Habitat

	Assessment Endpoint	**Measures of Ecological Effect**[5]
	Aquatic Phase PCEs (Aquatic Breeding Habitat and Aquatic Non-Breeding Habitat)	
	Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel	a. Most sensitive aquatic plant EC_{50} (guideline or ECOTOX) b. Distrib

[5] All toxicity data reviewed for this assessment are included in Section 4.

	or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.	ution of EC_{25} values for terrestrial monocots (seedling emergence, vegetative vigor, or ECOTOX) c. Distribution of EC_{25} va

		lues for terrestrial dicots (seedling emergence, vegetative vigor, or ECOTOX)
	Alteration in water chemistry/quality including temperature, turb	a. Most sensitive EC_{50} values for aquatic

	idity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs and their food source.[6]	plants (guideline or ECOTOX) b. Distribution of EC_{25} values for terrestrial monocots (seedling emergence or vegetat

[6] Physico-chemical water quality parameters such as salinity, pH, and hardness are not evaluated because these processes are not biologically mediated and are not relevant to the endpoints included in this assessment.

ive vigor, or ECOTOX) c. Distribution of EC_{25} values for terrestrial dicots (seedling emergence, vegetative vigor, or ECO

		TOX)
	Alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source.	a. Most sensitive EC_{50} or LC_{50} values for fish or aquatic-phase amphibians and aquatic invertebrates (guideline or

ECOTOX) b. Most sensitive NOAEC values for fish or aquatic-phase amphibians and aquatic invertebrates (guideline

		or ECOTOX)
	Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae)	a. Most sensitive aquatic plant EC_{50} (guideline or ECOTOX)
	Terrestrial Phase PCEs *(Upland Habitat and Dispersal Habitat)*	
	Elimination and/or disturbance of upland habitat; ability of	a. Distribution of EC_{25} values for mon

	habitat to support food source of CRLFs: Upland areas within 200 ft of the edge of the riparian vegetation or dripline surrounding aquatic and riparian habitat that are comprised of grasslands, woodlands, and/		ocots (seedling emergence, vegetative vigor, or ECOTOX) b. Distribution of EC_{25} values for dicots (seedling emergence,

	or wetland/riparian plant species that provides the CRLF shelter, forage, and predator avoidance		vegetative vigor, or ECOTOX) c. Most sensitive food source acute EC_{50}/LC_{50} and NOAEC values for terrestrial vertebr
	Elimination and/or disturbance of dispersal habitat: Upland or riparian dispersal habitat within designated		

	units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal		ates (mammals) and invertebrates, birds or terrestrial-phase amphibians, and freshwater fish.
	Reducti		

	on and/or modification of food sources for terrestrial phase juveniles and adults	
	Alteration of chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs and their	

	food source.	

2.9 Conceptual Model

2.9.1 Risk Hypotheses

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

- Labeled uses of ODM within the action area may directly affect the CRLF by causing mortality or by adversely affecting growth or fecundity;
- Labeled uses of ODM within the action area may indirectly affect the CRLF by reducing or changing the composition of food supply;
- Labeled uses of ODM within the action area may indirectly affect the CRLF and/or modify designated critical habitat by reducing or changing the composition of the terrestrial plant community (i.e., riparian habitat) required to maintain acceptable water quality and habitat in the ponds and streams comprising the species' current range and designated critical habitat;
- Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing or changing breeding and non-breeding aquatic habitat (via modification of water quality parameters, habitat morphology, and/or sedimentation);
- Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing the food supply required for normal growth and viability of juvenile and adult CRLFs;
- Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing or changing upland habitat within 200 ft of the edge of the riparian vegetation necessary for shelter, foraging, and predator avoidance.
- Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing or changing dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites which do not contain barriers to dispersal.
- Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by altering chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs.

2.9.2 Diagram

The conceptual model is a graphic representation of the structure of the risk assessment. It specifies the stressor (ODM), release mechanisms, biological receptor types, and effects endpoints of potential concern. The conceptual models for aquatic and terrestrial phases of the

CRLF are shown in Figures 2c and 2d, and the conceptual models for the aquatic and terrestrial PCE components of critical habitat are shown in Figures 2e and 2f. Exposure routes shown in dashed lines are not quantitatively considered because the resulting exposures are expected to be so low as not to cause adverse effects to the CRLF.

Long-range atmospheric transport is not expected due to the non-volatility and non-persistent nature of ODM. Likewise, groundwater transport is considered unlikely due to the low persistence of ODM, even when its mobility in soil is considered. The operative routes of exposure will be spray drift at the time of application, and run-off due to precipitation.
.

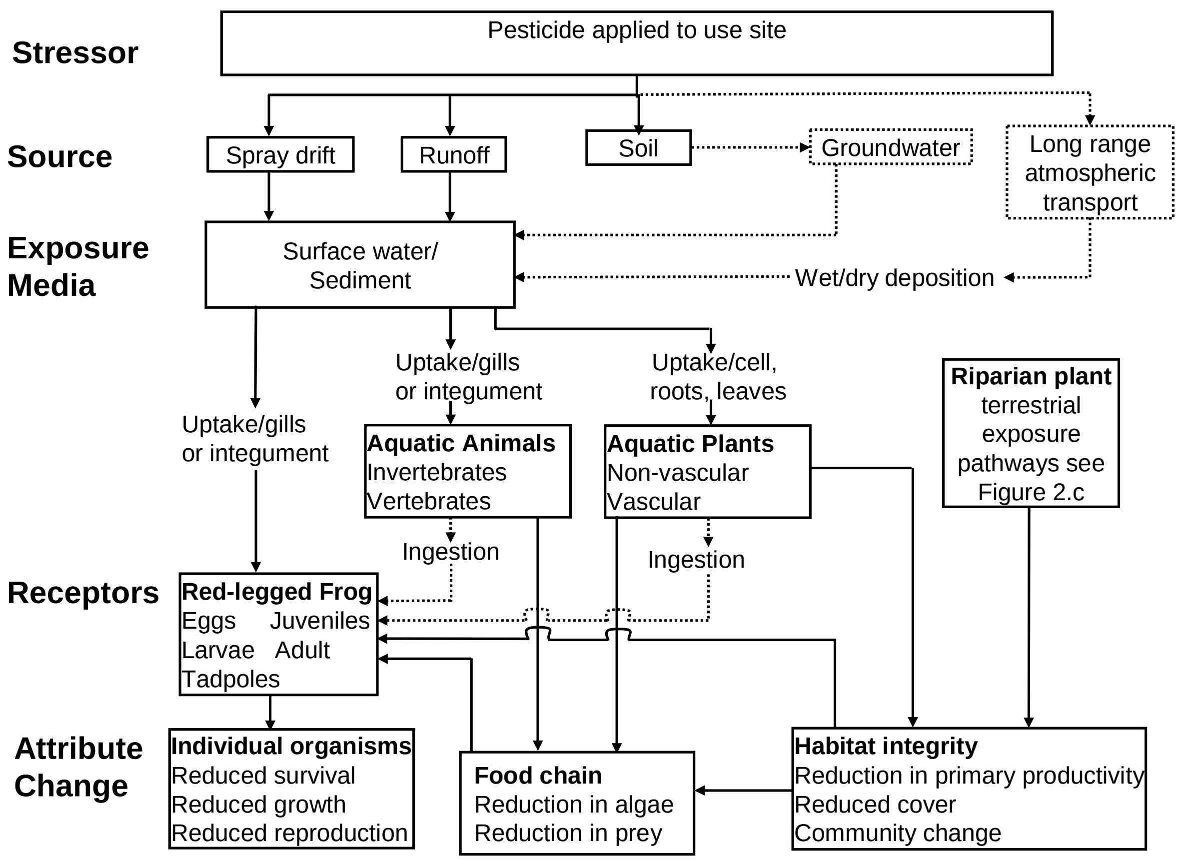


Figure 2d. Conceptual Model for Pesticide Effects on Aquatic Phase of the Red-Legged Frog

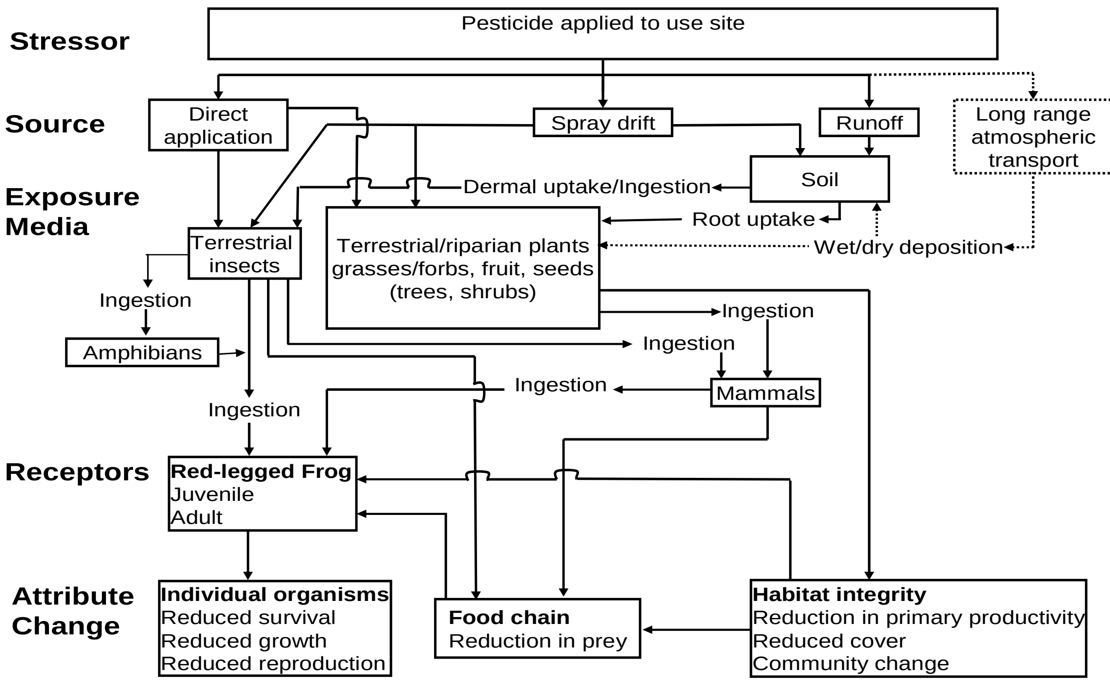


Figure 2e. Conceptual Model for Pesticide Effects on Terrestrial Phase of Red-Legged Frog

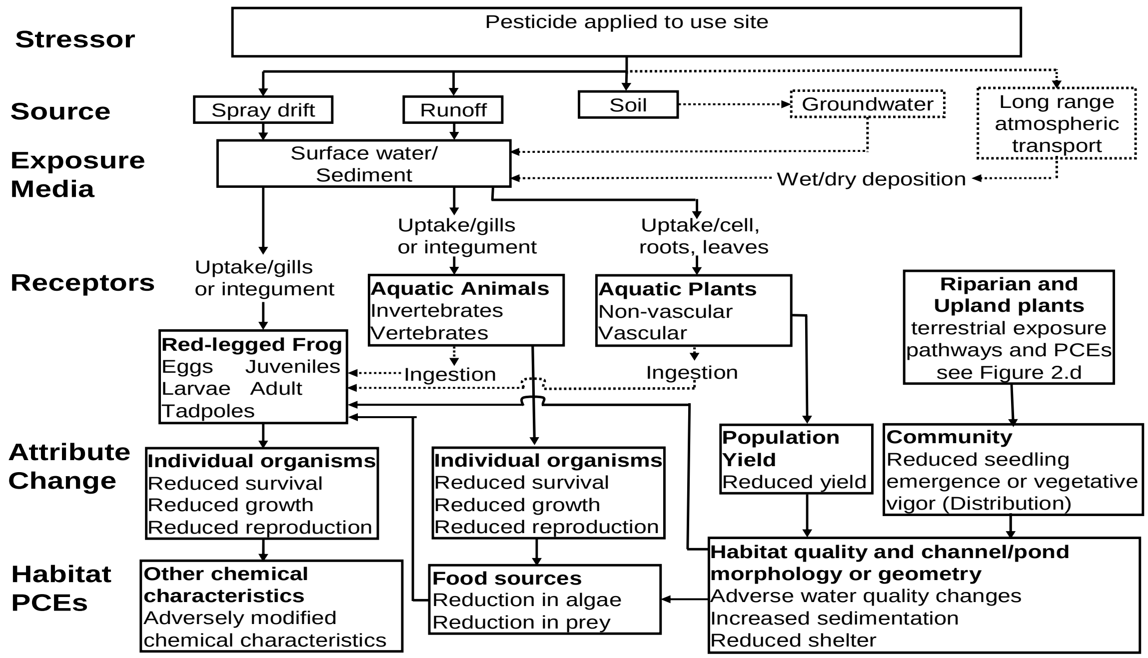


Figure 2f. Conceptual Model for Pesticide Effects on Aquatic Components of Red-Legged Frog Critical Habitat

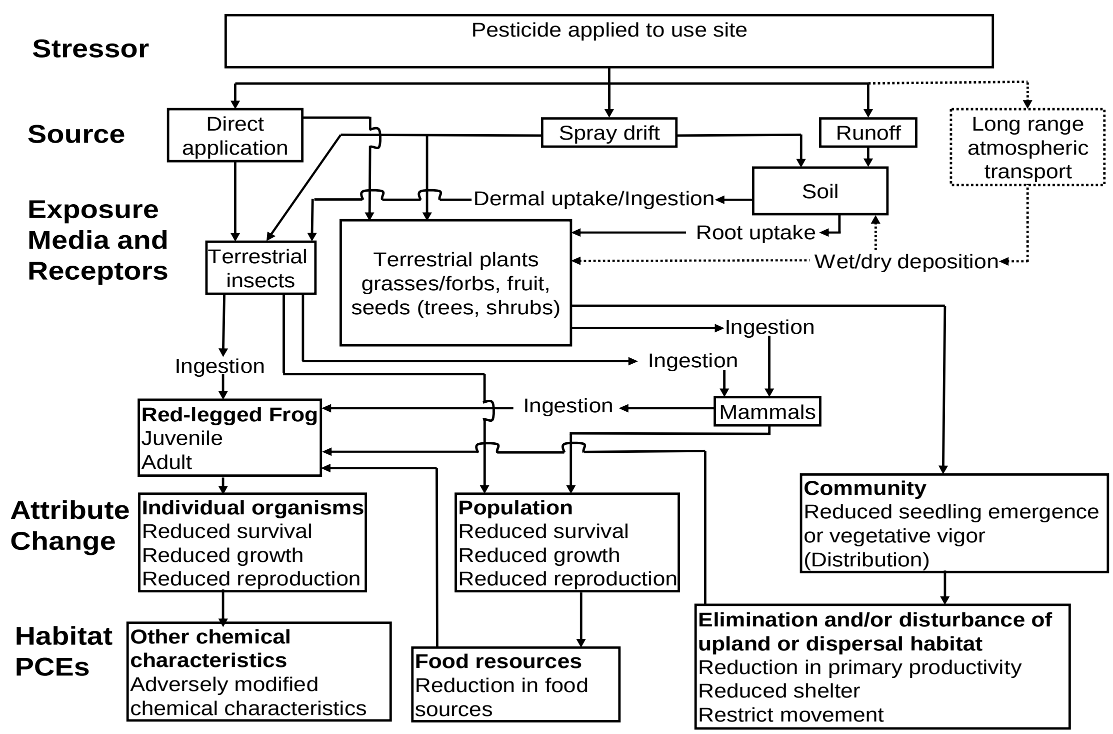


Figure 2g. Conceptual Model for Pesticide Effects on Terrestrial Components of Red-Legged Frog Critical Habitat

2.10 Analysis Plan

Analysis of ODM risks to the California Red-Legged Frog (both direct and indirect) and to its critical habitat will be assessed according to the Overview Document (EPA, 2004) and Agency guidance for ecological risk assessments.

2.10.1 Exposure Analysis

Aquatic. Risks (direct effects) to the aquatic phase CRLF will be assessed by comparing modeled surface water exposure concentrations of ODM to acute and chronic effect concentrations for aquatic phase amphibians (surrogate freshwater fish) from laboratory studies (see the Effects Analysis section below). Risks (indirect effects) to aquatic dietary food resources (aquatic invertebrates) of the aquatic phase CRLF or risks (indirect effects) to aquatic habitat that support the CRLF will also be assessed by comparing modeled surface water exposure concentrations of total ODM residues to laboratory established effect levels appropriate for the taxa.

For the screening assessment, the standard EXAMS water body of 2 meters maximum depth, and 20,000 cubic meters volume, will be used. Since ODM is applied by numerous application methods, the model accounts for loading into the surface water via spray drift, run-off and erosion (Figure 2d and 2f). Agricultural scenarios appropriate for labeled ODM uses will be used to account for local soils, weather and growing practices which impact the magnitude and frequency of ODM loading to the surface water. Maximum labeled application rates, with maximum number of applications and shortest intervals, will be used to help define (1) the Action Area within California for the Federal Action and (2) for evaluating effects to the CRLF.

Concentrations of ODM estimated by PRZM-EXAMS represent loading in water bodies adjacent to any treated field and assume that the concentration applies to any water body within the treated area.

Terrestrial. Risks to the terrestrial phase CRLF will be assessed by comparing modeled exposure to effect concentrations from laboratory studies. Exposure in the terrestrial phase will be quantified using the TREX model, which automates the calculation of dietary exposure according to the Hoerger-Kenaga nomogram, as modified by Fletcher et al. (1994). The nomogram tabulates the 90th and 50th percentile exposure expected on various classes of food items, and scales the exposure (in dietary terms) to the size and daily food intake of several size classes of birds and mammals. Birds are also used as surrogates to represent reptiles and terrestrial-phase amphibians. A foliar decay half-life of 35 days will be used. This is the default value used in EFED when the foliar dissipation half-life is not known and no data exist from which to estimate it.

The LOC is expected to be exceeded for ODM for birds (the surrogate organism for the CRLF). Therefore, the T-HERPS model will be used to characterize direct risks to the CRLF. This model utilizes the same principles as in TREX, except that the estimated daily food intake is adjusted for herpetofauna given that they consume less food per day than homeotherms.

Effects to terrestrial invertebrates will be estimated by using the dose-based EEC obtained from TREX for 20g birds consuming large insects (in mg/kg bw) multiplied by an estimated value for bee bodyweight (0.128g) to obtain a dose in µg/bee, which can then be divided by the toxicity value (also in µg/bee) to calculate an RQ.

2.10.2 Effects Analysis

As previously discussed, assessment endpoints for the frog include direct toxic effects on survival, reproduction, and growth of the species itself, as well as indirect effects, such as reduction of the prey base and/or modification of its habitat. Direct effects to the red-legged frog are based on toxicity information for freshwater fish and birds, which are generally used as a surrogate for aquatic and terrestrial phase amphibians, respectively. The open literature will be screened also for available frog toxicity data. Indirect effects to the red legged frog are assessed by looking at available toxicity information of the frog's prey items and habitat requirements (freshwater invertebrates, freshwater vertebrates, terrestrial invertebrates, and terrestrial vertebrates).

2.10.3 Action Area Analysis

The Action Area for the federal action is the geographic extent of exceedence of listed species Levels of Concern (LOCs) for any taxon or effect (acute or chronic, direct or indirect) resulting from the maximum label-allowed use of ODM. To define the extent of the Action Area for ODM with respect to the CRLF and its habitat, the following exposure assessment tools will be used: PRZM-EXAMS, TREX, THERPS, AgDrift, AgDISP, and ArcGIS, a geographic information system (GIS) program. Other tools may be used as required if these are inadequate to define the maximum extent of the Action Area.

Terrestrial. To determine the terrestrial extent of the Action Area for terrestrial effects, a distance around the initial area of concern over which effects are potentially extended by spray drift must be estimated. To estimate this distance, the rate (in lb ai/acre) needed to bring all RQs below their respective LOC (0.1 for acute, non-endangered birds and mammals, and 1.0 for chronic) is calculated by dividing the LOC by the RQ, and multiplying the result by the highest single application rate (0.75 lb/acre):

Rate below LOC (lb ai/acre) = (LOC/RQ)*(application rate, lb ai/acre).

The AgDrift or AgDISP model is then used to calculate the buffer distance needed to reduce the rate to below LOCs. If the result is beyond the range of these models, then the Gaussian extension to AgDISP is used.

Aquatic. To determine the downstream extent of the Action area for any aquatic effects, ODM residues will also estimated for downstream from the treated areas by assuming dilution with stream water (derived from land area) from unaffected sources propagating downstream, until a point is reached beyond which there are no relevant LOC exceedances. Once the distribution of predicted stream water concentrations is obtained, it is further processed using a model that calculates expected dilution in the stream according to contributing land area. As the land area surrounding the field on which ODM is applied is enlarged, it encompasses a progressively greater drainage area; in effect, a progressively larger 'sub-watershed' is created, with a concomitant increase in dilution at the drainage point. This drainage point moves down-gradient along the stream channel as the sub-watershed is expanded. At a certain point the predicted stream concentrations will fall below the LOC. The area below this point is then assumed not to be at risk, with the upstream areas (up to the initial application area) assumed to present the potential for (direct and indirect) impact on the RLF. Additional ODM inputs within the same watershed will cause the area bounded by the LOC to increase, extending the length of stream that is likely to be impacted.

In order to determine the extent of the action area downstream from the initial area of concern, the Agency will need to complete the screening level risk assessment. Once all aquatic risk quotients (RQs) are calculated, the Agency determines which RQ to level of concern (LOC) ratio is greatest for all aquatic organisms (plant and animal). For example, if fish have an acute RQ of 1 and aquatic invertebrates have an acute RQ of 2, the invertebrate RQ to LOC ratio (2/0.05) would be greater than for plants (1/0.05). Therefore, the Agency would identify all stream reaches downstream from the initial area of concern where the percent catchment area (PCA) for the land uses identified for ODM are greater than 1/40, or 2.5%. All streams identified as draining upstream catchments greater than 2.5% of the land class of concern, will be considered part of the action area.

3. Exposure Assessment

3.1 Label Application Rates and Intervals

Application rates and application intervals for ODM uses analyzed in this risk assessment are presented in Table 3-1.

Table 3-1. Label Use Rates for ODM in California.

Use	Max. One-Time Application. Rate	Max No. Applications	Min. Appl. Interval
Cabbage	0.75 lbs ai/A	3	7 days
Peppermint and spearmint	0.75 lbs ai/A	2	10 days
Brussel sprouts	0.5 lbs ai/A	3	7 days
Beans, lima	0.5 lbs ai/A	2	7 days
Broccoli	0.5 lbs ai/A	2	7 days
Broccoli raab	0.5 lbs ai/A	2	7 days
Cauliflower	0.5 lbs ai/A	2	7 days
Corn, sweet	0.5 lbs ai/A	2	7 days
Lettuce, head	0.5 lbs ai/A	2	7 days
Safflower	0.5 lbs ai/A	2	7 days
Alfalfa (grown for seed)	0.5 lbs ai/A	2	14 days
Clover grown for seed	0.5 lbs ai/A	2	14 days
Onions, Spanish (bulb)	0.5 lbs ai/A	2	14 days
Beets, sugar	0.5 lbs ai/A	1	N/A
Cotton	0.5 lbs ai/A	1	N/A
Curcurbits[2]	0.5 lbs ai/A	1	N/A
Fruit trees, non-bearing[1]	0.375 lbs ai/A	2	7 days
Grapes, non-bearing	0.375 lbs ai/A	2	7 days
Ornamental plants grown for cut flowers	0.375 lbs ai/A	2	7 days
Walnuts	0.375 lbs ai/A	1	N/A

[1]Apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces
[2]Cucumbers, pumpkins, summer squash, winter squash, watermelons, muskmelons (canteloupes), other melons

3.2 Aquatic Exposure Assessment

As discussed in section 2.5.4, the CRLF occupies a variety of shallow, static and flowing aquatic habitats in the aquatic phase of its life cycle (egg to tadpole). The current range of the CRLF is represented by the core areas, critical habitat and occurrence sections in Figure 2a.

3.2.1 Conceptual Model of Exposure

Aquatic exposure of the CRLF within the action area is estimated with the PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) model (EPA, 2004). Screening-level exposures (estimated environmental concentrations, EEC) are produced using the standard farm pond of 20,000 cubic meters volume. Watersheds where ODM is used are assumed to have 100% cropped area. The downstream extent of streams with exposures above the Level of Concern (LOC) is estimated (using GIS methods) by expanding the watershed considered until uncontaminated stream flow dilutes the initial pond concentration to below the LOC. For the ODM application rates listed in Table 3-1 above, this results in a downstream extent into areas containing ≥27% of areas containing crops associated with ODM.

Standard assumptions of 1% spray drift for ground application and 5% drift for aerial application are used. If the pond concentration from PRZM-EXAMS exceeds the LOC, a spray drift buffer is calculated (using AgDrift model) that will reduce the pond concentration to below the LOC. If a spray drift buffer cannot be used to reduce the pond concentration to below the LOC, then a separate spray drift buffer (neglecting run-off) is calculated with AgDrift to ensure that pond concentrations are below the LOC (see section 2.10.3 above).

3.2.2 Existing Monitoring Data

The state of California performed monitoring for ODM in Sacramento county in 1991 (Aug 26, Oct 25, and Oct 26) and 1992 (Feb 9 and 10). There were no detections in 180 samples with a detection limit of 0.1 or 1.0 ppb. The general areas monitored included the American River, Chicken/Strong Ranch Slough, City of Folsom urban runoff, and the Sacramento River. These data are not considered sufficient for the exposure assessment, so modeling will be used instead.

3.2.3 Modeling Approach

The Tier 2 model, PRZM-EXAMS, was used to estimate aquatic exposures to ODM in the absence of adequate monitoring data in the areas of interest. PRZM scenarios were chosen to represent the registered crop uses (see Table 3-2 below). Model input parameters were chosen in accordance with the Input Parameter Guidance of Feb. 28, 2002.

Use sites and the PRZM scenarios used to represent them are given in Table 3-2.
Risk quotients (RQs) were initially based on EECs derived using the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) standard ecological pond scenario according to the methodology specified in the Overview Document (U.S. EPA, 2004). Where LOCs for direct/indirect effects and/or adverse habitat modification are exceeded based on the modeled EEC using the static water body (i.e., "may affect"), refined modeling may be used to differentiate "may affect, but not likely to adversely affect" from "may affect and likely to adversely affect" determinations for the CRLF and its designated critical habitat.

The general conceptual model of exposure for this assessment is that the highest exposures are expected to occur in the headwater streams adjacent to agricultural fields. Many of the streams and rivers within the action area defined for this assessment are in close proximity to agricultural use sites. Twenty-eight California scenarios were used in this assessment, 16 of which were developed for the CRLF assessment. Each scenario is intended to represent a high-end exposure setting for a particular crop. Each scenario location is selected based on various factors including crop acreage, runoff and erosion potential, climate, and agronomic practices. Once a location is selected, a scenario is developed using locally specific soil, climatic, and agronomic data. Each PRZM scenario is assigned a specific climatic weather station providing 30 years of daily weather values.

Specific California PRZM scenarios were chosen for this assessment (Table 3-2), plus a scenario for mint from Oregon. All scenarios were used within the standard framework of PRZM/EXAMS modeling using the standard graphical user interface (GUI) shell, PE4v01.pl.

Table 3-2. Application Parameters for Modeled Crops

PRZM Scenario[1]	Crop	Rate lb/acre	Number of applications	Interval (days)	First Application Date
Cole crop	Broccoli, cauliflower, broccoli raab	0.5	2	7	Feb. 1
	Brussel sprouts	0.5	3	7	Feb. 1
	Cabbage	0.75	3	7	Feb. 1
Oregon mint	Peppermint, spearmint	0.75	2	10	Apr. 20
Row Crop	Lima Beans	0.5	2	14	Mar. 1
Corn	Sweet Corn	0.5	2	7	Apr. 15
Lettuce	Head Lettuce	0.5	2	7	Mar. 1
Alfalfa	Alfalfa, clover (both grown for seed)	0.5	2	14	Mar 1
Onion	Spanish Onion (bulb)	0.5	2	14	Mar. 1
Sugarbeet	Sugarbeet	0.5	1	n/a	Mar. 1
Cotton	Cotton	0.5	1	n/a	May 10
Melons	Curcubits (cucumbers, pumpkins, summer and winter squash, watermelons, muskmelons, canteloupes	0.5	1	n/a	May 20
Fruit	Non-bearing apples, apricots, cherries, crab apples, nectarines, peaches, plums, prunes, quinces	0.375	2	7	Mar. 1
Nursery	Ornamental plants grown for flowers	0.375	2	7	Mar. 1
Almond	Walnut	0.375	1	n/a	Mar. 1

[1]Where applicable, both ground and aerial applications were modeled. Aerial applications are prohibited for cotton, fruit trees, grapes, mint, walnuts, nurseries.

3.2.3.1 Model Inputs

The estimated water concentrations from surface water sources were calculated using Tier 2 PRZM/EXAMS. PRZM is used to simulate pesticide transport as a result of runoff and erosion from a standardized watershed, and EXAMS estimates environmental fate and transport of pesticides in surface waters. The linkage program shell (PE4v01.pl) that incorporates the site-specific scenarios was used to run these models.

The PRZM/EXAMS model was used to calculate concentrations using the standard ecological water body scenario in EXAMS. Weather and agricultural practices were simulated over 30 years so that the 1 in 10 year exceedance probability at the site was estimated for the standard ecological water body.

Models to estimate the effect of setbacks on load reduction for runoff are not currently available. It is well documented that vegetated setbacks can result in a substantial reduction in pesticide load to surface water (USDA, NRCS, 2000). Therefore, the aquatic EECs presented in this assessment are likely to over-estimate exposure in areas with well-vegetated setbacks. While the extent of load reduction cannot be accurately predicted through each relevant stream reach in the action area, data from USDA (USDA, 2000) suggest reductions could range from 11 to 100%.

The appropriate PRZM input parameters (Table 3-3) 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 2.3, February 28, 2002.

Table 3-3. PRZM-EXAMS Input Parameters

Input Parameter	Value	Source/Comment
Molecular Weight	246.29 g/mol	EFGWB one-liner
Aerobic Soil half-life	9.6 days (3 times single value of 3.2 days)	MRID 42830501
Freundlich constant, Kf	0.01	MRID 40884202
Aqueous Solubility	1,000,000 ppm (miscible)	EFGWB one-liner
Vapor Pressure	2.85 E-5 torr	EFGWB one-liner
Hydrolysis half-life	41 days (pH 7)	MRID 00143057
Aqueous photolysis half-life	136 days	MRID 40781501
Benthic half-life	10.5 days (3 times single value of 3.5 days)	MRID 42901801
Aerobic aquatic half-life	19.2 days	2 times soil input value as per Input Parameter guidance
Chemical Application Method (CAM)	2 (foliar spray)	Pesticide Labels
Incorporation Depth	0 cm	Appropriate for foliar spray
Application Efficiency	0.99 (ground spray) 0.95 (aerial spray)	as per Input Parameter guidance
Spray Drift	1% (ground) 5% (aerial)	as per Input Parameter guidance

Table 3-2 provides details of the application parameters utilized in each scenario modeled. The date of first application was set at March 1, because most uses for which there are data (PUR) show use in California in most months of the year, and March corresponds to both a rainy part of the year (thereby capturing higher run-off values), and the reproductive season of the frog. Other dates were used where the PRZM scenario emergence, maturation and harvest dates for the crop made March 1 inappropriate. Safflower was not modeled, because there was no appropriate PRZM scenario to use as a surrogate.

3.2.3.2 Results

The following results were obtained from PRZM-EXAMS (Table 3-4); output from PRZM-EXAMS is provided in Appendix A. The highest peak exposures were for the cole crops (broccoli, cauliflower, cabbage, brussel sprouts) because the crop emergence date for the PRZM scenario dictated a first application date in early February, which is a particularly rainy period. The higher rainfall results in higher run-off, and therefore higher exposure. These uses also have some of the highest application rates with the shortest application interval.

Table 3-4. PRZM-EXAMS Modeled Exposure to ODM.

Crop	Application Method	Peak Conc. (ppb)	21-Day Conc. (ppb)	60-Day Conc. (ppb)
Cabbage	Ground	33.11	26.22	17.19
	Aerial	34.52	28.09	18.49
Mint	Ground	0.49	0.39	0.26
Brussel sprouts	Ground	22.07	17.26	11.32
	Aerial	23.01	18.71	12.32
Lima beans	Ground	3.32	2.44	1.54
	Aerial	5.00	3.69	2.47
Broccoli, Cauliflower	Ground	20.31	15.04	9.46
	Aerial	21.52	15.94	10.06
Corn	Ground	0.74	0.56	0.34
	Aerial	2.74	1.96	1.23
Lettuce	Ground	9.60	7.33	4.55
Alfalfa	Ground	5.40	4.13	2.58
	Aerial	6.76	5.24	3.29
Onion	Ground	1.00	0.79	0.49
	Aerial	2.66	1.94	1.36
Sugar beets	Ground	2.82	2.04	1.21
	Aerial	3.53	2.55	1.62
Cotton	Ground	0.43	0.27	0.18
Melons	Ground	0.28	0.19	0.11
	Aerial	1.40	0.94	0.49
Fruit	Airblast	3.06	2.23	1.45
Grapes	Airblast	2.93	2.27	1.47
Nursery	Ground	3.84	2.90	1.77
	Aerial	4.68	3.81	2.36
Walnuts	Ground	0.80	0.61	0.42
	Airblast	1.61	1.17	0.78

3.3 Terrestrial Exposure Assessment

As discussed in section 2.5.4, adult CRLF occupy a variety of terrestrial dispersal habitats. The current range of the CRLF is represented by the core areas, critical habitat and occurrence sections in Figure 2a.

3.2.4 Conceptual Model of Exposure

Terrestrial exposure of the CRLF on agricultural fields within the action area is estimated with the T-REX model, which automates exposure analysis according to the Hoerger-Kenaga nomogram modified by Fletcher et al (1994). The nomogram relates the pesticide application rate to residues measured on crops in numerous field studies. T-REX utilizes the nomogram to estimate initial residue values on the day of application, and automates the calculation of daily residue decay. T-REX then calculates both a diet-based exposure value and a dose-based exposure value for birds and mammals. This model is a screening-level tool with which to determine effects to the CRLF, and is also a tool used to estimate on-field exposure to mammalian and terrestrial invertebrate food items. In the event that the RQ exceeds the listed-species LOC for birds, which is the surrogate organism for the terrestrial-phase CRLF, the T-HERPS model is used to obtain a more refined estimate of exposure to the CRLF for exposure characterization. This model provides a dose-based estimate of exposure by taking into account a more realistic estimate of food intake for the CRLF given that they are poikilotherms and consume less food. Off-field exposure of animals is estimated with the AgDrift and AgDISP models. Where the estimated travel distance of ODM drift exceeds the limit within the AgDrift model, the Gaussian extension of the AgDISP model is used to estimate the distance to which terrestrial animals are exposed as a result of spray drift.

T-REX and T-HERPS estimate the daily decay of ODM residues using a first-order degradation model that requires an input for the foliar dissipation half-life. The default half-life value is 35 days, which is used when no other information is available. Willis and McDowell (1987) provide foliar dissipation half-life values for many active ingredients, and is primarily consulted to obtain this value. Alternatively, guideline magnitude of residue studies (171-4) submitted to the Agency may be consulted. Willis and McDowell (1987) does not list a half-life value for ODM, and the available magnitude of residue studies do not provide adequate information with which to estimate a half-life. Therefore, the default 35-day value will be used, but the effect of the half-life will be explored by substituting hypothetical values for risk characterization.

3.2.5 Modeling Approach

On-field exposures of the CRLF and its prey were estimated with T-REX. In order to bracket the possible risks, the lowest and highest rates of ODM application (walnuts and cabbage, respectively) were first modeled. Walnuts receive a one-time treatment of 0.375 lbs ai/acre while cabbage can receive 3 treatments of 0.75 lbs ai/acre spaced at 7-day intervals. The default 35-day half-life was used to model exposure to foliar residues, since there was no further information regarding the actual half-life. This may be an overestimation of the half-life, since ODM is not particularly persistent in the environment; however, it would result in a conservative estimate of exposure. Direct risk to the CRLF was bounded using 20-gram and 100-gram avian weight classes within T-REX, since the weight of young adult frog falls in in this range. The CRLF was assumed to consume the broadleaf plant/small insect food category, since the bulk of its diet is invertebrates, and the small insect food category provides a higher dose. In addition, large CRLF also consumes other frogs and mice.

Dose-based RQs for the combination of weight class and food item categories for birds within T-REX exceeded the listed-species LOC when modeled using the application rate for walnuts (Table 3-5). Therefore, T-HERPS was also run in order to characterize the potential daily dose of ODM to the CRLF with a more refined estimate.

Indirect risks to the CRLF through effects on its prey base were estimated in two ways. First, indirect effects via losses of larger prey items (for example, Pacific tree frog and California mouse) were estimated conservatively using the 37-gram weight class for amphibians within T-HERPS and the 15-gram weight class for mammals within TREX. For amphibian prey, the 37-gram/small herbivorous mammal class provided the most conservative estimate. The short-grass food category were used for the mammals, since it provides the highest dose estimate for that taxon and is included in its diet. Diet-based EECs were used to estimate chronic effects.

Indirect effects via losses of smaller prey items (terrestrial invertebrates) were estimated using the LD_{50} data for the honey bee, and an assumed body weight of 0.128 grams. The dose was calculated by multiplying the dose-based EEC for 20-gram birds consuming large insects (given in mg/kg bw, which is identical to µg/g bw) by an estimate of the body weight of a bee (0.128 g). This provides an estimated exposure value for the bee in units of µg/bee, which can be directly compared to the LD_{50} for honeybees to derive an RQ.

3.2.6 Model Inputs

TREX and T-HERPS model inputs included the lowest and highest application rates (0.375 to 0.75 lb ai/acre), number of applications (1-3), application interval (7 days), and default foliar dissipation rate (35 days).

3.2.7 Results

See Appendix B for details of the T-REX and T-HERPS EEC calculations. Summaries of the results are provided in the following sections.

3.2.7.1 EECs for Direct Effects to Terrestrial Phase CRLF

Table 3-5 presents the EECs for birds (surrogate for terrestrial phase CRLF) calculated with T-REX. The values presented are for uses involving the lowest and highest application rates and are based on the upper bound estimate of exposure from the Kenaga nomogram. The lowest application rate used in the model is for applications on walnuts in which the maximum one-time rate is 0.375 lbs ai/acre and only one application is allowed. The highest application rate is based on the use in cabbage, in which up to 3 applications of 0.75 lbs ai/acre may be made, each at 7 day intervals. Values from the T-REX model will be used to calculate RQs and determine direct effects to the CRLF.

Table 3-5. Upper Bound Kenaga Residues for 20-g and 100-g Birds (surrogates for CRLF) from T-REX

Weight Class	Exposure Type	EECs[1]			
		Small Insects		Large Insects	
		Low	High	Low	High
20 g	Dose-based	57.66	303.09	6.41	33.68
100 g	Dose-based	32.88	172.84	3.65	19.20
(no size class distinction)	Diet-based	50.63	266.13	5.63	29.57

[1]"Low" and "High" refer to EECs determined for the lowest application rate and the highest application rate (see text).

3.2.7.2 Terrestrial EECs for Indirect Effects to CRLF

EECs are determined for amphibian, mammalian, and insect prey items in order to estimate the risk of indirect effects to the CRLF as a result of the loss of these prey items. EECs for amphibians (using birds) and mammals were estimated using T-REX (Tables 3-6 and 3-7). These EECs are based on the same scenarios upon which the direct effects assessment are based. The smallest weight classes (20-g birds and 15-g mammals) are used. The short grass foraging class will be used to make determinations, since EECs are highest for this class and provide a protective assessment of exposure. Other foraging classes are included for further characterization.

Amphibians (Birds)

Table 3-6 provides EECs for potential amphibian prey items. These values were calculated using T-REX and represent a 20-g animal.

Table 3-6. Upper Bound Kenaga, Dose- and Diet-Based EECs for Amphibian prey items.

Exposure Type	EECs[1]							
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects	
	Low	High	Low	High	Low	High	Low	High
Dose-based	102.50	538.83	46.98	246.96	57.66	303.09	6.41	33.68
Diet-based	90.00	473.11	41.25	216.84	50.63	266.13	5.63	29.57

[1]"Low" and "High" refer to EECs determined for the lowest application rate and the highest application rate for ODM.

Mammals

EECs for mammalian prey are presented below (Table 3-7), based on T-REX output for the lowest and highest application scenarios.

Table 3-7. Upper Bound Kenaga, Dose- and Diet-Based EECs for 15-g Mammalian Prey.

Exposure Type	EECs[1]									
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
	Low	High	Low	High	Low	High	Low	High	Low	High
Dose-based	85.81	451.08	39.33	206.74	48.27	253.73	5.36	28.19	1.19	6.26
Diet-based	90.00	473.11	41.25	216.84	50.63	266.13	5.63	29.57	N/A	N/A

[1]"Low" and "High" refer to EECs determined for the lowest application rate and the highest application rate for ODM.

Terrestrial Invertebrates

Using the approach to estimating the EEC for terrestrial invertebrates described above, the dose estimated to terrestrial invertebrates for the walnut scenario (low value) is 0.82 μg/bee and for the cabbage scenario (high value) is 4.31 μg/bee.

4. Effects Assessment

This assessment evaluates the potential for ODM to directly or indirectly affect the CRLF and/or modify its designated critical habitat. As previously discussed, assessment endpoints for the CRLF include direct toxic effects on the survival, reproduction, and growth, as well as indirect effects, such as reduction of the prey base and/or modification of its habitat. In addition, potential modification of critical habitat are assessed by evaluating effects to the PCEs, which are components of the critical habitat areas that provide essential life cycle needs of the CRLF. Toxicity data used to evaluate direct effects, indirect effects, and modification to critical habitat in this risk assessment for ODM are summarized in Table 4-1.

Information on the toxicity of ODM to selected taxa is characterized based on registrant-submitted studies and a comprehensive review of the open literature on ODM. Values used for each measurement endpoint identified in Table 2-7 are selected from these data. Currently, no FIFRA data requirements exist for aquatic-phase or terrestrial-phase frogs and are therefore not part of typical registrant submitted data packages. A summary of the available ecotoxicity information; the selected individual, population, and community-level endpoints for characterizing risks; and interpretation of the LOC, in terms of the probability of an individual effect based on probit dose response relationship are provided in Sections 4.1 through 4.3, respectively.

4.1 Evaluation of Aquatic Ecotoxicity Data

Toxicity measurement endpoints are selected from data 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) (U.S. EPA, 2004). Open literature data presented in this assessment were obtained from a search of the ECOTOX database (February 2007). Table 4-1 summarizes the most sensitive results for each measurement endpoint, 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 is presented below. Additional information is provided in Appendices C-E.

In order to be included in the ECOTOX database, papers must meet the following minimum criteria:

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

Data that pass the ECOTOX screen are further evaluated for use in the assessment 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, matching measurement endpoints listed in Table 2-7, that are more conservative than the registrant-submitted data and that are found to be scientifically sound based on a review of the paper are used quantitatively. The degree to which open literature data are used quantitatively or qualitatively is dependent on whether the information is scientifically sound and whether it is quantitatively linked to the assessment endpoints (e.g., maintenance of California Red-Legged Frog survival, reproduction, and growth) identified in Table 2-7). For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, because quantitative relationships between degree and type of behavior modifications and reduction in species survival, reproduction, and/or growth are usually not available.

Where possible, the most sensitive values from studies using the technical grade active ingredient (TGAI) were selected for this assessment. In some cases, however (e.g., acute toxicity tests to birds), only tests with the technical formulation intermediate Metasystox-R (50% ai) containing methyl isobutyl ketone are available. This compound has minimal toxicity to mammals, fish, and birds (Toxnet, U.S. National Library of Medicine, available at: http://toxnet.nlm.nih.gov/), so when the test material has been clearly identified, the toxicity value may be adjusted for purity. In many cases, however, the reports do not state whether adjustment has already been done, and toxicity values are expressed in terms of active ingredient where possible. Further, Metasystox-R is also the name of emulsifiable concentrate products containing ODM (25% ai) that are no longer in use; some studies refer to Metasystox-R 50% EC while others refer to "technical" material with 50% ai without further clarification. Therefore, use of tests in which the test material is clearly defined as TGAI with high purity is preferred when possible.

Table 4-1. Summary of ODM Toxicity Data Used to Assess Direct Effects, Indirect Effects, and Modification to Critical Habitat for the CRLF.

Assessment Endpoints	Measures of Effect	Species	Toxicity Value and Slope (where applicable)	Study classification (Selection basis)	Reference
Survival and reproduction of individuals and communities of freshwater fish in close proximity to sites	Freshwater fish acute 96-hr LC_{50}	Rainbow trout *(Oncorhynchus mykiss)*	0.73 ppm ai Reliable estimate of slope not available	Acceptable (most sensitive value)	MRID 40269001 (USEPA 1978)
	Freshwater fish early life-stage NOAEC	Rainbow trout *(Oncorhynchus mykiss)*	0.005 ppm ai	Value was estimated using ACR derived from dichlorvos	N/A
Survival and reproduction of individuals and communities of freshwater invertebrates in close proximity to sites	Freshwater invertebrate acute 96-h LC_{50} (for scud 48-h LC_{50} or EC_{50} where the effect measured is surrogate)	Scud (*Gammarus lacustris*)	0.19 ppm Probit slope not available	Acceptable (most sensitive value)	MRID 00097842 (Sanders 1969)
	Freshwater invertebrate reproductive NOAEC	Waterflea *(Daphnia magna)*	0.046 ppm ai	Acceptable (only value available)	40986601 Burgess 1991
Abundance (i.e., survival, reproduction, and growth) of individuals and populations of birds in close proximity to sites.	Avian (single dose) acute oral LD_{50}	Rock pigeon (*Columbia livia*)	7 mg ai/kg bw Probit slope not available	Supplemental (most sensitive value)	MRID 00160000 (Hudson et al. 1984) MRID 05000975 (Tucker and Haegele 1971)
	Avian subacute 5-day dietary LC_{50}	Northern bobwhite (*Colinus virginianus*)	434 ppm ai Probit slope not available	Acceptable (most sensitive value)	MRID 00022923 (Hill et al. 1975)
	Avian reproduction NOAEC	Northern bobwhite *(Colinus virginianus)*	1.8 ppm ai	Acceptable (most sensitive value)	MRID 40747202 (Beavers et al. 1988)
Abundance (i.e., survival, reproduction, and growth) of individuals and populations of mammals in close proximity to sites	Mammalian acute oral (single dose) LD_{50}	Laboratory rat (*Rattus norvegicus*)	48 mg ai/kg bw (females) Probit slope = 8.2	Acceptable (most sensitive value)	MRID 40779801 (Eigenberg 1990)
	Mammalian reproductive NOAEC or NOAEL	Laboratory rat (*Rattus norvegicus*)	0.05 mg ai/kg bw/day (1 ppm)	Acceptable (most sensitive value based on reproductive paramet	MRIDs 00155396 00260513 00256926 Kroetlinger and Kaliner (1985)

Assessment Endpoints	Measures of Effect	Species	Toxicity Value and Slope (where applicable)	Study classification (Selection basis)	Reference
Survival of beneficial insect populations in close proximity to sites	Honey bee acute contact LD_{50}	Honey Bee *(Apis mellifera*	0.31 ug/bee Probit slope not available	Supplemental (most sensitive value)	MRID 05001991 (Stevenson 1978)

4.1.1 Toxicity to Freshwater Fish

No aquatic phase amphibian studies are available for ODM. Therefore toxicity studies with freshwater fish are used as surrogates for assessing direct acute and chronic effects to the aquatic phase CRLF as well as indirect acute and chronic effects to its food sources. Fish toxicity studies for two freshwater species using the TGAI are required to establish the acute toxicity of ODM to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warm water fish).

4.1.1.1 Freshwater Fish: Acute Exposure (Mortality) Studies

Two studies with the ODM TGAI are available. Based on these studies, ODM is moderately to highly toxic to freshwater fish on an acute basis (Table 4-2).

Table 4-2. Acute Toxicity of Technical Grade ODM to Freshwater Fish.

Species	% ai	96-hour LC_{50}	Toxicity category	MRID (Author, Year) *Status*
Bluegill sunfish (*Lepomis macrochirus*)	97.9	1.22 ppm ai	Moderately toxic	40269002 (USEPA, 1978)[1] *Acceptable*
Rainbow trout (*Oncorhynchus mykiss*)	97.9	0.73 ppm ai	Highly toxic	40269001 (USEPA, 1978)[1] *Acceptable*

[1]Static test

Other studies (Table 4-3) are also available with the 50% technical grade product or liquid concentrate (as stated). In some cases it is unclear whether the value presented is corrected for the purity of the test material. In all cases, however, the 96-hour LC_{50}s using the high purity TGAI provide more sensitive values whether they are adjusted or not. It should be noted that in the studies by Shellenberger (1970, MRID 00060635) the positive toxicity test with DDT resulted in higher toxicity values than normal for the test lab, which may explain the relatively higher values obtained for ODM. Data obtained from MRIDs 00003503 and 40098001 have been determined to be supplemental until such time that the raw data from these studies have been reviewed and the results verified. At this time, these data have not been reviewed for ODM.

Table 4-3. Acute Toxicity of 50% Technical Material ODM to Freshwater Fish.

Species	% ai	96-hour LC_{50}	Toxicity category	MRID (Author, Year) *Status*
Goldfish (*Carassius auratus*)	50	82.5 ppm ai[1]	Slightly toxic	00060635 (Shellenberger 1970) *Supplemental*
Rainbow trout (*Oncorhynchus mykiss*)	50	4.3 ppm ai[1]	Moderately toxic	00060635 (Shellenberger 1970) *Supplemental*
Channel catfish (*Ictalurus punctatus*)	50	23.0 ppm ai[1]	Slightly toxic	00060635 (Shellenberger 1970) *Supplemental*
Bluegill sunfish (*Lepomis macrochirus*)	50	1.9 ppm [2]	Moderately toxic	00060639 (Lamb and Roney 1973) *Supplemental*
Rainbow trout (*Oncorhynchus mykiss*)	50	6.4 ppm[3]	Moderately toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*
Channel catfish (*Ictalurus punctatus*)	50	< 18.0 ppm[3]	N/A	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*
Bluegill sunfish (*Lepomis macrochirus*)	50	13.0 ppm[3]	Slightly toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*
Largemouth bass (*Micropterus salmoides*)	50	31.5 ppm[3]	Slightly toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*
Walleye (*Sander vitreus vitreus*)	50	18.0 ppm[3]	Slightly toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*

[1]Whether the test was static or flow-through or whether mean measured value were used is not described
[2]Nominal concentrations used, flow-through or static conditions not reported.
[3]Static test, use of nominal or mean measured concentrations not described.

Three additional studies (Table 4-4) with the 25% formulated product Metasystox-R Concentrate are also available. The registrant submitted studies are acceptable for studies with a formulated product. The additional study with Tilapia was obtained from the ECOTOX database (Reference #12184), and is classified as supplemental.

Table 4-4. Toxicity of Metasystox-R (25% ai) Formulated Product to Freshwater Fish.

Species	% ai	96-hour LC_{50}	Toxicity category	MRID (Author, Year) *Status*
Rainbow trout (*Oncorhynchus mykiss*)	25	26.0 ppm	Slightly toxic	00074349 (Nelson et al. 1977) *Acceptable*
Bluegill sunfish (*Lepomis macrochirus*)	25	23.0 ppm	Slightly toxic	00074349 (Nelson et al. 1977) *Acceptable*
Tilapia (*Tilapia mossambica*)	25	6.85 ppm	Moderately toxic	ECOTOX #12184 (Moses et al. 1985) *Supplemental*

4.1.1.2 Freshwater Fish: Chronic Exposure (Chronic/Reproduction) Studies

A freshwater fish early life-stage test using the TGAI is required for ODM because the end-use product is expected to be transported to water from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, and (2) any aquatic acute LC50 or EC50 is less than 1 mg/l (rainbow trout LC_{50} = 0.73 mg/L). The results of this study are presented in Table 4-5.

Table 4-5. Freshwater Fish Early Life Stage Toxicity of ODM Under Flow-Through Conditions.

Species	% ai	NOAEC/LOAEC	Endpoints Affected	MRID (Author, Year) *Status*
Rainbow trout (*Oncorhynchus mykiss*)	97.7	NOAEC = 2.6 ppm ai LOAEC = 4.9 ppm ai	Fry survival and growth	41054501 43635701 (Cohle 1989) *Acceptable*

Uncertainty is associated with the use of this value in risk assessment, since the NOAEC for this species is higher than the LC_{50}. Therefore, a chronic value will be estimated using the highest acute-to-chronic ratio for rainbow trout from among all organophosphates that have LC_{50} and fish early life stage data for rainbow trout. Nineteen organophosphates were found that have both an acute and chronic study for rainbow trout (Table 4-6). The ACR ranged from 5.4 for Terbufos to 144.0 for Dichlorvos. In order to provide the most conservative estimate for the chronic freshwater fish NOEC for ODM, the ACR of 144 will be used to estimate the NOAEC for rainbow trout. The estimated chronic NOAEC for rainbow trout as derived from the ACR of 144 and LC_{50} of 0.73 ppm is 0.005 ppm or 5 ppb. This value was derived as follows. The (ODM) rainbow trout LC_{50} used in this assessment is 0.73 ppm ai. The largest acute-to-chronic ratio from the organophosphates is 144 for Dichlorvos. This ratio is used to calculate the final NOEC for ODM.

0.750 ppm ai (acute)/0.0052 ppm ai (chronic) = 144 = ACR ratio for Dichlorvos

$$\text{Estimated NOAEC for ODM} = \frac{LC_{50}}{\text{NOEC}} = \frac{0.73\ \text{ppm ai}}{\text{est. NOAEC}} = 144$$

Estimated NOAEC for ODM = 0.73/144 = 0.005 ppm ai

The table below (4-6) shows the inputs for the organophosphates that were considered for the ODM ACR.

Table 4-6. ODM Acute to Chronic Ratio for Rainbow Trout NOEC

Chemical	96-hr LC_{50} (ppm ai)	MRIDs	NOAEC (ppm ai)	MRIDs	ACR	ODM NOEC (ppm ai)
Azinphos methyl	0.0088	03125193	0.00029	00145592	30.344	0.024
Coumaphos	0.890	40098001	0.0117	43066301	76.068	0.010
Dichlorvos	0.750	43284702	0.0052	43788001	144.23	0.005
Dimethoate	7.500	TN 1069*	0.430	43106303	17.441	0.042
Disulfoton	1.850	40098001	0.220	41935801	8.4090	0.089
Fenamiphos	0.068	40799701	0.0038	41064301	17.894	0.041
Fenitrothion	2.000	40098001	0.046	40891201	43.478	0.017
Fenthion	0.830	40214201	0.0075	40564102	110.66	0.007

Chemical	96-hr LC_{50} (ppm ai)	MRIDs	NOAEC (ppm ai)	MRIDs	ACR	ODM NOEC (ppm ai)
Fonofos	0.050	00090820	0.0047	40375001	10.638	0.069
Isofenphos	1.800	00096659	0.153	00126777	11.764	0.062
Phosmet	0.105	40098001	0.0032	40938701	32.812	0.022
terbufos	0.0076	40098001	0.0014	41475801	5.4285	0.134

* TN 1069 is test number for EPA's Animal Biology Lab, McCann, 1977

4.1.1.3 Freshwater Fish: Sublethal Effects and Open Literature Information

No other studies were available for ODM in the ECOTOX database or elsewhere in which sublethal effects to freshwater fish are described.

4.1.2 Toxicity to Freshwater Invertebrates

Toxicity studies on freshwater invertebrates were evaluated to assess the potential for ODM to induce indirect effects to the aquatic phase CRLF via a reduction in invertebrate prey. Acute studies with several species and a chronic study with waterflea (*Daphnia magna*) are available. The results of these studies are presented in the sections below.

4.1.2.1 Freshwater Invertebrates: Acute Exposure Studies

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of ODM to aquatic invertebrates. The preferred test species is *Daphnia magna*; however, two studies are also available with the scud (*Gammarus lacustris*). Results of studies using the technical grade material or technical material dissolved in acetone or water (Sanders 1969 and 1972 studies) are presented in Table 4-7. Studies involving the scud (Sanders 1969, 1972; MRID 00097842 and 05017538, respectively) were scientifically sound, but were determined to be supplemental because the purity of the test compound is not provided, it is unknown whether the results presented are adjusted for purity, mature scuds were used instead of immature scuds, and because the study did not follow guidelines. The test material was reported as technical grade material. The value from MRID 00097842 is a more sensitive value than that obtained from the study with *Daphnia*; therefore, it will be used in this risk assessment.

Table 4-7. Acute Toxicity of Technical ODM to Waterflea and Scud.

Species	% ai	48-hour LC_{50}	Toxicity category	MRID (Author, Year) *Status*
Waterflea (*Daphnia magna*)	94.6	0.24 ppm ai	Highly toxic	40286801 (Forbis, 1987) *Acceptable*
Scud (*Gammarus lacustris*)	Tech.	0.190 ppm	Highly toxic	00097842 (Sanders 1969) *Supplemental*
Scud (*Gammarus lacustris*)	Tech.	1.1 ppm	Moderately toxic	05017538 (Sanders 1972) *Supplemental*

Five studies are also available that utilize test material with 50% ai. Based on the study by Nelson et al. (1977; MRID 00074350), the 50% technical product is very highly toxic to waterflea on an acute basis (Table 4-8). All studies are supplemental for reasons provided in the table footnotes. A more sensitive value is obtained in the study with 50% Metasystox-R technical by Nelson et al. (1977, MRID 00074350) compared to the studies above; however, the value is very inconsistent with others for *Daphnia* and the report does not contain information about parameters related to survival. In all of the other studies, it is not known whether the toxicity value presented is adjusted for purity.

Table 4-8. Acute Toxicity of 50% ai Technical Product Metasystox-R to Waterflea.

Species	**% ai**	**LC_{50}**	**Toxicity category**	**MRID (Author, Year)** ***Status***
Waterflea (*Daphnia magna*)	50	0.0033 ppm ai (48-hr)	Very highly toxic	00074350 (Nelson et al. 1977) *Supplemental*[1]
Waterflea (*Daphnia magna*)	50	0.16 ppm (48-hr)	Highly toxic	00165007 (Heimbach 1985) *Supplemental*[2]
Scud (*Gammarus lacustris*)	50	1.0 ppm (96-hr)	Highly toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*[3]
Scud (*Gammarus lacustris*)	50	1.2 ppm (96-hr)	Moderately toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*[3]
Aquatic sowbug (*Asellus brevicaudus*)	50	1.4 ppm (96-hr)	Moderately toxic	00003503 (Johnson and Finley 1980) 40098001 (Mayer and Ellersieck 1986) *Supplemental*[3]

[1]First and second instars were used in the study, and dissolved oxygen was not reported.
[2]Classified as supplemental because TGAI not used but was submitted in response to a DCI for a study with TGAI. Study is otherwise scientifically sound.
[3]All data from these studies have been classified as supplemental until raw data are obtained to verify the results.

4.1.2.2 Freshwater Invertebrates: Chronic Exposure Studies

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for ODM since the end-use product is expected to be transported to water from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, and (2) aquatic acute LC_{50} or EC_{50} is less than 1 mg/l (rainbow trout LC_{50} = 0.73 mg/L and daphnia EC_{50} = 0.23 Mg/L). The preferred test species is *Daphnia magna*. Results of the test are presented in Table 4-9.

Table 4-9. 21-Day Renewal Chronic Toxicity Test to Waterflea.

Species	**% ai**	**21-Day NOAEC**	**Endpoints Affected**	**MRID (Author, Year)** ***Status***
Waterflea (*Daphnia magna*)	97.7	0.046 ppm ai	Adult mean length, survival, and young/adult/day	40986601 (Burgess 1991) *Acceptable*

4.1.2.3 Freshwater Invertebrates: Sublethal Effects and Additional Open Literature Information

Additional studies with ODM in freshwater aquatic invertebrates are not available.

4.1.3 Freshwater Field Studies

No field studies on freshwater plants or animals are available for ODM.

4.2 Evaluation of Terrestrial Ecotoxicity Data

Data collected on birds, mammals, terrestrial plants, and terrestrial insects are utilized in this risk assessment to estimate direct effects to the terrestrial phase CRLF resulting from acute and chronic exposure, indirect effects to the CRLF resulting from loss of prey and loss/disturbance of riparian, upland, and dispersal habitat, and modification of Critical Habitat PCEs. Toxicity endpoints available for this assessment and the endpoints actually selected for quantitative assessment of direct and indirect effects to the CRLF are summarized in the sections below.

4.2.1 Toxicity to Birds

4.2.1.1 Birds: Acute Exposure (Mortality) Studies

No terrestrial phase amphibian studies are available for ODM. Therefore birds are used as a surrogate for the terrestrial phase CRLF. An oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the acute toxicity of ODM to birds. Two dietary studies using the TGAI are also required to establish the subacute toxicity to birds. The preferred guideline test species is mallard (a waterfowl) or Northern bobwhite (an upland gamebird). For ODM, acute exposure studies are available for the guideline species and several others, including a passerine and "near-passerine" species. Only studies with the 50% technical product are available. These data do indicate that on an acute oral basis, ODM ranges from moderately to very highly toxic to birds; on a subacute dietary basis, ODM is practically non-toxic to highly toxic (Table 4-10).

We note here that in the EFED RED Chapter the subacute dietary LC_{50} values presented for birds from the Hill et al. (1975) study (MRID 00022923) were adjusted for the purity of the test substance. However, it is stated in that reference that the LC_{50} values are presented as ppm of active ingredient, so they have been corrected below.

Table 4-10. Avian Acute Oral and Subacute Dietary Toxicity Data for ODM from Acceptable and Supplemental Studies

Species	% ai	Endpoint	Toxicity category[1]	MRID (Author, Year) *Status*
Acute Oral				
Northern bobwhite (*Colinus virginianus*)	50	LD_{50} = 17 mg ai/kg (♂) LD_{50} = 18.5 mg ai/kg (♀)	Highly toxic	00060636 (Lamb et al. 1972) *Acceptable*
Chukar (*Alectoris graeca*)	50	LD_{50} = 60 mg ai/kg	Moderately toxic	00160000 (Hudson et al. 1984) *Supplemental*[2,3]
California quail	50	LD_{50} = 24 mg ai/kg	Highly	

Species	% ai	Endpoint	Toxicity category[1]	MRID (Author, Year) *Status*
(*Callipepla californica*)			toxic	
Chukar (*Alectoris graeca*)	50	LD_{50} = 57 mg ai/kg	Moderately toxic	05000975 (Tucker and Haegele 1971) *Supplemental*[2,3]
Rock pigeon (*Columbia livia*)	50	LD_{50} = 7.5 mg ai/kg	Very highly toxic	
Mallard (*Anas platyrhynchos*)	50	LD_{50} = 27 mg ai/kg	Highly toxic	00160000 (Hudson et al. 1984) 05000975 (Tucker and Haegele 1971) *Supplemental*[2,3]
Japanese quail (*Coturnix coturnix japonica*)	50	LD_{50} = 42 mg ai/kg	Highly toxic	
Ring-necked pheasant (*Phasianus colchicus*)	50	LD_{50} = 21 mg ai/kg	Highly toxic	
House sparrow (*Passer domesticus*)	50	LD_{50} = 35 mg ai/kg	Highly toxic	
Rock pigeon (*Columbia livia*)	50	LD_{50} = 7 mg ai/kg	Very highly toxic	
Subacute Dietary				
Northern bobwhite (*Colinus virginianus*)	50	LC_{50} = 434 ppm ai	Highly toxic	00022923 (Hill et al. 1975) *Acceptable*[2]
Mallard (*Anas platyrhynchos*)	50	LC_{50} >5000 ppm ai	Practically non-toxic	
Japanese quail (*Coturnix coturnix japonica*)	50	LC_{50} = 1309 ppm ai	Slightly toxic	
Ring-necked pheasant (*Phasianus colchicus*)	50	LC_{50} = 1497 ppm ai	Slightly toxic	

[1]Category for material tested. It is unclear whether values reported under MRID 00160000 and 05000975 are adjusted for % active ingredient, so toxicity categories may be different for technical material with high purity.
[2]Mallard and Northern bobwhite are preferred guideline species.
[3]Methods are not well described.

4.2.1.2 Birds: Chronic Exposure (Chronic/Reproduction) Studies

Avian reproduction studies using the TGAI were required because the CRLF may be subject to repeated or continuous exposure to ODM. The preferred test species are mallard duck and bobwhite quail. Acceptable studies are available for both species (Table 4-11). Adverse effects were observed in the bobwhite study (MRID 40747202) in which 14-day old survivor weights were significantly reduced in the 6.9 ppm ai and higher treatment group. The number of eggs laid and number of eggs set were also significantly affected, but these were increased in treatment groups compared to controls. In the mallard study (MRID 40747202), reduced food consumption was observed in adults in the 17.3 ppm ai treatment, but no affects on reproduction were observed.

Table 4-11. Avian Acute Oral and Subacute Dietary Toxicity Data for ODM from Acceptable and Supplemental Studies

Species	% ai	NOAEC/LOAEC	NOAEC Endpoints	MRID (Author, Year) *Status*
Northern bobwhite (*Colinus virginianus*)	92.4	1.8 ppm ai / 6.9 ppm ai	14-day old survivor weight[1]	40747202 (Beavers et al. 1988) *Acceptable*
Mallard (*Anas platyrhynchos*)	92.4	17.3 ppm ai / 54.0 ppm ai	Reduced adult food consumption	40747201 (Beavers et al. 1988) *Acceptable*

[1]Number of eggs laid and set per hen were also significantly *higher* in the 6.9 ppm ai and higher treatment groups.

4.2.1.3 Birds: Sublethal Effects and Additional Open Literature Information

A search in the ECOTOX open literature database provided one teratogenicity study with domestic chickens (*Gallus domesticus*) in which chick embryos were exposed to ODM (technical grade, 89% purity) at doses ranging from 0.01 mg to 2.00 mg via direct injection into the egg (Lenselink et al. 1993, ECOTOX # 88893). Survival to later stages was significantly reduced at 0.50 mg and higher doses ($p<0.001$), with none of the embryos surviving at the highest dose level of 2.00 mg. The percentage of animals showing developmental anomalies was significantly greater at dose levels ≥ 0.05; however they did not show a clear dose-response relationship as the 1.00 mg dose group did not show a significant percentage of affected animals. These included the musculoskeletal effects of wry neck, absent or malformed limbs, eye abnormalities, and thoracogastroschisis; and cardiovascular effects such as ventricular septal defects and aortic arch anomalies. The study does not report whether the dose values used in the study are corrected for percentage of active ingredient, so these values may be lower. Whether these effects occur in wild birds is questionable because it is not known whether injection into the egg represents potential exposure that would occur in the field. However, this study does demonstrate that ODM has the potential to affect birds during development within the egg. How this may apply to amphibians is unknown, but may indicate some potential for teratogenicity.

4.2.2 Toxicity to Wild Mammals

4.2.2.1 Wild Mammals: Acute Exposure Studies

Toxicity studies on mammals were evaluated to assess the potential for ODM to induce indirect effects to the terrestrial phase CRLF via a reduction in prey base. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. One study with a Peromyscus species was also submitted (MRID 00060626); however, the report submitted consists of raw data and no description of the study design and therefore is not valid for use.

The majority of acute oral studies for ODM involving mammals were conducted with the 25% active ingredient formulation (Metasystox-R) or with this formulation given in combination with other compounds. One study using technical grade material is available, and based on the LD_{50} value for females in this study, ODM is categorized as highly toxic to small mammals on an acute oral basis (Table 4-12).

A search in the ECOTOX database resulted in one study that reported a mouse acute oral LD_{50} of 118 mg/kg bw (Kumari et al. 1995 [ECOTOX #88896]); however, the source of this information was not reported and the study itself cannot be evaluated. Nevertheless, the value is greater than that estimated for the rat in registrant submitted studies.

Table 4-12. Acute Oral Toxicity of ODM to the Laboratory Rat.

Species	**% ai**	**LD_{50}**	**Toxicity category**	**MRID (Author, Year)** ***Status***
Laboratory rat (*Rattus norvegicus*)	93.3	61 mg ai/kg (♂) 48 mg ai/kg (♀)	Highly toxic[1]	40779801 (Eigenberg 1990; also listed as Sheets 1988) *Acceptable*
[1]Toxicity category for wild mammals. Male LD_{50} value would be categorized as moderately toxic.				

4.2.2.2 Wild Mammals: Chronic Exposure Studies

Chronic toxicity data for mammals are needed to assess the potential for ODM to induce indirect effects to the terrestrial phase CRLF via a reduction in prey base due to chronic effects of prey items. Chronic tests are not conducted on wild mammals, so the two-generation rat reproduction study required by HED is used as a substitute. Two acceptable reproduction studies are available, and the most sensitive reproductive NOAEL/LOAEL is presented in Table 4-13.

The 1999 EFED RED Chapter and its revisions utilized data from the study by Eigenberg (1990) (MRID 41461901); however, a study with a more sensitive endpoint is presented for the rat in the HED RED Chapter for ODM. In this study, significant reproductive effects that were observed included decreased parental body weight, decreased parental testes weight, decreased fertility index, vacuolation of the epithelial cells of the corpus epididymus, decreased pup weight and increased pup mortality (Kroetlinger and Kaliner 1985, primary MRID 00155396).

In the Eigenberg (1990) study, similar effects were observed, including decreases in male and female fertility were also observed in the P and F_1 generations, epididymal vacuolation, body weight reduction, testes weight reduction, ovarian weight reduction, and nominally increased estrous cycle length in females. Based on cholinesterase inhibition in adults, a NOAEC of < 1.0 ppm (NOAEL < 0.043 mg/kg-bw/day) and a LOAEC of 1.0 ppm can be established as chronic values for wild mammals. The parental NOAEL is less than that established by the Kroetlinger and Kaliner (1985) study. However, there is uncertainty associated with the NOAEL value from the Eigenberg study based on ChE activity, and the other parameters measured produce higher NOAEC values. Since the ChE NOAEL represents effects on a critical biological variable, this value should be considered in the risk assessment. Therefore, values from both studies will be modeled where necessary to bracket the chronic risk.

A search in the ECOTOX database did not find studies with lower LOAEL/NOAEL values than the studies presented below.

Table 4-13. Chronic/Reproductive Toxicity of ODM to the Laboratory Rat.

Species	% ai	NOAEL/LOAEL	NOAEL/LOAEL Endpoints	MRID (Author, Year) *Status*
Laboratory rat (*Rattus norvegicus*)	52.5	Parental, reproductive and offspring: LOAEL = 0.5 mg a.i./kg-bw/day (10 ppm) NOAEL = 0.05 mg a.i./kg-bw/day (1 ppm)	Parental systemic: male and female body weight, female gestation weight Reproductive: absolute testes weight, vacuolation in the corpus epididymus Offspring: viability index (mortality), pup weight during lactation	00155396 00260513 00256926 Kroetlinger and Kaliner (1985) *Acceptable*
Laboratory rat (*Rattus norvegicus*)	50	Parental systemic: LOAEL = 2.1 mg a.i./kg-bw/day (50 ppm) NOAEL = 0.38 mg a.i./kg-bw/day (9 ppm) Parental ChE: LOAEL = 0.043 mg a.i./kg-bw/day (1 ppm) NOAEL < 0.043 mg a.i./kg-bw/day (1 ppm) Offspring: LOAEL = 2.1 mg a.i./kg-bw/day (50 ppm) NOAEL = 0.38 mg a.i./kg-bw/day (9 ppm) Offspring ChE: LOAEL = 0.38 mg a.i./kg-bw/day (9 ppm) NOAEL = 0.13 mg a.i./kg-bw/day (3 ppm)	Parental systemic: male and female fertility Parental ChE: brain, plasma, and RBC ChE activity Offspring: Litter size, pup weight during lactation Offspring ChE: brain, plasma, RBC ChE activity	41461901 Eigenberg (1990) *Acceptable*

4.2.2.3 Wild Mammals: Sublethal Effects and Open Literature Information

A search in the ECOTOX database provided several studies detailing sublethal effects of exposure to ODM in laboratory mammals. These studies are described below.

Tayyaba et al. (1981) (ECOTOX ref. # 89144) studied nucleic acid metabolism alterations in the brain due to exposure to Metasystox-R (25% ODM) in laboratory rats. Injections of 4 mg/kg-bw were given to the rats daily for 10 days. Mortality was not observed in any of the rats; however, sublethal effects that were observed included unconsciousness, muscular fasciculations, hyperexcitability to tactile stimuli, convulsions, and ataxia. Further, the authors found that the test material altered the concentration of nucleic acids in the brain and also the functional activity of lysosomal enzymes in the brain. This study provides some additional information on sublethal effects of ODM in mammals, although the exposure route in the study is not necessarily relevant to a field situation.

In a study in which female laboratory rats were exposed dermally to ODM as Metasystox-R, Raizada et al. (1993) (ECOTOX ref. # 89143) alone and in combination with hexachlorocyclohexane (lindane), which is a broad-spectrum insecticide. Rats were exposed dermally to 125 mg/kg-bw/day ODM alone and in combination with 100 mg/kg-bw/day HCH for 7, 15, and 30 days (the study does not report whether the dose is corrected for percentage ai in the test material). Mortality was observed in all test groups, but further details are not provided. Exposure to ODM alone for 30 days produced severe sublethal effects, including tremor, dyspnea, salivation, convulsion, and diarrhea. ODM also produced severe necrosis in liver cells and changes in the granular and molecular layer of the cerebellum. Further, significant reductions in brain AChE activity occurred by 15 and 30 days of exposure in the ODM group. The degree of inhibition was >20% in all cases, indicating sufficient AChE depression to cause sublethal effects and behavioral changes. Inhibition was also observed in erythrocyte ChE on all days examined. Effects observed in the ODM-only group were more pronounced in the group receiving the combination of pesticides. This study demonstrates that severe sublethal effects and some mortality may result from dermal exposure to ODM in the field. However, it is not known how this study represents levels of actual exposure, except that rats were tested at the same concentration for varying lengths of time. Currently there is no methodology that adequately quantifies dermal exposure, so how well this study represents effects that would be observed in the field is not known.

Kumari et al. (1995) (ECOTOX #88896) administered sublethal doses of 28, 56, and 80 mg/kg Metasystox-R orally to Swiss albino mice (7-8 weeks old). Cells from animals were observed for signs of mutagenicity. The study reports effects based on statistical significance; however, the significance may be misleading because of batches of cells from multiple animals were combined and each cell was considered to be the experimental unit. However, the study does report observations of mutagenicity based on chromosomal aberration and abonormal sperm cells. The authors also note induction of micronuclei, potentially indicating DNA damage. The data from this study requires a revised analysis, but does demonstrate the potential for mutagenic effects that may affect fertility and reproductive success in mammals.

In contrast to the studies described above, Clemens et al (1990) (ECOTOX #88987) demonstrated few effects with repeated oral exposure during gestation in female laboratory rats. In a one-generation reproduction study, the authors dosed female rats with 0.0 to 4.5 mg/kg of ODM (90.6% purity) orally from Days 6 to 16 of gestation. Females were studied from Day 16 of gestation through Day 21 postpartum to observe body weight, food consumption, and blood and brain ChE activity. Abnormalities were observed in fetuses, and offspring that were delivered were observed for neurobehavioral function with a series of behavioral challenges (e.g., time to righting after being dropped from 38 cm, degree of negative geotaxis, reaction to auditory startle, performance in a maze, activity in an open field, olfactory discrimination, and visual placing). Tremor and reduced food consumption was observed in dams at the highest test dose, but reproductive parameters were not affected. Brain AChE activity was significantly affected in all test groups, and in the two highest test groups brain AChE was depressed to >50% on Day 16 and in the highest test group on Day 20. No significant effects were observed in the offspring. The authors conclude that limited effects occurred as a result of repeated exposures during gestation; however, the AChE effects observed in the brain indicate the potential for sublethal effects and mortality to occur.

4.2.3 Toxicity to Nontarget Insects

Toxicity studies on terrestrial invertebrates are utilized to assess the potential for ODM to induce indirect effects to the terrestrial phase CRLF via a reduction in invertebrate prey base. The acute contact LD_{50}, using the honey bee, *Apis mellifera*, is an acute contact, single-dose laboratory study designed to estimate the quantity of toxicant required to cause 50% mortality in a test population of bees. One acute oral and three acute contact studies provide data for adult and larval honey bees (Table 4-14). Based on the most sensitive values, ODM is classified as highly toxic to honey bees on an acute oral and acute contact basis.

Table 4-14. Acute Contact and Acute Oral Toxicity of ODM to Honey Bees.

Species	**Test Type**	**% ai**	**LD_{50}**	**Toxicity category**	**MRID (Author, Year)** ***Status***
Honey bee (*Apis mellifera*)	Acute contact	Tech.	3.0 ug/bee	Moderately toxic	00036935 (Atkins et al. 1975) *Acceptable*
Honey bee (*Apis mellifera*)	Acute contact	Tech.	2.2 ug/larva	Moderately toxic	00074486 (Atkins and Kellum 1980) *Supplemental*[1]
Honey bee (*Apis mellifera*)	Acute contact	Tech.	0.54 ug/bee	Highly toxic	05001991 (Stevenson 1978) *Acceptable*
Honey bee (*Apis mellifera*)	Acute oral	Tech.	0.31 ug/bee	Highly toxic	05001991 (Stevenson 1978) *Acceptable*

[1]No guideline exists for study on bee larvae. Larvae were 3-4 days old.

Another study submitted to the Agency provides additional information for toxicity to honey bees and other nontarget insects. Johansen and Eves (1965, MRID 00060628) estimated the toxicity of residual ODM applied at 0.5 lbs ai/acre on foliage to honey bees and alkali bees (*Nomia melanderi*), and showed that ODM had short-lived toxicity to both species exposed to foliar residues. Hand treatments of ODM formulated product (25% ai) were made to small plots of alfalfa and bees were housed with the vegetation at 3 hours post application. Mortality was observed after 24 hours, and residues resulted in 2% and 20% mortality in honey bees and alkali bees, respectively, indicating low to moderate toxicity via exposure to foliar residues.

No other useful or valid toxicity values were found in the ECOTOX literature database for honeybees or other nontarget insects for ODM.

4.2.4 Terrestrial Field Studies

A simulated field study with House sparrows (*Passer domesticus*), Northern bobwhite (*Colinus virginianus*), and New Zealand rabbits (*Oryctolagus cuniculus*) was conducted to assess the potential effects of ODM to wildlife in the field (Lamb and Jones 1973, MRID 00060638). This study was submitted in order to fulfill the guideline requirement (71-5) for a simulated or actual field study, and was rated as supplemental. The animals were exposed to both treated and untreated alfalfa at an application rate of 2.25 lb ai/A, applied three times with a two week application interval. One pair of each species was placed in a metal cage, and the cage was placed on either a control plot or treatment plot of alfalfa. Each plot had six cages of each species. The commercial feed for half of the cages for each species was withheld for 6 hours after each application so that only natural food was available for the animals. Cages were moved on days 6, 13, 20, 27, and 34 to fresh alfalfa that had received previous applications. Animals were observed daily for toxic signs, and dead animals were replaced.

There was no treatment-related mortality of quail during the 42 day study. Weight losses for both treated and control birds were equivalent. The treated rabbits had no toxic symptoms or deaths, although one control rabbit died. There were high mortalities of control and treated sparrows, particularly during the last week of the study. The high death rate was attributed to stress due to being caged over an extended period of time.

The data indicate that a formulated product of Metasystox-R was not significantly hazardous to caged bobwhite, house sparrows, and New Zealand rabbits. However, issues such as repellency were not considered, and the study does not provide adequate information (e.g., cage size) to evaluate exposure. Therefore, the study does have deficiencies that limit its usefulness for estimating risk.

4.3 Toxicity to Aquatic and Terrestrial Plants

<u>Aquatic Plants -</u> A Tier I aquatic plant study with green algae (*Scenedesmus subspicatus*) showed no significant effects on population growth at test concentrations up to 100 ppm ai (MRID 44657701). A study is not available with a vascular aquatic plant species; however, effects are expected to be minimal.

<u>Terrestrial Plants -</u> Tier I and II seedling emergence and vegetative vigor tests for terrestrial plants have not been submitted for ODM and were not requested by EFED in its RED Chapter. Some plant data are available in the ECOTOX database that demonstrate the effects of ODM on seed germination and growth. Based on information from Panda (1983), barley seeds soaked in water containing 100 ppm ai ODM for 6 hours did not demonstrate significant decreases in germination rate compared to controls. This value can be related to the highest one-time application rate currently registered for ODM (0.75 lbs ai/acre) by estimating the concentration of ODM in a 1-cm zone saturated with water at the soil surface. Assuming a soil bulk density of 1.3 g/cm^3, the application rate of 0.75 lbs ai/acre would result in a soil concentration of 6.5 ppm, which is well below the NOAEC value derived from the Panda (1983) study. A NOAEC value for growth was determined to be 1500 ppm ai in this study based on seedling height after one week. Another study using similar test methods with onion showed a NOAEC for seed germination rate of 2000 ppm (Pandita 1986). Based on this information, effects on terrestrial plants are expected to be minimal.

4.4 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 the CRLF and aquatic and terrestrial animals that may indirectly affect the CRLF (U.S. EPA, 2004). As part of the risk characterization, an interpretation of acute RQ for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (i.e., mortality or immobilization) should exposure at the EEC actually occur for a species with sensitivity to ODM 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. The upper and lower bounds of the effects probability are based on available information on the 95% confidence interval of the slope. A statement regarding the confidence in the estimated event probabilities is also included. Studies with good probit fit characteristics (i.e., statistically appropriate for the data set) are associated with a high degree of confidence. Conversely, a low degree of confidence is associated with data from studies that do not statistically support a probit dose response relationship. In addition, confidence in the data set may be reduced by high variance in the slope (i.e., large 95% confidence intervals), despite good probit fit characteristics. In the event that dose response information is not available to estimate a slope, a default slope assumption of 4.5 (95% C.I.: 2 to 9) (Urban and Cook, 1986) is used.

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.

For ODM, mortality was observed in acute toxicity studies for freshwater fish, freshwater invertebrates, birds, mammals, and honey bees. Where probit slopes are provided, they are used along with their upper and lower confidence limits (if available) to estimate the probability of individual morality and its potential variability. In cases where they are unavailable, the default slope assumption of 4.5 with default upper and lower slope bounds of 2 and 9 are used as per original Agency assumptions of a typical slope cited in Urban and Cook (1986). The chance of individual mortality will be determined using the listed species LOC as the threshold of concern and also the RQ determined for each taxon. These analyses are presented below in the Risk Characterization along with calculations of RQs for each taxon.

4.5 Incident Database Review

The Ecological Incident Information System (EIIS) was searched for incidents involving ODM. Only one incident (I002680-001) was recorded involving ODM. This incident occurred in October 1987 in Monterey County, California, and is associated with its use in broccoli. In this case, four California quail were found dead in a farm yard adjacent to a broccoli field. Several of the birds had broccoli leaves in their crops, and residues of ODM and methamidophos (another organophosphate insecticide) were detected in these crop contents. The causal relationship between ODM and the birds' deaths was determined to be possible, although the degree to which methamidophos contributed is unknown.

5. Risk Characterization

Risk characterization is the integration of the exposure and effects characterizations to determine the potential ecological risk from the assessed ODM use scenarios within the action area and likelihood of direct and indirect effects on the California Red Legged Frog. The risk characterization provides estimation and description of the likelihood of adverse effects; articulates risk assessment assumptions, limitations, and uncertainties; and synthesizes an overall conclusion regarding the effects determination (i.e., "no effect," "likely to adversely affect," or "may affect, but not likely to adversely affect") for the California Red Legged Frog.

5.1. Risk Estimation

Risk was estimated by calculating the ratio of estimated environmental concentrations (EECs; see Tables 3-4 through 3-7) and the appropriate toxicity endpoint (see Tables 4-1 through 4-14). 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 (Table 5-1). Appendix F describes the categories of toxicity.

Table 5-1. Levels of Concern for Listed Terrestrial and Aquatic Organisms

Taxa	Acute LOC	Chronic LOC
Avian[1] (terrestrial phase amphibians)	0.1	1
Mammalian[2]	0.1	1
Terrestrial plants[3]	1	
Aquatic Animals[4] (aquatic phase amphibians)	0.05	1
Insects [5]	0.05	1

Used in RQ calculations:
[1] LD_{50} and estimated NOEL
[2] LD_{50} and NOEC
[3] EC25
[4] LC/EC_{50} and estimated and reproductive NOEC
[5] LD_{50} per EFED's CRLF Steering Committee

5.1.1. Aquatic Direct and Indirect Effects

5.1.1.1. Direct Effects

Aquatic exposure estimates from PRZM-EXAMS were compared to fish acute and chronic toxicity endpoints, and Risk Quotients were calculated. Peak and 60-day EECs used in these calculations are presented above in the Exposure Characterization section. In the absence of amphibian data, the fish represents the CRLF. For ground and aerial applications, all RQs were below the LOC of 0.05 for acute risk and exceeded the LOC of 1.0 for chronic risk for broccoli and cauliflower, brussel sprouts, and cabbage (Table 5-2). The chronic RQ for aerial applications to lettuce is essentially equal to the no effect level, so chronic effects are expected to be unlikely as a result of applications to lettuce. Therefore, direct effects to the aquatic phase CRLF is expected as a result of chronic exposure due to applications to the cole crops listed above.

Table 5-2. Acute and Chronic Freshwater Fish RQs Resulting from Ground and Aerial or Airblast Applications of ODM. RQs that Exceed the LOCs are Presented in Bold.

	Ground Applications		Aerial or Airblast Applications	
Crop	**Fish acute RQ[1]**	**Fish Chronic RQ[2]**	**Fish acute RQ[1]**	**Fish Chronic RQ[2]**
Cabbage	0.045	**3.438**	0.047	**3.698**
Mint	0.001	0.053	N/A	N/A
Brussel sprouts	0.030	**2.263**	0.032	**2.464**
Lima beans	0.005	0.308	0.007	0.494
Broccoli, Cauliflower	0.028	**1.892**	0.029	**2.013**
Corn	0.001	0.068	0.004	0.245
Lettuce	0.013	0.910	0.015	1.064
Alfalfa	0.007	0.516	0.009	0.658
Onion	0.001	0.098	0.004	0.273
Sugar beets	0.004	0.243	0.005	0.324
Cotton	0.001	0.036	N/A	N/A
Melons	<0.001	0.023	0.002	0.097
Fruit (airblast)	N/A	N/A	0.004	0.290
Grapes (airblast)	N/A	N/A	0.004	0.293
Nursery	0.005	0.354	0.006	0.473
Walnuts	0.001	0.083	0.002	0.157

[1]Calculated using rainbow trout LC_{50} of 730 ppb.
[2]Calculated using estimated freshwater fish NOAEC of 5 ppb.

5.1.1.2. Indirect Effects

Aquatic phase CRLFs may be indirectly affected through losses of aquatic plant and invertebrate food items. However, since ODM has been demonstrated to have low toxicity to aquatic plants, indirect effects are not expected to occur via this route. They can also occur through losses of aquatic invertebrates.

To determine the potential for losses to aquatic invertebrates that can cause indirect effects to the aquatic phase CRLF, peak and 21-day aquatic exposure estimates from PRZM-EXAMS were compared to aquatic invertebrate toxicity endpoints to calculate acute and chronic RQs (Table 5-3). Acute RQs were above the LOC of 0.05 for cole crops and lettuce for both ground and aerial or airblast applications, indicating that toxic effects on invertebrates are expected for those uses. All other acute RQs were below this LOC and all chronic RQs were below the LOC of 1.0.

Table 5-3. Acute and chronic freshwater invertebrate RQs resulting from ground and aerial or airblast applications of ODM. RQs that exceed the LOCs are presented in bold.

	Ground Applications		Aerial or Airblast Applications	
Crop	**Invertebrate Acute RQ[1]**	**Invertebrate Chronic RQ[2]**	**Invertebrate Acute RQ[1]**	**Invertebrate Chronic RQ[2]**
Cabbage	**0.174**	0.570	**0.182**	0.611
Mint	0.003	0.008	N/A	N/A
Brussel sprouts	**0.116**	0.375	**0.121**	0.407

	Ground Applications		Aerial or Airblast Applications	
Crop	**Invertebrate Acute RQ[1]**	**Invertebrate Chronic RQ[2]**	**Invertebrate Acute RQ[1]**	**Invertebrate Chronic RQ[2]**
Lima beans	0.017	0.053	0.026	0.080
Broccoli, Cauliflower	**0.107**	0.327	**0.113**	0.347
Corn	0.004	0.012	0.014	0.043
Lettuce	**0.051**	0.159	**0.057**	0.185
Alfalfa	0.028	0.090	0.036	0.114
Onion	0.005	0.017	0.014	0.042
Sugar beets	0.015	0.044	0.019	0.056
Cotton	0.002	0.006	N/A	N/A
Melons	0.001	0.004	0.007	0.020
Fruit (airblast)	N/A	N/A	0.016	0.049
Grapes (airblast)	N/A	N/A	0.015	0.049
Nursery	0.020	0.063	0.025	0.083
Walnuts	0.004	0.013	0.008	0.026

[1]Calculated using the scud LC_{50} of 190 ppb.
[2]Calculated using the *Daphnia* (waterflea) NOAEC of 46 ppb.

5.1.2. Terrestrial Direct and Indirect Effects

5.1.2.1. Direct Effects

Using the T-REX tool for estimating exposure to the CRLF, dose- and diet-based acute and chronic RQs exceed the listed species LOCs of 0.1 (acute) and 1.0 (chronic) for CRLF consuming small insects (Table 5-4). This is true for the lowest and highest application rates. For CRLF consuming large insects, only the diet-based acute RQs did not exceed the LOC. Based on these findings, direct effects to the terrestrial phase CRLF are expected following application of ODM in all uses assessed.

Table 5-4. Upper Bound Kenaga Residues for 20-g and 100-g Birds (surrogates for CRLF) from T-REX.

Weight Class	Exposure Type	RQs			
		Small Insects		Large Insects	
		Low	High	Low	High
20 g[2]	Dose-based Acute	**8.23**	**43.30**	**0.92**	**4.81**
100 g[2]	Dose-based Acute	**4.70**	**24.70**	**0.52**	**2.74**
(no size class distinction)[3]	Diet-based Acute	**0.12**	**0.61**	0.01	0.07
(no size class distinction)[4]	Diet-based Chronic	**28.13**	**147.85**	**3.13**	**16.43**

[1]"Low" and "High" refer to RQs determined for the lowest application rate (to walnuts) and the highest application rate (to cabbage).
[2]Calculated using rock pigeon LD_{50} of 7 mg/kg bw.
[3]Calculated using Northern bobwhite LC_{50} of 434 ppm.
[4]Calculated using Northern bobwhite NOAEC of 1.8 ppm.

5.1.2.2. Indirect Effects

Terrestrial food sources are mainly accounted for by terrestrial insects, but as described above, the terrestrial phase CRLF also consumes small mammals, other frogs, and may consume fish. Indirect effects are expected due to losses of other amphibians, as evidenced by the direct effects to the CRLF described above. Indirect effects can occur to the terrestrial phase CRLF through losses of aquatic (fish) and terrestrial prey items (terrestrial invertebrates, small mammals, other amphibians) and also riparian and upland plants. Since ODM has low toxicity to terrestrial plants, indirect effects due to losses of terrestrial vegetation are not expected to occur. RQ calculations for fish were described above in Section 5.5.1.2 and RQs for amphibians were described above in Section 5.5.2.1 for direct effects on the aquatic and terrestrial phase CRLF, respectively. Findings in these analyses also apply to the analysis of indirect effects on fish and other amphibians as prey items, so these analyses will not be reiterated here. Therefore, this section contains analyses for mammalian and terrestrial invertebrates that can be food items for the terrestrial phase CRLF.

Mammals

RQs for mammals were also examined using the T-REX spreadsheet model (Table 5-5). Dose-based acute RQs calculated for 15-g mammals exceed the LOC for the lowest application rate assessed (for walnuts) except for those that consume large insects and for granivores. At the highest application rate, all feeding classes exceed mammal LOCs. For both dose- and diet-based RQs, chronic RQs exceed the LOC in all cases.

Table 5-5. Upper Bound Kenaga, Acute and Chronic Mammalian Dose- and Diet-Based Risk Quotients

RQ Type	RQs[1]									
	Short Grass		Tall Grass		Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Granivore	
	Low	High	Low	High	Low	High	Low	High	Low	High
Dose-based acute[2]	**0.81**	**4.28**	**0.37**	**1.96**	**0.46**	**2.41**	0.05	**0.27**	0.01	0.06
Dose-based chronic[3]	**907.96**	**4772.97**	**416.15**	**2187.61**	**510.73**	**2684.79**	**56.75**	**298.31**	**12.61**	**66.29**
Diet-based chronic[4]	**90.00**	**473.11**	**41.25**	**216.84**	**50.63**	**266.13**	**5.63**	**29.57**	N/A	N/A

[1]"Low" and "High" refer to EECs determined for the lowest (walnuts) and highest (cabbage) application rates for ODM.
[2]Calculated with adjusted rat LD_{50} of 105.5 mg/kg bw.
[3]Calculated with adjusted rat NOAEL of 0.09 mg/kg bw/day.
[4]Calculated using rat NOAEC of 1.0 ppm.

Terrestrial Invertebrates

For terrestrial insects, the RQs determined using EECs converted to μg/bee were determined to be **2.65** for the lowest application rate (walnuts) and **13.90** for the highest application rate. Both of these values exceed the terrestrial invertebrate LOC on 0.05. Details of the calculations used to arrive at these numbers are provided above in Section 3.3.2.

5.1.1. Probability of Individual Mortality for Acute Direct and Indirect Effect to the CRLF

The risk of mortality to the CRLF is based on acute RQs derived for fish (representing the aquatic phase) and birds (representing the terrestrial phase). Chances of individual effects for CRLF prey items are derived from their respective RQs as well. The individual chance of effect is calculated using the probit-slope determined from acute toxicity studies and a specified threshold of effect. If the slope is not available from the toxicity study, then a default value of 4.5 (CI 2.0 – 9.0) is used (Urban and Cook, 1986). The threshold of effect is designated as the LOC, which is used to derive a general estimate of the chance of mortality for each taxon, or the RQ, which is used to derive an estimate based on the effects observed on that taxon. These probabilities are calculated using the Excel spreadsheet developed by Ed Odenkirchen, OPP (IEC v1.1, June 22, 2004). Results of these analyses for taxa concerning direct and indirect effects are provided below.

Direct Effects to the CRLF

Acute RQs for fish did not exceed the listed-species LOC, so no direct effects resulting from acute mortality to the aquatic-phase CRLF are expected. Therefore, the chance of individual mortality is not determined for the aquatic-phase CRLF. Acute RQs did exceed for the birds, representing the terrestrial-phase CRLF. The slope for the rock pigeon LD_{50} study is not available, so the default value would be used to estimate the chance of individual terrestrial-phase CRLF mortality. As a result, the chance of individual mortality, using the LOC of 0.1 as the threshold of effect, would be 1 in 2.94×10^5, with variability ranging from 1 in 8.86×10^{18} to 1 in 44. Using the highest RQ calculated above (42.13), the probability of individual mortality is 1 in 1 or approaching 100%. These findings also apply to the assessment of indirect effects.

Indirect Effects to the CRLF

<u>*Aquatic vertebrates*</u> – The chance of individual effect is not determined for fish or aquatic-phase amphibians in this assessment because RQs based on the fish LC50 did not exceed the acute listed species LOC.

<u>*Aquatic invertebrates*</u> – The slope for the LC_{50} study with the scud is not available, so the default value would be used to estimate the chance of individual mortality to an aquatic invertebrate food item for the CRLF. As a result, the chance of individual mortality is 1 in 4.18×10^8, with variability ranging from 1 in 1.75×10^{31} to 1 in 216 when the threshold of effect is the LOC of 0.05. If the highest acute RQ calculated above (0.182) is used as the threshold, then the chance

of individual mortality is actually 1 in 2,300 with variability ranging from 1 in 7.27×10^{10} to 1 in 14.

Mammals – The probit slope determined from the rat LD_{50} used to estimate acute RQs was 8.2. Confidence intervals were not provided in the study report, so the reliability cannot be evaluated. However, based on this slope, and using the listed species LOC for terrestrial vertebrates, the chance of individual mortality in mammals as a result of ODM use is 1 in 8.32×10^{15}. If the highest acute RQ calculated above (4.28) is used as the threshold, the chance is actually 1 in 1 or 100%.

Birds/Amphibians -- The assessment for direct effects to the CRLF (above) is applicable. At the calculated RQ, the individual chance of effect approaches 100%.

Terrestrial Invertebrates – The slope for the LC_{50} study with the honeybee is not available, so the default value would be used to estimate the chance of individual mortality to terrestrial invertebrates. Since the same LOC is used, the findings based on the default would be the same, which were the chance of individual mortality is 1 in 4.18×10^{8}, with variability ranging from 1 in 1.75×10^{31} to 1 in 216. However, if the highest acute RQ calculated above (13.90) is used as the threshold, then the chance of individual mortality is actually 1 in 1 (100%), with variability ranging from 1 in 1.01 (99%) to 1 in 1 (100%).

5.2. Risk Description

The risk description synthesizes an overall conclusion regarding the likelihood of adverse impacts leading to an effects determination (i.e., "no effect," "may affect, but not likely to adversely affect," or "likely to adversely affect") for the California Red Legged frog.

If the RQs presented in the Risk Estimation (Section 5.1.2) show no indirect effects, and LOCs for the CRLF are not exceeded for direct effects (Section 5.1.1), a "no effect" determination is made based on ODM's use within the action area. If, however, indirect effects are anticipated and/or exposure exceeds the LOCs for direct effects, the Agency concludes a preliminary "may affect" determination for the CRLF. Following a "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 CRLF and potential community-level effects to aquatic plants and terrestrial plants growing in semi-aquatic areas. 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 CRLF.

The criteria used to make determinations that the effects of an action are "not likely to adversely affect" the CRLF 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. For example, use of dose-response information to estimate the likelihood of effects can inform the evaluation of some discountable effects.

- 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 CRLF is provided in Sections 5.6.1 through 5.6.3.

5.2.1. Direct Effects to the California Red Legged Frog

The federal action is all labeled uses. In order to compare the location of the labeled uses with the areas important to the frog, the potential use areas in California were overlaid with the core areas, critical habitat and known occurrence areas of the CRLF. The result of this layering is the ability to discern areas of overlap between potential use and the CRLF life-cycle.

5.2.1.1. Aquatic Phase

Risk Quotients for freshwater fish (surrogates for the CRLF) are below LOC for acute effects for all uses (Table 5-2). RQs exceed the LOC for chronic effects for broccoli, cauliflower, cabbage, and aerial applications to lettuce (Table 5-2). Chronic RQs range from 1.9 to 3.4 for CRLF for ground applications to these crops and from 1.1 to 3.7 for aerial applications. Applications made to these crops have the highest rates (0.5 – 0.75 lbs ai/acre), have multiple applications (2-3), and have the shortest application interval (7 days) compared to the other crops for which RQs did not exceed. Therefore, risk to the aquatic phase CRLF due to adverse reproductive and other chronic effects is anticipated resulting from these labeled uses of ODM. Whether this results in a LAA determination depends on whether aquatic phase CRLFs co-occur in areas with these crops and areas affected downstream by aquatic residues resulting from applications to these crops. This analysis is discussed in Section 5.7.1.2 below.

5.2.1.2. Terrestrial Phase

Risk Quotients for terrestrial-phase CRLF, as represented by 20-gram and 100-gram birds, exceed LOC for both acute and chronic (reproductive) effects (Table 5-4). Dose-based acute RQs range from 0.5 to 8.2 for CRLF minimum exposure resulting from applications to walnuts (1 application of 0.375 lbs ai/acre) and from 2.7 to 43.3 for maximum exposure from applications made to cabbage (3 applications of 0.75 lbs ai/acre made 7 days apart). Only diet-based RQs for the large insect food source are below LOC (0.1). Chronic RQs range from 3.1 to 28.1 for CRLF for minimum exposure and 16.4 to 147.9 for maximum exposure. Based on this analysis, both mortality and adverse reproductive effects to the terrestrial-phase CRLF (from a diet including both small and large insects) are anticipated from all labeled uses of ODM assessed in this document.

Refinement of RQ for CRLF terrestrial phase (T-HERPS analysis)

Birds are currently used as surrogates for reptiles and terrestrial-phase amphibians. However, reptiles and amphibians are poikilotherms (body temperature varies with environmental temperature) while birds are homeotherms (temperature is regulated, constant, and largely independent of environmental temperatures). Therefore, reptiles and amphibians (collectively referred to as herptiles hereafter) 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 or reptiles on a daily dietary intake basis, assuming similar caloric content of the food items. This can be seen when comparing the estimated caloric requirements for free living iguanid lizards (Iguanidae) (**EQ 1**) to passerines (song birds) (**EQ 2**) (U.S. EPA, 1993):

$$\textbf{iguanid FMR (kcal/day)= 0.0535 *(bw in g)}^{0.799} \qquad \textbf{(EQ 1)}$$

$$\textbf{passerine FMR (kcal/day) = 2.123 *(bw in g)}^{0.749} \qquad \textbf{(EQ 2)}$$

With relatively comparable exponents (slopes) to the allometric functions, one can see that, given a comparable body weight, the free living metabolic rate of birds can be 40 times higher than reptiles, though the requirement differences narrow with high body weights. Consequently, use of avian food intake allometric equation as a surrogate to herptiles is likely to result in an over-estimation of exposure for reptiles and terrestrial-phase amphibians.

Because of the need to evaluate dietary exposure to the CRLF, the T-REX model (version 1.3.1.) has been altered to allow for an estimation of food intake for herptiles T-HERPS using the same basic procedure that T-REX uses to estimate avian food intake. This tool is thus used to make a refined estimate of exposure and risk based on body weights, food items, and daily food intake rates that are more appropriate for the CRLF. A comparison is made below between the results for the CRLF obtained with the T-REX model and results obtained from the T-HERPS model.

Table 5-6 presents the EECs for herptiles calculated with the T-HERPS model. The values presented are for uses involving the lowest and highest application rates as above for T-REX.

Table 5-6. Upper Bound Kenaga, Acute Terrestrial Herpetofauna Dose-Based and Diet-Based EECs from T-HERPS

Dose-Based EECs, Amphibian Size Class (grams)	EECs[1] (mg/kg bw)									
	Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Small Herbivore Mammals		Small Insectivore Mammal		Small Amphibians	
	Low	High	Low	High	Low	High	Low	High	Low	High
1.4	1.97	10.34	0.22	1.15	N/A	N/A	N/A	N/A	N/A	N/A
37	1.93	10.13	0.21	1.13	56.10	294.9	3.51	18.43	0.07	0.35
238	1.27	6.66	0.14	0.74	8.72	45.85	0.55	2.87	0.04	0.23
Diet-Based EECs	**EECs[1] (ppm)**									
(no size class distinction)	50.63	266.13	5.63	29.57	59.30	311.75	3.71	19.48	1.76	9.24

[1]"Low" and "High" refer to EECs determined for the lowest application rate and the highest application rate (see text).

RQs from the T-HERPS modeling are presented in Table 5-7. Although dose-based EECs and RQs for herptiles are lower based on this analysis compared to those from T-REX, LOCs are still exceeded for the low application rate three of the five feeding categories and for the high application rate in all but the small amphibian feeding class. Diet-based RQs (and EECs above) are the same for the small and large insect food categories; they are retained below for comparison to other feeding categories. Based on this analysis, diet-based RQs exceed the chronic LOC for both the low and high application rate in all feeding classes. The exception is for the small amphibian feeding class under the low application rate scenario; however, this value does approach the LOC. Therefore, based on this refined analysis, acute and chronic risk is still anticipated for the CRLF.

Table 5-7. Upper Bound Kenaga, Acute and Chronic Terrestrial Herpetofauna Dose-Based and Diet-Based RQs

Dose-Based Acute RQ, Amphibian Size Class (grams)[2]	RQs[1]									
	Broadleaf Plants/ Small Insects		Fruits/Pods/ Seeds/ Large Insects		Small Herbivore Mammals		Small Insectivore Mammal		Small Amphibians	
	Low	High	Low	High	Low	High	Low	High	Low	High
1.4	**0.28**	**1.48**	0.03	**0.16**	N/A	N/A	N/A	N/A	N/A	N/A
37	**0.28**	**1.45**	0.03	**0.16**	**8.01**	**42.13**	**0.50**	**2.63**	0.01	0.05
238	**0.18**	**0.98**	0.02	**0.11**	**1.25**	**6.55**	0.08	**0.41**	0.01	0.03
Diet-Based RQs (Acute and Chronic)										
Acute[3]	**0.12**	**0.61**	0.01	0.07	**0.14**	**0.72**	0.01	0.04	<0.01	0.02
Chronic[4]	**28.13**	**147.85**	**3.13**	**16.43**	**32.95**	**173.20**	**2.06**	**10.82**	0.98	**5.13**

[1]"Low" and "High" refer to RQs determined for the lowest application rate (to walnuts) and the highest application rate (to cabbage).
[2]Calculated using rock pigeon LD_{50} of 7 mg/kg bw.
[3]Calculated using Northern bobwhite LC_{50} of 434 ppm.
[4]Calculated using Northern bobwhite NOAEC of 1.8 ppm.

5.2.2. Indirect Effects Due to Reduction in Food Items

5.2.2.1. Aquatic Phase

Sub-adult and adult CRLF consume invertebrates. Acute RQs for freshwater invertebrates range up to 0.18 (Table 5-3), so there is a "May Affect" finding. However, since the RQ is below the Acute Risk LOC (0.5), other factors must be considered in determining if this constitutes a "Likely to Adversely Affect" or "Not Likely to Adversely Affect" finding, as explained below in section 5.4.2. Based on the likelihood of individual effects on aquatic invertebrates (Section 5.5.3), indirect risk to the CRLF via effects on aquatic invertebrates is considered "NLAA."

5.2.2.2. Terrestrial Phase

Risk quotients for two common prey animals (small mammals and frogs [represented by bird RQs]) greatly exceed both acute and chronic LOC (Tables 5-4 and 5-5) at even the lowest labeled application rate. These prey animals are thus anticipated to suffer adverse effects (mortality and reproductive effects) from all labeled ODM uses. The acute RQ for a terrestrial invertebrate (honey bee), representing the bulk of the terrestrial phase CRLF diet, ranges from 2.7 to 13.9. Thus, adverse indirect effects to the CRLF, mediated via reduction in prey base, are anticipated.

5.2.3. Effects to Critical Habitat

Activities that may destroy or adversely modify critical habitat are those that alter the CRLF's PCEs and jeopardize its continued existence. Evaluation of actions related to ODM use that may alter these PCEs form the basis of the critical habitat impact analysis. As previously discussed in the Problem Formulation, PCEs that are identified as assessment endpoints are limited to those that are of a biological nature and those PCEs for which ODM effects data are available.

Adverse modification of designated critical habitat via actions that may directly impact aquatic and terrestrial plants are associated with those characteristics necessary for normal behavior, growth, and viability of all CRLF life stages. However, effects on terrestrial and aquatic plants were not assessed, since ODM has been demonstrated to be of low toxicity to plants. Therefore, adverse modifications to critical habitat are not expected to occur as a result of losses of aquatic and terrestrial plants. As a result, major alterations of the normal sedimentation, water chemistry, water temperatures, and hydrologic functioning of aquatic habitats are not expected as a result of aquatic or riparian plant losses occurring after applications of ODM. Further, elimination or alteration of riparian, dispersal, and/or upland habitat is also not expected.

Aquatic. Indirect effects due to reduction of invertebrate food based were determined to be insignificant, and this conclusion also applies to effects to critical habitat as a result in losses in prey base.

Terrestrial. Indirect effects were also predicted to occur to all terrestrial species as a result of applications of ODM to all uses included in this analysis. These losses would affect the terrestrial prey base for the terrestrial phase CRLF. Further, community and ecosystem functioning could also be altered. For example, losses of insects could affect the pollination rate for flowering plants, which would indirectly affect riparian, dispersal, and upland vegetation. Similarly, losses of birds and mammals could affect seed dispersal, thus indirectly affecting plants. Perturbations of populations within the community could also disrupt normal community function.

5.3. Action Area

The Action Area for listed species from the labeled use of a pesticide is defined by the degree to which the screening level RQs exceed the listed species LOC for any taxon. If necessary, standard modeling assumptions are changed to determine the limits of LOC exceedence. For example, the spray drift assumption for aerial application can be lowered from the standard 5% until the RQ no longer exceeds the LOC. The distance at which this occurs beyond the boundary of a treated field is used to define the action area. This analysis does assume, however, that no secondary poisoning occurs due to movement of contaminated animals.

5.3.1. Aquatic Phase

The Action Area for effects on aquatic species consists of two parts. One is a spray drift perimeter around the use site, and the other is a downstream dilution factor. Both parts are intended to find the geographic extent of Listed species LOC exceedance.

5.3.1.1. Spray Perimeter

The estimate of the spray perimeter around aquatic habitats for determining the aquatic species action area is based on chronic effects to listed aquatic vertebrates (fish). RQs for aquatic invertebrates exceed the listed species acute LOC. However, the likelihood of an individual effect on scud at its highest RQ is very low (Section 5.5.3); thus, this effect is insignificant.

In order to be below the chronic LOC for listed aquatic vertebrates (1.0), the 60-day concentration in the EXAMS pond would need to 5 ppb (chronic LOC [1.0] * NOAEC [5 ppb]). With the standard drift assumption for ground application of 1%, the lettuce 60-day concentration is below the LOC (5 ppb) for lettuce. However, for the broccoli and cauliflower scenario, the 60-day EEC is 8.8 ppb, which is not low enough. Since the cabbage application rate is higher than that of broccoli and cauliflower, concentrations are expected to be higher. Therefore, a buffer to reduce exposure to below LOC cannot be established for any of the cole crops.

5.3.1.2. Downstream Dilution

The downstream dilution analysis calculates how far downstream the EEC remains above the listed species LOC, given flow contributions from both contaminated and uncontaminated streams in the watersheds of potential ODM use. The initial area of concern was defined by Figure 2B., which shows all agricultural land in all counties in California where ODM is used. Flow contributions from streams in the corresponding watersheds are included in a Geographic Information System (GIS) analysis, until the pesticide concentrations (initially the EXAMS pond peak EEC) from contaminated and uncontaminated streams, weighted for flow, fall below the Listed species LOC.

The downstream dilution factor that must be achieved is defined by the maximum ratio between an RQ and its corresponding LOC. In the case of ODM, this is the chronic RQ for fish from aerial applications to cabbage (3.7), divided by the chronic LOC (1.0), which gives a dilution factor of 3.7.

5.3.2. Terrestrial Phase

The Action Area due to effects on listed species is also defined by the geographic extent of LOC exceedence. Quantitative estimates of exposure of avian (including reptiles and terrestrial amphibians) and mammal species is done with the TREX model, which automates exposure analysis according to the Hoerger-Kenaga nomogram, as modified by Fletcher (1994).

The lowest ratio between the LOC for listed terrestrial avian and mammalian species (0.1 for acute effects and 1.0 for chronic effects) and the RQ, times the maximum single application rate, is used to determine the exposure (in lb/acre) that is below LOC, as shown in Table 5-8.

Exposure below LOC = (LOC/RQ)*(max application rate [lb/acre]).

The Action Area for ODM is dominated by its effects on terrestrial species, due to the much higher RQs in the terrestrial analysis and exceedances for all uses included in the assessment. The highest risk quotient for any terrestrial animal was for mammals, in which the chronic RQ based on the estimated daily dose from the modeling for applications to cabbage was 4,773.

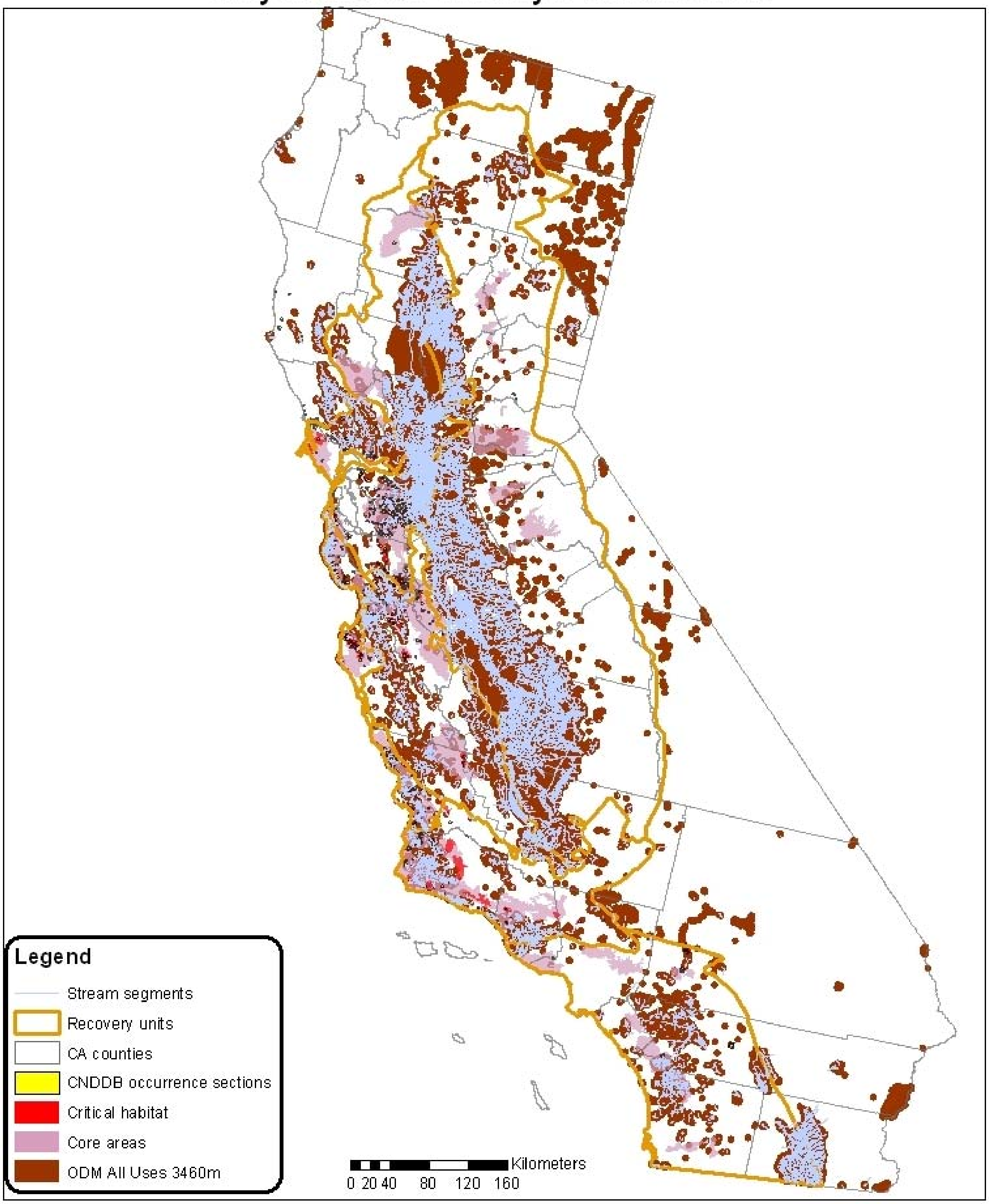
Based on this RQ, the dose (in lb/acre) that results in an RQ below the chronic level of concern is then 1/4773*0.75 = 0.0002 lb ai/acre. Using the AgDISP model with the far-field Gaussian extension to calculate the spray drift buffer needed to reduce exposures to below 0.0002 lb ai/acre for aerial applications. The inputs used in the analysis are presented in Table 5-8; all other inputs were default values. This analysis indicates that the required spray drift buffer needed to define the Action Area for terrestrial effects is 11,338 feet (about 2.15 miles).

Table 5-8. AgDISP Input Parameters for Estimation of Action Area Size

Input parameter	Value
Release height	15 feet
Wind Speed	15 mph
Drop Size Distribution	ASAE Very fine to Fine
Spray volume rate	5 gallons per acre
Non-volatile fraction	0.075
Active Fraction	0.019
Canopy	None
Specific gravity (Carrier)	0.97
Initial Average Deposition	0.0002 lb/acre

The figure below shows the full extent of the Action Area, based on the terrestrial effects distance of 11,338 feet and the downstream dilution factor of 3.7.

Oxydemeton-methyl Action Area



Compiled from California County boundaries (ESRI, 2002), USDA National Agriculture Statistical Service (NASS, 2002) Gap Analysis Program Orchard/ Vineyard Landcover (GAP) National Land Cover Database (NLCD) (MRLC, 2001)

Map created by US Environmental Protection Agency, Office of Pesticides Programs, Environmental Fate and Effects Division. September, 2007. Projection: Albers Equal Area Conic USGS, North American Datum of 1983 (NAD 1983)

5.4. Listed Species Effects Determination for the California Red Legged Frog

5.4.1. "No Effect" Determination

As stated in the Problem Formulation (Section 2), uses on ornamental, forest, non-bearing trees, and Christmas trees for which applications are made by injection are expected to pose little opportunity for exposure to the CRLF and other organisms upon which it depends. Thus, these uses are concluded to have "No Effect" on the CRLF.

Available data indicate that plants inhabiting aquatic, terrestrial, and semi-aquatic environments are not sensitive to exposure to ODM at residue concentrations above those expected for aquatic and terrestrial habitats for the assessed uses of ODM in California. Therefore, it is concluded that there is "No Effect" on the CRLF via plant-related endpoints. These represent indirect effects due to reduction or modification of the aquatic and terrestrial plant community as well as effects on Critical Habitat PCEs related to plants.

5.4.2. "May Effect" Determination

When the action area overlaps (spatially) the designated Core Areas and Critical Habitats a "May Affect" determination is made. Upon a "May Affect" determination the probability of effect is considered and a "Likely to Adversely Affect" or "Not Likely to Adversely Affect" determination is made.

Based on the action area for ODM use in California, the use of ODM "May Effect" the aquatic- and terrestrial-phase CRLF. Table 5-9 displays the proportion of the core area within each recovery unit that overlaps with the potential use areas.

Table 5-9. Terrestrial Spatial Summary Results for ODM Uses with 11,338-ft Buffer.

Measure	RU1	RU2	RU3	RU4	RU5	RU6	RU7	RU8	Total
Initial Area of Concern (no buffer, sq km)	3	56	16	36	126	333	375	326	**1271**
Established species range area (sq km)	3,654	2,742	1,320	3,278	3,647	5,307	4,916	3,326	**28,190**
Overlapping area (sq km)	1,092	607	321	1,730	2,289	2,243	2,611	1,185	**12,078**
Percent area affected	29.9	22.1	24.3	52.8	62.8	42.3	53.1	35.6	**42.8**
# Occurrence Sections[1]	3	0	32	225	249	84	80	28	**701**

[1]30 *occurrence sections occur outside of Recovery Units.*

Table 5-10 displays the kilometers of streams that are affected within the CRLF habitat. Within the initial area of concern, there are 49,130 kilometers of stream waters that are potentially affected. Using the downstream dilution model adds 843 kilometers to this area, giving a total of

49,973 potentially affected streams. Since cole crops were the only ones to affect the aquatic-phase CRLF, only these crops were included in the analysis.

Table 1-10. Stream miles affecting habitat where Cole Crops are used.

Recovery Unit	Stream Length (km)
1	269
2	179
3	130
4	484
5	772
6	788
7	891
8	373

5.4.3. "Adverse Effect" Determination

Risk Quotients for direct chronic effects to the aquatic-phase CRLF are above the LOC for four uses of ODM, including ground and aerial applications to broccoli, cauliflower, cabbage, and aerial applications to lettuce. Acute RQs for aquatic invertebrates exceed the acute LOC for these uses as well; however, the effect is considered insignificant based on low likelihood of individual effect. Nonetheless, since chronic effects are predicted for fish and amphibians, indirect effects could occur due to the losses of fish and amphibian food items. Based on this information, and since there is overlap of streams that may contain ODM with CRLF habitat, it is thus concluded that **direct adverse effects to the aquatic-phase CRLF are anticipated for these four uses.**

Risk Quotients for direct acute and chronic effects to the terrestrial-phase CRLF (Tables 5-4 and 5-7) are well above their respective LOCs for all uses assessed. RQs also exceed for acute and chronic effects to mammals, amphibians (birds), and terrestrial invertebrates for all uses as well. Furthermore, chronic effects to fish are anticipated as a result of applications to broccoli, cauliflower, cabbage, and lettuce. Overlap of areas that potentially contain ODM residues and CRLF habitat are demonstrated. Therefore, indirect effects are anticipated for the terrestrial-phase CRLF due to impacts on fish species that are part of the CRLF diet. As a result of these effects, it is concluded that **both direct and indirect adverse effects to the terrestrial-phase CRLF and its critical habitat are anticipated for all assessed uses**.

Based on this analysis, it is concluded that the labeled uses of ODM in California "may affect, and are likely to adversely effect" the California Red-Legged Frog, where the Action area overlaps its habitat, due to terrestrial and aquatic effects.

Table 5-11. Effects Determination Summary for ODM Use and the California Red-Legged Frog.

Assessment Endpoint	Effects determination	Basis for Determination
Aquatic Phase (Eggs, larvae, tadpoles, juveniles, and adults)		
Direct Effects and Critical Habitat Effects		
1. Survival, growth, and reproduction of CRLF	May Affect, Likely to Adversely Affect	Chronic RQs exceed LOC for surrogate species (rainbow trout) for 3 cole crops (broccoli, cauliflower, brussel sprouts)
	May Affect, Not Likely to Adversely Affect	No chronic exceedance for aquatic vertebrates for lettuce. No chronic exceedance for aquatic vertebrates for lettuce, since aquatic EEC is essentially equal to the no effect level
	No Effect	Exposure not expected from all non-food uses applied via tree injection due to lack of exposure. Acute and chronic RQs do not exceed LOCs for food uses other than cole crops.
Indirect Effects		
2. Reduction or modification of aquatic prey base	May Affect, Likely to Adversely Affect	Chronic RQs exceed LOC for fish (rainbow trout) for 3 cole crops, resulting in impacts to fish and amphibian prey base
	May Affect, Not Likely to Adversely Affect	Acute LOC is exceeded for aquatic invertebrates for 3 cole crops, however effect is considered insignificant based on low likelihood of individual effect. No chronic exceedance for aquatic vertebrates for lettuce, since aquatic EEC is essentially equal to the no effect level
	No Effect	Exposure to aquatic organisms not expected from all non-food uses applied via tree injection. Acute and chronic RQs do not exceed LOCs for invertebrates with food uses other than cole crops.
3. Reduction or modification of aquatic plant community	No Effect	No LOC exceedences for any plant species
4. Degradation of riparian vegetation	No Effect	No LOC exceedences for any plant species.
Terrestrial Phase (Juveniles and Adults)		
Direct Effects		
5. Survival, growth, and reproduction of CRLF	May Affect, Likely to Adversely Affect	Acute and Chronic LOC exceedences for birds, the surrogate species for direct effects to frogs, at lowest use rate. Probability of effect approaches 100% at calculated RQs.
	No Effect	Exposure to terrestrial organisms not expected from all non-food uses applied via tree injection.
Indirect Effects and Critical Habitat Effects		
6. Reduction or modification of terrestrial prey base	May Affect, Likely to Adversely Affect	Acute and Chronic LOC exceedences for multiple components of CRLF prey base (mammals, birds, and terrestrial invertebrates) at lowest use rate. LAA to terrestrial phase CRLF and its critical habitat based on acute RQs exceeding 0.5 and chronic RQs over LOC for mammals, insects, birds. Adverse terrestrial critical habitat modification is expected.

Assessment Endpoint	Effects determination	Basis for Determination
	No Effect	Exposure to terrestrial organisms not expected from all non-food uses applied via tree injection.
7. Degradation of riparian vegetation	No Effect	No plant LOC exceedences.

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

- Enhanced information on the density and distribution of CRLF life stages within specific recovery units and/or designated critical habitat within the action area. This information would allow for quantitative extrapolation of the present risk assessment's predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the species.
- Quantitative information on prey base requirements for individual aquatic- and terrestrial-phase frogs. While existing information provides a preliminary picture of the types of food sources utilized by the frog, 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 frogs and potential modification to critical habitat.

5.5 Risk Hypotheses Revisited

Table 5-11 below revisits the risk hypotheses presented in section 2.9.1. The risk hypotheses were accepted or rejected in accordance with the “No Effect,” “May Affect,” and “Likely to Adversely Affect,” or “Not Likely to Adversely Affect” findings in this assessment.

Table 5-12 Risk Hypotheses Revisited

Risk Hypothesis	Conclusions
Labeled uses of ODM within the action area may directly affect the CRLF by causing mortality or by adversely affecting growth or fecundity.	Accepted for aquatic phase. “Likely to Adversely Affect” finding. Accepted for terrestrial phase. “Likely to Adversely Affect” finding.
Labeled uses of ODM within the action area may indirectly affect the CRLF by reducing or changing the composition of food supply.	Rejected for aquatic phase. “Not Likely to Adversely Affect” finding. Accepted for terrestrial phase. “Likely to Adversely Affect” finding.
Labeled uses of ODM within the action area may indirectly affect the CRLF and/or modify designated critical habitat by reducing or changing the composition of the terrestrial plant community (i.e., riparian habitat) required to maintain acceptable water quality and habitat in the ponds and streams comprising the species’ current range and designated critical habitat.	Rejected. “No Effect” finding for terrestrial plants.
Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing or changing breeding and non-breeding aquatic habitat.	Rejected. “No Effect” finding for aquatic plants.
Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing the food supply required for normal growth and viability of juvenile and adult CRLFs.	Rejected for aquatic phase. “Not Likely to Adversely Affect” for indirect effects via invertebrates. Accepted for terrestrial phase. “Likely to Adversely Affect” finding for indirect effects via terrestrial prey losses.
Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing or changing upland habitat within 200 ft of the edge of the riparian vegetation necessary for shelter, foraging, and	Rejected for terrestrial phase. “Not Likely to Adversely Affect” finding for indirect effect via effects on plants.

predator avoidance.	
Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by reducing or changing dispersal habitat within designated units and between occupied locations within 0.7 mi of each other that allow for movement between sites including both natural and altered sites. which do not contain barriers to dispersal	Rejected for terrestrial phase. "Not Likely to Adversely Affect" finding for indirect effect via effects on plants.
Labeled uses of ODM within the action area may modify the designated critical habitat of the CRLF by altering chemical characteristics necessary for normal growth and viability of juvenile and adult CRLFs.	Accepted. Presence of ODM in terrestrial habitat is believed to have direct and indirect effects on CRLF.

6. Uncertainties

6.1. Maximum Use Scenario

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

6.2. Usage Uncertainties

County-level usage data were obtained from California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database. Four years of data (2002 – 2005) 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 use 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.

6.3. Exposure Assessment Uncertainties

Due to lack of appropriate PRZM scenarios for California, not all labeled uses were modeled for aquatic exposure. However, it is likely that the cabbage use (3 applications of 0.75 lbs ai/acre with a 7-day application interval) provides the highest aquatic exposure estimate, including those not modeled, all of which have lower maximum one-time application rates, fewer applications, and/or shorter application intervals.

All exposure estimates were done with maximum application rates, minimum intervals, and maximum number of applications, to define the Action Area for the Federal action. Actual exposures will depend on actual use rates, which may be lower. However, due to the length of the growing season in California, some crops may be grown multiple times in one year. The approach of this risk assessment was to only model exposure based on per crop-cycle exposures, but multiple crop cycles may result in exposure that is greater than what has been estimated. This could cause LOCs to be exceeded for more uses; however, this would not materially change the risk conclusion or the action area.

Chronic RQs for fish exceed the LOC, which is unexpected given that ODM is not persistent. One explanation could be related to the aquatic exposure assessment and its limits related to lack of data. Aquatic exposure modeling inputs were based on the available guideline data. Some inputs (e.g., soil metabolism half-life = 3.2 days) were based on a single value, which by EFED policy is multiplied by 3 to account for uncertainty, and because there was no aquatic metabolism half-life study, that value was multiplied by 2. Because there are no additional studies to estimate variability in degradation rates, this value may or may not overestimate persistence (and, thus, chronic concentrations). However, it is likely that this approach results in a conservative estimate.

Spray drift estimates were set at 1% for ground application and 5% for aerial application, per EFED policy. Actual spray drift from aerial application may be higher.

The decay half-life of ODM on foliage and other food items for the T-REX and T-HERPS analysis was set at the default value of 35 days. No other values were available for use in this assessment, and this value is expected to be lower. However, since acute and chronic RQs for terrestrial animals were very high, reducing this value is not expected to affect the risk conclusions. For example, the chronic RQ for mammals under the cabbage scenario is 2765 if a foliar half-life of 5 days is used. This value would result in an estimate of 9,600 feet (1.8 miles) for the terrestrial action area buffer distance.

6.3.1. PRZM Modeling Inputs and Predicted Aquatic Concentrations

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, aquatic-phase CRLFs may inhabit water bodies of different size and depth and/or are located adjacent to larger or smaller drainage areas than the EXAMS pond. The Agency does not currently have sufficient information regarding the hydrology of these aquatic habitats to develop a specific alternate scenario for the CRLF. As previously discussed in Section 2.X and Attachment 1, CRLFs prefer habitat with perennial (present year-round) or near-perennial water and do not frequently inhabit vernal (temporary) pools because conditions in these habitats are generally not suitable (Hayes and Jennings 1988). Therefore, the EXAMS pond is assumed to be representative of exposure to aquatic-phase CRLFs. 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).

6.3.2. Aquatic Exposure Estimates

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 a farmer's 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.

6.3.3. 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.

6.3.4. Dietary Intake

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.

6.4. Effects Assessment Uncertainties

6.4.1. 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, such as ODM, 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 of the California Red Legged Frog.

6.4.2. Extrapolation of Long-term Environmental Effects from Short-term Laboratory Tests

The influence of length of exposure and concurrent environmental stressors to the California Red Legged Frog (i.e., urban expansion, habitat modification, decreased quantity and quality of water in CRLF habitat, predators, etc.) will likely affect the species' response to ODM. Additional environmental stressors may decrease the CRLF's sensitivity to the insecticide, 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 will 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 intentionally set very low, and conservative estimates are made in the screening level risk assessment to account for these uncertainties.

6.4.3. Sublethal Effects

For an acute risk assessment, 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 assessment 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.

6.4.4. Location of Wildlife Species

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

6.5. Use of Surrogate Data for Amphibians

Toxicity data for terrestrial phase amphibians was not available for use in this assessment. Therefore, avian and freshwater fish toxicity data were used as a surrogate for risk estimation for the terrestrial- and aquatic-phase CRLF, respectively. There is uncertainty regarding the relative sensitivity of herptiles, birds, and fish to ODM. If birds are substantially more or less sensitive than the California Red Legged Frog, then risk would be over- or underestimated, respectively.

6.6. Assumptions Associated with the Acute LOCs

The risk characterization section of this endangered species assessment includes an evaluation of the potential for individual effects. 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 for the effects study corresponding to the taxonomic group for which the LOCs are exceeded.

6.7. Action Area

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 Action Area (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, Agency believes that this model gives us the best available estimates under current circumstances.

The buffer used to estimate action area based on terrestrial effects was determined to be 11,338 ft, due to chronic effects in mammals that result in indirect effects to the CRLF. This value is consistent with EFED's current methodology for estimating the action area. However, the actual distance at which CRLF may be affected is expected to be shorter than this distance, thus the action area may actually be smaller. For instance, the AgDISP model cannot account for the effects of topography and vegetation that would interfere with drift. Since the buffer was determined using the RQ determined from the highest application rate (0.75 lbs ai applied 3 times with 7-day intervals), the methodology also assumes that wind blows in exactly the same direction over the buffer distance each time applications are made and for the duration that ODM remains in the air. These assumptions are not entirely realistic, but further information to refine these aspects of the methodology is not available. Nonetheless, the action area is expected to be large enough to be protective to the CRLF.

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