Risks of BROMACIL and BROMACIL LITHIUM Use to the Federally Listed California Red-Legged Frog
(*Rana aurora draytonii*)

Pesticide Effects Determination

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

October 19, 2007

Primary Authors
Kristina Garber, Biologist
Cheryl A. Sutton, Ph. D., Environmental Scientist

Reviewers
Thomas Steeger, Ph.D., Senior Biologist
Marietta Echeverria, RAPL

Branch Chief, Environmental Risk Branch 4
Elizabeth Behl

Acknowledgement

The bromacil chemical team would like to acknowledge the contribution of the California Red-Legged Frog Steering Committee in compiling detailed information on the threatened species. Additionally, the Steering Committee has provided invaluable guidance toward achieving greater consistency in format and content between chemicals being assessed. We acknowledge the contribution of Mr. Kurt Pluntke in providing the Geographic Information System analysis used to define the potential overlap between California red-legged frog and their designated critical habitat with the action area.

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1. Executive Summary

The purpose of this assessment is to evaluate potential direct and indirect effects on the California red-legged frog *(Rana aurora draytonii*; CRLF) arising from FIFRA regulatory actions regarding use of bromacil and its salt, bromacil lithium, on agricultural and non-agricultural sites. In addition, this assessment evaluates whether these actions can be expected to result in modification of the species' designated critical habitat. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998 and procedures outlined in the Agency's Overview Document (U.S. EPA, 2004).

The CRLF was listed as a threatened species by USFWS in 1996. The species is endemic to California and Baja California (Mexico) and inhabits both coastal and interior mountain ranges. 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) in California.

This assessment considers registrations of bromacil, as well as bromacil lithium, which dissociates to form bromacil. Bromacil and bromacil lithium are currently registered herbicides for use on non-cropland areas, including (but not necessarily limited to) airports, parking lots, industrial areas, rights-of-way (for railroads, highways, pipeline and utilities), storage areas, lumberyards, tank farms, under asphalt and concrete pavement and fence rows. These chemicals can also be used in uncultivated portions of agricultural areas, including farmyards, fuel storage areas, fence rows and barrier strips. In addition, bromacil is registered for use in citrus orchards and pineapple fields. The maximum use rates of bromacil and bromacil lithium on non-cropland areas are 2 applications per year of 15.4 lbs a.i./A and 1 application per year of 12 lbs a.i./A, respectively. The maximum use rate of bromacil on citrus orchards is 1 application per year of 6.4 lbs a.i./A. All exposure modeling and resulting risk conclusions are made based on these maximum application rates.

In this assessment, it is assumed that uses of bromacil and bromacil lithium could potentially result in exposures of bromacil to aquatic and terrestrial habitats of the CRLF. In this assessment, when uses of non-cropland areas are discussed, bromacil and bromacil lithium are considered. Since bromacil lithium dissociates in water to form bromacil, this assessment refers to exposures resulting from non-cropland uses in terms of bromacil. Fate and effects data for bromacil are considered relevant for both bromacil and bromacil lithium.

The environmental fate properties of bromacil along with monitoring data identifying its presence in surface waters and ground waters in California indicate that bromacil has the potential to be transported to non-target areas. In this assessment, transport of bromacil from initial application sties through runoff and spray drift are considered in deriving quantitative estimates of bromacil exposure to CRLF, its prey and its habitats.

Since CRLFs exist within aquatic and terrestrial habitats, exposure of the CRLF, its prey and its habitats to bromacil are assessed separately for the two habitats. Tier-II exposure models (PRZM/EXAMS) are used to estimate high-end exposures of bromacil in aquatic habitats resulting from runoff and spray drift from different uses. Peak model-estimated environmental concentrations resulting from maximum label rates of bromacil for citrus and non-agricultural uses are 0.050 and 2.34 mg/L, respectively, in aquatic habitats. These estimates are 1-3 orders of magnitude greater than the maximum concentration of bromacil (0.0075 mg/L) measured in non-targeted monitoring in California surface waters.

To estimate bromacil exposures to terrestrial-phase CRLF, and its potential prey resulting from uses involving maximum application rates of bromacil or bromacil lithium, the T-REX model is used. To further characterize exposures of terrestrial-phase CRLF to dietary- and dose-based exposures of bromacil, T-HERPS is used. AgDRIFT and AGDISP are also used to estimate deposition of bromacil on terrestrial habitats from spray drift. To estimate bromacil exposures to terrestrial-phase habitat, including plants inhabiting semi-aquatic and dry areas, the TerrPlant model is used.

The assessment endpoints for the CRLF include direct toxic effects on the survival, reproduction, and growth of the aquatic- and terrestrial-phase CRLF itself, as well as indirect effects, such as reduction of the prey base and/or modification of its habitat. Direct effects to the CRLF in the aquatic habitat are based on toxicity information for freshwater fish, which are generally used as a surrogate for aquatic-phase amphibians. In the terrestrial habitat, direct effects are based on toxicity information for birds, which are used as a surrogate for terrestrial-phase amphibians. Given that the CRLF's prey items and designated critical habitat requirements in the aquatic habitat are dependant on the availability of freshwater aquatic invertebrates and aquatic plants, toxicity information for these taxonomic groups is also discussed. In the terrestrial habitat, indirect effects due to depletion of prey are assessed by considering effects to terrestrial insects, small terrestrial mammals and frogs. Indirect effects due to modification of the terrestrial habitat are characterized by available data for terrestrial monocots and dicots.

Bromacil is slightly toxic to freshwater fish and practically non-toxic to freshwater invertebrates on an acute exposure basis. Toxicity categories for aquatic plants have not been defined. If classification for animals were applied to aquatic plants, bromacil would be classified very highly toxic to unicellular and vascular plants. The NOAECs for the fathead minnow and waterflea are 3.0 and 8.2 mg a.i./L, respectively. Bromacil is practically nontoxic to birds and slightly toxic to mammals on an acute exposure basis. Chronic exposures to bobwhite quail in reproduction studies indicate reproductive effects (embryo viability and survival, hatchability and hatchling survival) with a NOAEC of 1500 mg/kg-diet/day. Chronic exposures to rats in a reproduction study indicate a NOAEL for body weight reductions of 250 mg/kg-diet/day. Seedling emergence and vegetative vigor studies with wheat (a monocot) result in EC_{25} values of 0.030 and 0.042 lbs a.i./A, respectively. Seedling emergence and vegetative vigor studies with rape (a dicot) result in EC_{25} values of 0.0047 and 0.0055 lbs a.i./A, respectively.

Risk quotients (RQs) are derived as quantitative estimates of potential high-end risk. Acute and chronic RQs are compared to the Agency's levels of concern (LOCs) for Federally-listed threatened species to identify if bromacil or bromacil lithium use within the action area has any direct or indirect effect on the CRLF. Based on estimated environmental concentrations for the currently registered uses of bromacil or bromacil lithium, RQ values are above the Agency's LOC for direct acute effects on the CRLF resulting from applications to citrus and non-cropland areas; this represents a "may affect" determination. RQs for uses on citrus and non-cropland areas exceed the LOC for exposures to aquatic unicellular plants. Therefore, there is a potential to indirectly affect larval (tadpole) CRLF due to effects to the algae forage base in aquatic habitats. The effects determination for indirect effects to the CRLF due to effects to its prey base is "may affect." When considering the prey of larger CRLF in terrestrial habitats (*e.g.* frogs, fish and small mammals), RQs for some of these taxa also exceed the LOC for acute and chronic exposures, resulting in a "may affect" determination. RQ values for plants in aquatic and terrestrial habitats exceed the LOC; therefore, indirect effects to the CRLF through effects on aquatic and terrestrial habitats result in a "may affect" determination.

All "may affect" determinations are further refined using available evidence to determine whether they are "not likely to adversely affect" (NLAA) or "likely to adversely affect" (LAA). Additional evidence is employed to distinguish between NLAA and LAA determinations. This evidence includes available monitoring data and likelihood of individual mortality analysis.

Refinement of all "may affect" determinations from bromacil use on citrus results in a "NLAA" determination for direct effects to the CRLF, a "LAA" determination for indirect effects to the CRLF based on effects to its prey, specifically algae, and a "LAA" determination for indirect effects to the CRLF based on effects to aquatic and terrestrial habitat (**Table 1**). Consideration of CRLF critical habitat indicates a determination of "habitat modification" for aquatic and terrestrial habitats based on bromacil use on citrus. **The overall CRLF effects determination for bromacil use on citrus is "LAA."**

Refinement of all "may affect" determinations from bromacil and bromacil lithium use on non-cropland areas result in a "LAA" determination for direct effects to the CRLF, a "LAA" determination for indirect effects to the CRLF based on effects to its prey, specifically algae, and a "LAA" determination for indirect effects to the CRLF based on effects to aquatic and terrestrial habitat (**Table 2**). Consideration of CRLF critical habitat indicates a determination of "habitat modification" for aquatic and terrestrial habitats based on non-cropland uses of bromacil and bromacil lithium. **The overall CRLF effects determination for bromacil and bromacil lithium use on non-cropland areas is "LAA."**

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

Table 1. Effects Determination Summary for the CRLF based on bromacil use on citrus.

Assessment Endpoint	Effects Determination[1]	Basis for Determination
Direct effects to CRLF	NLAA	- Acute and chronic RQs for CRLF in aquatic habitats do not exceed the listed species LOC, therefore, the risk of bromacil exposures to CRLF in this habitat is low. -Dose-based and dietary-based acute RQs for the terrestrial phase CRLF are indiscreet because dose-based and dietary-based studies did not quantify LD_{50} and LC_{50} values (respectively), which were greater than the highest concentrations tested. -Refined RQs (using T-HERPS) indicates a <u>potential</u> LOC exceedance for medium sized (37g) terrestrial-phase CRLF consuming small herbivore mammals (based on acute, dose based exposures). No other dose-based RQs exceed the LOC for CRLF of other feeding categories. Risk of mortality and sublethal effects to the CRLF is unlikely since comparison of EECs to the lowest concentration where sublethal effects were observed in an acute oral study with birds indicates that exposure concentrations are insufficient to reach levels where sublethal effects were observed. -RQ for acute, dietary-based exposure to the terrestrial phase CRLF does not exceed LOC. -RQ for chronic exposure of the terrestrial phase CRLF to bromacil does not exceed listed species LOC.
Indirect effects to tadpole CRLF via reduction of prey (*i.e.*, algae)	LAA	-RQ exceeds LOC by>8x. - According to available toxicity data for 4 species of unicellular aquatic plants, EECs are sufficient to exceed the LOC for 3 of 4 species. - Non-target monitoring data are at levels sufficient to exceed the LOC for unicellular aquatic plants. - Exposures of bromacil in aquatic habitats have the potential to affect populations and possibly communities of aquatic algae.
Indirect effects to juvenile CRLF via reduction of prey (*i.e.*, invertebrates)	NLAA	- Aquatic Invertebrates: Acute and chronic RQs do not exceed LOC, indicating low risk of mortality to these organisms. - Terrestrial Invertebrates: RQs for small and large insects potentially exceed the LOC. RQs are indiscreet because the available acute toxicity study did not quantify LD_{50}. Direct comparison of the level were 1.2% mortality was observed with EECs calculated by T-REX for small and large insects exposed to bromacil applied to citrus, the EECs are insufficient to reach the level where 1.2% mortality was observed in honey bees. Indirect effects to the CRLF due to effects to terrestrial invertebrates are insignificant.
Indirect effects to adult CRLF via reduction of prey (*i.e.*, invertebrates, fish, frogs, mice)	NLAA	- Aquatic Invertebrates: Acute and chronic RQs do not exceed LOC, indicating low risk of mortality to these organisms. - Terrestrial Invertebrates: RQs for small and large insects potentially exceed the LOC. RQs are indiscreet because the available acute toxicity study did not quantify LD_{50}. Direct comparison of the level were 1.2% mortality was observed with EECs calculated by T-REX for small and large insects exposed to bromacil applied to citrus, the EECs are insufficient to reach the level where 1.2% mortality was observed in honey bees. Indirect effects to the CRLF due to effects to terrestrial invertebrates are insignificant. - Fish and aquatic-phase frogs: Acute and chronic RQs do not exceed listed species LOC for fish and aquatic-phase amphibians, indicating low risk of mortality to these organisms. - Terrestrial-phase frogs: For terrestrial frogs serving as CRLF prey, refined EECs from T-HERPS result in RQs which are insufficient to exceed acute and chronic listed species LOCs. - Mice: Acute RQ exceeds listed species LOC by 8.2X for small terrestrial mammals consuming short grass. Exposures up to 23 feet beyond the edge of the citrus orchard are sufficient to exceed the LOC. The likelihood of individual mortality for mice directly on the field is 34.5%. -Chronic RQ exceeds listed species LOC by 6.1 to 53X for small terrestrial mammals consuming short grass. Chronic exposures (dose-based) up to 132 feet beyond the edge of the citrus orchard are sufficient to exceed the LOC. Chronic EECs are sufficient to exceed the LOAEC concentration for the available chronic mammalian toxicity study. - <u>Summary</u>: Because the adult CRLF is an opportunistic feeder, it will consume available prey. Since effects are not expected for the majority of its possible prey items (4 of 5), it is expected that there will be sufficient prey to maintain the adult CRLF. Potential effects to mice are considered insignificant to the adult CRLF, when considering its entire diet.
Indirect effects to CRLF via reduction of habitat and/or primary productivity (*i.e.*, plants)	LAA	-RQs for plants inhabiting acute and terrestrial habitats exceed LOC by several orders of magnitude. -For terrestrial dicots, spray drift exposures up to 4026 feet (0.76 miles) beyond the edge of the citrus orchard are sufficient to exceed the LOC. -Several ecological incidents have been reported related to effects of runoff of bromacil to non-target plants. -Bromacil is an herbicide, and is expected to cause effects to plants.

[1]LAA = likely to adversely affect; NLAA = not likely to adversely affect; NE = no effect

Table 2. Effects Determination Summary for the CRLF based on bromacil and bromacil lithium use on non-cropland areas.

Assessment Endpoint	Effects Determination[1]	Basis for Determination
Direct effects to CRLF	LAA	- Acute aquatic RQs for the maximum use rate of bromacil on rights of ways and impervious surfaces exceed the listed species LOC. The likelihood of individual mortality to a CRLF individual is 1 in $2.17e^7$. Since the chance of this occurring is approximately 0.000005%, potential direct effects are insignificant. Therefore, the risk of bromacil exposures to CRLF in this habitat is low. - Acute aquatic RQs that result from the maximum use rate of bromacil lithium are insufficient to exceed the listed species LOC. - The chronic aquatic RQ does not exceed listed species LOC. - Dose-based and dietary-based acute RQs for the terrestrial phase CRLF are indiscreet because dose-based and dietary-based studies did not quantify LD_{50} and LC_{50} values (respectively), which were greater than the highest concentrations tested. - Refined RQs (using T-HERPS) indicates <u>potential</u> LOC exceedances for several feeding categories and body sizes of CRLF when considering applications of bromacil and bromacil lithium at their respective maximum use rates. - Comparison of EECs to effects observed in acute tests indicated that EECs exceed levels where sublethal effects and mortality (20%) were observed. Therefore, there is potential for direct effects to the terrestrial-phase CRLF resulting from acute exposures. - For chronic exposures of the CRLF in the terrestrial habitat, the LOC is exceeded for applications of bromacil, specifically for CRLF feeding on small insects and on small herbivore mammals. Chronic RQs for bromacil lithium applications also exceed the LOC. Direct comparison of chronic dietary-based EECs resulting from bromacil applications to the chronic avian reproduction study LOAEC indicate that EECs are sufficient to exceed the level where reproductive effects were observed in birds. - Acute effects directly to terrestrial-phase CRLF resulting from bromacil and bromacil lithium applications at the maximum allowed rates to and to non-cropland areas cannot be discounted. - At the maximum use rate of bromacil, there is potential for risk directly to the terrestrial-phase CRLF based on chronic exposures.
Indirect effects to tadpole CRLF via reduction of prey (*i.e.*, algae)	LAA	-RQ exceeds LOC by>300x. - According to available toxicity data for 4 species of unicellular aquatic plants, EECs are sufficient to exceed the LOC for 4 of 4 species. - Non-target monitoring data are at levels sufficient to exceed the LOC for unicellular aquatic plants. - Exposures of bromacil in aquatic habitats have the potential to affect populations and possibly communities of aquatic algae.
Indirect effects to juvenile CRLF via reduction of prey (*i.e.*, invertebrates)	NLAA	- Aquatic Invertebrates: Acute and chronic RQs do not exceed LOC, indicating low risk of mortality to these organisms. - Terrestrial Invertebrates: Direct comparison of the level were 1.2% mortality was observed with EECs calculated by T-REX for large insects, indicates that EECs are insufficient to reach the level where 1.2% mortality was observed in honey bees. For small insects, EECs are approximately 3x the level where 1.2% mortality was observed in honey bees. It is expected that beyond the edge of the application site, EECs will be below the level where 1.2% mortality was observed in honey bees. On application sites, use of bromacil on non-cropland areas could potentially result in mortality to >1.2% of small sized insects. There is potential for effects to some terrestrial invertebrates (small sized) representing CRLF prey; however, it seems unlikely that large sized terrestrial invertebrates will be affected by bromacil applications to non-cropland areas, leaving terrestrial invertebrates to serve as prey to terrestrial-phase CRLF.
Indirect effects to adult CRLF via reduction of prey (*i.e.*, invertebrates, fish, frogs, mice)	NLAA	- Aquatic Invertebrates: Acute and chronic RQs do not exceed LOC, indicating low risk of mortality to these organisms. - Terrestrial Invertebrates: There is potential for effects to some terrestrial invertebrates (small sized) representing CRLF prey; however, it seems unlikely that large sized terrestrial invertebrates will be affected, leaving terrestrial invertebrates to serve as prey to terrestrial-phase CRLF. - Fish and aquatic-phase frogs: The likelihood of individual mortality to an individual fish or frog is <0.001%. The chronic LOC is not exceeded. - Terrestrial-phase frogs: For terrestrial frogs serving as CRLF prey, refined EECs from T-HERPS result in acute and chronic RQs which potentially exceed acute listed species LOC. - Mice: Acute RQ exceeds listed species LOC by 35X for small terrestrial mammals consuming short grass. Exposures up to 771 feet beyond the edge of the application site are sufficient to exceed the LOC. The likelihood of individual mortality for mice directly on the field is approximately 100%. -Chronic RQ exceeds listed species LOC by 26 to 225X for small terrestrial mammals consuming short grass. Chronic exposures (dose-based) up to 3113 feet beyond the edge of the site of application are sufficient to exceed the LOC. Chronic EECs are sufficient to exceed the LOAEC concentration for the available chronic mammalian toxicity study. - <u>Summary</u>: Because the adult CRLF is an opportunistic feeder, it will consume available prey. Since effects are not expected for the majority of its possible prey items (3 of 5), it is expected that there will be sufficient prey to maintain the adult CRLF. Potential effects to mice and terrestrial species of prey frogs are considered insignificant to the adult CRLF, when considering its entire diet.
Indirect effects to CRLF via reduction of habitat and/or primary productivity (*i.e.*, plants)	LAA	-RQs for plants inhabiting acute and terrestrial habitats exceed LOC by several orders of magnitude. -For terrestrial dicots, spray drift exposures up to 5909 feet (1.12 miles) beyond the edge of the application site are sufficient to exceed the LOC. -Several ecological incidents have been reported related to effects of runoff of bromacil to non-target plants. -Bromacil is an herbicide, and is expected to cause effects to plants.

[1]LAA = likely to adversely affect; NLAA = not likely to adversely affect; NE = no effect

When evaluating the significance of this risk assessment's direct/indirect and habitat modification 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.

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 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 bromacil and its lithium salt as an herbicide on citrus and non-cropland areas, including industrial and right-of-way areas. 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. 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.

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 bromacil and bromacil lithium 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 bromacil and bromacil lithium 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 bromacil and bromacil lithium at the use sites described in this document to affect CRLF individuals and/or result in the 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 the 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 bromacil and bromacil lithium as it relates to this species and its designated critical habitat. If, however, direct or indirect effects to individual CRLFs are anticipated 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 bromacil and bromacil lithium.

If a determination is made that use of bromacil and bromacil lithium 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 bromacil and bromacil lithium use sites) and further evaluation of the potential impact of bromacil and bromacil lithium on the PCEs are 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 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 bromacil and bromacil lithium are expected to directly impact living organisms within the action area (defined in Section 2.7), critical habitat analyses for bromacil and bromacil lithium are limited in a practical sense to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes (i.e., the biological resource requirements for the listed species associated with the critical habitat or important physical aspects of the habitat that may be reasonably influenced through biological processes). Activities that may modify critical habitat are those that alter the

PCEs and appreciably diminish the value of the habitat. Evaluation of actions related to use of bromacil and bromacil lithium 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

This assessment considers registrations of bromacil, as well as its salt, bromacil lithium, which dissociates to form bromacil in water. Bromacil and bromacil lithium are currently registered for use as herbicides on non-cropland areas, including (but not necessarily limited to) airports, parking lots, industrial areas, rights-of-way (for railroads, highways, pipeline and utilities), storage areas, lumberyards, tank farms, under asphalt and concrete pavement and fence rows. These chemicals can also be used as herbicides in uncultivated portions of agricultural areas, including farmyards, fuel storage areas, fence rows and barrier strips. In addition, bromacil (but not bromacil lithium) is registered for use in citrus orchards and pineapple fields. Although labels allow applications of bromacil to pineapple, this crop is generally not grown in California and is therefore, not relevant to this assessment (USDA 2007).

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 bromacil and bromacil lithium in accordance with the approved product labels for California are "the actions" being assessed.

Although current registrations of bromacil and bromacil lithium allow for use nationwide, this ecological risk assessment and effects determination addresses currently registered uses of bromacil and bromacil lithium 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.

In this assessment, it is assumed that uses of bromacil and bromacil lithium could potentially result in exposures of bromacil to aquatic and terrestrial habitats of the CRLF. In this assessment, when uses of non-cropland areas are discussed, bromacil and bromacil lithium are considered. Since bromacil lithium dissociates in water to form bromacil, this assessment refers to exposures resulting from non-cropland uses in terms of bromacil. Fate and effects data for bromacil are considered relevant for both bromacil and bromacil lithium.

Consistent with what was done for the environmental fate and ecological risk assessment in support of the reregistration eligibility decision on bromacil, only parent bromacil (and bromacil lithium) are included in this assessment. Although bromacil photodegrades rapidly at pH 9, information on photodegradates is not available. In soil, bromacil degrades slowly (half-life of 275 days), and CO_2 is the only major degradate. Five aerobic soil minor degradates were identified, but were present at only 0.6-3.4% of total residues. The major and persistent anaerobic aquatic degradate, 3-sec-butyl-6-methyluracil (Metabolite F), which represented a maximum of 80.7% of the applied (day 304), was not determined to be of toxicological concern (Linda Taylor, HED/OPP) in the bromacil RED.

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, the data 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).

Bromacil has registered products that contain multiple active ingredients, including diuron; 2,4-dichlorophenoxyacetic acid; sodium chlorate; sodium metaborate; and 2,4-dichlorophenoxy)-2,ethylhexyl ester. Analysis of the available acute oral mammalian LD_{50} data (*and available open literature for Bromacil*) for multiple active ingredient products relative to the single active ingredient are provided in **Appendix A**. The results of this analysis show that an assessment based on the toxicity of the single active ingredient of bromacil or bromacil lithium is appropriately conservative since the technical grade active ingredient is more toxic than the formulated end product.

This assessment considers only the single active ingredients bromacil and bromacil lithium. However, the assessed species and their environments may be exposed to multiple pesticides simultaneously. Interactions of other toxic agents with bromacil could result in additive effects, synergistic effects or antagonistic effects. Evaluation of pesticide mixtures is beyond the scope of this assessment because of the myriad factors that cannot be quantified based on the available data. Those factors include identification of other possible co-contaminants and their concentrations, differences in the pattern and duration of exposure among contaminants, and the differential effects of other physical/chemical characteristics of the receiving waters (*e.g.* organic matter present in sediment and suspended water). Evaluation of factors that could influence additivity/synergism is beyond the scope of this assessment and is beyond the capabilities of the available data to allow for an evaluation. However, it is acknowledged that not considering mixtures could over- or under-estimate risks depending on the type of interaction and factors discussed above.

2.3 Previous Assessments

Bromacil was first registered as an herbicide in the U.S. in 1961. EPA issued a Registration Standard for bromacil in September 1982 (PB87-110276). In 1996, the Agency completed a Reregistration Eligibility Decision (RED) for bromacil and its lithium salt (USEPA 1996).

2.4 Stressor Source and Distribution

2.4.1 Environmental Fate Assessment

The environmental fate database for bromacil is largely complete. Bromacil is a persistent and mobile herbicide. The primary routes of dissipation appear to be photolysis in water under alkaline conditions (pH 9) and microbial degradation under anaerobic conditions. However, the photodegradates under alkaline conditions have not been defined, and the rate of degradation under anaerobic conditions has not been accurately determined.

In laboratory studies, bromacil was stable to hydrolysis, photodegradation in water at pH's 5 and 7, and photodegradation on soil. At pH 9, where an absorption spectrum shift occurs, bromacil photodegraded fairly rapidly with a half-life of 4-7 days. However, the radiolabeled residues in the pH 9 test solution was not further characterized, so degradates were not identified or quantified.

Microbial degradation of bromacil in aerobic soil is slow, with a half-life of 275 days in a silty clay loam soil. Carbon dioxide was the major degradate, totaling 40.3% of the applied at 12 months posttreatment.

Bromacil may be expected to degrade more rapidly under anaerobic than aerobic conditions. In an open-literature laboratory study, bromacil had an observed half-life of 144 to 198 days in Greenfield sandy loam soil under saturated (anaerobic) soil conditions (Wolf, 1974). However, since there is no acceptable guideline study a conservative assumption of "stable to anaerobic microbial degradation" is used in this assessment for modeling aquatic exposures.

In field studies, bromacil was very persistent, with dissipation half-lives of 124-155 days in the surface soil of bareground plots in Delaware and California, and detections in the upper 10 cm of the plots through 538 and 415 days posttreatment, respectively.

Bromacil accumulates only slightly in fish and depurates rapidly. Maximum bioconcentration factors (BCF) were 4.6X for muscle, 6.8-8.3X for viscera, 2.1-2.2X for carcass, and 2.5-2.8X for whole fish. Depuration was rapid, with >96% of the accumulated [^{14}C]residues eliminated from the fish tissues by day 3 of the depuration period.

Table 3 summarizes the chemical identities of bromacil and bromacil lithium. **Table 4** summarizes the environmental chemistry, fate and transport properties of bromacil.

Table 3. Chemical identities of bromacil and bromacil lithium.

PARAMETER	Bromacil	Bromacil lithium
PC code	012301	012302
CAS No.	314-40-9	53404-19-6
Chemical name	5-bromo-3-sec-butyl-6-methyluracil	5-bromo-3-sec-butyl-6-methyluracil, lithium salt
Chemical formula	$C_9H_{13}BrN_2O_2$	$C_9H_{13}BrN_2O_2Li^+$

Table 4. Summary of environmental chemistry, fate and transport properties of bromacil.

<table>
<tr><th>PARAMETER</th><th colspan="2">VALUE</th><th>REFERENCE/ COMMENTS</th></tr>
<tr><td colspan="4">Selected Physical/Chemical Parameters</td></tr>
<tr><td>Molecular weight</td><td colspan="2">261.12 g/mol</td><td>USEPA, 1996</td></tr>
<tr><td>Water solubility (25 °C)</td><td colspan="2">815 mg/L</td><td>USEPA, 1996</td></tr>
<tr><td>Vapor pressure (25 °C)</td><td colspan="2">3.1×10^{-7} torr</td><td>USEPA, 1996</td></tr>
<tr><td>Henry's law constant</td><td colspan="2">$1.1 \text{ X } 10^{-9}$ atm*m^3/mol</td><td>USEPA, 1996</td></tr>
<tr><td>Log K_{ow}</td><td colspan="2">2.11</td><td>Hansch & Leo, 1995</td></tr>
<tr><td>pk_a</td><td colspan="2">9.1</td><td>bromacil ionizes at pH 9.1; USEPA, 1996</td></tr>
<tr><td colspan="4">Persistence</td></tr>
<tr><td>Hydrolysis</td><td colspan="2">pH 5: stable
pH 7: stable
pH 9: stable</td><td>MRID 40951505</td></tr>
<tr><td>Photolysis in water ($t_{1/2,}$ days)</td><td colspan="2">pH 5: 356
pH 7: 102
pH 9: 7, 4.3</td><td>MRIDs 40951507, 40951508
Absorption spectrum shift occurs in alkaline conditions (at pk_a of 9.1).</td></tr>
<tr><td>Photolysis in soil ($t_{1/2,}$ days)</td><td colspan="2">166</td><td>MRID 40951509</td></tr>
<tr><td>Aerobic soil metabolism ($t_{1/2,}$ days)</td><td colspan="2">275</td><td>MRID 40951510</td></tr>
<tr><td>Anaerobic soil metabolism</td><td colspan="2">No data</td><td>No studies submitted.</td></tr>
<tr><td>Aerobic aquatic metabolism</td><td colspan="2">No data</td><td>No studies submitted.</td></tr>
<tr><td>Anaerobic aquatic metabolism</td><td colspan="2">No data</td><td>Submitted study is unacceptable.</td></tr>
<tr><td colspan="4">Mobility</td></tr>
<tr><td rowspan="5">Column Leaching</td><td>Soil Texture</td><td>% of applied bromacil found in leachate of the four columns</td><td rowspan="5">MRID 40951512; Koc of 32 used in assessment is from SCS/ARS database (only column leaching data were available from submitted studies)</td></tr>
<tr><td>Sand</td><td rowspan="4">total residues in leachate = 91.2-99.6% of the applied;
bromacil in leachate = 89.0-94.1% of the applied</td></tr>
<tr><td>Sandy loam</td></tr>
<tr><td>Clay loam</td></tr>
<tr><td>Silt loam</td></tr>
<tr><td colspan="4">Field Dissipation</td></tr>
<tr><td>Terrestrial field dissipation ($t_{1/2,}$ days)</td><td colspan="2">155 (silty clay loam soil in DE)
124 (loam soil in CA)</td><td>MRID 41677101; dissipation from soil surface of bare ground plots</td></tr>
<tr><td colspan="4">Bioaccumulation</td></tr>
<tr><td>Accumulation in fish, BCF</td><td colspan="2">2.5-2.8X</td><td>MRID 40951513</td></tr>
</table>

2.4.2 Environmental Transport Assessment

Laboratory mobility data, in addition to groundwater monitoring information, have clearly demonstrated that bromacil is mobile in soil. However, bromacil's tendency to leach was not overwhelmingly apparent from the two field dissipation studies. The timing and amount of rainfall/irrigation in these studies is a possible explanation.

In column leaching studies, bromacil was mobile in columns of sand, sandy loam, clay loam, and silt loam soils. [^{14}C]Residues in the leachates of all four soils totaled 91.2-99.6% of the applied (bromacil comprised 89.0-94.1% of the applied).

Aged (30 days) bromacil residues were also mobile in a column of silt loam soil. [^{14}C]Residues in the leachate totaled 87.3% of the applied radioactivity. Bromacil was the only compound identified in the leachate, comprising 82.8% of the applied radioactivity.

Batch equilibrium data were not submitted for bromacil. For this assessment, the Koc value of 32 L/kg$_{oc}$ used in modeling aquatic exposures was obtained from the Soil Conservation Service Agricultural Research Station (SCS/ARS) database. This value is similar in magnitude to values reported in the open literature. Gerstl (1984) found an average Koc value of 23 L/kg$_{oc}$ from experimental values determined in 8 soils and 4 sediments. These values indicate that bromacil is mobile in soil, a conclusion which is consistent with the results observed in the column leaching studies.

In the field, Bromacil was persistent, but did not demonstrate the degree of mobility that was predicted based on the laboratory studies and the available groundwater monitoring data. One possible explanation for the limited mobility in the two sites could be the amount and timing of rainfall/irrigation. However, the average rainfall for the test period was about or above the 30-year annual average of 43.36 inches for Wilmington, Delaware, so minimal irrigation was needed. The average rainfall at the second field site was below the 30-year annual average of 9.84 inches for Fresno, California, so substantial irrigation was needed. Irrigation was based on common agricultural practice for the area. Bromacil (Hyvar® X Herbicide, 80% WP), applied at 12 lb ai/A, dissipated with half-lives of 155 days from the upper 10 cm of a bare ground plot of silty clay loam soil located in Delaware, and 124 days from the upper 10 cm of a bare ground plot of loam soil located in California. Bromacil was detected at the Delaware and California sites in the upper 10 cm of the plots through 538 and 415 days post treatment, respectively.

Potential transport mechanisms for bromacil include 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. Based on the vapor pressure and Henry's Law constant of bromacil, volatilization from treated areas resulting in atmospheric transport and deposition represent unlikely transport pathways leading to exposure of the CRLF and its habitats.

2.4.3 Mechanism of Action

Bromacil is classified in as a uracil herbicide. Bromacil interferes with the photosynthesis of a plant by blocking electron transport in photosystem II. Symptoms of plant injury include chlorosis and death of leaf tissue (Martin 2000).

2.4.4 Use Characterization

Analysis of labeled use information is the critical first step in evaluating the federal action. The current labels for bromacil and bromacil lithium represent the FIFRA regulatory action; therefore, labeled use and application rates specified on the label form the basis of this assessment. The assessment of use information is critical to the development of the action area and selection of appropriate modeling scenarios and inputs. Bromacil and bromacil lithium are currently registered for use on non-cropland areas, including (but not necessarily limited to) airports, parking lots, industrial areas, rights-of-way (for railroads, highways, pipeline and utilities), storage areas, lumberyards, tank farms, under asphalt and concrete pavement and fence rows. These chemicals can also be used in uncultivated portions of agricultural areas, including farmyards, fuel storage areas, fence rows and barrier strips. In addition, bromacil (but not bromacil lithium) is registered for use in citrus orchards and pineapple fields. Although labels allow applications of bromacil to pineapple, this crop is not grown in California and is therefore, not relevant to this assessment (USDA 2007). Maximum application rates and numbers of applications for uses of bromacil and bromacil lithium are presented in **Table 5**. Products of bromacil and bromacil lithium include granular and liquid formulations.

Table 5. Uses and maximum use rates of bromacil and bromacil lithium.

Use	Chemical	Max. single application rate in lbs a.i./A (kg a.i./ha)	Max. # applications per year	Timing of applications	Formulation Type	Application Type
Citrus	Bromacil	6.4 (7.2)	1	Any time (best in late fall to early winter or winter to early summer)	wettable powder, dispersible granules	Broadcast, soil broadcast, spot soil treatment, spray
Non-cropland[1]	Bromacil	15.4 (17.3)	2	Any time (varies from pre-emergence to establishment of predominant weed species)	liquid, granular, water-emulsifiable concentrate, pellet, wettable powder, dispersible granules, emulsion, aerosol, water-soluble liquid	Broadcast, spot treatment, spray, prepaving treatment, basal spray treatment, directed spray
Non-cropland[1]	Bromacil lithium	12 (13.4)	1	Any time (varies from pre-emergence to establishment of predominant weed species)	Liquid, water-soluble liquid	Broadcast, spot treatment, spray, basal spray treatment, directed spray, sprinkle

[1]Non-cropland use includes non-agricultural areas, sewage disposal areas, sewage systems, paved areas, drainage systems, urban areas, and outdoor industrial areas. Examples of non-cropland use include parking lots, around buildings, fence rows, railroad sidings, industrial plants, tank farms, storage yards, pipelines, rights-of-way, lumber yards, highways, under asphalt and concrete pavement, oil refineries, cable coverings, runway lights, utility poles and substations, vacant lots, waste lagoons, airports, sewage disposal areas, and other similar sites.

Estimates of national use of bromacil in agriculture are available; however, national-level uses of bromacil and bromacil lithium in non-cropland areas are not available. Approximately 410 thousand pounds of the active ingredient bromacil were used on citrus in 2002. Bromacil was used on citrus in California, Arizona, Texas and Florida (**Figure 1**; USGS 2007). Use data for bromacil-lithium, which has no agricultural uses, are unavailable.

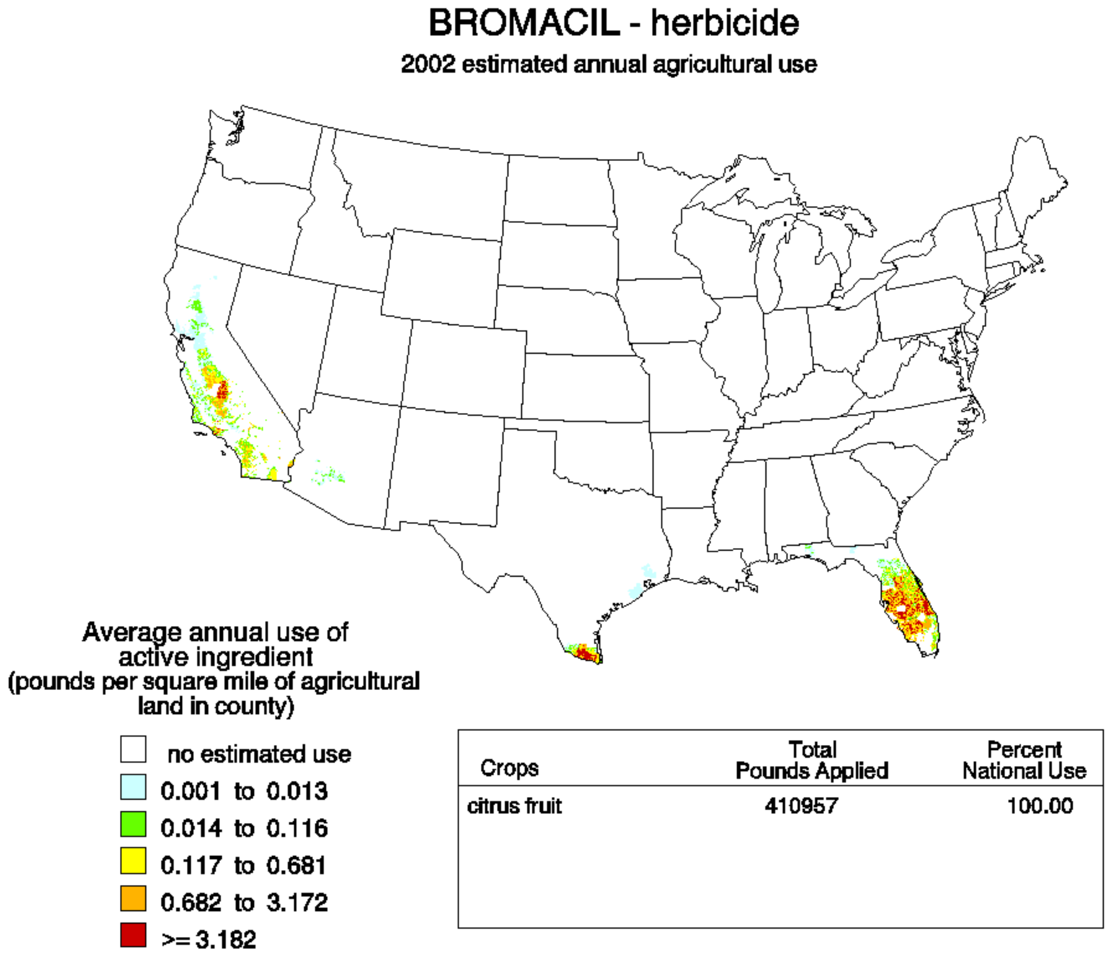


Figure 1. Historical (2002) extent of bromacil use in agricultural areas.

Pesticide use data available from the California Department of Pesticide Regulation (CDPR 2007a), includes county-level data for various bromacil uses, including both agricultural and non-agricultural uses. From 2002-2005, an annual average of 54 thousand pounds of bromacil were used in California. The percentage of total bromacil use in California was highest on oranges (39.9% of total pounds applied), rights-of-way (36.3%), lemons (8.1%), landscape maintenance (6.7%) and grapefruit (3.4%). Use on citrus and rights-of-way represent 91.5% of total pounds of bromacil applied in California during 2002-2005. Applications of bromacil to citrus and rights-of-way occurred in counties throughout the state, including those also containing CRLF core areas and critical habitat.

Pesticide use data for bromacil lithium indicates that from 2002-2005, an annual average of 9.9 thousand pounds of bromacil lithium were used in California. Rights-of-way represent 98.3% of the total applied pounds, while the remaining 1.7% of bromacil lithium applied was used for “landscape maintenance.” Applications of bromacil lithium occurred in counties throughout the state, including those also containing CRLF core areas and critical habitat (CDPR 2007a).

Analysis of CDPR data for bromacil use in California from 2001-2005 (CDPR 2007a) indicates that, although the majority of single applications for citrus were at rates that fell below the maximum single application rate of 6.4 lbs a.i./A, some applications were possibly above this application rate. Estimated application rates ranged 0.01-20 lbs a.i./A, with a 90^{th} percentile of 1.7 lbs a.i./A (n = 916). Fewer data are available for specific applications of bromacil to non-cropland areas. Of the available data, application rates ranged 0.4-14.5 lbs a.i./A, with a 90^{th} percentile of 5.1 lbs a.i./A (n = 20).

The uses considered in this risk assessment represent all currently registered uses according to a review of all current labels. No other uses are relevant to this assessment. Any reported use, such as may be seen in the CDPR PUR database, 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.

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**). 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 6** and shown in **Figure 2**.

Core Areas

USFWS has designated 35 core areas across the eight recovery units to focus their recovery efforts for the CRLF (see **Figure 2**). **Table 6** 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.

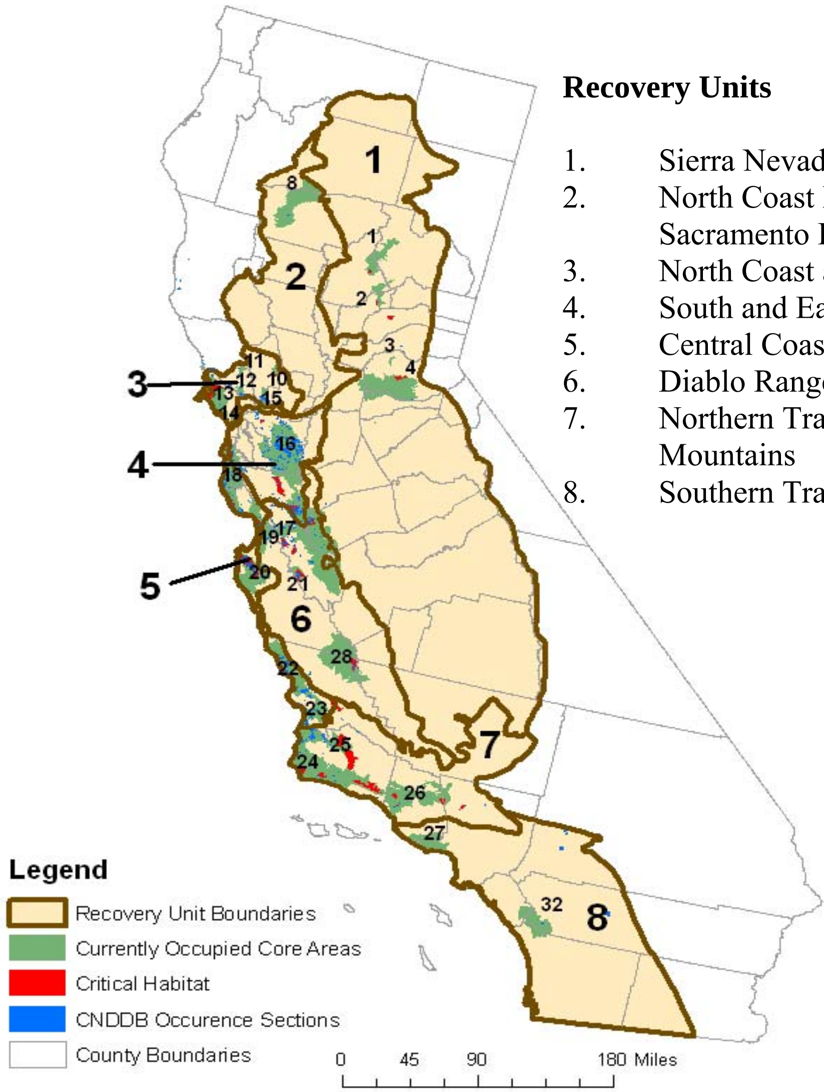
For purposes of this assessment, designated critical habitat, currently occupied (post-1985) core areas, and additional known occurrences of the CRLF from the CNDDB are considered. Each type of locational information is evaluated within the broader context of recovery units. For example, if no labeled uses of bromacil or bromacil lithium 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 6** (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 6. California Red-legged Frog Recovery Units with Overlapping Core Areas and Designated Critical Habitat.

Recovery Unit [1] (Figure 2)	Core Areas [2,7] (Figure 2)	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 2. 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 3** depicts CRLF annual reproductive timing.

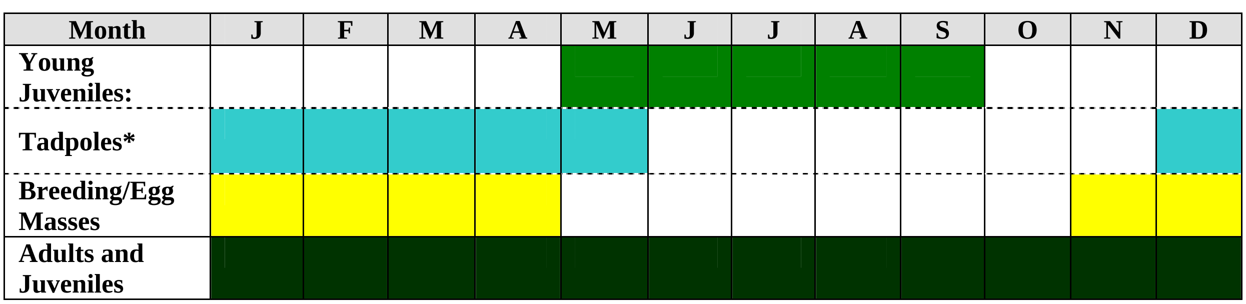


Figure 3. CRLF Reproductive Events by Month.

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.

'Critical habitat' is defined in the ESA as the geographic area occupied by the species at the time of the listing where the physical and biological features necessary for the conservation of the species exist, and there is a need for special management to protect the listed species. It may also include areas outside the occupied area at the time of listing if such areas are 'essential to the conservation of the species.' 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 destruction or adverse modification with regard to actions carried out, funded, or authorized by a federal Agency. Section 7 requires consultation on federal actions that are likely to result in the destruction or adverse modification of critical habitat.

To be included in a critical habitat designation, the habitat must be 'essential to the conservation of the species.' Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species or areas that contain certain primary constituent elements (PCEs) (as defined in 50 CFR 414.12(b)). PCEs include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species. 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 bromacil and bromacil lithium 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 bromacil and bromacil lithium is expected to directly impact living organisms within the action area, critical habitat analysis for bromacil and bromacil lithium 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.

2.7 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 bromacil and bromacil lithium is likely to encompass considerable portions of the United States based on the uses on citrus and the large array of uses on non-cropland areas. 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 bromacil and bromacil lithium may be expected to have on the environment, the exposure levels to bromacil that are associated with those effects, and the best available information concerning the use of bromacil 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 bromacil and bromacil lithium. An analysis of labeled uses and review of available product labels was completed. This analysis indicates that for bromacil and bromacil lithium, the following uses are considered as part of the federal action evaluated in this assessment:

- Citrus (oranges, lemons, tangerines, tangelos, grapefruit, etc.)
- Non-cropland areas (airports, parking lots, industrial areas, rights-of-way (for railroads, highways, pipeline and utilities), storage areas, lumberyards, tank farms, under asphalt and concrete pavement and fence rows, etc.)

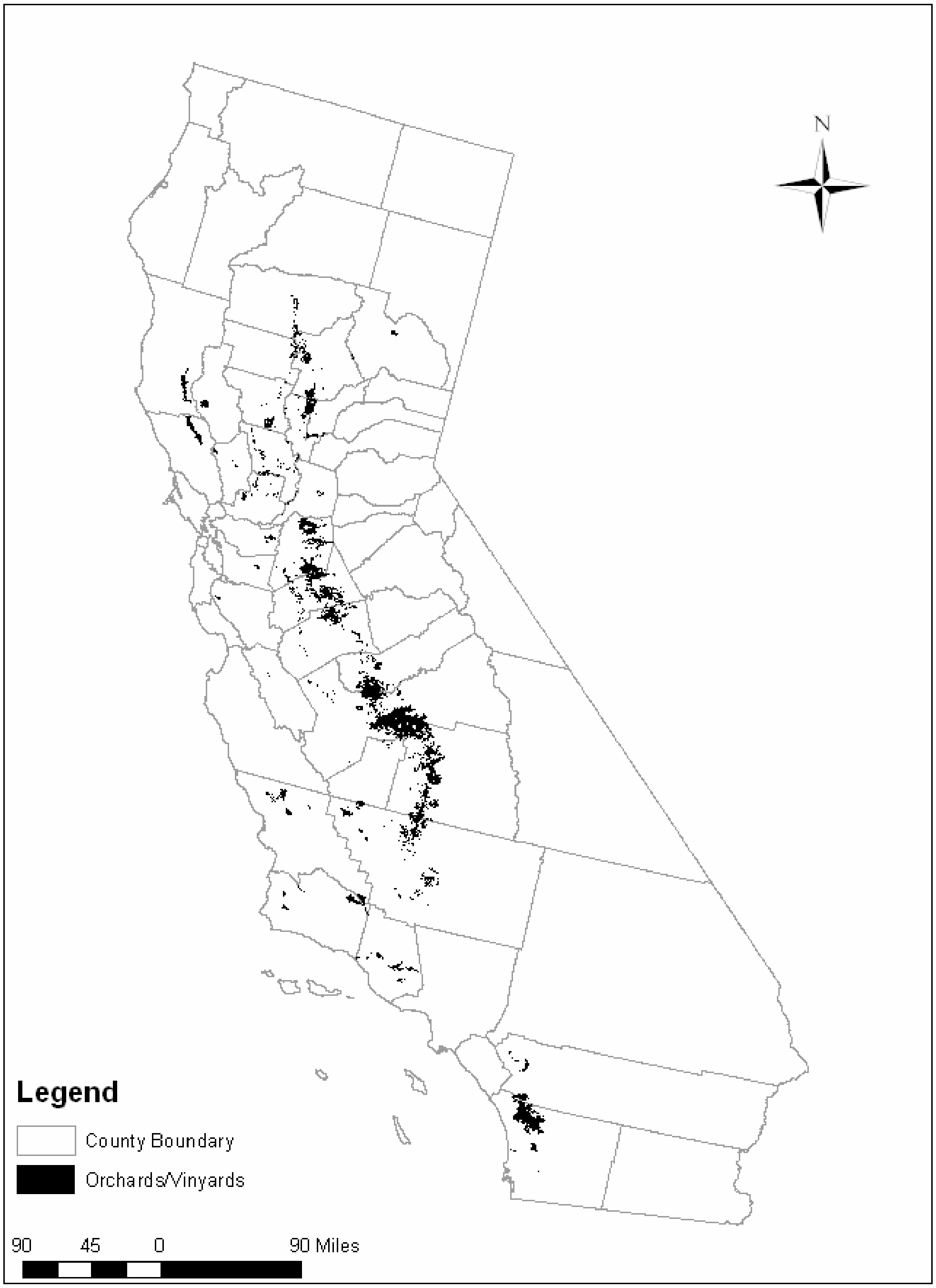
The analysis indicates that pineapple, which is a registered use of bromacil, is not considered in this assessment, since the crop is not grown in California and therefore, the use is not expected to result in exposure to the CRLF.

After the determination of which uses will be assessed, an evaluation of the potential "footprint" of the use pattern is 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 bromacil and bromacil lithium uses. The initial area of concern is defined as all land cover types that represent the labeled uses described above. The initial area of concern is represented by 1) orchard and vineyard landcovers which are assumed to be representative of citrus and 2) rights-of-way which are assumed to be representative of non-cropland areas. Maps representing the land cover types that make up the initial areas of concern for citrus and non-cropland areas are presented in **Figures 4 and 5,** respectively. These maps represent the areas directly affected by the federal action.

It should be noted that the initial action area map for non-cropland areas is defined only by rights-of-way, and does not include several other potential non-cropland uses of bromacil and bromacil lithium (e.g. parking lots, fence rows, tank farms, storage yards, etc.). The initial action area for non-cropland areas is actually larger than what is depicted in **Figure 5**; however, spatial data are unavailable at this time to define the extent of these additional non-cropland areas where bromacil and bromacil lithium can be applied. Since rights-of-way areas make up the majority of past use of bromacil (81.0%) and bromacil lithium (98.3%) on non-cropland areas, rights-of-way are relevant for defining the spatial extent of non-cropland areas.

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. In this assessment, transport of bromacil through runoff and spray drift is considered in deriving quantitative estimates of bromacil exposure to CRLF, its prey and its habitats.

Since this screening level risk assessment defines taxa that are predicted to be exposed through runoff and drift to bromacil at concentrations above the Agency's Levels of Concern (LOC), there is need to expand the action area to include areas that are affected indirectly by this federal action. Two methods are employed to define the areas indirectly affected by the federal action, and thus the total action area. These are the down stream dilution assessment for determining the extent of the affected lotic aquatic habitats (flowing water) and the spray drift assessment for determining the extent of the affected terrestrial habitats. In order to define the final action areas relevant to uses of bromacil and bromacil lithium on citrus and non-cropland areas, it is necessary to combine areas directly affected, as well as aquatic and terrestrial habitats indirectly affected by the federal action. It is assumed that lentic (standing water) aquatic habitats (*e.g.* ponds, pools, marshes) overlapping with the terrestrial areas are also indirectly affected by the federal action. **The analysis of areas indirectly affected by the federal action, as well as the determination of the final action area for bromacil and bromacil lithium is described in the risk discussion (Section 5.2.5).** Additional analysis related to the intersection of the bromacil and bromacil lithium action area and CRLF habitat used in determining the final action area is described in A**ppendix H**.



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 U.S. Environmental Protection Agency, Office of Pesticides Programs, Environmental Fate and Effects Division. April 11, 2007.
Projection: Albers Equal Area Conic USGS, North American Datum of 1983 (NAD 1983)

Figure 4. Initial action area for crops described by orchard and vineyard landcover which corresponds to potential bromacil use sites on citrus. This map represents the area potentially directly affected by the federal action.

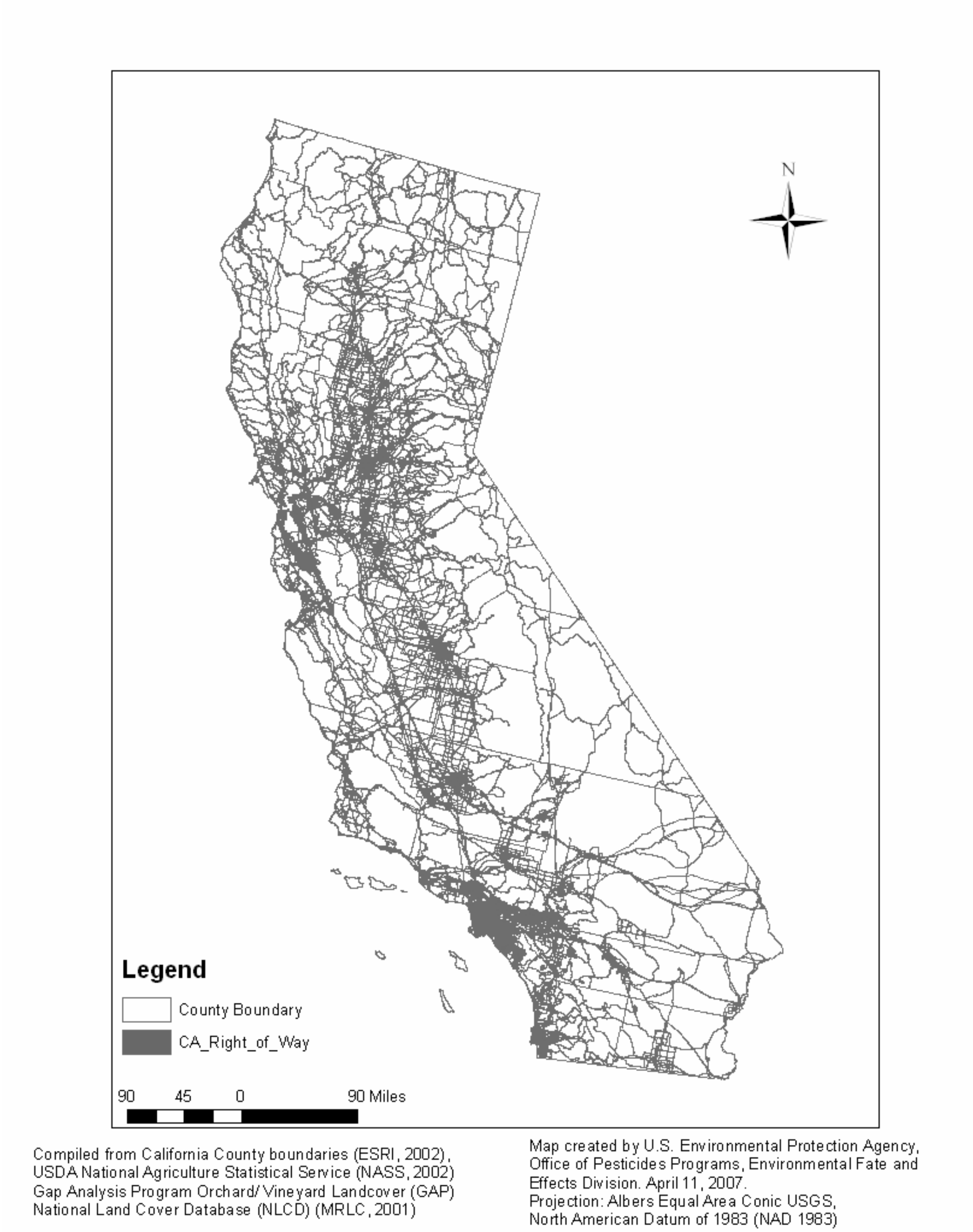


Figure 5. Initial action area for crops described by right-of-way landcover which corresponds to potential bromacil and bromacil lithium use sites on (some) non-cropland areas. This map represents the area potentially directly affected by the federal action.

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” (USEPA 1992). 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 bromacil and bromacil lithium (e.g., runoff, spray drift, etc.), and the routes by which ecological receptors are exposed to bromacil and bromacil lithium -related contamination (e.g., direct contact, etc).

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 bromacil and bromacil lithium is provided in **Table 7**.

Table 7. Summary of Assessment Endpoints and Measures of Ecological Effects for Direct and Indirect Effects of bromacil and bromacil lithium on the California Red-legged Frog.

Assessment Endpoint	Measures of Ecological Effects
Aquatic Phase (eggs, larvae, tadpoles, juveniles, and adults)[1]	
1. Survival, growth, and reproduction of CRLF individuals via direct effects on aquatic phases	1a. most sensitive fish[2] 96-h LC_{50} = 36 mg/L (Rainbow trout) 1b. most sensitive fish[2] chronic NOAEC = 3.0 mg/L (Rainbow trout)
2. Survival, growth, and reproduction of CRLF individuals via effects to food supply (*i.e.,* freshwater invertebrates, non-vascular plants)	2a. most sensitive fish 96-h LC_{50} = 36 mg/L (Rainbow trout) 2b. most sensitive fish chronic NOAEC = 3.0 mg/L (Rainbow trout) 2c. Most sensitive aquatic invertebrate 48-h EC_{50} = 121 mg/L (waterflea) 2d. Most sensitive aquatic invertebrate chronic NOAEC = 8.2 mg/L (waterflea) 2e. Most sensitive aquatic unicellular plant EC_{50} = 0.0068 mg/L (green algae)
3. Survival, growth, and reproduction of CRLF individuals via ndirect effects on habitat, cover, and/or primary productivity (*i.e.,* aquatic plant community)	3a. Most sensitive aquatic unicellular plant EC_{50} = 0.0068 mg/L (green algae) 3b. Vascular aquatic plant EC_{50} = 0.045 mg/L (duckweed)
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.	4a. Most sensitive EC_{25} for monocots = 0.030 lbs a.i./A (wheat) 4b. Most sensitive EC_{25} for dicots = 0.0047 lbs a.i./A (rape)
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[3] acute LD_{50} >2250 mg/kg (Northern bobwhite quail) 5b. Most sensitive bird[3] sub-acute LC_{50} >10,000 mg/kg-diet (Northern bobwhite quail) 5c. Most sensitive bird[3] chronic NOAEC = 1550 mg/kg-diet (Northern bobwhite quail)
6. Survival, growth, and reproduction of CRLF individuals via effects on prey (*i.e.,*terrestrial invertebrates, small terrestrial vertebrates, including mammals and terrestrial phase amphibians)	6a. Most sensitive terrestrial invertebrate LD_{50}>1209 µg a.i./g (honey bee) 6b. Most sensitive terrestrial mammal acute LD_{50} = 812 mg/kg (laboratory rat) 6c. Most sensitive terrestrial mammal chronic NOAEL = 250 mg/kg-diet/day (laboratory rat) 6d. Most sensitive bird[3] acute LD_{50} >2250 mg/kg (Northern bobwhite quail) 6e. Most sensitive bird[3] sub-acute LC_{50} >10,000 mg/kg-diet (Northern bobwhite quail) 6f. Most sensitive bird[3] chronic NOAEC = 1550 mg/kg-diet (Northern bobwhite quail)
7. Survival, growth, and reproduction of CRLF individuals via indirect effects on habitat (*i.e.,* riparian vegetation)	7a. Most sensitive EC_{25} for monocots = 0.030 lbs a.i./A (wheat) 7b. Most sensitive EC_{25} for dicots = 0.0047 lbs a.i./A (rape)

[1]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.
[2] Frogs are used as surrogates for aquatic-phase CRLF and aquatic-phase frog species which are prey to CRLF.
[3] Birds are used as surrogates for terrestrial phase CRLF and terrestrial-phase frog species which are prey to 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 bromacil and bromacil lithium 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 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 bromacil and bromacil lithium effects data are available.

Assessment endpoints and measures of ecological effect selected to characterize potential modification to designated critical habitat associated with exposure to bromacil and bromacil lithium are provided in **Table 8**. 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 bromacil and bromacil lithium on critical habitat of the CRLF are described in **Table 8**. 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 8. Summary of Assessment Endpoints and Measures of Ecological Effect for Primary Constituent Elements of Designated Critical Habitat.

Assessment Endpoint	Measures of Ecological Effect
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 or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.	1a. Most sensitive aquatic unicellular plant EC_{50} = 0.0068 mg/L (green algae) 1b. Vascular aquatic plant EC_{50} = 0.045 mg/L (duckweed) 1c. Most sensitive EC_{25} for monocots = 0.030 lbs a.i./A (wheat) 1d. Most sensitive EC_{25} for dicots = 0.0047 lbs a.i./A (rape)
Alteration in water chemistry/quality including temperature, turbidity, and oxygen content necessary for normal growth and viability of juvenile and adult CRLFs and their food source. [1]	2a. Most sensitive aquatic unicellular plant EC_{50} = 0.0068 mg/L (green algae) 2b. Vascular aquatic plant EC_{50} = 0.045 mg/L (duckweed) 2c. Most sensitive EC_{25} for monocots = 0.030 lbs a.i./A (wheat) 2d. Most sensitive EC_{25} for dicots = 0.0047 lbs a.i./A (rape)
Alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source.	3a. most sensitive fish[2] 96-h LC_{50} = 36 mg/L (Rainbow trout) 3b. most sensitive fish[2] chronic NOAEC = 3.0 mg/L (Rainbow trout) 3c. Most sensitive aquatic invertebrate 48-h EC_{50} = 121 mg/L (waterflea) 3d. Most sensitive aquatic invertebrate chronic NOAEC = 8.2 mg/L (waterflea) 3e. Most sensitive aquatic unicellular plant EC_{50} = 0.0068 mg/L (green algae)
Reduction and/or modification of aquatic-based food sources for pre-metamorphs (*e.g.*, algae)	4a. Most sensitive aquatic unicellular plant EC_{50} = 0.0068 mg/L (green algae)
Terrestrial Phase PCEs ***(Upland Habitat and Dispersal Habitat)***	
Elimination and/or disturbance of upland habitat; ability of 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/or wetland/riparian plant species that provides the CRLF shelter, forage, and predator avoidance	5a. Most sensitive EC_{25} for monocots = 0.030 lbs a.i./A (wheat) 5b. Most sensitive EC_{25} for dicots = 0.0047 lbs a.i./A (rape) 5c. Most sensitive terrestrial invertebrate LD_{50}>1209 µg a.i./g (honey bee) 6d. Most sensitive terrestrial mammal acute LD_{50} = 812 mg/kg (laboratory rat) 5e. Most sensitive terrestrial mammal chronic NOAEL = 250 mg/kg-diet/day (laboratory rat) 5f. Most sensitive bird[3] acute LD_{50} >2250 mg/kg (Northern bobwhite quail) 5g. Most sensitive bird[3] sub-acute LC_{50} >10,000 mg/kg-diet (Northern bobwhite quail) 5h. Most sensitive bird[3] chronic NOAEC = 1550 mg/kg-diet (Northern bobwhite quail)
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	
Reduction 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.	

[1]Physico-chemical water quality parameters such as salinity, pH, and hardness are not evaluated because these processes are not biologically mediated and, therefore, are not relevant to the endpoints included in this assessment.
[2] Frogs are used as surrogates for aquatic-phase CRLF and aquatic-phase frog species which are prey to CRLF.
[3] Birds are used as surrogates for terrestrial phase CRLF and terrestrial-phase frog species which are prey to CRLF.

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 bromacil and bromacil lithium to the environment. The following risk hypotheses are presumed for this endangered species assessment:

- Labeled uses of bromacil and bromacil lithium within the action area may directly affect the CRLF by causing mortality or by adversely affecting growth or fecundity;
- Labeled uses of bromacil and bromacil lithium within the action area may indirectly affect the CRLF by reducing or changing the composition of food supply;
- Labeled uses of bromacil and bromacil lithium within the action area may indirectly affect the CRLF or modify designated critical habitat by reducing or changing the composition of the aquatic plant community in the ponds and streams comprising the species' current range and designated critical habitat, thus affecting primary productivity and/or cover;
- Labeled uses of bromacil and bromacil lithium within the action area may indirectly affect the CRLF 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 bromacil and bromacil lithium 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 bromacil and bromacil lithium 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 bromacil and bromacil lithium 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 bromacil and bromacil lithium 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 bromacil and bromacil lithium 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 (bromacil and bromacil lithium), 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 6 and 7**, and the conceptual models for the aquatic and terrestrial PCE components of critical habitat are shown in **Figures 8 and 9**. 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.

The environmental fate properties of bromacil, along with monitoring data identifying its presence in surface water and groundwater in California, indicate that runoff and spray drift represent potential transport mechanisms of bromacil to the aquatic and terrestrial habitats of the CRLF. In this assessment, transport of bromacil through runoff/ leaching and spray drift is considered in deriving quantitative estimates of bromacil exposure to CRLF, its prey and its habitats. Based on the vapor pressure and Henry's Law constant of bromacil, volatilization from treated areas resulting in atmospheric transport and deposition represent unlikely transport pathways leading to exposure of the CRLF and its habitats. Therefore, exposure of the CRLF and its habitat to bromacil through runoff and spray drift to surface waters, and leaching to groundwater with subsequent interaction of groundwater to surface waters are the exposure pathways considered in this assessment. The exposure route from groundwater interacting with runoff is implicitly accounted for in exposure modeling which relies on the curve number method which is based on stream response (whether overland or subsurface) to a rain event. Both overland and subsurface flows are driven by rain events. Also, acute exposure concentrations from ground water are likely to be lower than those estimated for surface water.

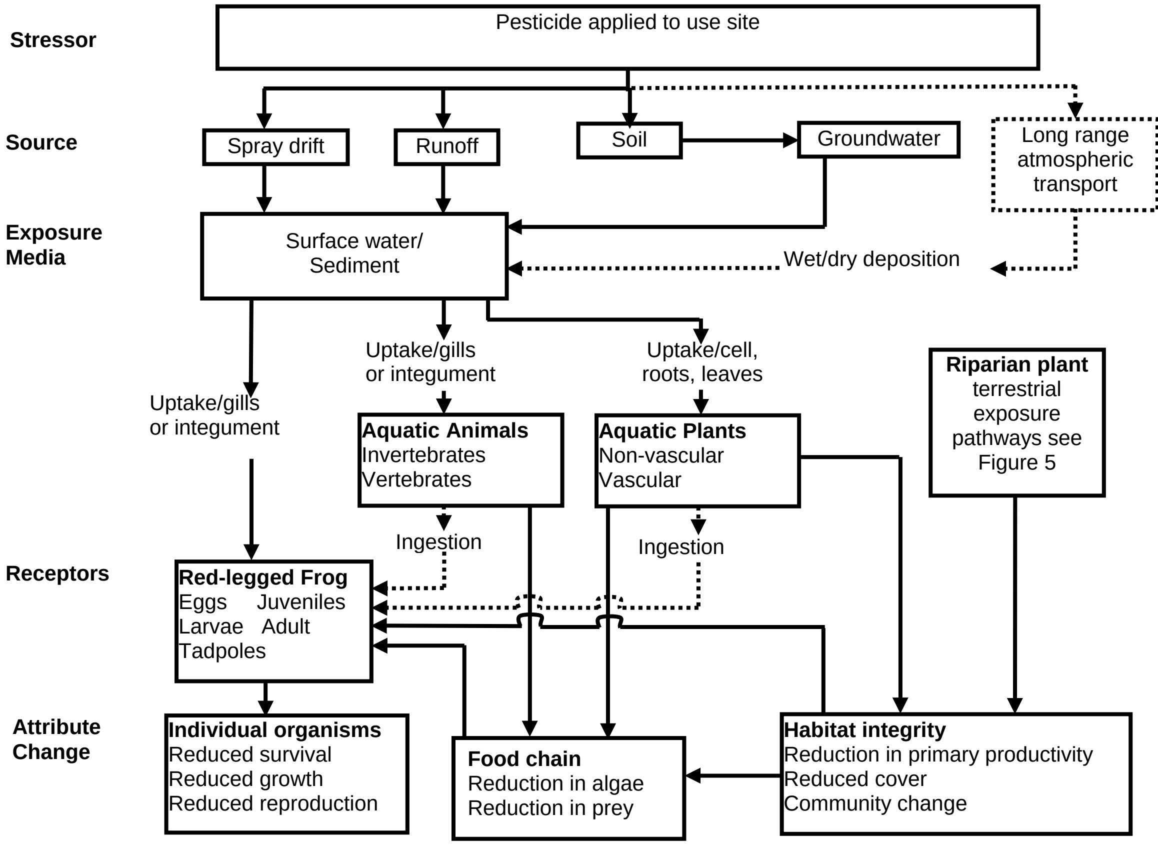


Figure 6. Conceptual Model for Pesticide Effects on Aquatic Phase of the Red-Legged Frog.

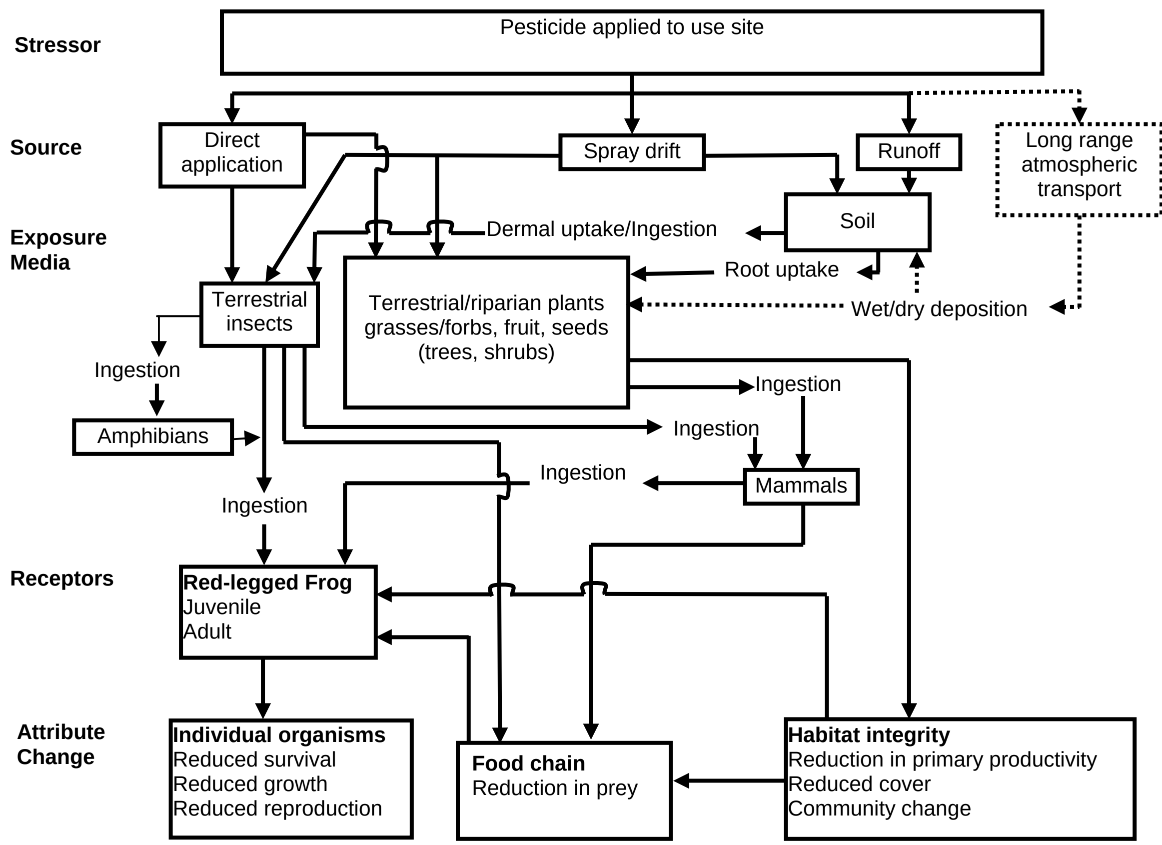


Figure 7. Conceptual Model for Pesticide Effects on Terrestrial Phase of Red-Legged Frog.

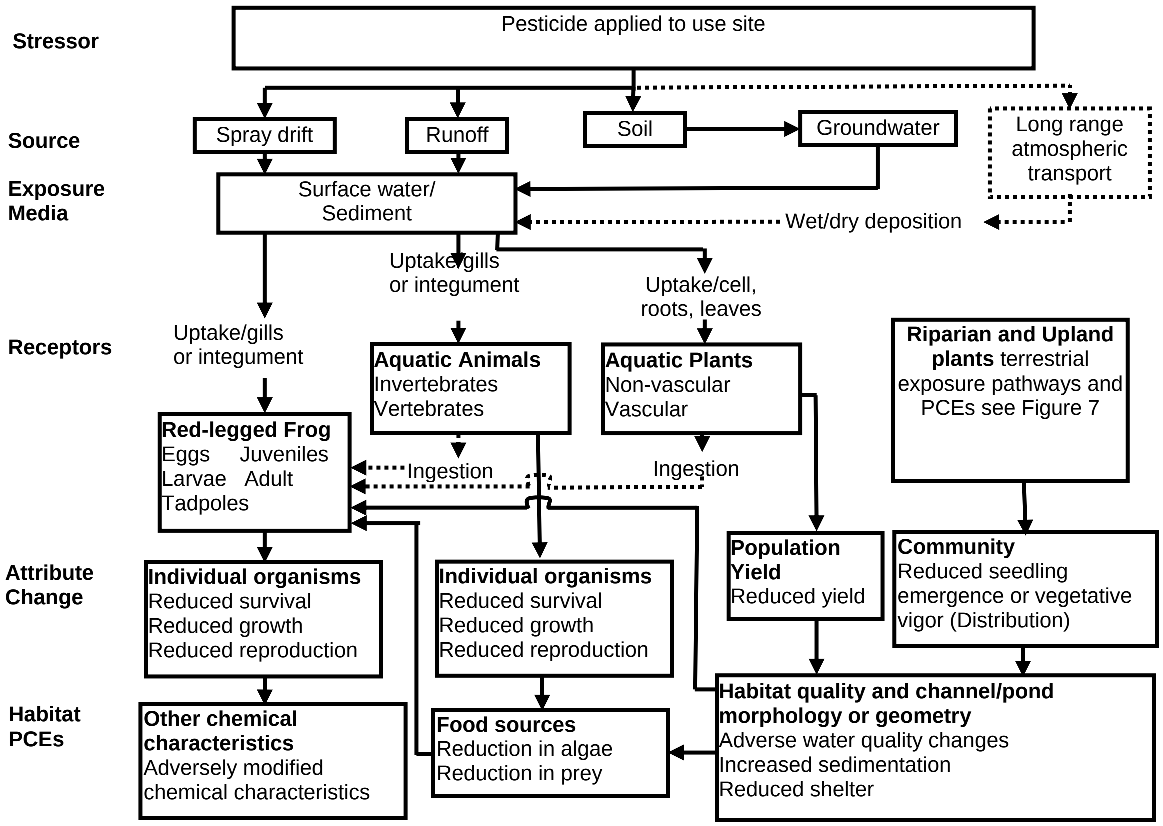


Figure 8. Conceptual Model for Pesticide Effects on Aquatic Components of Red-Legged Frog Critical Habitat.

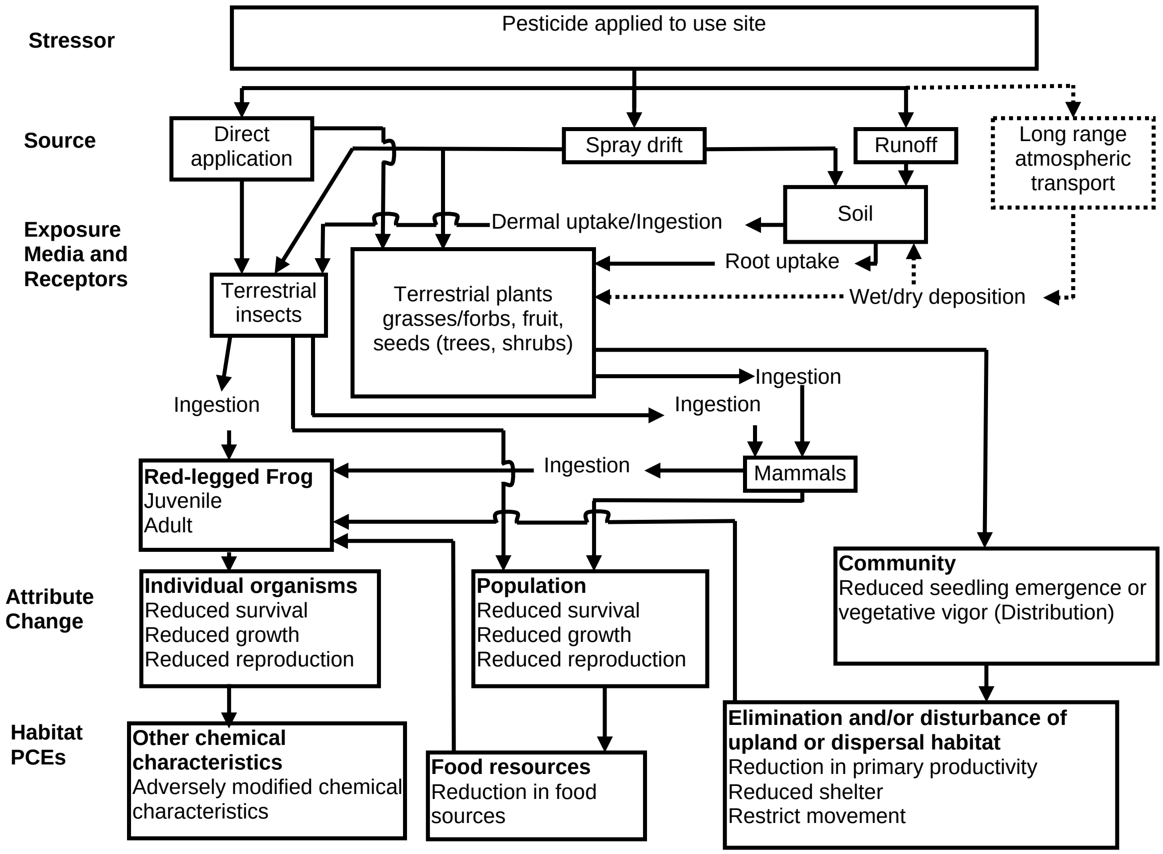


Figure 9. Conceptual Model for Pesticide Effects on Terrestrial Components of Red-Legged Frog Critical Habitat.

2.10 Analysis Plan

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

2.10.1. Measures to Evaluate the Risk Hypothesis and Conceptual Model

2.10.1.1. Measures of Exposure

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

PRZM (v3.12beta, May 24, 2001) and EXAMS (v2.98.04, Aug. 18, 2002) are screening simulation models coupled with the input shell pe4v01.pl (Aug.8, 2003) to generate daily exposures and 1-in-10 year EECs of bromacil that may occur in surface water bodies adjacent to application sites receiving bromacil through runoff and spray drift. PRZM simulates pesticide application, movement and transformation on an agricultural field and the resultant pesticide loadings to a receiving water body via runoff, erosion and spray drift. EXAMS simulates the fate of the pesticide and resulting concentrations in the water body. The standard scenario used for ecological pesticide assessments assumes application to a 10-hectare agricultural field that drains into an adjacent 1-hectare water body that is 2 meters deep (20,000 m^3 volume) with no outlet. PRZM/EXAMS is used to estimate screening-level exposure of aquatic organisms to bromacil. The measures of exposure for aquatic species are the 1-in-10 year return peak or rolling mean concentration. The 1-in-10 year peak is used for estimating acute exposures of direct effects to the CRLF, as well as indirect effects to the CRLF through effects to potential prey items, including: algae, aquatic invertebrates, fish and frogs. The 1-in-10-year 60-day mean is used for assessing chronic exposure to the CRLF and fish and frogs serving as prey items. The 1-in-10-year 21-day mean is used for assessing aquatic invertebrate chronic exposure, which are also potential prey items.

Exposure estimates for terrestrial phase CRLF and terrestrial invertebrates and mammals (serving as potential prey) assumed to be in the target area or in an area exposed to spray drift are derived using the T-REX model (version 1.3.1, 12/07/2006). This model incorporates the Kenega nomograph, as modified by Fletcher *et al.* (1994), which is based on a large set of actual field residue data. The upper limit values from the nomograph represented the 95th percentile of residue values from actual field measurements (Hoerger and Kenega, 1972). The Fletcher *et al.* (1994) modifications to the Kenega nomograph are based on measured field residues from 249 published research papers, including information on 118 species of plants, 121 pesticides, and 17 chemical classes. These modifications represent the 95th percentile of the expanded data set. For modeling purposes, direct exposures of the CRLF to bromacil through contaminated food are estimated using the EECs for the small bird (20 g) which consumes small insects. Dietary-based and dose-based exposures of potential prey (small mammals) are assessed using the small mammal (15 g) which consumes short grass. The small bird (20g) consuming small insects and the small mammal (15g) consuming short grass are used because these categories represent the largest RQs of the size and dietary categories in T-REX that are appropriate surrogates for the CRLF and one of its prey items. Estimated exposures of terrestrial insects to bromacil are bound by using the dietary based EECs for small insects and large insects.

Birds are currently used as surrogates for terrestrial-phase CRLF. However, amphibians are poikilotherms (body temperature varies with environmental temperature) while birds are homeotherms (temperature is regulated, constant, and largely independent of environmental temperatures). Therefore, amphibians tend to have much lower metabolic rates and lower caloric intake requirements than birds or mammals. As a consequence, birds are likely to consume more food than amphibians on a daily dietary intake basis, assuming similar caloric content of the food items. Therefore, the use of avian food intake allometric equation as a surrogate to amphibians is likely to result in an over-estimation of exposure and risk for reptiles and terrestrial-phase amphibians. Therefore, T-REX (version 1.3.1) has been refined to the T-HERPS model (v. 1.0), which allows for an estimation of food intake for poikilotherms using the same basic procedure as T-REX to estimate avian food intake.

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

Two spray drift models, AGDisp and AgDRIFT are used to assess exposures of terrestrial phase CRLF and its prey to bromacil deposited on terrestrial habitats by spray drift. AGDisp (version 8.13; dated 12/14/2004) (Teske and Curbishley 2003) is used to simulate aerial and ground applications using the Gaussian farfield extension. AgDrift (version 2.01; dated 5/24/2001) is used to simulate spray blast applications to orchard crops.

2.10.1.2. Measures of Effect

Data identified in Section 2.8 are used as measures of effect for direct and indirect effects to the CRLF. Data were obtained from registrant submitted studies or from literature studies identified by ECOTOX. The ECOTOXicology database (ECOTOX) was searched in order to provide more ecological effects data and in an attempt to bridge existing data gaps. ECOTOX is a source for locating single chemical toxicity data for aquatic life, terrestrial plants, and wildlife. ECOTOX was created and is maintained by the USEPA, Office of Research and Development, and the National Health and Environmental Effects Research Laboratory's Mid-Continent Ecology Division (ECOTOX, 2006).

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

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

2.10.1.3. Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the use of bromacil on citrus and non-cropland areas, and the likelihood of direct and indirect effects to CRLF in aquatic and terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of bromacil risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs) (USEPA, 2004) (see **Table 9**). These criteria are used to indicate when bromacil's and bromacil lithium's uses, as directed on the label, have the potential to cause adverse direct or indirect effects to the CRLF.

Table 9. Agency risk quotient (RQ) metrics and levels of concern (LOC) per risk class.

Risk Class	Description	RQ	LOC
Aquatic Habitats			
Acute Listed Species	CRLF may be potentially affected by use by direct or indirect effects.	Peak EEC/EC_{50}[1]	0.05
Chronic Listed and Non-Listed Species	Potential for chronic risk to CRLF through direct or indirect effects. Indirect effects represented by effects to invertebrates, fish or amphibians, which represent potential prey.	60-day EEC/NOEC (CRLF) 21-day EEC/NOEC (invertebrates)	1
Non-Listed	Potential for effects in non-listed plants.	Peak EEC/ EC_{50}	1
Terrestrial Habitats			
Acute Listed Species	CRLF may be potentially affected by use by direct or indirect effects.	Dietary EEC [2]/LC_{50} Or Dose EEC [2]/LD_{50}	0.1
Acute Listed Species	Potential effects to terrestrial invertebrates. CRLF may be potentially affected by use by direct or indirect effects.	EEC [2]/LD_{50}	0.05
Acute Non-Listed Species	CRLF may be potentially affected by use by indirect effects through effects to animal prey (i.e. mice and terrestrial-phase amphibians).	Dietary EEC [2]/LC_{50} Or Dose EEC [2]/LD_{50}	0.5
Chronic Listed Species	Potential for chronic risk to CRLF through direct or indirect effects. Indirect effects represented by effects to small mammals, which represent potential prey.	EEC [2]/NOAEC	1
Non-Listed	Potential for effects in non-listed plants.	Peak EEC/ EC_{25}	1

[1] LC_{50} or EC_{50}.
[2] Based on upper-bound Kenaga values.

2.10.2. Data Gaps

Environmental Fate

Degradate information is not available for aqueous photodegradation at pH 9 (at which an absorption spectrum shift occurs relative to more acidic pHs), where bromacil is relatively rapidly degraded.

Additionally, the half-life for anaerobic aquatic metabolism has not been accurately determined. Because OPP does not find the reported half-life to be valid, an assumption of stability had to be used in the aquatic exposure modeling for this assessment in lieu of data.

Mobility data are only available for column leaching studies; batch equilibrium studies have not been submitted, so Kd and Koc values are lacking. For aquatic exposure modeling, the Koc value was obtained from the SCS/ARS database, and indicates a high level of mobility that is in agreement with the mobility observed in the column leaching studies (in which [^{14}C]residues in the leachates of all four soil columns totaled 91.2-99.6% of the applied).

While two terrestrial field dissipation studies have been submitted, both were on bare ground plots. A citrus field dissipation study on soils in California is not available.

Effects characterization

No data are available for defining the toxicity of bromacil to amphibians. As a result, direct effects to the CRLF in aquatic habitats are based on toxicity information for freshwater fish, which serves as a surrogate for aquatic amphibians. Also, direct effects to the CRLF in terrestrial habitats are based on toxicity information for birds, which serve as a surrogate for terrestrial-phase amphibians.

Data are unavailable to define the sub-acute (dietary) exposure of technical bromacil to birds. In place of this gap, data are used from a study involving dietary exposures of birds to a formulated product containing bromacil.

3. Exposure Assessment

3.1. Aquatic Exposure Assessment

3.1.1. Existing Water Monitoring Data for California

Surface and groundwater monitoring data are available for California waters. These data include United States Geological Survey's (USGS) National Water Quality Assessment (NAWQA) and the California Department of Pesticide Regulation (CDPR) Surface Water Database. These data are described below.

3.1.1.1. NAWQA Data (1993-2005) for California

NAWQA monitoring data are available for bromacil from California surface waters (USGS 2007) (**Table 10**). Samples were analyzed using HPLC. Although NAWQA monitoring does not target specific chemicals, bromacil was detected in 6.6% of 347 samples from 1993-2005, with a maximum concentration of 1.9 µg/L. Bromacil was detected in a total of 23 samples collected from 5 different sites in 5 counties in California. These counties (Sacramento, Merced, Stanislaus, San Joaquin and Orange) also contain CRLF core areas and critical habitat. NAQWA data include information on the landcover composition of the watershed of the waters from which samples were taken. Detection rates and maximum detections of bromacil in surface water samples are differentiated in **Table 10** by watershed landcover categories. The sample containing the maximum concentration of bromacil was collected in January, 1994 in an area receiving runoff from a landcover classified "mixed."

Table 10. NAWQA 1993 - 2005 data for bromacil detections [1,2] in CA SURFACE waters. Data are distinguished by the landcover (e.g. agricultural, urban, etc.) of the watershed of the sampled water bodies.

Statistics	Agricultural	Mixed	Urban	Other	Total
Number of samples	96	179	11	61	347
Number Detections	4	17	0	2	23
% Detects	4.2%	9.5%	0%	3.3%	6.6%
Maximum Concentration (µg/L)	0.0373	1.9	<0.035	1.43	1.9

[1]Excludes samples identified by "<", which signify non-detections.

[2]Method detection limit = 0.035 µg/L

Groundwater NAWQA monitoring data are also available for bromacil from California (USGS 2007) (**Table 11**). Samples were analyzed using HPLC. From 1993-2005, bromacil was detected in 5.0% of 402 samples, with a maximum concentration of 0.545 µg/L. Bromacil was detected in a total of 20 samples collected from 19 different sites in 10 counties in California. These counties (Colusa, Fresno, Madera, Merced, Orange, Riverside, Sacramento, San Bernardino, Stanislaus, and Tulare) also contain CRLF core areas and critical habitat. The sample containing the maximum concentration of bromacil was collected in May 2000 in an area receiving runoff from a landcover classified "mixed."

Table 11. NAWQA 1993 - 2005 data for bromacil detections [1,2] in CA GROUND waters. Data are distinguished by the landcover (e.g. agricultural, urban, etc.) of the watershed of the sampled water bodies.

Statistics	Agricultural	Mixed	Urban	Other	Total
Number of samples	209	89	63	41	402
Number Detections	7	9	1	3	20
% Detects	3.3%	10.1%	1.6%	7.3%	5.0%
Maximum Concentration (µg/L)	0.190	0.545	0.0.026	0.081	0.545

[1]Excludes samples identified by "<", which signify non-detections.

[2]Method detection limit = 0.035 µg/L

3.1.1.2. California Department of Pesticide Regulation Surface Water Database

CDPR maintains a database of monitoring data of pesticides in CA surface waters. The sampled water bodies include rivers, creeks, urban streams, agricultural drains, the San Francisco Bay delta region and storm water runoff from urban areas. The database contains data from 51 different studies by federal state and local agencies as well as groups from private industry and environmental interests. Some data reported in this database are also reported by USGS in NAWQA; therefore, there is some overlap between these two data sets (CDPR 2007).

From 1992-2002, 1008 samples from CA surface waters were analyzed for bromacil. Of these, bromacil was detected in 7.7%, with a maximum concentration of 7.5 µg/L, which was detected in 1992 in San Joaquin County. These samples included 65 different sites from 16 counties; including counties where CRLF core areas and critical habitat are located.

3.1.2. Modeling Approach

As stated above, the Tier II models used to calculate aquatic EECs are PRZM and EXAMS. For this modeling effort, PRZM scenarios designed to represent different crops and geographic areas of CA are used in conjunction with the standard pond environment in EXAMS. Use-specific and chemical-specific parameters for the PE4 shell as well as PRZM scenarios are described below. The PRZM/EXAMS output files generated by this modeling approach are located in **Appendix B**.

3.1.2.1. PRZM scenarios

For modeling aquatic exposures resulting from applications of bromacil use on citrus, the CA citrus scenario is used**.**

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

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

Although the non-cropland classification includes a wide variety of areas (see Use Characterization, Section 2.4.4), rights-of-way are used to represent these areas. Available data for California indicate that use of bromacil on rights-of-way represents a significant portion of the past (2002-2005) use of bromacil (36.3% of total use). Of uses of bromacil on non-cropland areas, 81.0% was applied to rights-of-way (CPUR 2007a).

Rights-of-way are roads, highways, railroads, utilities and pipelines. These areas contain both impervious (i.e. cement, asphalt, metal surfaces) and pervious surfaces. It is assumed that bromacil will be applied to the pervious surfaces, where weeds are expected to grow. It is also assumed that bromacil is not applied to impervious surfaces in rights-of way, but that there is a 1% incidental spray onto impervious surfaces in the right-of-way. Further details on how the 1% value was derived and characterization of alternative assumptions are provided in the Barton Springs salamander endangered species risk assessment for atrazine (U.S. EPA, 2006).

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

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

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

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

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

3.1.2.3. Input Parameters

The appropriate chemical-specific PRZM/EXAMS input parameters are selected from reviewed environmental fate data submitted by the registrant (**Table 4**) and in accordance with EFED water model input parameter selection guidance (U.S. EPA 2002). A summary of the chemical specific model inputs used in this assessment are provided in **Table 12**.

PRZM/EXAMS input parameters specific to uses of bromacil and bromacil lithium on citrus and non-cropland areas are described below and are summarized in **Table 13**. Parameters for these uses are determined based on label recommendations.

Table 12. Chemical specific PRZM/EXAMS Input Parameters for deriving aquatic EECs for bromacil.

Input Parameter	Value	Source/Comments
Koc (L/kg_{OC})	32	Value obtained from SCS/ARS database; only column leaching data were available from submitted studies
Henry's Law Constant (atm-m^3/mol)	1.1×10^{-9}	bromacil RED
Hydrolysis Half-life (days)	0 (stable)	MRID 40951505
Aerobic Soil Metabolism Half-life (days)	825	MRID 40951510; input is 3X the measured half-life value (275 days) to account for uncertainty in using a single value, per EFED guidance
Aerobic Aquatic Metabolism Half-life (days)	1650	default input value of 2X aerobic soil input, per EFED guidance
Anaerobic Aquatic Metabolism Half-life (days)	0 (stable)	conservative assumption in lieu of data, per EFED guidance
Aqueous Photolysis Half-life (days; pH 7)	102	MRIDs 40951507 40951508
Vapor pressure (torr at 25°C)	3.1×10^{-7}	bromacil RED
Solubility in water (mg/L @ pH 7, 25°C)	8150	10X measured solubility of 815 ppm, per EFED guidance
Molecular Wt. (g/mol)	261.12	bromacil RED

Table 13. Use-specific PRZM/EXAMS Input Parameters for deriving aquatic EECs for bromacil.

Input Parameter	Citrus	Non-cropland areas: Rights of Way	Non-cropland areas: Impervious
Single Application Rate (kg a.i./ha)	7.2	17.3	0.173[1]
Number of applications per year	1	2	2
Application Interval (days)	NA	14	14
CAM	1	1	1
Spray Drift	0.01	0.01	0
Application Efficiency	0.99	0.99	1
Application Date	January 25	January 25	January 25

[1] As noted above, it is assumed that 1% of bromacil applied to the pervious portion of a right-of-way is incidentally sprayed onto the pervious surface.

Citrus

According to current labels, the maximum single application rate of bromacil on citrus is 6.4 lbs a.i./A (7.2 kg a.i./ha). Labels indicate that one maximum application should be made per year (registrations 352-287, 352-505, 70506-83 and 81927-4).

Labels indicate that bromacil applications should be made beneath and/or between trees. In PRZM, application methods are defined by the CAM (Chemical Application Method) values; a CAM value of 1 is used to represent applications to soil with no incorporation. This value is selected for representing applications of bromacil to the areas between citrus trees.

The labels also indicate that contact of the product with tree foliage should be avoided. Based on this, as well as instructions that applications should be made beneath and/or between trees, it is unlikely that aerial methods would be employed for applications of bromacil to citrus. Therefore, the spray drift assumption for ground applications, 1%, is used in modeling aquatic EECs. The accompanying application efficiency of 99% is used.

The application date is chosen based on label directions which indicate that applications made in late fall or early winter will have the best results in terms of weed control. The label also indicates that applications should be made at a time when rainfall (or irrigation) would occur. Consideration of the meteorological data associated with the CA citrus scenario indicates that the largest rainfall events occur in January. Based on this information, an application date of January 25 was chosen. In actuality, applications of bromacil can be made any time of the year, and according to available pesticide use data for California, applications of bromacil to citrus have been made throughout the year.

Non-cropland

According to current labels, the maximum single application rate of bromacil on non-cropland areas is 15.4 lbs a.i./A (17.3 kg a.i./ha), with 2 maximum applications allowed per year (registration 10088-68).

The minimum application interval is not indicated on this label. It is assumed that the pesticide user would apply the pesticide and then wait to see results. After two weeks, the pesticide user may then reapply bromacil to the treatment site. Therefore, it is assumed that a second application may be made 14 days after the other.

To represent applications of bromacil to rights-of way and to impervious surfaces, a CAM of 1 is used to represent applications directly to the ground.

The label with the maximum use rate for non-cropland areas (registration 10088-68) clearly prohibits applications by aerial methods. Therefore, the spray drift assumption for ground applications, 1% and the accompanying application efficiency of 99% are used in modeling aquatic EECs.

Label instructions indicate that applications of bromacil to non-cropland areas can be made any time during the year. Consideration of the meteorological data associated with the CA rightofway and CA impervious scenarios indicates that the largest rainfall events occur in January. In general, the greater amount of rainfall in a single event, the greater the EEC in the receiving aquatic habitat. In order to select an application date resulting in a conservative estimate of exposure of aquatic habitats to bromacil, an application date of January 25 was chosen.

3.1.3. Aquatic Modeling Results

PRZM/EXAMS EECs representing 1-in-10 year peak, 21-day, and 60-day concentrations of bromacil in the aquatic environment are located in **Table 14**.

Table 14. Aquatic EECs from PRZM/EXAMS modeling for maximum application rates of bromacil. EECs are based on the appropriate PRZM scenario and the standard EXAMS pond.

Use	Scenario	Peak EEC (mg/L)	21-day EEC (mg/L)	60 -day EEC (mg/L)
Citrus	CA citrus	0.056	0.056	0.056
Non-cropland	CA rightofway and CA impervious	2.34	2.33	2.32

3.2. Terrestrial Exposure Assessment

3.2.1. Exposure to Plants

TerrPlant is used to calculate EECs for non-target plant species inhabiting dry and semi-aquatic areas. Parameter values for application rate, drift assumption and incorporation depth are based upon the use and related application method (**Table 15**). A runoff value of 0.5 is utilized based on bromacil's solubility, which is classified by TerrPlant as >100 mg/L. For ground application methods, a drift assumption of 1% is selected. EECs relevant to terrestrial plants consider pesticide concentrations in drift and in runoff. These EECs are listed by use in **Table 15**. Output from TerrPlant v.1.2.2 are available in **Appendix C**.

Table 15. TerrPlant inputs and resulting EECs for plants inhabiting dry and semi-aquatic areas exposed to bromacil through runoff and drift.

Use	Application rate (lbs a.i./A)	Application method	Drift Value (%)	Spray drift EEC (lbs a.i./A)	Dry area EEC (lbs a.i./A)	Semi-aquatic area EEC (lbs a.i./A)
Citrus	6.4	ground	0.01	0.064	0.32	3.2
Non-cropland	15.4	ground	0.01	0.154	0.924	7.85

3.2.2. Exposures to animals

3.2.2.1. Modeling Approach

T-REX is used to calculate dietary and dose-based EECs of bromacil for the CRLF and its potential prey (*e.g.* terrestrial invertebrates, small mammals, terrestrial-phase frogs) inhabiting terrestrial areas. EECs used to represent CRLF are also used to represent exposure values for frogs serving as potential prey of CRLF adults. T-REX simulates a 1-year time period. Foliar dissipation data are unavailable for estimating a half-life for bromacil. As a result, the default value of 35 days is used. Use specific input values, including number of applications, application rate and application interval are located in **Table 16**. Outputs for T-REX v.1.3.1 are available in **Appendix D**.

Table 16. Input parameters for T-REX used to derive terrestrial EECs for bromacil.

Use	Number of applications	Application rate (lbs a.i./A)
Citrus	1	6.4
Non-cropland	2*	15.4

*Application interval of 14 days.

3.2.2.2. Terrestrial Animal Exposure Modeling Results

For modeling purposes, exposures of the CRLF to bromacil through contaminated food are estimated using the EECs for the small bird (20 g) which consumes small insects. Dietary-based EECs calculated by T-REX for small and large insects (units of µg a.i./g) are used to bound an estimate of exposure to terrestrial invertebrates. Dietary-based and dose-based exposures of potential prey are assessed using the small mammal (15 g) which consumes short grass. Upper-bound Kenega nomogram values reported by T-REX for these two organism types are used for derivation of EECs for the CRLF and its potential prey (**Table 17**).

Table 17. Upper-bound Kenega nomogram EECs for exposures of the CRLF and its prey to bromacil.

Organism	Exposure	Units	Citrus EEC*	Non-cropland EEC*
CRLF	Dietary	ppm	864	3655
	Dose	mg/kg-bw	984	4162
small insects (prey)	Contact	µg a.i./g (of insect)	864	3655
large insects (prey)	Contact	µg a.i./g (of insect)	96.0	406
small mammals (prey)	Dietary	ppm	1536	6497
	Dose	mg/kg-bw	1464	6194
small frogs (prey)	Dietary	ppm	864	3655
	Dose	mg/kg-bw	984	4162

*based on a default foliar dissipation half-life of 35 days.

3.2.3. Spray Drift Modeling

In order to determine the extent of terrestrial habitats of concern beyond application sites, it is necessary to estimate the distance spray applications can drift from the treated field and still be greater than the level of concern. Spray drift modeling was done for animals and plants to determine the farthest distance required to not exceed the LOC for exposures to bromacil drifted to non-target areas. This assessment requires the use of the spray drift model, AgDrift (version 2.01; dated 5/24/2001). In cases where estimates of drift exceed the limits of the AgDrift model, the AGDisp (version 8.13; dated 12/14/2004) (Teske and Curbishley, 2003) is used to simulate aerial and ground applications using the Gaussian farfield extension.

The Tier I version of AgDrift was used for simulating applications of bromacil to citrus and non-cropland areas by ground methods. It was assumed that a high boom height would be used for ground applications. Given that labels did not describe any spray drift mitigations, the most conservative assumption for spray drop size distributions, "ASAE very fine to fine" was used to determine the range of possible depositions of bromacil. The maximum single application rate for citrus (6.4 lbs a.i./A) and non-cropland areas (15.4 lbs a.i./A) was used to determine the farthest distance from the edge of field where there are no LOC exceedances for animals or plants (based on point deposition) (**Table 18**). AgDrift is useful for estimating point deposition out to 990 feet from the edge of a field. In cases where estimates of exposure at 990 feet estimated by AgDrift were sufficient to exceed the LOC for a taxonomic group, AGDisp was used. The parameters used for AGDisp are defined in **Table 19**, with results in **Table 18**.

Table 18. Distance away from edge of field where terrestrial animal and plant LOCs are not exceeded by exposures to bromacil through spray drift.

Organism	Exposure	LOC	Point deposition that does not exceed LOC (lbs a.i./A)	Distance (in feet) from edge of field where LOC is not exceeded-results differ based on Use	
				Citrus	Non-cropland areas
CRLF	dose-acute	0.1	>1.1	<16	<36
	dietary-acute	0.1	>7.5	NA	<7
	dietary chronic	1	11	NA	NA
Terrestrial invertebrates	acute small	0.05	>0.44	<39	<89
	acute large	0.05	>4.0	<3	<13
Terrestrial mammals	dose-acute	0.1	0.75	23	52
	dose-chronic	1	0.12	132	292
	dietary-chronic	1	1.04	17	39
Terrestrial plants	monocots-drift	1	0.03	437	810
	dicots-drift	1	0.0047	4026[1] (0.76 mile)	5909[1] (1.12 mile)

NA = not applicable
[1]990 feet represents the range of AgDRIFT. Any value beyond this distance was calculated using AGDISP.

Table 19. Scenario and standard management input parameters for simulation of bromacil in spray drift using AgDisp with Gaussian farfield extension.

Parameter Description	Parameter Value for Citrus	Parameter Value for Non-cropland	Comments
Application Method	Ground	Aerial	Product Labels
Nozzle type[1]	Flat fan	NA	Program default
Boom Pressure[1]	60 lb	NA	Program default
Release height	4 feet	15 feet	Program default
Spray lines	20	20	Program default
Nozzles	42	42	None available
Droplet Size Distribution (DSD)	Fine to very fine	Fine to very fine	Default; draft guidance
Swath Width	60 ft	60 ft	Program default
Wind Speed	15 mph	15 mph	Default; draft guidance
Wind direction	- 90°	- 90°	Default
Air temperature	65° F	65° F	Program default
Relative Humidity	50%	50%	Program default
Spray Material	Water	Water	Program default
Fraction of active solution that is non-volatile	0.08	0.0098	Product labels
Fraction of additive solution that is non-volatile	0.1	1	Product labels
Upslope angle	0°	0°	Assume flat surface
Side slope angle	0°	0°	Assume flat surface
Canopy type	none	none	Default from guidance
Surface roughness	0.0246 ft	0.0246 ft	Program default, none provided
Transport	0 ft	0 ft	Program default
Height for wind peed measurement	6.56 ft	6.56 ft	Program default
Maximum comp. Time	600 sec	600 sec	Program default
Maximum downwind distance	2608.24 ft	2608.24 ft	Program default
Vortex decay rate OGE	0.3355	0.3355	Program default
Vortex decay rate IGE	1.25	1.25	Program default
Aircraft drag coefficient	0.1	0.1	Program default
Propeller efficiency	0.8	0.8	Program default
Ambient pressure	29.91	29.91	Program default
Ground reference	0 ft	0 ft	Program default
Evaporation rate	84.76 $\mu g \cdot (K \cdot s)^{-1}$	84.76 $\mu g \cdot (K \cdot s)^{-1}$	Program default
Specific Gravity (non-volatile)	1.0	0.939	For citrus, assume that product is dissolved in water.

[1] parameter for ground spray only

NA = Not Applicable

4. Effects Assessment

This assessment evaluates the potential for bromacil to adversely affect the CRLF. As previously discussed in Section 2.7, assessment endpoints for the CRLF include direct toxic effects on the survival, reproduction, and growth of the CRLF itself, as well as indirect effects, such as reduction of the prey base and/or modification of its habitat.

Direct effects to the CRLF in aquatic habitats are based on toxicity information for freshwater vertebrates, specifically fish, which are generally used as a surrogate for amphibians. Direct effects to the CRLF in terrestrial habitats are based on toxicity information for birds, which are generally used as a surrogate for terrestrial-phase amphibians.

Given that the CRLF's prey items and habitat requirements are dependent on the availability of freshwater aquatic invertebrates and aquatic plants, fish, frogs, terrestrial invertebrates and terrestrial mammals, toxicity information for these organisms is also discussed.

Acute (short-term) and chronic (long-term) toxicity information is characterized based on registrant-submitted studies and a comprehensive review of the open literature on bromacil. A summary of the available freshwater and terrestrial ecotoxicity data relevant to this assessment is discussed below.

The focus of this assessment is on the technical grade active ingredient (TGAI) of bromacil. Data available for exposures of organisms to formulated products are not used for deriving RQs, with the exception of instances where no suitable data are available for exposures of organisms to the TGAI. Effects data are available for exposures of animals and plants to formulated products containing bromacil or bromacil lithium. Some of these data are described in Appendix A.

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (U.S. EPA, 2004). Open literature data presented in this assessment were obtained from ECOTOX in May 2007, from a search which included all open literature data for bromacil and its salts (including lithium, sodium and dimethylamine), only one of which (lithium) is still registered for use. In order to be included in the ECOTOX database, papers must meet the following minimum criteria:

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

Data that pass the ECOTOX screen are evaluated along with the registrant-submitted data, and may be incorporated qualitatively or quantitatively into this endangered species assessment. In general, effects data in the open literature that are more conservative than the registrant-submitted data are considered. A list of citations accepted and rejected by ECOTOX and the rational for rejection is available in **Appendix G**.

This section also includes information related to reported incidents of ecological effects associated with bromacil. Available incidents include effects to terrestrial and wetland plants, as well as effects to fish.

4.1. Evaluation of Aquatic Ecotoxicity Studies for Bromacil

As described in the Agency's Overview Document (U.S. EPA, 2004), the most sensitive endpoint for each taxa is evaluated. For this assessment, evaluated taxa relevant to the aquatic habitat of the CRLF include freshwater fish, freshwater aquatic invertebrates, and freshwater aquatic plants. Currently, no guideline tests exist for frogs. Therefore, surrogate species (fish) are used as described in the Overview Document (U.S. EPA, 2004) to represent direct exposures to the CRLF in the aquatic habitat. No ecotoxicity data for amphibians exposed to bromacil are available from the open literature. **Table 20** summarizes the most sensitive aquatic, ecological toxicity endpoints for the CRLF, its prey and its habitat, based on an evaluation of both the submitted studies and the open literature, as previously discussed. The values presented in **Table 20** are used for deriving quantitative RQs for this risk assessment. A brief summary of submitted and open literature data considered relevant to this ecological risk assessment is presented below.

Table 20. Summary of most sensitive toxicity for assessing direct and indirect effects of bromacil to CRLF in aquatic habitats.

Assessment Endpoint	Species (common name)	End-point	Mean concentration (mg/L)	Study Classification	Ref. (MRID)
Measures of Direct Effects					
Acute toxicity to CRLF	*Oncorhyncus mykiss* (Rainbow Trout)	LC_{50}	36	Acceptable	40951503
Chronic toxicity to CRLF	*Oncorhyncus mykiss* (Rainbow Trout)	NOAEC	3.0	Supplemental	44566101
Measures of Indirect Effects					
Toxicity to unicellular plants composing aquatic habitat and representing prey for tadpole CRLF	*Pseudokirchneriella subcapitatum* (green algae)	EC_{50}	0.0068	Supplemental	42516401
Toxicity to multicellular plants composing aquatic habitat	*Lemna gibba* (duckweed)	EC_{50}	0.045	Acceptable	46095401
Acute toxicity to invertebrates (prey)	*Daphnia magna* (Water Flea)	EC_{50}	121	Acceptable	40951504
Chronic toxicity to invertebrates (prey)	*Daphnia magna* (Water Flea)	NOAEC	8.2	Acceptable	44566401
Acute toxicity to fish and frogs representing prey	*Oncorhyncus mykiss* (Rainbow Trout)	LC_{50}	36	Acceptable	40951503
Acute toxicity to fish and other species of frogs (prey)	*Oncorhyncus mykiss* (Rainbow Trout)	NOAEC	3.0	Supplemental	44566101

Acute toxicity to aquatic fish and invertebrates is categorized using the system shown in **Table 21** (U.S. EPA, 2004). Based on thesecategories bromacil is classified slightly toxic to practically nontoxic to freshwater fish and invertebrates, respectively, on an acute exposure basis. Toxicity categories for aquatic plants have not been defined. If classification for animals were applied to aquatic plants, bromacil would be classified very highly toxic to unicellular and vascular plants.

Table 21. Categories of Acute Toxicity for Aquatic Animals.

LC_{50} (mg/L)	Toxicity Category
< 0.1	Very highly toxic
> 0.1 – 1	Highly toxic
> 1 – 10	Moderately toxic
> 10 – 100	Slightly toxic
> 100	Practically nontoxic

4.1.1. Toxicity to freshwater fish

Acute exposures

Registrant submitted studies are available for acute exposures of rainbow trout (*Onchoryhnchus mykiss*) and bluegill sunfish (*Lepomis macrochirus*) to bromacil. One data point is available in ECOTOX for acute exposure of a freshwater fish to bromacil. This value, which is reported as a 96-h LC_{50} of 186 mg/L for fathead minnows (*Pimephales promelas*) (Geiger et al. 1988), represents a less conservative value than registrant-submitted data. Therefore, this value is not considered further in this assessment.

The available registrant-submitted study involving rainbow trout was a static, 96-h exposure, resulting in a LC_{50} of 36 mg/L (95% confidence interval: 30-40 mg/L). This LC_{50} value represents the most sensitive endpoint available for acute exposures of fish to bromacil. Sublethal effects observed in surviving fish exposed to 22.5 mg/L bromacil and higher included loss of equilibrium, swollen appearance and sinking to the bottom of test vessels. No effects were described at 16.9 mg/L (MRID 40951503).

The registrant-submitted study involving bluegill sunfish was a static, 96-h exposure, resulting in a LC_{50} of 127 mg a.i./L. Sublethal effects observed in surviving fish exposed to 95 mg/L bromacil and higher included loss of equilibrium. No effects were described at 71 mg/L (MRID 409515-02).

Chronic exposures

Data are available from a registrant-submitted study where rainbow trout were exposed to bromacil for 90 days in a flow-though study. The NOAEC and LOAEC values for this study were 3.0 and 7.2 mg a.i./L, respectively, based on treatment-related effects to mean wet weight, which was the only measured endpoint that was affected. At the highest test concentration (7.2 mg a.i./L), measured wet weights of juvenile fish were 32.4% lower than controls. No treatment related effects on survival were observed in any of the treatment groups (maximum of 7.2 mg a.i./L). This study is scientifically sound, but is classified supplemental, due to excessive variation in measured concentrations of bromacil in the treatment levels (MRID 44566101).

No data are available in ECOTOX for chronic exposures of fish to bromacil.

4.1.2. Toxicity to freshwater invertebrates

Acute exposures

A registrant-submitted study is available for acute exposures of freshwater invertebrates to bromacil. Data are also available in ECOTOX for acute exposures of freshwater invertebrates to bromacil.

The available registrant-submitted study involving waterflea (*Daphnia magna*) was a static, 48-h exposure, resulting in an EC_{50} of 121 mg/L (95% confidence interval: 111-148 mg/L), based on immobility. Effects were observed at 111 and 148 mg/L (20% and 100% immobility, respectively, with no effects described at 83 mg/L (MRID 409515-04). This EC_{50} value is used in this risk assessment for quantifying RQ values for acute exposures of aquatic invertebrates to bromacil.

ECOTOX includes data for a study involving 48-h exposures of waterfleas (*Ceriodaphnia dubia*) to bromacil. Resulting EC_{50}values, based on immobility, were 65 mg a.i./L (95% confidence interval: 56-75 mg a.i./L) for exposures in laboratory water and 75 mg a.i./L (95% confidence interval: 63-88 mg a.i./L) for exposures in field-collected water (Foster et al. 1998). Due to insufficient data available in the publication, (including raw data) the acceptability of this study could not be evaluated. Therefore, these data are not utilized for quantifying RQ values representing acute exposures of aquatic invertebrates to bromacil. As published, these EC_{50} values represent lower values than the value used for deriving RQs, so, these data are used at face value to characterize potential risk of aqueous exposures of bromacil to aquatic invertebrates (see section 5.2.2).

Chronic exposures

Data are available from a registrant-submitted study where waterfleas (*D. magna*) were exposed to bromacil for 21 days. The NOAEC and LOAEC values for this study were 8.2 and 21 mg a.i./L, respectively, based on treatment-related effects to reproduction and growth. In the 21 mg a.i./L treatment level, adults did not produce offspring. Also, at that treatment level, adults had significantly reduced body lengths and dry weights in comparison to organisms in the negative control (13% and 45% decreases, respectively; MRID 44566401).

No data are available in ECOTOX for chronic exposures of freshwater invertebrates to bromacil.

4.1.3. Toxicity to aquatic plants

Unicellular plants

Data relevant to exposures of unicellular, aquatic plants to bromacil are available from several registrant submitted studies. No data are available in ECOTOX for exposures of aquatic, unicellular plants to technical bromacil.

Registrant-submitted studies for algae and diatoms (unicellular plants) include EC_{50} values ranging 6.8-69.9 µg a.i./L, based on decreased cell density. Effects were observed at exposures of green algae at the lowest bromacil concentrations tested, *i.e.*, 1.1 µg a.i./L (**Table 22**).

Table 22. EC_{50} and NOAEC values from registrant submitted studies involving exposures of bromacil to unicellular, aquatic plants.

Species (common name)	EC_{50}* units: µg a.i./L (95% C.I.)	NOAEC (µg a.i./L)	Study Classification	Ref. (MRID)
Pseudokirchneriella subcapitatum (green algae)	6.8 (5.9-7.8)	<1.1	Supplemental	42516401
Navicula pelliculosa (Freshwater diatom)	6.91 (5.59-8.54)	3.39	Acceptable	44218501
Skeletonema cosatum (marine diatom)	12.1 (8.3-17.6)	5.5	Acceptable	44218503
Anabaena flos-aquae (Blue-green algae)	69.9 (54.2-90.1)	11.2	Acceptable	44218502

*Effects based on decreased cell density.

Vascular plants

Data are available from a registrant-submitted study where duckweed (*Lemna gibba*) was exposed to bromacil for 14 days. The NOAEC and EC_{50} values based on decrease in frond number were 17 and 45 µg a.i./L, respectively. Effects to dry weight were also observed during this study (MRID 46095401) albeit at higher concentrations. No data are available in ECOTOX for exposures of aquatic vascular plants to bromacil.

4.2. Evaluation of Terrestrial Ecotoxicity Studies for Bromacil

As described in the Agency's Overview Document (U.S. EPA, 2004), the most sensitive endpoint for each taxa is evaluated. For this assessment, evaluated taxa relevant to the terrestrial habitat of the CRLF include birds, terrestrial insects, mammals and terrestrial plants. Currently, no guideline tests exist for terrestrial-phase amphibians. Therefore, surrogate species (birds) are used as described in the Overview Document (U.S. EPA, 2004) to represent direct exposures to the CRLF in the terrestrial habitat. No ecotoxicity data for amphibians exposed to bromacil are available from the open literature. **Table 23** summarizes the most sensitive terrestrial, ecological toxicity endpoints for the CRLF, its prey and its habitat, based on an evaluation of both the registrant-submitted studies and the open literature, as previously discussed. The values presented in **Table 23** are used for deriving quantitative RQs for this risk assessment. A brief summary of registrant-submitted and open literature data considered relevant to this ecological risk assessment is presented below.

Table 23. Summary of most sensitive toxicity for assessing direct and indirect effects of bromacil to CRLF in terrestrial habitats.

Assessment Endpoint	Species (common name)	End-point	Mean concentration	Study Classification	Ref. (MRID)
Measures of Direct Effects					
Acute toxicity to CRLF	*Colinus virginianus* (Northern bobwhite quail)	LD_{50}	>2250 mg/kg	Acceptable	40951501
Sub-acute toxicity to CRLF	*Colinus virginianus* (Northern bobwhite quail)	LC_{50}	>10,000 mg/kg-diet	Supplemental	00013295
Chronic toxicity to CRLF	*Colinus virginianus* (Northern bobwhite quail)	NOAEC	1550 mg/kg-diet	Acceptable	44844801
Measures of Indirect Effects					
Acute toxicity to invertebrates (prey)	*Apis mellifera* (Honey bee)	LD_{50}	>1209 µg a.i./g (of bee)	Supplemental	00018842
Acute toxicity to mammals (prey)	*Rattus norvegicus* (laboratory rat)	LD_{50}	812 mg/kg	Acceptable	44196209
Chronic toxicity to mammals (prey)	*Rattus norvegicus* (laboratory rat)	NOAEL	250 mg/kg-diet/day	Acceptable	41804601
Acute toxicity to frogs representing prey	*Colinus virginianus* (Northern bobwhite quail)	LD_{50}	>2250 mg/kg	Acceptable	40951501
Sub-acute toxicity to frogs representing prey	*Colinus virginianus* (Northern bobwhite quail)	LD_{50}	>10,000 mg/kg-diet	Supplemental	00013295
Chronic toxicity to other species of frogs (prey)	*Colinus virginianus* (Northern bobwhite quail)	NOAEC	1550 mg/kg-diet	Acceptable	44844801
Toxicity to monocot plants composing wetland and terrestrial habitat	*Triticum aestivum* (wheat)	EC_{25}	0.030 lbs a.i./A[1] 0.042 lbs a.i./A[2]	Supplemental	44488307
Toxicity to dicot plants composing wetland and terrestrial habitat	*Brassica napus* (rape)	EC_{25}	0.0047 lbs a.i./A[1] 0.0055 lbs a.i./A[2]	Supplemental	44488307

[1] based on effects to seedling emergence

[2]based on effects to vegetative vigor

Similar to toxicity categories for aquatic organisms, categories of acute toxicity ranging from “practically nontoxic” to “very highly toxic” have been established for terrestrial organisms based on LD_{50} values (**Table 24**), and avian species based on LD_{50} values (**Table 25**). Subacute dietary toxicity for avian species is based on the LC_{50} values

(**Table 26**). Based on these categories, bromacil is practically nontoxic to birds and slightly toxic to mammals on an acute exposure basis.

Table 24. Categories for mammalian acute toxicity based on median lethal dose in mg per kilogram body weight (parts per million).

LD_{50} (mg a.i./kg)	Toxicity Category
<10	Very highly toxic
10–50	Highly toxic
51–500	Moderately toxic
501–2000	Slightly toxic
>2000	Practically non-toxic

Table 25. Categories of avian acute oral toxicity based on median lethal dose in milligrams per kilogram body weight (parts per million).

LD_{50} (ppm)	Toxicity Category
<10	Very highly toxic
10-50	Highly toxic
51-500	Moderately toxic
501-2000	Slightly toxic
>2000	Practically non-toxic

Table 26. Categories of avian subacute dietary toxicity based on median lethal concentration in milligrams per kilogram diet per day (parts per million).

LC_{50} (ppm)	Toxicity Category
<50	Very highly toxic
50–500	Highly toxic
501–1000	Moderately toxic
1001–5000	Slightly toxic
>5000	Practically non-toxic

4.2.1. Toxicity to birds

Acute

Data are available from a registrant-submitted study, where bobwhite quail (*Colinus virginianus*) were given acute, oral doses of bromacil. No mortalities were observed during the 14-day study period, which resulted in a LD_{50} >2250 mg/kg (highest dose tested). Between days 0 and 3, reduced body weight gains in relation to the control were observed at the two highest test doses, resulting in a NOAEL of 810 mg/kg. At 1350 mg/kg, body weight gains in female birds were 5.1% lower than controls. At 2250 mg/kg, body weight gains in female and male birds were decreased 4.7 and 5.4%, respectively, when compared to controls. By the end of the study, body weight gains of females and males were similar in all treatment groups, including controls (MRID 40951501).

No data are available for sub-acute dietary exposures of birds to technical bromacil. *In lieu* of toxicity data for technical grade bromacil, available data from a study involving dietary-based exposures of birds to a formulated product (Hyvar® X Bromacil Weed Killer, 80% a.i.) of bromacil are used in this assessment. In this study, mallard ducks (*Anas platyrhynchos*) and bobwhite quail were exposed to a formulated product of bromacil (83.4% a.i.) through dietary exposures. The resulting 8-d LC_{50} values for both species exceeded the highest concentration tested, *i.e.*, >10,000 mg/kg-diet/day (of bromacil). No mortalities were observed in exposures involving mallard ducks. Bobwhite quail mortalities were observed in exposures involving several different treatment levels; however, the mortalities were less than 50% of individuals in each treatment group. In the test, 6.8% mortality was observed in controls, 10% mortality was observed in the 464 and 4640 mg/kg-diet/day treatment levels and 20% mortality was observed in the 2150 and 10,000 mg/kg-diet/day treatment levels (MRID 00013295). This study is classified acceptable for a formulated product, but supplemental for use in this assessment, since the test material was not technical bromacil.

No toxicity data are available in ECOTOX for acute exposures of birds to bromacil.

Chronic

Data are available from two registrant-submitted studies, where bobwhite quail and mallard ducks were given chronic (21 weeks), dietary exposures of bromacil. In the study involving Northern bobwhite quail, effects to hatchability, embryo viability, embryo survival and hatching survival were observed at 3100 mg/kg-diet/day, resulting in a NOAEC of 1550 mg a.i./kg-diet/day (MRID 44844801). In the study involving mallard ducks, significant effects were observed in egg shell thickness at the 3100 mg a.i./kg-diet/day treatment level. Significant effects to hatchability of mallards were observed at the 6200 mg a.i./kg-diet/day treatment level. The NOAEC for this study was also 1550 mg a.i./kg-diet/day (MRID 44844601).

4.2.2. Toxicity to mammals

Acute

Data are available from a registrant-submitted study, where laboratory rats (*Rattus norvegicus*) were given acute oral doses of technical grade bromacil. Mortalities were observed in animals dosed with 1000 and 2000 mg/kg, which resulted in an acute oral LD_{50} of 812 mg/kg for females and 1682 mg/kg for males. Sublethal effects that were observed included: hunched posture, ataxia, lethargy, decreased respiration, hemorrhagic lungs, and dark liver and kidneys (MRID 44196209). No data are available in ECOTOX for acute exposures of mammals to bromacil.

Chronic

Data are available from a 2-generation dietary exposure reproduction study in rats. The reported NOAEL was 250 mg/kg-diet/day, with a LOAEC of 2500 mg/kg-diet/day. Observed effects included decreased growth (body weight reductions) in parent and first and second generation offspring (MRID 41804601). The results of this study (i.e. the NOAEL) are used to derive RQs for mammals representing prey of the terrestrial phase CRLF.

ECOTOX includes data from a study in which laboratory rats were exposed to bromacil in the diet for 2 years. The reported NOAEL was 250 mg/kg-diet/day. The LOAEL of 1250 mg/kg-diet/day was based on observed decrease in body weight gains and food consumption (Sherman and Kaplan 1975). These results are consistent with those included in MRID 41804601.

4.2.3. Toxicity to terrestrial insects

Data are available on the acute toxicity of bromacil to honey bees (*Apis mellifera*). In an acute contact toxicity study, the LD_{50} was higher than the highest dose tested, i.e., >11 µg a.i./bee (MRID 00251374). In another study involving 96-h acute contact exposures of honeybees to a formulated product containing bromacil (Hyvar® X Bromacil Weed Killer, 80% a.i.), the LC_{50} was >193.38 µg/bee (MRID 00018842). At this level, 1.2% mortality was observed. Adjustment of this value for the % a.i. of the test substance results in an LD_{50} >155 µg a.i./bee. This toxicity value is converted to units of µg a.i./g (of bee) by multiplying by 1 bee/0.128 g thereby resulting in an LD_{50} >1209 µg a.i./g. No data are available in ECOTOX for exposures of insects to technical grade bromacil.

4.2.4. Toxicity to terrestrial plants

Toxicity data were submitted from seedling emergence and vegetative vigor studies involving separate exposures of wheat (monocot) and rape (dicot) to technical bromacil and technical bromacil lithium.

In the seedling emergence tests involving bromacil and bromacil lithium, percent survival, dry weight and plant height were significantly affected in both wheat and rape. The % inhibition in seedling emergence in the treated species as compared to the control ranged from -11 to 5% for bromacil and from -5 to 13% for bromacil lithium. The most sensitive endpoint for wheat and rape in the seedling emergence tests was dry weight. The following abnormalities were noted for bromacil: slight growth retardation, malformations, chlorosis and necrosis. The following abnormalities were noted for bromacil lithium: slight to moderate chlorosis, slight to severe growth retardation, slight unusual pigmentation and slight to severe burn or necrosis. NOAEC, EC_{25} and EC_{50} values for bromacil and bromacil lithium exposures t indicate that the two chemicals are of similar toxicities to wheat and to rape (MRID 444883-07; **Table 27**).

Table 27. Comparison of seedling emergence endpoints[1] for wheat and rape exposed to bromacil and bromacil lithium.

Endpoint	Wheat		Rape	
	Bromacil	**Bromacil Lithium**	**Bromacil**	**Bromacil Lithium**
NOAEC	0.020	0.020	0.006	0.006
EC_{25}	0.030	0.034	0.0047	0.010
EC_{50}	0.085	0.087	0.013	0.013

[1]Based on decreased dry weight.

In the vegetative vigor tests, the plant dry weight and plant height were affected by exposures to bromacil and bromacil lithium. The most sensitive endpoint for wheat and rape in the vegetative vigor tests was dry weight. The following abnormalities were noted in tests where plants were exposed to bromacil or bromacil lithium: chlorosis, necrosis and growth retardation. NOAEC, EC_{25} and EC_{50} values for bromacil and bromacil lithium exposures indicate that the two chemicals are of similar toxicities to wheat and to rape (MRID 444883-07; **Table 28**).

Table 28. Comparison of vegetative vigor endpoints1 for wheat and rape exposed separately to bromacil and bromacil lithium.

Endpoint	Wheat		Rape	
	Bromacil	**Bromacil Lithium**	**Bromacil**	**Bromacil Lithium**
NOAEC	0.020	0.001	0.006	0.003
EC_{25}	0.042	0.028	0.0055	0.0060
EC_{50}	0.068	0.065	0.010	0.010

[1]Based on decreased dry weight.

4.3. Incident Reports

A search of the EIIS (Environmental Incident Information System) database for ecological incidents (run on September 21, 2007) identified are a total of 32 incidents associated with bromacil that were reported from 1992-2005. No incidents are identified in EIIS in association with bromacil lithium. Incidents included in EIIS are defined by a certainty index associated with the likelihood that the pesticide application described resulted in the observed incident. The certainty index defines incidents as unrelated, unlikely, possible, probable and highly probable. One notable source of uncertainty associated with the EIIS database is the nature of reporting of incidents. Many more incidents may have occurred due to bromacil exposures but may not have been reported due to various factors, such as a lack of reporting, or a lack of witnessing of effects. Therefore, the lack of an incident report does not necessarily indicate a lack of an incident.

The majority (27) of the incidents associated with bromacil involve damage to terrestrial plants. These incidents are summarized in **Table 29**. These incidents involved applications classified as "misuse" and as "registered use." The certainty index associated with all of the incidents was defined as either "possible," "probable" or "highly probable." These incidents reported observed effects to individual plants, including trees, effects to lawns, and effects to crops covering areas greater than 100 acres. In some cases, other herbicides where applied along with bromacil (e.g. diuron, atrazine, metolachlor). Reports indicated that bromacil exposures occurred through direct treatment of areas, spray drift, runoff and carryover from one season to the next.

In addition, 5 of the incidents associated with bromacil involved mortalities of fish (**Table 30**). Of these 5 incidents reporting fish kills, 3 reported combined exposures of fish to 2,4-D and bromacil, 1 reported combined exposures of fish to copper and bromacil and 1 reported exposures of fish to bromacil only. This last report (# I008956-001) involved an incident where bromacil was dumped into a storm drain, which discharged to a local river. The certainty of this incident in relation to bromacil was "probable." However, this incident was classified as misuse which is not a component of the federal action under review in this assessment.

Table 29. Summary of reported incidents involving terrestrial plants in relation to applications of bromacil.

Incident ID	Use Site	Plants affected	Date	Legality	Certainty	State	County	Total Magnitude	Appl. Rate	Exposure route	Other pesticides
I013884-004	Home, exterior	yard	4/22/98	Registered use	Highly Probable	WA	Grant	Not given	N/R	Drift and runoff	diuron
I010837-045	N/R	corn	7/13/00	Undetermined	Possible	NY	Wyoming	ALL	N/R	Treated directly	atrazine, metolachlor
I008184-001	N/R	trees	8/19/98	Undetermined	Possible			UNKNOWN	N/R	Drift	NR
I010837-055	N/R	soybeans	6/19/00	Undetermined	Possible	PA	Huntington	35 ACRES	N/R	Treated directly	atrazine, metolachlor
I012457-012	Peanut	peanuts	5/28/01	Undetermined	Possible		Isle of Wight	52.5 acres	N/R	Treated directly	s-metolachlor, flumioxazin
I012684-012	Peanut	peanuts	5/29/01	Registered use	Possible	VA	Sussex	40 acres	N/R	Treated directly	s-metolachlor, flumioxazin
I010837-020	corn	corn	6/7/00	Undetermined	Possible	PA	Bradford	ALL	N/R	Treated directly	atrazine, metolachlor
I012457-017	N/R	peanuts	5/20/01	Undetermined	Possible	OK	Beckham	30 acres	N/R	Treated directly	flumioxazin
I012457-013	Peanut	peanuts	5/29/01	Undetermined	Possible	GA	Mitchell	102.7 acres	N/R	Treated directly	flumioxazin
I008441-001	Fence row	Trees and turf	11/6/98	Undetermined	Possible	KY	Mason	unknown	N/R	Runoff	NR
I010837-048	corn	corn	7/10/00	Undetermined	Possible	NY	Steuben	ALL	N/R	Treated directly	atrazine, metolachlor
I0144700-001	Right-of-way, utility	sod	5/1/04	Registered use	Possible	OK	Carter	Not given	12 LB / acre	runoff	diruon
I016569-001	Residential	Willow trees	7/25/05	Undetermined	Possible	NM	San Juan	45 (number)	N/R	Spray	diuron
I010837-030	N/R	sunflowers	6/27/00	Undetermined	Possible	SD	Douglas	ALL	N/R	carryover	Dicamba, 2,4-D, primisulfuron-methyl
I015360-001	Driveway	Trees (pine and deciduous)	8/24/04	Misuse (accidental)	Possible	OR	Grant	3 (number)	8 lbs/acre	N/R	diuron
I013850-001	Right-of-way, rail	Back yard	5/24/02	Registered use	Possible	MI	Washtenaw	1/3 of back yard	N/R	Spray	2,4-D, dimethylamine, diuron, glyphosate, isopropylamine salt
I014409-062	N/R	Trees and shrubs	7/3/92	Undetermined	Possible	WA	Benton	Not given	N/R	N/R	Diuron, oryzalin
I014177-001	Citrus	Bell peppers	3/15/02	Registered use	Possible	CA	Riverside	30 acres	N/R	carryover	diuron
I012457-019	Peanut	peanut	6/4/01	Undetermined	Possible	GA	Grady	88.7 acres	N/R	Treated directly	Ethalfluralin, flumioxazin
I013587-020	Right-of-way	Evergreen trees	3/2/98	Registered use	Possible	WA	Adams	N/R	N/R	drift	diuron
I015382-001	Residential area	Trees and grass	6/25/04	Undetermined	Probable	WY		N/R	N/R	runoff	diuron
I012708-001	Plants	Oaks (mature), shrubs, plants	6/1/01	Undetermined	Probable	FL	Polk	40 trees	N/R	Direct treatment	
I010837-031	N/R	sunflower	6/27/00	Undetermined	Probable	SD	Douglas	ALL	N/R	carryover	Dicamba, 2,4-D, primisulfuron-methyl
I005972-001	PLANT SITE	Mature oaks	9/1/97	Registered use	Probable	TX		3 (number)	N/A	runoff	Diuron, sulfometuron, imazapyr
I005075-001	PASTURE	Alfalfa, oats, hay		Misuse (accidental)	Probable	TX		3 Acres	N/R	unknown	diuron
I006010-003	Utility plant	Pasture grass and bullrush	8/19/97	Misuse (accidental)	Probable	MS		unknown	N/R	runoff	Diuron, glyphosate, isopropylamine salt, sulfometuron
I016610-001	lawn	Trees (pine, cottonwood, willow) and grass	9/1/03	Misuse (intentional)	Probable	ID	Blaine	Various	4 pounds	Direct treatment	diuron

N/R = not reported

Table 30. Summary of reported incidents involving fish kills in relation to applications of bromacil.

Incident ID	Use Site	Type of Fish	Date	Legality	Certainty	State	County	# fish killed	Appl. Method	Other pesticides	Product
I004875-001	N/R	N/R	3/10/96	Misuse (intentional)	Highly Probable	LA	East Baton Rouge	Hundreds (along 1.6 mile stretch of creek)	Leaking drum	2, 4-D	
I007154-001	Utility plant	N/R	3/18/98	Registered use	Possible	MS		some	Soil incorporation	Diuron, copper sulfate	KROVAR I DF
I008956-001	Sewer disposal	N/R	1/1/94	Misuse (intentional)	Probable	IA		Unknown	Dumped into drain	N/R	FENOCIL III
I004668-001	N/R	N/R	3/10/96	Misuse (accidental)	Probable	LA	East Baton Rouge	600	spill	2,4-D	
I003601-001	stream	White sucker, minnow, eel, dace	6/22/93	Registered use	Probable	DE	New Castle	1000	Surface application	2, 4-D	N/R

N/R = not reported

5. Risk Characterization

Risk characterization is the integration of the exposure and effects characterizations to determine the potential ecological risk from varying bromacil and bromacil lithium use within the action area and to determine likelihood of direct and indirect effects on the CRLF. The risk characterization provides estimation and description of the likelihood of adverse effects; it 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 CRLF.

5.1. Risk Estimation

Risk is estimated by calculating the ratio of exposure to toxicity. This ratio is the risk quotient (RQ), which is then compared to pre-established acute and chronic risk levels of concern (LOCs) for each category evaluated (**Appendix F**). For acute exposures to the CRLF and its animal prey in aquatic habitats, as well as terrestrial invertebrates, the acute risk to endangered species LOC is 0.05. For acute exposures to the CRLF and mammals, the acute risk to endangered species LOC is 0.1. The LOC for chronic risk to CRLF and its prey, as well as acute risk to plants is 1.0. As discussed in the analysis plan of the problem formulation (specifically, section 2.10.1.3), the acute risk to non-listed species LOC value for animal prey, which is 0.5, is also used for evaluating RQs.

Screening-level RQs are based on the most sensitive endpoints and modeled EECs from the following scenarios for bromacil:

- Use on citrus @ 6.4 lbs a.i./A; 1 application per year
- Use on non-cropland areas @ 15.4 pound a.i./A; 2 applications per year

For exposures of terrestrial plants inhabiting dry and semi-aquatic habitats, single maximum applications of use on citrus and non-cropland areas were modeled, based on the application rates listed above.

5.1.1. Exposures in the Aquatic Habitat

5.1.1.1. Direct Effects to CRLF

For assessing acute risks of direct effects to the larval and juvenile and adult CRLF inhabiting water, 1-in-10 year peak EECs in the standard pond are used with the lowest acute toxicity value for fish. For chronic risks, 1-in-10 year peak 60-day EECs and the lowest chronic toxicity value for fish are used. Resulting RQs exceed the acute risk to listed species LOC (RQ≥0.05) for applications to non-cropland areas. RQs do not exceed the acute or chronic risk LOCs for applications to citrus or the chronic risk LOC for applications to non-cropland areas (**Table 31**).

Table 31. RQ values for acute and chronic exposures directly to the CRLF in aquatic habitats.

Use	Peak EEC (mg/L)	60-d EEC (mg/L)	Acute CRLF RQ[1]	Chronic CRLF RQ[2]
Citrus	0.056	0.056	<0.01	0.02
Non-cropland	2.34	2.32	**0.065**[3]	0.77

[1]Calculated using LC_{50}=36 mg/L.
[2]Calculated using NOAEC = 3 mg/L.
[3]Exceeds acute, listed species LOC (0.05).

5.1.1.2 Indirect Effects to CRLF through effects to organisms composing diet (i.e. prey)

For assessing risks of indirect effects of bromacil to the aquatic-phase CRLF (tadpoles) through effects to its diet, 1-in-10 year peak EECs from the standard pond are used with the lowest acute toxicity value for aquatic unicellular plants to derive RQs. Resulting RQs exceed the acute risk LOC (RQ≥1.0) for aquatic plants from bromacil applications citrus and non-cropland areas (**Table 32**).

Table 32. RQ values for exposures to unicellular aquatic plants (diet of CRLF in tadpole life stage).

Use	Peak EEC (mg/L)	Unicellular Plant RQ[1]
Citrus	0.056	**8.24**[2]
Non-cropland	2.34	**344**[2]

[1]Calculated using EC_{50}=0.0068 mg/L.
[2] Exceeds aquatic plant LOC (1.0).

For assessing risks of indirect acute effects to the aquatic-phase CRLF through effects to prey (invertebrates) in aquatic habitats, 1-in-10 year peak EECs in the standard pond are used with the lowest acute toxicity value for invertebrates. For chronic risks, 1-in-10 year peak 21-day EECs and the lowest chronic toxicity value for invertebrates are used to derive RQs. Resulting RQs do not exceed the acute and chronic risk to listed species LOC (RQ≥0.05 and ≥1.0, respectively) for applications to citrus and non-cropland areas (**Table 33**).

Table 33. Risk Quotient (RQ) values for acute and chronic exposures to aquatic invertebrates (prey of CRLF juveniles and adults) in aquatic habitats.

Use	Peak EEC (mg/L)	21-d EEC (mg/L)	Acute Invert RQ[1]	Chronic Invert RQ[2]
Citrus	0.056	0.056	<0.01	0.01
Non-cropland	2.34	2.33	0.02	0.28

[1]Calculated using EC_{50}=121 mg/L.
[2]Calculated using NOAEC = 8.2 mg/L.

Fish and frogs also represent prey of CRLF. These RQs are represented by those used for direct effects to the CRLF in aquatic habitats (**Table 31**). RQs for non-cropland areas exceed the acute risk LOC for listed animals (RQ≥0.05), but not for non-listed animals (RQ≥0.5). The chronic risk LOC for non-listed and listed animals (RQ≥1.0) is not exceeded for non-cropland areas. RQs for citrus do not exceed the acute or chronic risk LOCs for non-listed and listed fish and frogs.

5.1.2.3. Indirect Effects to CRLF through effects to habitat (plants)

For assessing risks of indirect effects of bromacil to the aquatic habitat (plants) the 1-in-10 year peak EECs from the standard pond are used with the lowest acute toxicity value for aquatic unicellular plants and for aquatic vascular plants to derive RQs. Resulting RQs exceed the LOC (RQ≥1.0) for both unicellular and vascular aquatic plants from bromacil applications to citrus and non-cropland areas (**Table 34**).

Table 34. RQ values for exposures of aquatic plants to bromacil.

Use	Peak EEC (mg/L)	Unicellular Plant RQ[1]	Vascular Aquatic Plant RQ[2]
Citrus	0.056	**8.2**[3]	**1.2**[3]
Non-cropland	2.34	**344**[3]	**52**[3]

[1]Calculated using EC_{50}=0.0068 mg/L.
[2]Calculated using EC_{50}=0.045 mg/L.
[3] Exceeds aquatic plant LOC (1.0).

5.1.2. Exposures in the Terrestrial Habitat

5.1.2.1. Direct Effects to CRLF

As described above, to assess risks of bromacil to terrestrial-phase CRLF, dietary-based and dose-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates are used. Acute, subacute and chronic effects are estimated using the lowest available toxicity data for birds. EECs are divided by toxicity values to estimate acute and chronic dietary-based RQs as well as dose-based RQs.

For use on citrus, indiscreet, dose-based RQs potentially exceed the LOC. Acute and chronic, dietary-based RQs for use on citrus do not exceed the LOC. For use on non-cropland areas, the LOC is potentially exceeded by RQs for dose-based and dietary-based exposures (**Table 35**).

Table 35. RQ values for exposures of terrestrial-phase CRLF to bromacil. RQs estimated using T-REX.

Exposure	Toxicity Value	Citrus RQ	Non-cropland RQ
Dose-acute	LD_{50}>2250 mg/kg	**<0.61**[1]	**<2.6**[1]
Dietary-acute	LC_{50}>10,000 mg/kg-diet	<0.09	**<0.37**[1]
Dietary-chronic	NOAEC = 1550 mg/kg-diet	0.56	**2.36**[2]

[1]since this RQ is indiscreet, it potentially exceeds the acute listed species LOC of 0.1
[2]exceeds chronic, listed species LOC (1.0)

5.1.2.2. Indirect Effects to CRLF through effects to prey

In order to assess the risks to terrestrial invertebrates, which are considered prey of CRLF in terrestrial habitats, the honey bee is used as a surrogate for terrestrial invertebrates. As described earlier, the toxicity value for terrestrial invertebrates is calculated by multiplying the lowest available acute contact LD_{50} of >155 µg a.i./bee by 1 bee/0.128 g, which is based on the weight of an adult honey bee. EECs (µg a.i./g of bee) calculated by T-REX for small and large insects are divided by the calculated toxicity value for terrestrial invertebrates, which is >1209 µg a.i./g of bee. The resulting RQ values for large insect and small insect exposures bound the potential range of exposures for terrestrial insects from the use of bromacil. For all uses, RQ values potentially exceed the LOC (RQ≥0.05) for both large and small terrestrial insects (**Table 36**).

Table 36. RQ values for exposures of terrestrial animals to bromacil. RQs estimated using T-REX.

Organism	Exposure	Toxicity Value	Citrus RQ	Non-cropland RQ
small insects (prey)	Acute Contact	LD_{50}>1209 µg a.i./g	**<0.71**[1]	**<3.0**[1]
large insects (prey)	Acute Contact	LD_{50}>1209 µg a.i./g	**<0.079**[1]	**<0.34**[1]
small mammals (prey)	Dose-acute	LD_{50}=812 mg/kg	**0.82**[2]	**3.5**[2]
	Dose-chronic	NOAEC = 12.5 mg/kg-bw	**53**[3]	**225**[3]
	Dietary-chronic	NOAEL = 250 mg/kg-diet/day	**6.1**[3]	**26.0**[3]
small frogs (prey)	Dose-acute	LD_{50}>2250 mg/kg	**<0.61**[4]	**<2.6**[4]
	Dietary-acute	LC_{50}>10,000 mg/kg-diet	<0.09	**<0.37**[4]
	Dietary-chronic	NOAEC = 1550 mg/kg-diet	0.56	**2.36**[3]

[1]since this RQ is indiscreet, it potentially exceeds the LOC for terrestrial invertebrates (0.05)
[2]exceeds the acute listed species LOC of 0.1
[3]exceeds chronic, listed species LOC (1.0)
[4]since this RQ is indiscreet, it potentially exceeds the acute listed species LOC of 0.1

As described above, to assess risks of bromacil to prey (small mammals) of larger terrestrial-phase CRLF, dietary-based and dose-based exposures modeled in T-REX for a small mammal (15g) consuming short grass are used. Acute, subacute and chronic effects are estimated using the most sensitive mammalian toxicity data. EECs are divided by the toxicity value to estimate acute and chronic dietary-based RQs as well as acute dose-based RQs. For all uses on citrus and non-cropland, acute RQ values exceed the acute risk to listed species and non-listed species LOCs (RQ≥0.1 and 0.5, respectively) and chronic dose-based and dietary-based RQ values exceed the chronic risk LOC (RQ≥1.0) for mammals considered as potential prey species for CRLF (**Table 36**).

An additional prey item of the adult CRLF is other species of frogs. In order to assess risks to these organisms, dietary-based and dose-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates are used. These are the same EECs, toxicity values and RQs used to assess direct effects to the CRLF. For use on citrus, dose-based RQs potentially exceed the LOC. Acute and chronic, dietary-based RQs for use on citrus do not exceed the LOC. For use on non-cropland areas, the LOC is potentially exceeded by RQs for dose-based and dietary-based exposures (**Table 36**).

5.1.2.3. Indirect Effects to CRLF through effects to habitat (plants)

For use on citrus and non-cropland areas, RQs exceed the LOC for monocots and dicots exposed to bromacil through runoff and drift (**Table 37**).

Table 37. RQ values for exposures of terrestrial plants to bromacil. RQs estimated using TerrPlant.

Plant type	Exposure	Citrus RQ	Non-cropland RQ
Monocot[1]	Dry Areas (runoff and drift)	**13**[3]	**31**[3]
	Semi-Aquatic Areas (runoff and drift)	**109**[3]	**262**[3]
	Spray Drift only	**2.1**[3]	**5.1**[3]
Dicot[2]	Dry Areas (runoff and drift)	**82**[3]	**197**[3]
	Semi-Aquatic Areas (runoff and drift)	**694**[3]	**1671**[3]
	Spray Drift only	**14**[3]	**33**[3]

[1]based on EC_{25} = 0.03 lbs a.i./A (effects on seedling emergence)
[2]based on EC_{25} = 0.0047 lbs a.i./A (effects on seedling emergence)
[3]exceeds LOC (1.0) for non-listed terrestrial plants

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 CRLF.

If the RQs presented in the Risk Estimation (**Section 5.1**) show no indirect effects and LOCs for the CRLF are not exceeded for direct effects, a "no effect" determination is made, based on use of bromacil and bromacil lithium 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. 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:

- <u>Significance of Effect</u>: 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:

- o 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.

- o 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.

5.2.1. Direct Effects

5.2.1.1. Aquatic-phase

Citrus

Acute and chronic RQ values representing uses of bromacil on citrus are insufficient to exceed the LOCs for direct effects to the CRLF in aquatic habitats. Therefore, the determination for direct effects to the CRLF in aquatic habitats is “No Effect” for uses of bromacil on citrus.

Non-cropland

For bromacil and bromacil lithium uses on non-cropland areas, the acute risk LOC is exceeded for direct effects to the CRLF in aquatic habitats. The chronic risk LOC is not exceeded for direct effects to the CRLF in aquatic habitats, indicating that chronic exposures to the CRLF in aquatic habitats are not of concern. Therefore, the determination is “May Affect” based on acute exposures resulting from applications of bromacil and bromacil lithium.

In this assessment, it is assumed that modeling the highest rate possible for bromacil (2 applications of 15.4 lbs a.i./A per year) is a conservative representation of applications of both bromacil and bromacil lithium, the latter of which has a lower maximum application rate of 12 lbs a.i./A (1 application per year). Modeling the highest application scenario results in higher aquatic EECs. In this case, aquatic EECs resulting from the maximum use of bromacil are sufficient to exceed the listed species LOC for acute exposures. However, aquatic EECs resulting from applications of bromacil lithium at its maximum use rate are insufficient to exceed the listed species LOC (**Table 38**). Therefore, for bromacil lithium, the determination for acute exposures of bromacil to the CRLF is "Not Likely to Adversely Affect."

Table 38. RQ values for acute and chronic exposures directly to the CRLF in aquatic habitats resulting from applications of bromacil and bromacil lithium to non-cropland areas at the maximum uses allowed by labels.

Chemical	Max single application rate (number of applications/year) (in lbs a.i./A)	Peak EEC (mg/L)	60-d EEC (mg/L)	Acute CRLF RQ[1]	Chronic CRLF RQ[2]
Bromacil	15.4 (2)	2.34	2.32	**0.065**[3]	0.77
Bromacil lithium	12 (1)	0.83	0.83	0.023	0.28

[1]Calculated using LC_{50}=36 mg/L.
[2]Calculated using NOAEC = 3 mg/L.
[3]Exceeds acute, listed species LOC (0.05).

Estimates of acute exposure of CRLF to bromacil from uses in rights-of-way result in RQs that exceed the acute risk LOC by a factor of 1.3X. An analysis of the likelihood of individual direct mortality is conducted using the LC_{50} of 36 mg/L and the default slope of 4.5. For non-cropland areas, the likelihood of individual mortality is 1 in $2.17e^7$, which is equivalent to a 0.00005% chance.

Based the above information, acute effects directly to aquatic-phase CRLF resulting from bromacil applications at the maximum allowed rate to non-cropland areas although possible, are insignificant. Therefore, the determination for effects to the aquatic-phase CRLF resulting from bromacil and bromacil lithium use on non-cropland areas is "Not Likely to Adversely Affect."

5.2.1.2. Terrestrial-phase

Although dietary-based RQ values are considerably lower than dose-based RQ values (**Table 35**), the former do not take into account that different sized animals consume differing amounts of food and that depending on the forage item, an animal has to consume varying amounts due to differing nutrition levels in the food item. If dietary-based RQ values are adjusted to account for differential food consumption, the adjusted RQ value would likely approximate the dose-based RQ value.

Exposure modeling with T-REX results in some LOC exceedances for RQs representing bromacil exposures to the terrestrial-phase CRLF. As discussed above (Section 2.10.1.1), the use of avian food intake allometric equation as a surrogate to amphibians is likely to result in an over-estimation of exposure and risk for reptiles and terrestrial-phase amphibians. The T-HERPS model was used to account for amphibian-specific exposures.

In order to explore influences of amphibian-specific food intake equations on potential dose-based and dietary-based exposures of the terrestrial-phase CRLF to bromacil, T-HERPS was used. With T-REX, applications of bromacil to citrus and non-cropland areas, results in dietary-based exposures of 864 and 3655 ppm, respectively. Dietary-based EECs for CRLF modeled using T-HERPS range 704-1536 ppm for citrus, and 421-6728 ppm for non-cropland areas, depending upon the food source. With T-REX, dose-based EECs of 984 and 4162 mg/kg-bw, were derived for citrus and non-cropland areas, respectively. Dose-based EECs for CRLF modeled using T-HERPS range 2.40-957 mg/kg-bw for citrus and 10.5-4194 for non-cropland areas (**Table 39**). Outputs from T-HERPS are available in **Appendix E**.

Table 39. Dietary-based and dose-based EECs relevant to direct effects to the CARLF through consumption of prey contaminated by bromacil. Modeling done with T-HERPS.

Food	Dietary Based EEC (ppm)	Dose Based EEC (mg/kg-bw) 1.4 g CRLF	Dose Based EEC (mg/kg-bw) 37 g CRLF	Dose Based EEC (mg/kg-bw) 238 g CRLF
Citrus				
Small Insects	1536	59.7	58.7	38.4
Large Insects	704	27.4	26.9	17.6
Small Herbivore mammals	864	33.6	33.0	21.6
Small Insectivore mammals	96.0	3.73	3.67	2.40
Small Terrestrial Phase Amphibians	1012	N/A	957	149
Non-cropland areas				
Small Insects	6728	261	257	168
Large Insects	3084	120	118	77.2
Small Herbivore mammals	3784	147	145	94.7
Small Insectivore mammals	421	16.3	16.1	10.5
Small Terrestrial Phase Amphibians	4433	N/A	4194	652

Acute dose-based and dietary-based RQs are based upon indiscreet toxicity endpoints, where the LD_{50} and LC_{50} values, (defined as >2250 mg/kg and >10,000 mg/kg-diet, respectively), were not quantified. In the available LD_{50} study for birds, no mortality was observed in any of the treatment groups. In the LC_{50} study with quail, mortalities were observed in several of the treatment groups; however, mortality in each treatment group was <50%. Therefore, acute RQ values are indiscreet, and, in cases where LOC exceedances are observed, there is only the potential for an exceedance, *i.e.*, RQ values are actually less than the calculated value; however, the extent to which they are lower is uncertain. Because LD_{50} and LC_{50} values were not defined, likelihood of individual mortality could not be determined for direct acute affects to the terrestrial phase CRLF.

Citrus

For citrus, the acute dose-based RQ potentially exceeds the LOC, resulting in a "may affect" determination for acute exposures of the CRLF to bromacil. For acute and chronic dietary-based exposures resulting from bromacil use on citrus, RQs do not exceed the

LOCs. Therefore, dietary-based exposures of CRLF to bromacil are not considered in determining risk.

Amphibian-specific refinement of dose-based exposure modeling using T-HERPS indicates that the LOC is potentially exceeded for 37 g CRLF consuming small herbivorous mammals (**Table 40**). Since there is uncertainty associated with this RQ, available sublethal effects information are used to further characterize the risk to this size of CRLF feeding on mammals. In the avian acute oral toxicity study (MRID 40951501), sublethal effects (5.1% reductions in body weight gains) were observed as low as 1350 mg/kg. Direct comparison of this value to dose-based EECs calculated by T-HERPS for citrus (**Table 39**) indicates that estimated exposure concentrations are insufficient to reach the levels where these effects were observed, indicating that sublethal effects would be unlikely from dose-based acute exposures. Since sublethal effects are unlikely to occur, it follows that lethal effects would also be unlikely to occur resulting from applications of bromacil to citrus.

Table 40. Acute and chronic, dietary-based RQs and dose-based RQs for direct effects to the terrestrial-phase CRLF, based on bromacil exposures resulting from applications to citrus. RQs calculated using T-HERPS.

Food	Dietary Based Acute RQ	Dietary Based Chronic RQ	Dose Based RQ 1.4 g CRLF	Dose Based RQ 37 g CRLF	Dose Based RQ 238 g CRLF
Small Insects	<0.09	0.56	<0.01	<0.01	<0.01
Large Insects	<0.01	0.06	<0.01	<0.01	<0.01
Small Herbivore mammals	<0.10	0.65	N/A	**<0.43**[1]	<0.01
Small Insectivore mammals	<0.01	0.04	N/A	<0.03	<0.01
Small Terrestrial-phase Amphibians	<0.01	0.02	N/A	<0.01	<0.01

NA = not applicable

[1]since this RQ is indiscreet, it potentially exceeds the acute listed species LOC (0.1)

Based the above information, acute and chronic effects directly to terrestrial-phase CRLF resulting from bromacil applications at the maximum allowed rates to citrus are unlikely to occur. Therefore, the determination for effects to the terrestrial-phase CRLF resulting from bromacil use on citrus is "Not Likely to Adversely Affect."

Non-Cropland

For non-cropland areas, RQs for acute dose-based and dietary-based exposures potentially exceed the LOC. Also, RQs for chronic dietary-based exposures exceed the LOC. Therefore, a "may affect" determination is made for direct effects to the CRLF resulting from bromacil exposures from use on non-cropland areas.

Amphibian-specific refinement of exposure modeling using T-HERPS indicates that RQs representing exposures of CRLF to bromacil from applications non-cropland areas still exceed the LOC for some feeding categories and exposure types. Dietary-based RQs for bromacil uses exceed the acute and chronic risk LOCs for direct effects to CRLF consuming small insects and small herbivorous mammals. RQs for dose-based exposures resulting from bromacil applications to non-cropland areas potentially exceed the LOC for 37-g CRLF consuming small herbivorous and insectivorous mammals and 238-g CRLF consuming small herbivorous mammals (**Table 41**).

Table 41. Acute and chronic, dietary-based RQs and dose-based RQs for direct effects to the terrestrial-phase CRLF, based on bromacil exposures resulting from bromacil applications to non-cropland areas (max rate = 2 applications of 15.4 lbs a.i./A). RQs calculated using T-HERPS.

Food	Dietary Based Acute RQ	Dietary Based Chronic RQ	Dose Based RQ 1.4 g CRLF	Dose Based RQ 37 g CRLF	Dose Based RQ 238 g CRLF
Small Insects	**<0.38**[1]	**2.44**[2]	<0.07	<0.06	<0.04
Large Insects	<0.04	0.27	<0.01	<0.01	<0.01
Small Herbivore mammals	**<0.44**[1]	**2.86**[2]	N/A	**<1.86**[1]	**<0.29**[1]
Small Insectivore mammals	<0.03	0.18	N/A	**<0.12**[1]	<0.02
Small Terrestrial-phase Amphibians	<0.01	0.08	N/A	<0.01	<0.01

NA = not applicable
[1]since this RQ is indiscreet, it potentially exceeds the acute listed species LOC (0.1)
[2]exceeds chronic, listed species LOC (1.0)

Consideration of the lower maximum application rate of bromacil lithium (i.e. 1 application of 12 lbs a.i./A/year) results in acute dose-based EECs sufficient to potentially exceed the LOC for 37-g and 238-g CRLF consuming small herbivorous mammals. Acute dietary-based EECs are sufficient to potentially exceed the LOC for CRLF consuming small insects and small herbivore mammals. Chronic dietary-based EECs are sufficient to exceed the LOC for CRLF consuming small insects and small herbivore mammals (**Table 42**).

Table 42. Acute and chronic, dietary-based RQs and dose-based RQs for direct effects to the terrestrial-phase CRLF, from bromacil lithium applications to non-cropland areas (max rate = 1 application of 12 lbs a.i./A). RQs calculated using T-HERPS.

Food	Dietary Based Acute RQ	Dietary Based Chronic RQ	Dose Based RQ 1.4 g CRLF	Dose Based RQ 37 g CRLF	Dose Based RQ 238 g CRLF
Small Insects	**<0.16**[1]	**1.05**[2]	<0.03	<0.03	<0.02
Large Insects	<0.02	0.12	<0.01	<0.01	<0.01
Small Herbivore mammals	**<0.19**[1]	**1.22**[2]	N/A	**<0.80**[1]	**<0.12**[1]
Small Insectivore mammals	<0.01	0.08	N/A	<0.05	<0.01
Small Terrestrial-phase Amphibians	<0.01	0.04	N/A	<0.01	<0.01

NA = not applicable
[1]since this RQ is indiscreet, it potentially exceeds the acute listed species LOC (0.1)
[2]exceeds chronic, listed species LOC (1.0)

In the avian acute oral toxicity study (MRID 40951501), sublethal effects (5.1% reductions in body weight gains) were observed as low as 1350 mg/kg. For non-cropland areas, direct comparison of the NOAEL of 1350 mg/kg to EECs (**Table 39**) indicates that exposure levels for only one feeding category (37 g CRLF consuming small herbivore mammals) is sufficient to exceed the level where sublethal effects were observed in the available acute oral study with birds.

In the avian subacute dietary toxicity study (MRID 00013295), mortality was observed in treatment levels as low as 464 mg/kg-diet/day (10% mortality), while 20% mortality was observed in treatment levels as low as 2150 mg/kg-diet/day. Direct comparison of refined acute dietary-based EECs (from T-HERPS; **Table 39**) indicates that EECs for some feeding categories (CRLF consuming small insects and small herbivore mammals) exceed the levels where 10% and 20% mortality was observed in this laboratory study. It should be noted that there is uncertainty regarding the significance of these results in comparison to controls, where 6.8% mortality was observed.

In the chronic toxicity studies involving birds, the NOAEC was 1550 mg/kg-diet/day. This value is used for deriving RQs in the risk estimation of this assessment. In this study, the lowest level where effects were observed (i.e. the LOAEC) was 3100 mg/kg-diet/day. Direct comparison of chronic dietary-based EECs resulting from bromacil applications to the LOAEC indicate that EECs are sufficient to exceed the level where reproductive effects were observed in birds. Direct comparisons of chronic dietary-based EECs resulting from applications of bromacil lithium are insufficient to exceed the LOC indicating that there is uncertainty associated with the chronic effects of bromacil on the CRLF resulting from applications of bromacil lithium.

Acute effects directly to terrestrial-phase CRLF resulting from bromacil and bromacil lithium applications at the maximum allowed rates to non-cropland areas cannot be discounted. At the maximum use rate of bromacil, there is also potential for risk directly to the terrestrial-phase CRLF based on chronic exposures. Therefore, the determination for effects to the terrestrial-phase CRLF resulting from bromacil and bromacil lithium uses non-cropland areas is “Likely to Adversely Affect.”.

5.2.2. Indirect Effects (through effects to prey)

As discussed in section 2.5.3, the diet of tadpole CRLF is composed primarily of unicellular aquatic plants and detritus. Juvenile CRLF consume primarily aquatic and terrestrial invertebrates. The diet of adult CRLF is composed of aquatic and terrestrial invertebrates, fish, frogs and mice. These prey groups are considered in determining indirect effects to the CRLF caused by direct effects to its prey.

Unicellular plants

Based on LOC exceedances of RQs for algae (**Table 32**), applications of bromacil to citrus and bromacil and bromacil lithium to non-cropland areas result in potential effects to this food source. Therefore, a “may affect” determination is also made for indirect effects to the CRLF through reductions to a food source resulting from bromacil exposures from use on citrus and non-cropland areas.

Available effects data for green algae (EC_{50}=6.8 μg/L; MRID 42516401) represent the most sensitive data for unicellular aquatic plants. Toxicity data are available for other unicellular aquatic plants exposed to bromacil (**Table 22**). Comparison of peak aquatic EECs resulting from bromacil use on citrus is sufficient to result in RQ values that would exceed the LOC for 3 of 4 unicellular aquatic plant species for which toxicity data exist. Comparison of peak aquatic EECs resulting from bromacil use on non-cropland areas is sufficient to result in RQ values that would exceed the LOC for 4 of 4 unicellular aquatic plant species (**Table 43**).

Table 43. Species specific RQs for unicellular aquatic plants.

Use	Green Algae RQ	FW Diatom RQ	Marine Diatom RQ	Blue Green Algae RQ
Citrus	**8.2**[1]	**8.1**[1]	**4.6**[1]	0.8
Non-cropland	**344**[1]	**339**[1]	**193**[1]	**34**[1]

[1]exceeds LOC (1.0) for non-listed aquatic plants

A source of uncertainty in the derivation of RQs is the estimation of exposure. Peak EECs are several orders of magnitude above the highest measured concentration of bromacil in California surface waters (0.0075 mg/L); however, the highest measured concentration of bromacil is sufficient to exceed the LOC for aquatic unicellular plants.

Based on this information, exposures of bromacil in aquatic habitats have the potential to affect populations and even communities of aquatic algae.

Aquatic invertebrates

Acute and chronic RQ values representing uses of bromacil on citrus and non-cropland areas are insufficient to exceed the LOCs for effects to invertebrates in aquatic habitats. Even if RQs were derived using more conservative endpoints for acute toxicity available in the literature (48-h EC_{50} = 65 mg a.i./L; Foster et al. 1998), these values would not exceed the LOC. Therefore, aquatic invertebrates are unlikely to be directly affected due to exposures to bromacil in aquatic habitats.

Terrestrial invertebrates

Because the LD_{50} used in deriving RQs for terrestrial invertebrates is not quantified, RQs for acute exposures of bromacil to small and large terrestrial invertebrates <u>potentially</u> exceed the LOC of 0.05 for citrus and non-cropland areas (**Table 36**). This results in a "may affect" determination for indirect effects to the CRLF due to acute exposures of terrestrial invertebrates to bromacil.

In the one of the available toxicity studies with honey bees, 1.2% mortality was observed at 1209 μg a.i./g (MRID 00018842). Direct comparison of the level were 1.2% mortality was observed with EECs calculated by T-REX for small and large insects exposed to bromacil applied to citrus, the EECs are insufficient to reach the level where 1.2% mortality was observed in honey bees. Therefore, for bromacil applications to citrus, mortality to terrestrial invertebrates is insignificant.

For large insects, EECs for non-cropland areas are also below the level where 1.2% mortality was observed in honey bees, indicating that EECs directly on the application site resulting from applications of bromacil to non-cropland areas are insufficient to cause 1.2% mortality in bees. For small insects, EECs for non-cropland areas are approximately 3x the level where 1.2% mortality was observed in honey bees, indicating that applications of bromacil to non-cropland areas could potentially result in mortality to >1.2% of small sized insects. It is expected that beyond the edge of the application site, EECs will be below the level where 1.2% mortality was observed in honey bees.The intent of estimating exposures and subsequent risks to two size classes of insects is to bound potential effects to this prey class. There is potential for effects to some terrestrial invertebrates (small) representing CRLF prey; however, it seems unlikely that large sized terrestrial invertebrates will be affected significantly by bromacil applications to non-cropland areas, leaving terrestrial invertebrates to serve as prey to terrestrial-phase CRLF. Based this information, indirect effects to terrestrial-phase CRLF from acute effects to terrestrial invertebrates resulting from bromacil applications to non-cropland areas are insignificant.

Fish and aquatic-phase amphibians

RQ values representing direct exposures of bromacil to aquatic-phase CRLF can also be used to represent exposures of bromacil to fish and frogs in aquatic habitats. Therefore, the conclusions made above for direct effects to the CRLF (section 5.2.1.1) also apply to effects to fish and aquatic amphibians representing prey for the CRLF. Acute and chronic effects are unlikely for fish and aquatic amphibians exposed to bromacil after applications to citrus. Acute and chronic effects are insignificant for fish and aquatic amphibians exposed to bromacil after applications of bromacil and bromacil lithium to non-cropland areas.

Small terrestrial mammals

Estimates of acute exposure of small mammals (consuming grass) to bromacil from uses in citrus and non-cropland areas result in RQs that exceed the acute risk LOC by factors of 8.2X and 35X, respectively. Estimates of bromacil exposures resulting from bromacil lithium applications to non-cropland areas result in RQs that exceed the acute risk LOC by 15.4X. Where bromacil or bromacil lithium is applied, exposures are sufficient to exceed the LOC for up to 23 and 52 feet beyond the edge of the field of citrus and non-cropland areas, respectively (**Table 18**).

An analysis of the likelihood of individual acute mortality for mice on the site of application is conducted using the LD_{50} of 812 mg/L and the default slope of 4.5. For citrus, the likelihood of individual mortality is estimated as 1 in 2.9, or 34.5%. For non-cropland areas, the likelihood of individual mortality is approximately 1 in 1, or 100%. As the distance from the edge of the field increases, the exposure decreases, and along with that, the likelihood of individual mortality decreases.

For chronic exposures of bromacil resulting from use on citrus, dietary-based and dose-based RQs exceed the LOC by factors of 6.1 and 53, respectively. For chronic exposures of bromacil resulting from use on non-cropland areas, dietary-based and dose-based RQs exceed the LOC by factors of 26 and 225, respectively. Estimates of bromacil exposures resulting from bromacil lithium applications to non-cropland areas result in dietary-based and dose-based RQs that exceed the acute risk LOC by 11.5X and 100X, respectively. If RQs were derived using the LOAEC (2500 mg/kg-diet/day) from the available study involving chronic exposures of rats to bromacil, chronic RQs would still be sufficient to exceed the LOC for uses on citrus and on non-cropland areas. Where bromacil or bromacil lithium is applied, exposures are sufficient to exceed the LOC for up to 132 and 292 feet beyond the edge of the field of citrus and non-cropland areas, respectively. As the distance from the edge of the field increases, the exposure decreases, and along with that, the likelihood of effects decreases.

Therefore, on the site of applications of bromacil and bromacil lithium as well as some distance beyond the edge of the field, there is potential for effects to small mammals.

Small terrestrial-phase amphibians

An additional prey item of the adult CRLF is other species of terrestrial-phase frogs. In order to assess risks to these organisms, dietary-based and dose-based exposures modeled in T-REX for a small bird (20g) consuming small invertebrates are used. For use on citrus, dose-based RQs potentially exceed the LOC. Acute and chronic, dietary-based RQs for use on citrus do not exceed the LOC. For use on non-cropland areas, the LOC is potentially exceeded by RQs for dose-based and dietary-based exposures (**Table 36**). Therefore, for bromacil use on citrus and bromacil and bromacil use on non-cropland areas, there is potential for effects to terrestrial-phase amphibians which are potential prey to CRLF. Where bromacil or bromacil lithium is applied, exposures are sufficient to exceed the LOC for up to 16 and 36 feet beyond the edge of the field of citrus and non-cropland areas, respectively (**Table 18**).

In order to explore influences of amphibian-specific food intake equations on potential dose-based and dietary-based exposures of amphibians (prey of CRLF) to bromacil, T-HERPS is used. The Pacific tree frog is used to represent amphibian prey species. The weight of the animal is assumed to be 2.3 g, and its diet is assumed to be composed of small and large insects. A range of RQs is presented in **Table 44** for each use corresponding to EECs resulting from bromacil exposures to frogs consuming large (low RQ) and small insects (high RQ).

For Pacific tree frogs consuming small and large insects, acute dietary-based exposures as well as dose based exposures of bromacil resulting from applications to citrus are insufficient to exceed the acute or chronic LOCs (**Table 44**). Therefore, acute and chronic effects are unlikely for terrestrial-phase amphibians exposed to bromacil after applications to citrus.

Table 44. RQ values for exposures of terrestrial frogs (prey of CRLF) to bromacil. RQs estimated using T-HERPS.

Exposure	Toxicity Value	Citrus RQ	Non-cropland RQs	
			Bromacil	**Bromacil lithium**
Dose-acute	LD_{50}>2250 mg/kg	<0.01	<0.01-0.06	<0.01-0.02
Dietary-acute	LC_{50}>10,000 mg/kg-diet	<0.01-0.09	<0.04-**0.38**[1]	<0.02-**0.16**[1]
Dietary-chronic	NOAEC = 1550 mg/kg-diet	0.06-0.56	0.27-**2.44**[2]	0.12-**1.05**[1]

[1]Potentially exceeds acute, listed species LOC (0.1).
[2]exceeds chronic, listed species LOC (1.0).

For applications of bromacil and bromacil lithium to non-cropland areas, the acute, dietary-based RQ for Pacific tree frogs potentially exceeds the listed species LOC (**Table 44**). In the sub-acute dietary study used to define acute dietary-based RQs for frogs, less than 50% mortality was observed at bromacil exposures of 10,000 mg/kg-diet (MRID 00013295). Direct comparison of bromacil EECs for the Pacific tree frog resulting from applications to non-cropland areas indicates that EECs are below the level where less than 50% mortality was observed in this laboratory study. In this study, 20% mortality was observed in treatment levels as low as 2150 mg/kg-diet/day. Direct comparisons of acute dietary-based EECs for the Pacific tree frog indicate that EECs for frogs consuming large invertebrates are insufficient to exceed this level while EECs for small invertebrates exceed this level where 20% mortality was observed.

For applications of bromacil and bromacil lithium to non-cropland areas, chronic dietary-based RQs exceed the LOC for frogs consuming small insects but not for those consuming large insects (**Table 44**). Since frogs would be expected to consume both small and large insects, it seems likely that the actual EEC should fall somewhere between the extreme EECs representing diets composed only of small insects and diets composed only of large insects.

Summary of indirect effects to the CRLF based on effects to prey

Based on the above information, there is potential for applications of bromacil or bromacil lithium to citrus and non-cropland areas to cause effects to aquatic algae. Since CRLF rely upon aquatic algae as a food source during the tadpole stage, decreased availability of algae biomass could indirectly affect the CRLF during this life stage. Effects to aquatic and terrestrial invertebrates, which compose the diet of the juvenile CRLF, are not expected from bromacil or bromacil lithium applications to citrus or to non-cropland areas. Because the adult CRLF is an opportunistic feeder, it will consume available prey. Potential prey includes aquatic and terrestrial invertebrates, fish, aquatic frogs, terrestrial frogs and mice. Although there is potential for effects to mice and near the site of application, indirect effects to the CRLF based on decreased availability of prey are not expected. It is expected that there will be sufficient prey to maintain the adult CRLF.

For applications of bromacil or bromacil lithium to citrus and non-cropland areas, the determination for indirect effects to the tadpole-phase of the CRLF, based on decreased availability of prey, is “Likely to Adversely Affect.” For the juvenile and adult life stages of the CRLF, the determination is “Not Likely to Adversely Affect.”

5.2.3. Indirect Effects (through effects to habitat)

Aquatic habitat

The aquatic habitat of the CRLF is composed of unicellular and vascular aquatic plants, as well as riparian vegetation. Citrus and non-cropland RQs for all three groups exceed the LOC (**Tables 34 and 37**), resulting in a “may affect” determination for indirect effects to the CRLF based on effects to its aquatic habitat.

Available effects data for green algae (EC_{50}=6.8 µg/L; MRID 42516401) represent the most sensitive data for unicellular aquatic plants. Comparison of peak aquatic EECs resulting from bromacil use on citrus is sufficient to result in RQ values that would exceed the LOC for 3 of 4 unicellular aquatic plant species for which toxicity data exist. Comparison of peak aquatic EECs resulting from bromacil use on non-cropland areas is sufficient to result in RQ values that would exceed the LOC for 4 of 4 unicellular aquatic plant species. Therefore, EECs are at levels sufficient to decrease populations of algae by >50% in multiple species of algae. This indicates concern for alteration of algal communities by decreasing overall algal biomass and altering dominant species.

EECs are also sufficient to exceed concentrations where frond numbers were significantly decreased in duckweed. This indicates that at estimated exposure concentrations, bromacil has the potential to decrease populations of vascular aquatic plants.

Concentrations of bromacil reaching riparian vegetation through runoff and spray drift are at levels where reduced dry weight was observed in monocots and dicots. This indicates that exposures of bromacil could result in reduced biomass in riparian vegetation.

Loss of aquatic and riparian vegetation could result in alteration of physical and chemical characteristics of the aquatic habitat of the CRLF. These potentially include: alteration of the morphology of channels and ponds, alterations of geometry of channels and ponds, increases in sediment depositions, loss of shelter for CRLF, alteration in water chemistry (including temperature, turbidity, and oxygen content). These changes could potentially alter the conditions necessary for normal growth and viability of juvenile and adult CRLFs and their food source.

Therefore, the determinations for indirect effects to the CRLF caused by effects to aquatic and riparian plants resulting from bromacil and bromacil lithium uses on citrus and non-cropland areas are “Likely to Adversely Affect.”

Terrestrial habitat

The terrestrial habitat of the CRLF is composed of vascular plants, including monocots and dicots. Citrus and non-cropland RQs for these plants exceed the LOC (**Table 37**), resulting in a "may affect" determination for indirect effects to the CRLF based on effects to its terrestrial habitat.

Exposures to plants inhabiting terrestrial habitats could come from both runoff and spray drift from the treatment site. EECs calculated by TerrPlant indicate that each exposure pathway by itself is sufficient to exceed the LOC for non-listed plants, including both monocots and dicots. Refined modeling of bromacil exposures of plants through spray drift indicate that exposures exceed the EC_{25}s for monocots and dicots up to 437 and 4026 feet, respectively, from the edge of citrus fields where bromacil is applied. Also, for bromacil and bromacil lithium applications to non-cropland areas, spray drift exposures exceed the EC_{25}s for monocots and dicots up to 810 and 5909 feet, respectively, from the edge of the treatment area (**Table 18**).

As discussed in section 4.3, there are a number of reported incidents associated with bromacil involving damage to terrestrial plants. These incidents reported observed effects to individual plants, including trees, effects to lawns, and effects to crops covering areas greater than 100 acres. In some cases, other herbicides where applied along with bromacil (*e.g.* diuron, atrazine, metolachlor). Reports indicated that bromacil exposures occurred through direct treatment of areas, spray drift, runoff and carryover from one season to the next.

Loss of vegetation in the terrestrial habitat of the CRLF could impact the ability of that habitat to support the food source of the CRLF. Loss of this vegetation could also reduce available shelter for CRLF.

Therefore, the determinations for indirect effects to the CRLF caused by effects to terrestrial plants resulting from bromacil and bromacil lithium uses on citrus and non-cropland areas are "Likely to Adversely Affect."

5.2.4. Primary Constituent Elements of Designated Critical Habitat

5.2.4.1. Aquatic-Phase (Aquatic breeding habitat and aquatic non-breeding habitat)

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

- Alteration of channel/pond morphology or geometry and/or increase in sediment deposition within the stream channel or pond: aquatic habitat (including riparian vegetation) provides for shelter, foraging, predator avoidance, and aquatic dispersal for juvenile and adult CRLFs.

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

Due to RQ exceedances for several species of algae, as well as for aquatic vascular plants, bromacil use on citrus and bromacil and bromacil lithium use on non-cropland areas use results in a determination of "habitat modification."

The remaining aquatic-phase PCE is "alteration of other chemical characteristics necessary for normal growth and viability of CRLFs and their food source." As stated previously, RQs for algae, which represent a food source for larval CRLF (tadpoles), exceed the LOC. Therefore, the determination for this endpoint is also "habitat modification."

5.2.4.2. Terrestrial-Phase (upland habitat and dispersal habitat)

Similar to the aquatic-phase PCEs, three of the four assessment endpoints for the terrestrial-phase PCEs of designated critical habitat for the CRLF are related to potential effects to aquatic and/or terrestrial plants:

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

Due to RQ exceedances for exposures of plants inhabiting dry areas to bromacil contained in runoff and in drift, bromacil use on citrus and bromacil and bromacil lithium use on non-cropland areas use results in a determination of "habitat modification."

The remaining terrestrial-phase PCE is "reduction and/or modification of food sources for terrestrial phase juveniles and adults." Acute and chronic RQs for mice, which represent a food source for terrestrial phase CRLF, exceed the LOC for bromacil uses on citrus and bromacil and bromacil lithium uses on non-cropland areas. Therefore, the determination for this endpoint is "habitat modification."

5.2.5. Action Area

5.2.5.1. Areas indirectly affected by the federal action

The initial action area for bromacil was previously discussed in Section 2.7 and depicted in **Figures 4** and **5** of the problem formulation. In order to determine the extent of the action area in lotic (flowing) aquatic habitats, the greatest ratios of the RQ to the LOC for any endpoint for aquatic organisms for each use is used to determine the distance downstream for concentrations to be diluted below levels that would be of concern (*i.e.* result in RQs above the LOC). For this assessment, this applies to RQs for algae. The action area is determined based on risks to all listed species based on bromacil exposures resulting from applications of bromacil or bromacil lithium. Therefore, RQs for listed unicellular aquatic species are used, which are derived by dividing the peak aquatic EEC by the NOAEC for unicellular aquatic species (<1.1 µg a.i./L; MRID 42516401). Also, the LOC of 1.0 is used. The final RQ/LOC ratios are: 51 for bromacil use on citrus, and 2127 for bromacil and bromacil lithium use on non-cropland areas. The total stream kilometers within the action area that are at levels of concern are defined in **Table 45**.

Table 45. Quantitative results of spatial analysis of lotic aquatic action area relevant to bromacil.

Measure	Distance (km)	
	Citrus Areas	Non-cropland Areas
Total Streams in CA	332,962	332,962
Streams within initial area of concern	17,283	87,867
Downstream distance added	2,019	14,655
Streams in aquatic action area	19,302	102,522

When considering the terrestrial habitats of the CRLF, spray drift from use sites onto non-target areas could potentially result in exposures of the CRLF, its prey and its habitat to bromacil. Therefore, it is necessary to estimate the distance from the application site where spray drift exposures do not result in LOC exceedances for organisms within the terrestrial habitat. To account for this, first, the bromacil application rate which does not result in an LOC exceedance is calculated for each terrestrial taxa of concern (**Table 18**). The farthest distance where no LOC is exceeded applies to non-listed species of dicots (terrestrial plants). As mentioned above, the action area is determined based on risks to all listed species based on bromacil exposures resulting from applications of bromacil or bromacil lithium. Since effects thresholds for listed terrestrial plants are defined by the NOAEC of available seedling emergence and vegetative vigor data, the lowest NOAEC from terrestrial dicots (0.006 lbs a.i./A; MRID 44488307) is used to determine the farthest distance from the edge of the target area where there are no LOC exceedances for listed species. AgDISP was then used to determine the distance required to reach the NOAEC value. For bromacil use on citrus, this distance is 4167 feet. For bromacil and bromacil lithium use on non-cropland areas, this value is 5315 feet.

To understand the area indirectly affected by the federal action due to spray drift from application areas, the citrus (**Figure 4**) and non-cropland (**Figure 5**) landcovers are considered as potential application areas. These areas are “buffered” using ArcGIS 9.2. In this process, the original landcover is modified by expanding the border of each polygon representing a field out to a designated distance, which in this case, is the distance estimated where bromacil in spray drift does not exceed any LOCs. This effectively expands the action area relevant to terrestrial habitats so that it includes the area directly affected by the federal action, and the area indirectly affected by the federal action.

5.2.5.2. Final action area

In order to define the final action areas relevant to uses of bromacil and bromacil lithium on citrus and non-cropland areas, it is necessary to combine areas directly affected, as well as aquatic and terrestrial habitats indirectly affected by the federal action. This is done separately for citrus and non-cropland uses using ArcGIS 9.2. Landcovers representing areas directly affected by bromacil and bromacil lithium applications are overlapped with indirectly affected aquatic habitats (determined by down stream dilution modeling) and with indirectly affected terrestrial habitats (determined by spray drift modeling). It is assumed that lentic (standing water) aquatic habitats (*e.g.* ponds, pools, marshes) overlapping with the terrestrial areas are also indirectly affected by the federal action. The result is a final action area for bromacil uses on citrus (**Figure 10**) and a final action area for bromacil and bromacil lithium uses on non-cropland areas (**Figure 11**).

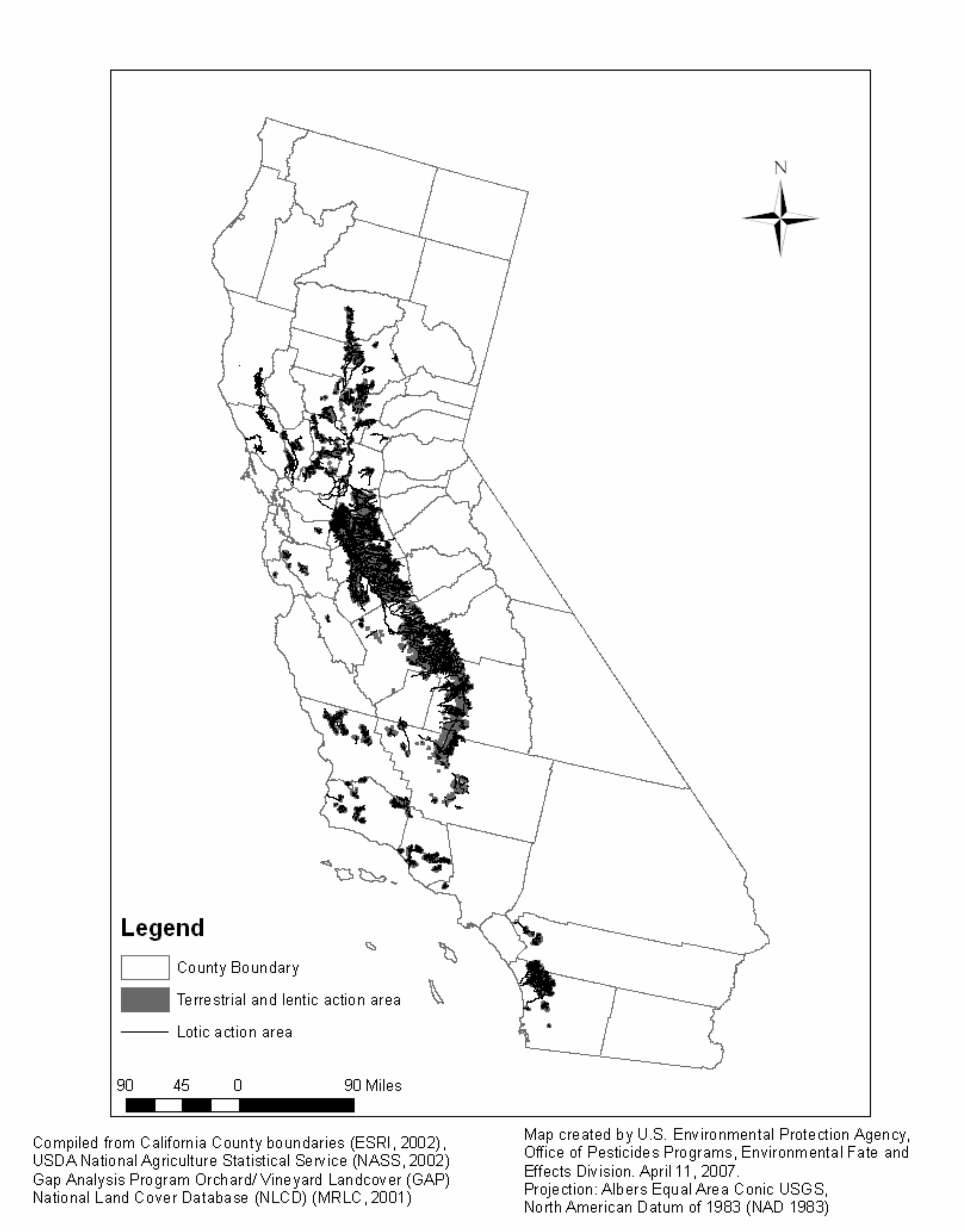


Figure 10. Final action area for crops described by the orchard/vineyard landcover which corresponds to potential bromacil use on citrus. This map represents the area potentially directly and indirectly affected by the federal action.

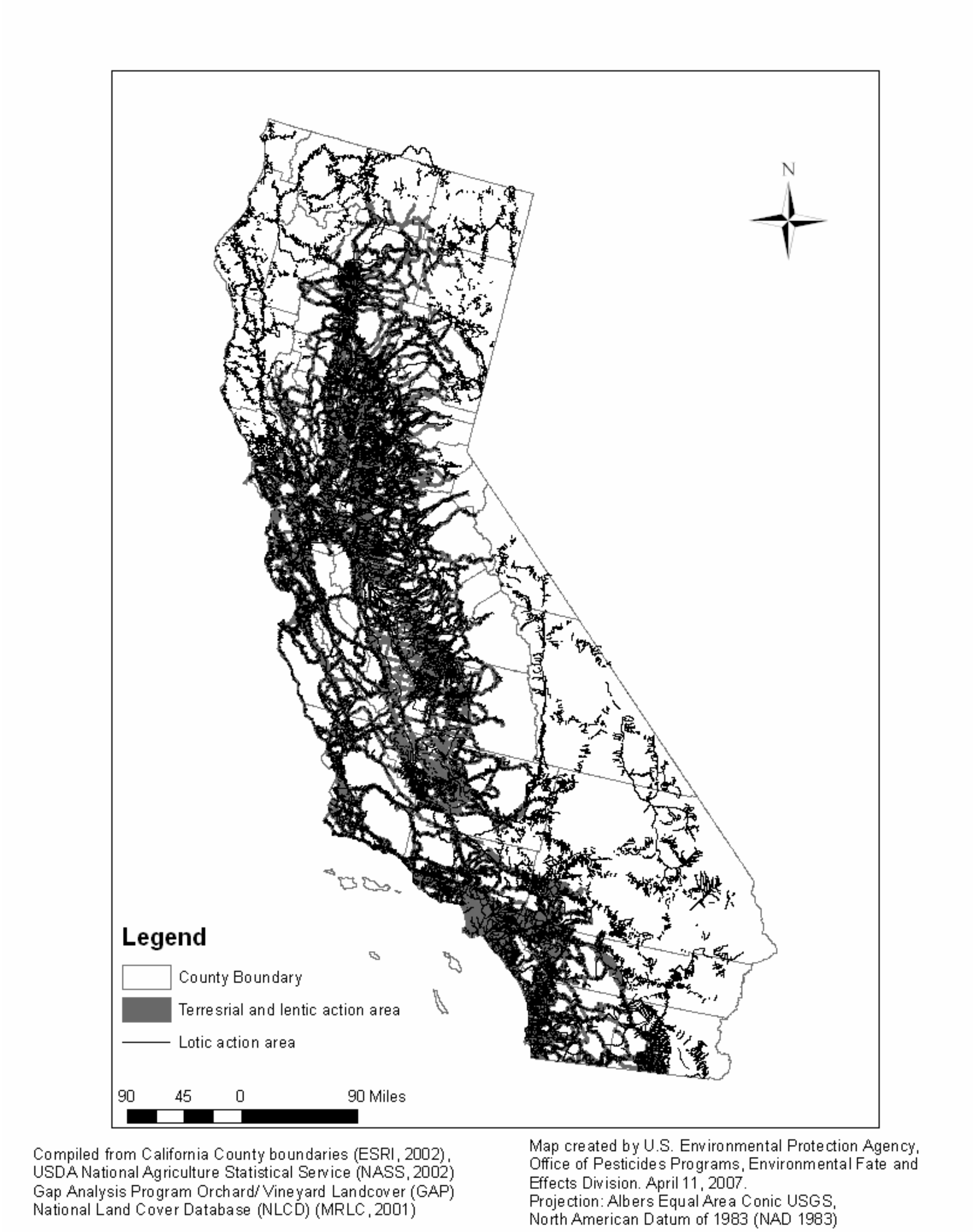


Figure 11. Final action area for crops described by right-of-way landcover which corresponds to potential bromacil and bromacil lithium use sites on non-cropland areas. This map represents the area potentially directly and indirectly affected by the federal action.

5.2.5.3. Overlap between CRLF habitat and final action area

In order to confirm that uses of bromacil and bromacil have the potential to affect CRLF through direct applications to target areas and runoff and spray drift to non-target areas, it is necessary to determine whether or not the final action areas for citrus and non-cropland uses overlap with CRLF habitats. Spatial analysis using ArcGIS 9.2 indicates that lotic aquatic habitats within the CRLF core areas and critical habitats potentially contain concentrations of bromacil sufficient to result in RQ values that exceed LOCs. In addition, terrestrial habitats (and potentially lentic aquatic habitats) of the final action areas overlap with the core areas, critical habitat and available occurrence data for CRLF (**Tables 46-47**). Thus, uses of bromacil use on citrus and bromacil and bromacil lithium use on non-cropland areas could result in exposures of bromacil to CRLF in aquatic and terrestrial habitats. Additional analysis related to the intersection of the bromacil and bromacil lithium action areas and CRLF habitat is described in **Appendix H**.

Table 46. Overlap between CRLF habitat (core areas and critical habitat) and citrus action area by recovery unit (RU#).

Measure	RU1	RU2	RU3	RU4	RU5	RU6	RU7	RU8	Total
CRLF habitat (km^2)*	3654	2742	1323	3279	3650	5306	4917	3326	28,197
Overlapping area of CRLF habitat and terrestrial/lentic aquatic action area (km^2)	7	14	2	50	27	159	435	497	1191
% CRLF habitat overlapping with terrestrial/lentic aquatic Action Area	0%	1%	0%	2%	1%	3%	9%	15%	4%
# Occurrences overlapping with terrestrial/lentic aquatic action area	2	0	0	15	1	3	10	0	31

*Area occupied by core areas and/or critical habitat.

Table 47. Overlap between CRLF habitat (core areas and critical habitat) and non-cropland action area by recovery unit (RU#).

Measure	RU1	RU2	RU3	RU4	RU5	RU6	RU7	RU8	Total
CRLF habitat (km^2)*	3654	2742	1323	3279	3650	5306	4917	3326	28,197
Overlapping area of CRLF habitat and terrestrial/lentic aquatic action area (km^2)	1990	1220	768	1632	1661	1777	2069	1643	12,760
% CRLF habitat overlapping with terrestrial/lentic aquatic Action Area	54%	44%	58%	50%	46%	33%	42%	49%	45%
# Occurrences overlapping with terrestrial/lentic aquatic action area	6	1	45	191	174	63	73	21	574

*Area occupied by core areas and/or critical habitat.

5.2.6. Description of Assumptions, Limitations, Uncertainties, Strengths and Data Gaps

5.2.6.1. Exposure Assessment

Aquatic habitat

The standard ecological water body scenario (EXAMS pond) used to calculate potential aquatic exposure to pesticides is intended to represent conservative estimates, and to avoid underestimations of the actual exposure. The standard scenario consists of application to a 10-hectare field bordering a 1-hectare, 2-meter deep (20,000 m^3) pond with no outlet. Exposure estimates generated using the EXAMS pond are intended to represent a wide variety of vulnerable water bodies that occur at the top of watersheds including prairie pot holes, playa lakes, wetlands, vernal pools, man-made and natural ponds, and intermittent and lower order streams. As a group, there are factors that make these water bodies more or less vulnerable than the EXAMS pond. Static water bodies that have larger ratios of pesticide-treated drainage area to water body volume 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 and in 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 2004a).

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.

There is uncertainty in the PRZM/EXAMS application timing relative to rainfall/runoff events. Label instructions indicate that applications of bromacil can be made any time during the year. Consideration of the meteorological data associated with the California PRZM scenarios indicates that the largest rainfall events occur in January. In general, the greater amount of rainfall in a single event, the greater the EEC in the receiving aquatic habitat. In order to select an application date resulting in a conservative estimate of exposure of aquatic habitats to bromacil, an application date of January 25 was chosen. Pesticide use data associated with bromacil (CPUR 2007) indicates that past applications of bromacil have been made throughout the year. Applications made at times where there is less rainfall could potentially result in less runoff and with that, lower concentrations of bromacil in aquatic habitats.

A source of uncertainty in the derivation of RQs is the estimation of exposure. The peak EEC for bromacil in aquatic environments 2.34 mg/L based on modeling for rights-of-way. As discussed above (section 3.1.1), concentrations of bromacil have been detected in non-target monitoring at a frequency of approximately 7% in California surface waters at levels over 500 times below these estimated concentrations (the maximum detected concentration was 0.0075 mg/L). Because the results of the monitoring data are based upon non-targeted monitoring, it is uncertain of whether or not available data represent high-end acute exposure concentrations in California surface waters.

There is uncertainty in this assessment associated with the environmental fate data gaps. Most significantly, there is some uncertainty in the EECs due to an assumption made in the aquatic exposure modeling with regard to the degradation of bromacil in anaerobic environments. While it is evident that the compound degrades in anaerobic soil/sediment, an accurate half-life value was not available, and the reported half-life (39 days) in the submitted study was not considered to be valid. *In lieu* of other data, the anaerobic half-life for bromacil using as an input in the Tier II modeling is 0 days (i.e., stable). While the use of the "0 days" as the input value would increase the EECs relative to using a value that more accurately depicts the more rapid degradation rate which could be expected in the environment, it is not clear whether this would result in significantly different risk conclusions. In a laboratory study reported in the literature, bromacil was persistent in a saturated sandy loam soil, with an observed half-life of 144 to 198 days (Wolf, 1974). Also, in the environment, bromacil would more likely be associated with the water column than with sediment since it does not have a tendency to sorb to soil/sediment particles.

There is no evidence of bromacil degradation in aquatic environments. As such, bromacil was assumed stable in the ecological pond used to estimate aquatic exposure concentrations. Since the ecological pond (used in our modeling) has no outlet, there was a modeled accumulation of bromacil in the pond throughout the 30 year simulations. In the case of persistent compounds, a 1-in-10 year EEC does not reflect varying meteorological conditions that are expected once every ten years, since the yearly peaks are not independent but are actually correlated to the previous year's peak concentration. This results in acute and chronic exposure concentrations that are very similar (*i.e*, < 2% difference between peak and 90-day average EECs). Based on this, EECs used for deriving RQs for aquatic organisms are potentially an overestimate of exposures in the aquatic habitats that do not accumulate bromacil.

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.

As discussed in the Use Characterization (section 2.4.4), uses of bromacil and bromacil lithium on non-cropland areas apply to a wide variety of areas, including: airports, parking lots, industrial areas, rights-of-way (for railroads, highways, pipeline and utilities), storage areas, lumberyards, tank farms, under asphalt and concrete pavement and fence rows. In this assessment, aquatic EECs were derived using rights-of-way to conceptualize the land area where these herbicides are applied. Given the difference in surface characteristics, use of one of these other types of non-cropland areas for defining the conceptual model of the use area could potentially result in different estimates of exposure. Since historical data for bromacil supports the idea that rights-of-way represent the major non-cropland use of bromacil in California, it was determined that the rights-of-way conceptual approach was suitably representative of bromacil exposures in aquatic habitats resulting from applications to non-cropland areas.

Right-of-way areas were represented by assuming that 50% of the surface of the watershed is impervious, while 50% is pervious. This is generally representative of a highway or road right-of-way, where bromacil is expected to be applied to the shoulder area of the roadway. In this case, it is assumed that runoff from the roadway and shoulder would be transported directly into the water body of concern (perhaps through drainage ditches emptying into the water body). Given the diversity of types of rights-of-way to which bromacil and bromacil lithium could be applied, it is expected that the relative percentages of impervious and pervious surfaces varies greatly. In deriving aquatic EECs using this approach, increase in the proportion of impervious surface of a watershed, results in a decrease in EEC. EECs included in this risk assessment result in an LOC exceedance for direct acute effects to the aquatic-phase CRLF. If the right-of-way surface were modeled as being composed of 60% impervious and 40% pervious, there would be no LOC exceedance. Using a conceptual approach assuming that 100% of a right-of-way surface is composed of pervious surface is relevant to utility rights-of-way which would be expected to have little impervious surface; however, it is unlikely that the entire watershed of a water body would be composed of this right-of-way. It would be more likely that the right-of-way would cut through a watershed, leaving only part of the watershed treated with bromacil or bromacil lithium. The use of a PRZM scenario assumes that the entire watershed of an area is treated with the pesticide of concern. Therefore, it is assumed that highway and road rights-of-way would result in higher end estimates of exposure due to applications of bromacil and bromacil lithium to non-cropland areas.

In this assessment, it is assumed that applications of bromacil and bromacil to non-cropland areas are made by ground methods. The label with the highest application rate (2 applications per year of 15.4 lbs a.i./A) prohibits aerial applications (registration 10088-68). However, other labels exist which allow for applications of bromacil at lower rates. Applications by aerial methods result in greater spray drift when compared to those made by ground methods. When compared to the spray drift exposure estimation included in this assessment, there is potential for greater exposures of bromacil resulting from aerial applications of lower application rates.

Model runs are conducted without irrigation. Given that it is unlikely that rights-of-ways and impervious surfaces will be irrigated, this is a reasonable approach. Although there is potential for citrus orchards to be irrigated, this is not captured in the current modeling approach due to limitations of PRZM.

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.

Terrestrial habitat

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

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

Differences in assimilative efficiency between laboratory and wild diets suggest that current screening assessment methods do not account for a potentially important aspect of food requirements. Depending upon species and dietary matrix, bird assimilation of wild diet energy ranges from 23 – 80%, and mammal's assimilation ranges from 41 – 85% (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.

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.

Mixtures

This assessment considers only the single active ingredients of bromacil or bromacil lithium. However, the assessed species and its environments may be exposed to multiple pesticides simultaneously. Interactions of other toxic agents with bromacil could result in additive effects, synergistic effects or antagonistic effects. Evaluation of pesticide mixtures is beyond the scope of this assessment because of the myriad factors that cannot be quantified based on the available data. Those factors include identification of other possible co-contaminants and their concentrations, differences in the pattern and duration of exposure among contaminants, and the differential effects of other physical/chemical characteristics of the receiving waters (*e.g.* organic matter present in sediment and suspended water). Evaluation of factors that could influence additivity/synergism is beyond the scope of this assessment and is beyond the capabilities of the available data to allow for an evaluation. However, it is acknowledged that not considering mixtures could over- or under-estimate risks depending on the type of interaction and factors discussed above.

5.2.6.2. Effects Assessment

As previously discussed, direct effects to aquatic-phase CRLF are based on freshwater fish data, which are used as a surrogate for aquatic-phase amphibians. Toxicity data for terrestrial-phase amphibians are not available for use in this assessment. Therefore, avian toxicity data are used as a surrogate for terrestrial-phase CRLF. There is uncertainty regarding the relative sensitivity of amphibians and their surrogates to bromacil. If the selected surrogate species are substantially more or less sensitive than the CRLF, then risk would be over or under estimated, respectively. In addition, given the small data set for freshwater fish species (3 acute toxicity values), the potential range of sensitivities of fish (and thus, aquatic amphibians) to bromacil.

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.

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

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

5.2.6.3. 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.

5.2.6.4. Use Data

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.

5.2.6.5. General Uncertainties

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.

5.2.7. Addressing the Risk Hypotheses

In order to conclude this risk assessment, it is necessary to address the risk hypotheses defined in section 2.9.1. Based on the conclusions of this assessment, none of the hypotheses can be rejected, meaning that the stated hypotheses represent concerns in terms of effects of bromacil on the CRLF.

6. Conclusions

Based on estimated environmental concentrations for the currently registered uses of bromacil or bromacil lithium, RQ values are above the Agency's LOC for direct acute effects on the CRLF resulting from applications to citrus and non-cropland areas; this represents a "may affect" determination. RQs for uses on citrus and non-cropland areas exceed the LOC for exposures to aquatic unicellular plants. Therefore, there is a potential to indirectly affect larval (tadpole) CRLF due to effects to the algae forage base in aquatic habitats. The effects determination for indirect effects to the CRLF due to effects to its prey base is "may affect." When considering the prey of larger CRLF in terrestrial habitats (*e.g.* frogs, fish and small mammals), RQs for some of these taxa also exceed the LOC for acute and chronic exposures, resulting in a "may affect" determination. RQ values for plants in aquatic and terrestrial habitats exceed the LOC; therefore, indirect effects to the CRLF through effects on aquatic and terrestrial habitats result in a "may affect" determination.

Refinement of all "may affect" determinations from bromacil use on citrus results in a "NLAA" determination for direct effects to the CRLF, a "LAA" determination for indirect effects to the CRLF based on effects to its prey, specifically algae, and a "LAA" determination for indirect effects to the CRLF based on effects to aquatic and terrestrial habitat (**Table 1**). Consideration of CRLF critical habitat indicates a determination of "habitat modification" for aquatic and terrestrial habitats based on bromacil use on citrus. **The overall CRLF effects determination for bromacil use on citrus is "LAA."**

Refinement of all "may affect" determinations from bromacil and bromacil lithium use on non-cropland areas result in a "LAA" determination for direct effects to the CRLF, a "LAA" determination for indirect effects to the CRLF based on effects to its prey, specifically algae, and a "LAA" determination for indirect effects to the CRLF based on effects to aquatic and terrestrial habitat (**Table 2**). Consideration of CRLF critical habitat indicates a determination of "habitat modification" for aquatic and terrestrial habitats based on non-cropland uses of bromacil and bromacil lithium. **The overall CRLF effects determination for bromacil and bromacil lithium use on non-cropland areas is "LAA."**

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated. **Attachment 2**, which includes information on the baseline status and cumulative effects for the CRLF, can be used during this consultation to provide background information on past US Fish and Wildlife Services biological opinions associated with the CRLF.

When evaluating the significance of this risk assessment's direct/indirect and habitat modification 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.

7. References

Altig, R. and R.W. McDiarmid. 1999. Body Plan: Development and Morphology. In R.W. McDiarmid and R. Altig (Eds.), Tadpoles: The Biology of Anuran Larvae.University of Chicago Press, Chicago. pp. 24-51.

Alvarez, J. 2000. Letter to the U.S. Fish and Wildlife Service providing comments on the Draft California Red-legged Frog Recovery Plan.

Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. 1969. Effect of pesticides on apiculture: Project No. 1499. Research report CR-7501. Unpublished study received May 8, 1971 under 1F1174; prepared by University of California-Riverside, Department of Entomology. Submitted by Ciba Agrochemical Co., Summit, NJ. MRID 00018842

CDPR. 2007. Surface Water Database. California Environmental Protection Agency, Department of Pesticide Regulation. Available online at: http://www.cdpr.ca.gov/docs/sw/surfcont.htm. (accessed 5/10/2007)

CDPR. 2007. a. Pesticide Use Reporting. California Environmental Protection Agency, Department of Pesticide Regulation. Available online at: http://www.cdpr.ca.gov/docs/sw/surfcont.htm. (accessed 5/31/2007)

Crawshaw, G.J. 2000. Diseases and Pathology of Amphibians and Reptiles *in:* Ecotoxicology of Amphibians and Reptiles; ed: Sparling, D.W., G. Linder, and C.A. Bishop. SETAC Publication Series, Columbia, MO.

Das, Y.T. 1988a. Hydrolysis of [2-^{14}C]Bromacil in aqueous solutions buffered at pH 5, 7, and 9. MRID: 40951505.

Das, Y.T. 1988b. Photodegradation of [2-^{14}C]Bromacil in aqueous solutions buffered at pH 5, 7, and 9. MRID: 40951507.

Das, Y.T. 1986. Photodegradation of [2-^{14}C]Bromacil on soil under artificial sunlight. MRID: 40951509.

Dieterich, W.H. 1965. Acute Oral Toxicity--Mallard Ducks, Bobwhite Quail: Project No. 201-154. (Unpublished study received Nov 22, 1965 under 352-287; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:100405-A) MRID 00013295.

Dreher, D. 1996. Bromacil Technical: Acute Oral Toxicity Test in the Rat: Lab Project Number: 008/346: 90000450. Unpublished study prepared by Safepharm Labs Ltd. 28 p. MRID 44196209.

Drottar, K.; Krueger, H. 1998. DPX-N976 Technical: A Semi-Static Life-Cycle Toxicity Test with the Cladoceran (Daphnia magna): Final Report: Lab Project Number:

112A-172: 1998- 01475. Unpublished study prepared by Wildlife International Ltd. 73 p. MRID 44566401.

Dulka, J.J., and T.W. Ryan. 1988. Photodegradation of [2-^{14}C]Bromacil in water at pH 9. MRID: 40951508.

Fellers, G. M., et al. 2001. Overwintering tadpoles in the California red-legged frog (*Rana aurora draytonii*). Herpetological Review, 32(3): 156-157.

Fellers, G.M, L.L. McConnell, D. Pratt, S. Datta. 2004. Pesticides in Mountain Yellow-Legged Frogs (Rana Mucosa) from the Sierra Nevada Mountains of California, USA. Environmental Toxicology & Chemistry 23 (9):2170-2177.

Fellers, Gary M. 2005a. *Rana draytonii* Baird and Girard 1852. California Red-legged Frog. Pages 552-554. *In*: M. Lannoo (ed.) Amphibian Declines: The Conservation Status of United States Species, Vol. 2: Species Accounts. University of California Press, Berkeley, California. xxi+1094 pp. (http://www.werc.usgs.gov/pt-reyes/pdfs/Rana%20draytonii.PDF)

Fellers, Gary M. 2005b. California red-legged frog, *Rana draytonii* Baird and Girard. Pages 198-201. *In*: L.L.C. Jones, et al (eds.) Amphibians of the Pacific Northwest. xxi+227.

Foster, S., Thomas, M., and Korth, W. (1998). Laboratory-Derived Acute Toxicity of Selected Pesticides to Ceriodaphnia dubia. *Aust.J.Ecotoxicol.* 4: 53-59. ECOTOX reference: 67777.

Gallagher, S.; Beavers, J.; Jaber, M. 1999a. DPX-N976 Technical: A Reproduction Study with the Northern Bobwhite (Colinus virginianus): Lab Project Number: AMR-4831-97: 112- 476. Unpublished study prepared by Wildlife International Ltd. 187 p. MRID 44844801.

Gallagher, S.; Beavers, J.; Jaber, M. 1999b. DPX-N976 Technical: A Reproduction Study with the Mallard (Anas platyrhynchos): Lab Project Number: AMR 4832-97: 112-477. Unpublished study prepared by Wildlife International Ltd. 186 p. MRID 44844601.

Geiger, D. L., Call, D. J., and Brooke, L. T. 1988. Acute Toxicities of Organic Chemicals to Fathead Minnows (Pimephales promelas). *Ctr.for Lake Superior Environ.Stud., Volume 4, Univ.of Wisconsin-Superior, Superior, WI* 355. ECOTOX reference: 12859.

Gerstl Z, Mingelgrin U. 1984. J Environ Sci Health B19: 297-312.

Grimes, J. 1986. H-16287: An Acute Oral Toxicity Study with the Bobwhite: Final Report: Wildlife International Ltd., Project No. 112-173. Unpublished study prepared by WildlifeInternational Ltd. 18 p. MRID 40951501.

Hansch, C., Leo, A., D. Hoekman. Exploring QSAR - Hydrophobic, Electronic, and Steric Constants. Washington, DC: American Chemical Society., 1995., p. 61.

Hayes, M.P. and M.M. Miyamoto. 1984. Biochemical, behavioral and body size differences between *Rana aurora aurora* and *R. a. draytonii*. Copeia 1984(4): 1018-22.

Hayes and Tennant. 1985. Diet and feeding behavior of the California red-legged frog. The Southwestern Naturalist 30(4): 601-605.

Heldreth, K.; McKelvey, R. 1997. Influence of Bromacil on Seed Germination, Seedling Emergence, and Vegetative Vigor of Several Terrestrial Plants: Supplement No. 1: Lab Project Number: MR 11430: AMR 2304-92. Unpublished study prepared by DuPont Stine-Haskell Research Center and Haskell Laboratory for Toxicology and Industrial Medicine. 209 p. MRID 44488307.

Hoke, R. 1998. DPX-N976 Technical: Early Life-Stage Toxicity to Rainbow Trout (Oncorhynchus mykiss): Lab Project Number: HL-1998-01349: 11691. Unpublished study prepared by E.I. du Pont de Nemours and Company. 148 p. MRID 44566101.

Hughes, J.; Williams, T. 1992. Bromacil: Toxicity to Selenastrum capriconutum: Lab Project Number: B382-156-1: AMR 2402-92. Unpublished study prepared by Malcolm Pinie Inc. 27 p. MRID 42516401.

Hughes, J.; Alexander, M.; Conder, L. 1997a. Bromacil: Influence on Growth and Reproduction of Lemna gibba. Project Number: 19/05/4, AMR/3990/96. Unpublished study prepared by Carolina Ecotox, Inc. 74 p. MRID 46095401.

Hughes, J.; Alexander, M.; Conder, L. 1997b. Bromacil: Influence on Growth and Reproduction of Navicula pelliculosa: Lab Project Number: AMR 3799-96: 19-05-2. Unpublished study prepared by Carolina Ecotox, Inc. 84 p. Relates to L0000187. MRID 44218501.

Hughes, J.; Alexander, M.; Conder, L. 1997c. Bromacil: Influence on Growth and Reproduction of Skeletonema costatum: Lab Project Number: 19-05-3: AMR 3801-96. Unpublished study prepared by Carolina Ecotox, Inc. 86 p. Relates to L0000187. MRID 44218503.

Hughes, J.; Alexander, M.; Conder, L. 1997d. Bromacil: Influence on Growth and Reproduction of Anabaena flos-aquae: Lab Project Number: AMR 3800-96: 19-05-1. Unpublished study prepared by Carolina Ecotox, Inc. 83 p. Relates to L0000187. MRID 44218502.

Hutton, D. 1986a. Daphnia magna Static Acute 48-Hour EC50 of Bromacil: Project ID: HLR 341-86. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 10 p. MRID 40951504.

Hutton, D.G. 1986b. [2-^{14}C]Bromacil bioconcentration in bluegill sunfish. MRID: 40951513.

Hutton, D. 1988. Static Acute 96-Hour LC50a of Bromacil to Rainbow Trout (Salmo gairdneri): Haskell Laboratory Report No. 265-86; MR No. 4581-373. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 10 p. MRID 40951503.

Jennings, M.R. and M.P. Hayes. 1985. Pre-1900 overharvest of California red-legged frogs (*Rana aurora draytonii*): The inducement for bullfrog (*Rana catesbeiana*) introduction. Herpetological Review 31(1): 94-103.

Jennings, M.R. and M.P. Hayes. 1994. Amphibian and reptile species of special concern in California. Report prepared for the California Department of Fish and Game, Inland Fisheries Division, Rancho Cordova, California. 255 pp.

Kupferberg, S. 1997. Facilitation of periphyton production by tadpole grazing: Functional differences between species. Freshwater Biology 37:427-439.

Kupferberg, S.J., J.C. Marks and M.E. Power. 1994. Effects of variation in natural algal and detrital diets on larval anuran (*Hyla regilla*) life-history traits. Copeia 1994:446-457.

LeNoir, J.S., L.L. McConnell, G.M. Fellers, T.M. Cahill, J.N. Seiber. 1999. Summertime Transport of Current-use pesticides from California's Central Valley to the Sierra Nevada Mountain Range,USA. Environmental Toxicology & Chemistry 18(12): 2715-2722.

McConnell, L.L., J.S. LeNoir, S. Datta, J.N. Seiber. 1998. Wet deposition of current-use pesticides in the Sierra Nevada mountain range, California, USA. Environmental Toxicology & Chemistry 17(10):1908-1916.

Mullin, L. 1991. Reproductive and Fertility Effects with Bromacil Multigeneration Reproduction Study in Rats: Lab Project Number: 8767-001: 724-90. Unpublished study prepared by E.I. du Pont de Nemours and Co. 1092 p. MRID 41804601.

Rathburn, G.B. 1998. *Rana aurora draytonii* egg predation. Herpetological Review, 29(3): 165.

Reis, D.K. Habitat characteristics of California red-legged frogs (*Rana aurora draytonii*): Ecological differences between eggs, tadpoles, and adults in a coastal brackish and freshwater system. M.S. Thesis. San Jose State University. 58 pp.

Schneiders, G.E. 1990. Field soil dissipation of Hyvar X Herbicide. MRID: 41677101.

Seale, D.B. and N. Beckvar. 1980. The comparative ability of anuran larvae (genera: *Hyla*, *Bufo* and *Rana*) to ingest suspended blue-green algae. Copeia 1980:495-503.

Sherman, H. and Kaplan, A. M. 1975. Toxicity Studies with 5-Bromo-3-sec-Butyl-6-Methyluracil. *Toxicol.Appl.Pharmacol.* 34: 189-196.

Sparling, D.W. and G.M. Fellers, L.L. McConnell. 2001. Pesticides and amphibian population declines in California, USA. Environmental Toxicology & Chemistry 20(7): 1591-1595.

USDA. 2007. National Agricultural Statistics Service. United States Department of Agriculture. Available online at: http://www.nass.usda.gov/.

U.S. EPA. 1992. Framework for Ecological Risk Assessment. EPA/630/R-92/001.

U.S. EPA. 1998. Guidance for Ecological Risk Assessment. Risk Assessment Forum. EPA/630/R-95/002F, April 1998.

USEPA; Reregistration Eligibility Decisions (REDs) Database on Bromacil. Washington DC: USEPA, Off Prev Pest Toxic Sub USEPA 738-R-96-013 (1996).

U.S. EPA. 2004. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs. Office of Prevention, Pesticides, and Toxic Substances. Office of Pesticide Programs. Washington, D.C. January 23, 2004.

U.S. EPA. 2006. Risks of Atrazine Use to Federally Listed Endangered Barton Springs Salamanders (*Eurycea sosorum*). Pesticide Effects Determination. Office of Pesticide Programs, Environmental Fate and Effects Division. August 22, 2006.

U.S. Fish and Wildlife Service (USFWS). 1996. Endangered and threatened wildlife and plants: determination of threatened status for the California red-legged frog. Federal Register 61(101):25813-25833.

USFWS. 2002. Recovery Plan for the California Red-legged Frog (*Rana aurora draytonii*). Region 1, USFWS, Portland, Oregon. (http://ecos.fws.gov/doc/recovery_plans/2002/020528.pdf)

USFWS. 2006. Endangered and threatened wildlife and plants: determination of critical habitat for the California red-legged frog. 71 FR 19244-19346.

USFWS. Website accessed: 30 December 2006. http://www.fws.gov/endangered/features/rl_frog/rlfrog.html#where

U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). 1998. Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities Under Section 7 of the Endangered Species Act. Final Draft. March 1998.

USFWS/NMFS. 2004. 50 CFR Part 402. Joint Counterpart Endangered Species Act Section 7 Consultation Regulations; Final Rule. FR 47732-47762.

Vigon, B.W. and M.F. Arthur. 1988a. Aerobic soil metabolism of [2-^{14}C]Bromacil in Stine Farm, DE, silty clay loam. MRID: 40951510.

Vigon, B.W., and M.F. Arthur. 1988b. Anaerobic aquatic metabolism of [2-^{14}C]Bromacil in West Jefferson, OH pond sediment and water. MRID: 40951511.

Voudrias, E.A. 1988. Soil-column leaching of [2-^{14}C]Bromacil. MRID: 40951512.

Wassersug, R. 1984. Why tadpoles love fast food. Natural History 4/84.

Wolf DC, Martin JP. 1974. Soil Sci Amer Proc 38: 921-5.