Risks of Chlorophacinone Use

To the Federally Threatened Alameda Whipsnake (*Masticophis lateralis euryxanthus*), California Tiger Salamander (*Ambystoma californiense*), Central California Distinct Population Segment,

And the Federally Endangered California Tiger Salamander (*Ambystoma californiense*) Sonoma County Distinct Population Segment and Santa Barbara County Distinct Population Segment, Salt Marsh Harvest Mouse (*Reithrodontomys raviventris*), and San Joaquin Kit Fox (*Vulpes macrotis mutica*)

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Table of Contents

Appendices

Appendix A. Verification Memo for Chlorophacinone
Appendix B. Risk Quotient (RQ) Method and Levels of Concern (LOCs)
Appendix C. Example Output from GENEEC

Appendix D. Summary of Ecotoxicity Data
Appendix E. HED Toxicity Profile
Appendix F. Bibliography of ECOTOX Open Literature

Appendix G. Accepted ECOTOX Data Table (sorted by effect)
Appendix H. ECOTOX Open Literature Reviews
Appendix I. Summary of Chlorophacinone Incidents

Attachments

Attachment I. Supplemental Information on Standard Procedures for Threatened and Endangered Species Risk Assessments on the San Francisco Bay Species

Attachment II: Status and Life History for the San Francisco Bay Species

Attachment III: Baseline Status and Cumulative Effects for the San Francisco Bay Species

1. Executive Summary

1.1. Purpose of Assessment

The purpose of this assessment is to evaluate potential direct and indirect effects on the federally threatened Alameda whipsnake (AW), the federally endangered salt marsh harvest mouse (SMHM), California tiger salamander (CTS) [the federally endangered Sonoma County Distinct Population Segment (CTS-SCDPS), the federally endangered Santa Barbara DPS (CTS-SBDPS), and the federally threatened Central California DPS (CTS-CCDPS)], and the federally endangered San Joaquin kit fox (SJKF) arising from FIFRA regulatory actions regarding use of chlorophacinone on agricultural and non-agricultural sites. In addition, this assessment evaluates whether these actions can be expected to result in modification of designated critical habitat for the AW and CTS. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998), procedures outlined in the Agency's Overview Document (USEPA, 2004a), and consistent with a lawsuit in which chlorophacinone was alleged to be of concern to the SMHM, SJKF, AW, and CTS (*Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 07-2794-JCS).)

In this assessment, direct and indirect effects to the AW, SMHM, CTS, and SJKF and potential modification to designated critical habitat for the AW and CTS are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA, 2004a). A brief overview of each species including primary constituent elements (PCEs) is provided below:

- **Alameda Whipsnake (AW):** The AW was listed as threatened in 1997 by the USFWS. The species occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties in California. The PCEs for AWs are lands containing rock outcrops, talus, and small mammal burrows adjacent to woodland or annual grasslands contiguous with scrub/shrub communities with a mosaic of open and closed canopy.
- **Salt Marsh Harvest Mouse (SMHM):** The SMHM was listed by the USFWS as an endangered species in 1970. The species is found in tidal and non-tidal salt marshes along the San Francisco, San Pablo, and Suisun Bays in California. Critical habitat has not been designated for the SMHM; therefore, PCEs have not been defined.
- **California Tiger Salamander (CTS):** There are currently three CTS Distinct Population Segments (DPSs): the Sonoma County (SC) DPS, the Santa Barbara (SB) DPS, and the Central California (CC) DPS. Each DPS is considered separately in the risk assessment as they occupy different geographic areas. The main difference in the assessment will be in the spatial analysis. The CTS-SB and CTS-SC were downlisted from endangered to threatened in 2004 by the USFWS, however, the downlisting was vacated by the U.S. District Court. Therefore, the Sonoma and Santa Barbara DPSs are currently listed as endangered while the CTS-CC is listed as threatened. CTS utilize vernal pools, semi-permanent ponds, and permanent ponds, and the terrestrial environment in California. The aquatic environment is essential for breeding and reproduction and mammal burrows are also important habitat for aestivation. The PCEs for CTSs are standing bodies of freshwater sufficient for the species to complete the aquatic portion of its life cycle that are adjacent to barrier-free uplands that contain small mammal burrows. An additional PCE is upland areas between sites (as described above) that allow for dispersal of the species.

- **San Joaquin Kit Fox (SJKF):** The SJKF was listed as endangered in 1967 by the USFWS. The species is found in a variety of habitats in the Central Valley area of California. Critical habitat has not been designated for the SJKF; therefore, PCEs have not been defined.

1.2. Scope of Assessment

1.2.1. Uses Assessed

Chlorophacinone is an anticoagulant rodenticide used for the control of nuisance mammals in areas such as buildings, transport vehicles, in and around agricultural fields, range and pasture, waterways, campgrounds, and recreational areas. Formulation types include: grain baits, bait blocks, all-in-one bait stations, treated artichoke bracts, and tracking powders. There are 16 currently registered labels that are relevant for use in California (twelve Section 3 and four Special Local Needs labels); of these, eight are restricted to indoor use. The target pests include: Norway rat (*Rattus norvegicus*), black rat (*R. rattus*), house mouse (*Mus musculus*), California and montane voles (*Microtus californicus* and *M. montanus),* California ground squirrels (*Spermophilus beecheyi),* black-tailed jack rabbit (*Lepus californicus*), and muskrat *(Ondatra zibethicus*), burying pocket gophers (*Geomys* spp. and *Thomomys* spp.*),* voles *(Microtus* spp.*),* deer mice (*Peromyscus* spp.) and chipmunks (*Eutanius* spp.). Concentrations in bait are either 0.005% or 0.010% chlorophacinone. Terrestrial application rates are equivalent to 0.0005 lbs a.i./acre, 0.001 lbs a.i./acre, or 0.03 lbs a.i./acre (treated artichoke bracts only).

1.2.2. Environmental Fate Properties of Chlorophacinone

Chlorophacinone, 2-[2-(4-chlorophenyl)-2-phenylacetyl]indan-1,3-dione, may be considered moderately persistent (aerobic soil metabolism mean half-life: 32.1 days) and hardly mobile (K_{oc} = 20,292 $L \cdot kg^{-1}$) in the environment. Scientifically sound data on the degradation of chlorophacinone in the environment were not available. Chlorophacinone degrades slowly by acid hydrolysis ($T_{1/2}$ = 232 d @ pH 5) with no measurable hydrolysis at higher pHs. The major route of dissipation appears to be consumption of bait by target organisms. The major route of dissipation on uneaten bait appears to be aerobic soil metabolism. The solubility in water at 25°C is 3.4 $mg \cdot L^{-1}$.

1.2.3. Evaluation of Degradates and Stressors of Concern

Chlorophacinone has two identified minor degradates: *o*-phthalic acid and *p*-chlorophenylphenyl acetic acid and no identified major degradates. A comparison of the structures of these two degradates with those of the parent and other anticoagulant rodenticides suggest that the toxic moiety is no longer present in these degradates. Hence, these two degradates were not considered in the risk assessment.

1.3. Exposure Assessment

1.3.1. Aquatic Exposures

Given that aquatic risks have not been exceeded in previous risk assessments, the exposure assessment for this use is being conducted at the first tier using the GENEEC model, version 2.0, dated August 1, 2001. GENEEC is a metamodel of the Tier 2 models PRZM and EXAMS and as such mimics the output of these models. Peak model-estimated environmental concentrations resulting from different chlorophacinone uses range from 0.011 to 0.275 µg/L. Aquatic exposure from floating bait stations (muskrat use) was estimated assuming a full bait canister (5 lbs bait) was emptied into OPP's standard pond and resulted in an estimated chlorophacinone concentration of 5.7 ng/L. Aquatic monitoring data for chlorophacinone are not available.

1.3.2. Terrestrial Exposures

For this assessment, it was assumed that terrestrial animals could be exposed through two different pathways. Animals may directly consume bait (primary consumption), or animals may consume contaminated carcasses either killed or scavenged by the consumer (secondary consumption). Primary consumption of chlorophacinone was modeled using baits containing 0.005% and 0.010% chlorophacinone. Ingestion was modeled both on a dose basis (mg a.i./kg-bwt) and a dietary basis (mg a.i./kg-diet). On a dose basis, EECs ranged from 1.7 to 12.6 mg a.i./kg-bwt and 3.4 to 28.2 mg a.i./kg-bwt for 0.005% and 0.010% bait, respectively. On a dietary basis, EECs were 50 mg a.i./kg-bait and 100 mg a.i./kg-bait depending on the concentration in the bait.

Secondary consumption was modeled assuming a chlorophacinone concentration of 4.1 mg a.i./kg-carcass, which was based on targeted monitoring studies. As with primary consumption, ingestion was modeled both on a dose basis (mg a.i./kg-bwt) and a dietary basis (mg a.i./kg-diet). For secondary exposure estimation, there was no differentiation between bait concentrations. On a dose basis, EECs ranged from 0.06 to 6.18 mg a.i./kg-bwt/day. On a dietary basis, the carcass concentration of 4.1 mg a.i./kg-carcass was used.

1.4. Toxicity Assessment

1.4.1. Terrestrial Animals

The assessment endpoints include direct toxic effects on survival, reproduction, and growth of individuals, as well as indirect effects, such as reduction of the food source and/or modification of habitat. Federally-designated critical habitat has been established for the AW and CTS. Primary constituent elements (PCEs) were used to evaluate whether chlorophacinone has the potential to modify designated critical habitat. The Agency evaluated registrant-submitted studies and data from the open literature to characterize chlorophacinone toxicity. The most sensitive toxicity value available from acceptable or supplemental studies for each taxon relevant for estimating potential risks to the assessed species and/or their designated critical habitat was used.

Chlorophacinone is moderately to highly acutely toxic to birds based on the available LD_{50} (258 to 495 mg a.i./kg-bwt) and LC_{50} (56 to 426 mg a.i./kg-diet) toxicity data. The submitted avian reproduction study indicated no effects were observed at a dietary rate of 1 mg a.i./kg diet (NOAEC). Chlorophacinone is very highly acutely toxic to mammals based on the available LD_{50} (1.94 to 10.95 mg a.i./kg-bwt) and LC_{50} (1.14 to 1.26 mg ai/kg-diet) toxicity data. The submitted mammalian developmental study indicated no frank reproductive effects at a consumption rate of 0.010 mg a.i./kg-bw (NOAEL).

In addition to the standard toxicity studies, secondary toxicity studies were submitted to the Agency for several species of carnivorous birds and mammals. In these studies, small mammals were fed diets containing 0.005 or 0.010% chlorophacinone for 5 to 10 days till death or sacrifice. These chlorophacinone-contaminated carcasses were fed to the carnivorous birds and mammals for 1 to 10 days, followed by observation periods lasting 10 to 60 days during which 'clean' carcasses were fed to the test animals. In the reviewed carnivorous bird studies, no mortality of the tested birds was observed, although some birds did show symptoms of anticoagulant poisoning. In the reviewed carnivorous mammal studies, symptoms of anticoagulant poisoning and mortality were observed.

A two-phase study (survival and larval growth) on a burying beetle, *Nicrophorus orbicollis*, evaluated the impacts of chlorophacinone. The first phase [investigating effects of chlorophacinone on the emergence (number of beetles produced), growth, and sex ratio of burying beetles raised on chlorophacinone-dosed rat carcasses] resulted in reductions of numbers of beetles produced and total brood weight. Concentrations of chlorophacinone in the rat carcasses were not available. In the second phase of the study, no differences were found in survival and reproductive success of burying beetle adults fed chlorophacinone-dosed ground beef (3.0 mg a.i./kg-beef) or control ground beef for 28 days prior to being provided an undosed quail carcass for brooding of young.

A 14-day toxicity test on the earthworm (*Eisenia foetida*) resulted in an $LC_{50} > 1000$ mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (5 and 15% mortality at 556 and 100 mg a.i./lk-soil). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil.

Reported incident data documented several instances of mortality to both birds and mammals; including several mortalities of the endangered San Joaquin kit fox. The kit fox mortalities were attributed to both primary and secondary exposures. Other mortalities include animals that would be expected to consume bait directly (*e.g.*, squirrels and wild turkeys) and those that would be expected to consume contaminated carcasses (*e.g.*, badgers and red-tailed hawks).

1.4.2. Aquatic Animals

For acute aquatic affects, chlorophacinone is classified as highly toxic to freshwater fish (LC_{50} = 450 and 710 µg a.i./L) and invertebrates (EC_{50} = 640 µg a.i./L). No data are available to evaluate chronic effects to freshwater fish or invertebrates. No data are available to evaluate acute or chronic effects to estuarine/marine fish or invertebrates.

1.4.3. Plants

No toxicity data are available for aquatic or terrestrial plants. Given the mode of action of chlorophacinone, toxicity to plants is expected to be low.

1.5. Measures of Risk

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

1.6. Risk Conclusions

Based on the best available information, the Agency makes a **May Affect, and Likely to Adversely Affect** determination for the SMHM, SJKF, AW, and CTS from the all uses of chlorophacinone. Additionally, the Agency has determined that there is the potential for modification of designated critical habitat for the AW and CTS from the use of chlorophacinone. A summary of the risk conclusions and effects determinations for each listed species assessed here and their designated critical habitat is presented in **Table 1-1** and in **Table 1-2**. Use-specific determinations are provided in **Table 1-3** and **Table 1-4**. Given the LAA determination for the SMHM, SJKF, AW, and CTS and potential modification of designated critical habitat for the AW and CTS, a description of the baseline status and cumulative effects for the SMHM, SJKF, AW, and CTS is provided in **Attachment II**.

Table 1-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.

Species	Effects Determination	Basis for Determination
		Potential for Direct Effects
Salt marsh harvest mouse (SMHM) (*Reithrodontomys raviventris*)	May Affect, Likely to Adversely Affect (LAA)	Risk assessment indicates use of chlorophacinone will potentially result in direct effects to the SMHM from acute and chronic toxicity. Lines of evidence include: • the listed species and chronic LOCs are exceeded for the SMHM based on consumption of bait , • the likelihood of an individual effect (mortality) is approximately 1 in 1.0 based on gavage and dietary exposure, • mortality through primary exposure to chlorophacinone was documented through low LD_{50} and LC_{50} values obtained in toxicity studies, high mortality percentages observed in field efficacy trials, and mortality of the rodents when fed

Table 1-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.		
Species	**Effects Determination**	**Basis for Determination**
		chlorophacinone for the secondary exposure trials, and • reported incidents of mortality of small non-target herbivorous mammals after consumption of chlorophacinone bait.
		Potential for Indirect Effects
		Food sources Risk assessment indicates vegetative food sources are not expected to be affected by chlorophacinone application; however, terrestrial invertebrate prey populations may be reduced. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Adverse effects to birds and mammals may result in a reduction of abandoned bird and mammal nests, which are used as nest sites by the SMHM. Acute RQs for birds and mammals, and acute and chronic RQs for mammals, exceed LOCs. Therefore, use of chlorophacinone may adversely modify the habitat of the SMHM by reducing the availability of nest sites.
San Joaquin Kit Fox (SJKF) (*Vulpes macrotis mutica*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of chlorophacinone will potentially result in direct effects to the SJKF from acute and chronic toxicity. Lines of evidence include: • the listed species and chronic LOCs are exceeded for the SJKF based on consumption of bait, • the likelihood of an individual effect (mortality) is approximately 1 in 1.0 based on gavage and dietary exposure to bait, • mortality through primary exposure to chlorophacinone was documented through low LD_{50} and LC_{50} values obtained in toxicity studies, high mortality percentages observed in field efficacy trials, and mortality of the rodents when fed chlorophacinone for the secondary exposure trials, and • listed species, restricted use, and chronic LOCs are exceeded for the SJKF based on consumption of contaminated carcasses. • mortality through secondary exposure to chlorophacinone was documented for the secondary exposure trials where 43% to 88% of the secondary consumers died, and • EIIS contains reports of eleven incidents in the US that were considered probable or highly probable for death due to chlorophacinone. Mortalities included species that were likely primary consumers of the bait (*e.g.*, grey squirrel and wild turkey) and carnivorous species (*e.g.*, badger and red-tailed hawk) likely to have preyed upon the granivorous individuals. • incident reports included six endangered San Joaquin kit fox mortalities were included in the incident database. Four kit foxes had documented concentrations of chlorophacinone in the liver.
		Potential for Indirect Effects

Table 1-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.		
Species	**Effects Determination**	**Basis for Determination**
		Food sources This risk assessment indicates vegetative food sources are not expected to be affected by chlorophacinone application; however, terrestrial vertebrate and invertebrate prey populations may be reduced. For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the chance of an individual mortality occurrence is very high for both birds and mammals (greater than 1 in 3 at the acute RQ), thus there is a high likelihood that the availability of prey for SJKF use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the SJKF. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Risk assessment indicates use of chlorophacinone is not expected to adversely modify the habitat of this species by reducing the availability of nest sites. This conclusion is based on acute RQs for birds and mammals, and acute and chronic RQs for mammals, that exceed the LOC. Adverse effects to birds and mammals may result in a reduction of abandoned bird and mammal nests, which are used as nest sites by this species.
Alameda Whipsnake (AW) (*Masticophis lateralis euryxanthus*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects** This risk assessment indicates use of chlorophacinone will potentially result in direct effects to the AW from chronic toxicity. Lines of evidence include: • the chronic LOCs are exceeded for the AW based on consumption of chlorophacinone-contaminated prey, • the likelihood of an individual effect (mortality) is approximately 1 in 24 based on dietary exposure. **Potential for Indirect Effects** ***Food sources*** Risk assessment indicates terrestrial vertebrate and invertebrate prey populations may be reduced. For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the chance of an individual mortality occurrence is very high for both birds and mammals (greater than 1 in 3 at the acute RQ), thus there is a high likelihood that the availability of prey for AW use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence of mortality of potential prey animals exposed to chlorophacinone. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Risk assessment indicates use of chlorophacinone may adversely modify the habitat of this species by reducing the availability of burrows. This conclusion is based on acute and chronic RQs for mammals that exceed the LOC. Adverse effects to mammals may result in a reduction of available burrows, which are used as shelters by this species.

Table 1-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.		
Species	**Effects Determination**	**Basis for Determination**
California Tiger Salamander (CTS) (*Ambystoma californiense*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects** This risk assessment indicates use of chlorophacinone will potentially result in direct effects to the CTS from chronic toxicity. Lines of evidence include: • the chronic LOCs are exceeded for the CTS based on consumption of chlorophacinone-contaminated prey, • the likelihood of an individual effect (mortality) is approximately 1 in 24 based on dietary exposure. **Potential for Indirect Effects** ***Food sources*** Risk assessment indicates terrestrial vertebrate and invertebrate prey populations may be reduced. For birds (surrogate for herptiles) and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the chance of an individual mortality occurrence is very high for both birds and mammals (greater than 1 in 3 at the acute RQ), thus there is a high likelihood that the availability of prey for CTS use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the CTS. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Risk assessment indicates use of chlorophacinone may adversely modify the habitat of this species by reducing the availability of burrows. This conclusion is based on acute and chronic RQs for mammals that exceed the LOC. Adverse effects to mammals may result in a reduction of available burrows, which are used as shelters by this species.

Table 1-2. Effects Determination Summary for the Critical Habitat Impact Analysis		
Designated Critical Habitat for:	**Effects Determination**	**Basis for Determination**
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	Habitat Modification	This risk assessment indicates use of chlorophacinone may adversely modify the critical habitat of this species by reducing the availability of small mammal burrows. This may result in modification of PCE 3: "Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2." In addition, the availability of prey may be reduced in the critical habitat by toxicity to small birds, mammals, reptiles, and terrestrial-phase amphibians.
California Tiger Salamander (*Ambystoma californiense*)	Habitat Modification	This risk assessment indicates use of chlorophacinone may adversely modify the critical habitat of this species by reducing the availability of small mammal burrows. This may result in modification of PCE 3: "Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2." In addition, the availability of prey may be reduced in the critical habitat by toxicity to small mammals, reptiles, and terrestrial-phase amphibians.

Table 1-3. Use Specific Summary of The Potential for Adverse Effects to Aquatic Taxa						
Uses	**Potential for Effects to Identified Taxa Found in the Aquatic Environment:**					
	CTS-CC, CTS-SC, and CTS-SB, and Freshwater Vertebrates[1]		**Freshwater Invertebrates[2]**		**Vascular Plants[3]**	**Non-vascular Plants[3]**
	Acute	**Chronic**	**Acute**	**Chronic**		
0.005% a.i. bait (broadcast, spot, station)	No	No	No	No	No	No
0.010% a.i. bait (broadcast, spot, station)	No	No	No	No	No	No
0.005% a.i. in floating bait station (muskrat use)	No	No	No	No	No	No

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

Table 1-4. Use Specific Summary of The Potential for Adverse Effects to Terrestrial Taxa													
Uses	**Potential for Effects to Identified Taxa Found in the Terrestrial Environment:**												
	SMHM and Small Mammals[1]		**SJKF and Large Mammals [2]**		**Small Birds[3]**		**CTS-CC, CTS-SC, CTS-SB and Amphibians[4]**		**AW and Reptiles[5]**		**Invertebrates (Acute)[6]**	**Dicots[7]**	**Monocots[7]**
	Acute	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**			
0.005% a.i. bait (broadcast, spot, station)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
0.010% a.i. bait (broadcast, spot, station)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
0.005% a.i. in floating bait station (muskrat use)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No

1 A yes in this column indicates a potential for direct effects to SMHM and indirect effects to SMHM, SJKF, AW, CTS-CC, CTS-SC, and CTS-SB.
2 A yes in this column indicates a potential for direct and indirect effects to SJKF.
3 A yes in this column indicates a potential for indirect effects to the SMHM, SJKF, AW, CTS-CC, CTS-SC, and CTS-SB.
4 A yes in this column indicates a potential for direct effects to CTS-CC, CTS-SC, CTS-SB, and indirect effects to CTS-CC, CTS-SC, CTS-SB, and AW.
5 A yes in this column indicates the potential for direct and indirect effects to AW, and other reptiles.
6 A yes in this column indicates a potential for indirect effects to SMHM, SJKF, AW, CTS-CC, CTS-SC, and CTS-SB.
7 A yes in this column indicates a potential for indirect effects to SMHM, CTS-CC, CTS-SC, CTS-SB.

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

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

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

2. Problem Formulation

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

2.1. Purpose

The purpose of this endangered species assessment is to evaluate potential direct and indirect effects on individuals of the federally threatened Alameda whipsnake (AW), the federally endangered salt marsh harvest mouse (SMHM), California tiger salamander (CTS) [the federally endangered Sonoma County Distinct Population Segment (CTS-SCDPS), the federally endangered Santa Barbara DPS (CTS-SBDPS), and the federally threatened Central California DPS (CTS-CCDPS)], and the federally endangered San Joaquin kit fox (SJKF) arising from FIFRA regulatory actions regarding use of chlorophacinone in and around buildings, transport vehicles, in and around agricultural fields, sewers, rangeland, pastures, forest tree plantations, campgrounds, recreational areas, and waterways and wetlands adjacent to agricultural sites. This ecological risk assessment has been prepared consistent with a settlement agreement in the case *Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 07-2794-JCS).

In this assessment, direct and indirect effects to the AW, SMHM, CTS, and SJKF and potential modification to designated critical habitat for the AW and CTS are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA 2004a).
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 chlorophacinone is based on an action area. The action area is the area directly or indirectly affected by the federal action, as indicated by the exceedance of the Agency's Levels of Concern (LOCs). It is acknowledged that the action area for a national-level FIFRA regulatory decision associated with a use of chlorophacinone 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 AW, SMHM, CTS, and SJKF and their designated critical habitat within the state of California. As part of the "effects determination," one of the following three conclusions will be reached separately for each of the assessed species in the lawsuits regarding the potential use of chlorophacinone in accordance with current labels:

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

Additionally, for habitat and PCEs, a "No Effect" or a "Habitat Modification" determination is made. A description of routine procedures for evaluating risk to the San Francisco Bay Species are provided in **Attachment I**.

2.2. Scope

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

Chlorophacinone is an anticoagulant rodenticide used for the control of nuisance mammals in areas such as buildings, transport vehicles, in and around agricultural fields, range and pasture, waterways, campgrounds, and recreational areas.

Although current registrations of chlorophacinone allow for use nationwide, this ecological risk assessment and effects determination addresses currently registered uses of chlorophacinone in portions of the action area that are reasonably assumed to be biologically relevant to the AW, SMHM, CTS, and SJKF and their designated critical habitat. Further discussion of the action area for the AW, SMHM, CTS, and SJKF and their critical habitat is provided in **Section 2.5**.

2.2.1. Mechanism of Action

Chlorophacinone is an indandione anticoagulant rodenticide. It uncouples oxidative phosphorylation depressing hepatic synthesis of prothrombin and clotting factors VII, IX and X and, it causes direct damage to capillary permeability. The ultimate effect is widespread internal hemorrhage. In rodents, indandiones also cause neurologic and cardiopulmonary injuries which often lead to death before hemorrhage occurs (World Health Organization, 2010).

Anticoagulants are vitamin-K antagonists that disrupt normal blood-clotting mechanisms and induce capillary damage. Typically, death is delayed for four to ten or more days after a lethal dose is ingested, and animals may continue to feed and move about until shortly before death. Death results from hemorrhage, and exposed animals may exhibit behavior that may make them more susceptible to predation (Cox and Smith, 1992). This may result in secondary exposure to predatory animals. Chlorophacinone is metabolized by vertebrate animals that have eaten bait, but some is sequestered in various body tissues for days or weeks.

2.2.2. Environmental Fate and Transport Properties

Chlorophacinone, 2-[2-(4-chlorophenyl)-2-phenylacetyl]indan-1,3-dione, may be considered moderately persistent (aerobic soil metabolism half-lives on the order of weeks) and hardly mobile (K_{oc} = 20,300 $L \cdot kg^{-1}$) in the environment according to the FAO soil mobility

classification (Kashuba and Spatz, 2006). The major route of dissipation appears to aerobic soil metabolism.

The molecule has two chiral centers, one on the 9 carbon of the indanone and the second at the carbon which joins the two phenyl rings (**Figure 2.1**). The stereo chemistry at these two chiral centers is not known and no data are available to describe the differential stereochemical properties.

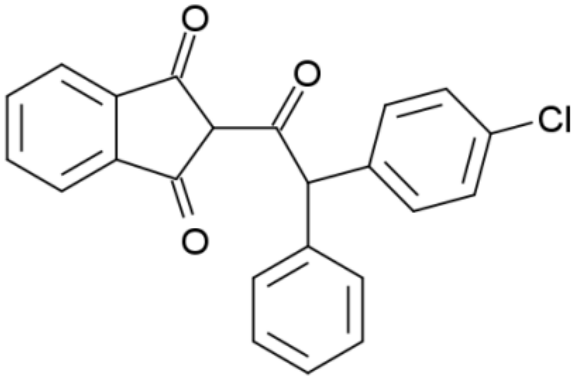


Figure 2.1. Structure of chlorophacinone.

Physical and chemical properties of chlorophacinone are summarized in **Table 2.1**. There is no evidence that chlorophacinone degrades by hydrolysis at pHs of 7 and 9. At pH 5, chlorophacinone degrades slowly, with a half-life of 232 d. Previous assessments indicated a rapid degradation of chlorophacinone by photolysis; however, both of these studies used acetone as a solvent to introduce chlorophacinone into the test system. As acetone is a strong photosensitizer, the results of these are likely not related to actual photodegradation rates in the environment and this study is now classified as invalid. The average rate of metabolic degradation in soils is 32.1 days based on two studies. Data on aquatic metabolism are not available; therefore, actual persistence in water/sediment is not known. Based on a octanol-water partition coefficient of 94, chlorophacinone is unlikely to bioaccumulate.

Table 2.1 Physical-chemical Properties of Chlorophacinone

Study	Value and units	Source
CAS Number	3691-35-8	
SMILES Code	c12ccccc1C(=O)C(C(=O)C(c3ccccc3)(c4cc(Cl)ccc4))C2(=O)	
Molecular weight	374.81	calculated
Hydrolysis	pH 5: 232 d pH 7: no evidence of degradation pH 9: no evidence of degradation	MRID 42205501
Solubility	3.43 mg/L @ 25ºC	MRID 42237401
Aerobic Soil Metabolism	$T_{1/2}$ = 47.2 days; sandy clay loam $T_{1/2}$ = 17.0 days; sandy loam	MRID 43159801

Table 2.1 Physical-chemical Properties of Chlorophacinone		
Study	**Value and units**	**Source**
Soil Water Partition Coefficient	Sassafras sand: K_f = 56; 1/n = 1.09 Hesperia loam: K_f = 126; 1/n = 1.23 Sequatchie sandy clay loam: K_f = 183; 1/n = 1.22 Sharkey clay: K_f = 1000; 1/n = 1.14 K_{oc} = 20,299 $L \cdot kg^{-1}$	MRID 42666001 MRID 42205503
Vapor pressure	3.58×10^{-6} torr	MRID 42237401
Henry's law constant	5.12×10^{-7} $atm \cdot m^3 \cdot mol^{-1}$	calculated*
K_{ow}	94.5	MRID 42237401
* the Henry's Law constant was estimated as the ratio of the vapor pressure to the solubility.		

Chlorophacinone is hardly mobile in the environment based on four batch equilibrium studies. Adsorption to soil is significantly correlated with soil organic carbon content with a K_{oc} of 20,300 $L \cdot kg^{-1}$ based on the regression of the adsorption coefficient, K_d, with the soil organic carbon content (R^2 = 99.4%). Due to chlorophacinone's limited immobility in soil, it is reasonable to conclude it is relatively immobile within bait formulations. Chlorophacinone baits typically retain the parent compound even after exposure to wet weather and moisture (Merson and Byers 1985). This means that movement in the environment will be minimal while chlorophacinone is still absorbed to the bait or on eroded sediment. Any material that is transported into water bodies by erosion may remain sorbed onto soil particles and settle to the bottom of the receiving lake or stream bed. Chlorophacinone has a relatively low octanol-water partition coefficient of 94, and consequently is not expected to bioaccumulate. The vapor pressure is also low (3.58×10^{-6} torr), indicating that chlorophacinone is not expected to volatilize.

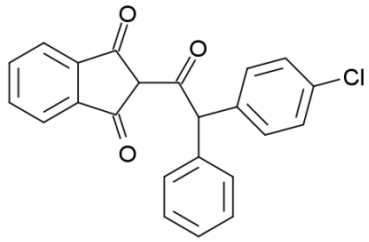
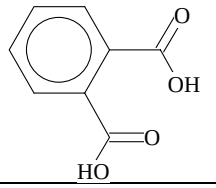
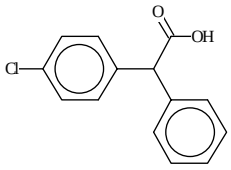
Chlorophacinone residues can be expected to occur in carcasses of animals that have consumed lethal levels of chlorophacinone (MRID 155540; Dowding *et al*. 2010; MRID 47333603). Further discussion of the implications of chlorophacinone residues in carcasses will be limited to **Section 2.4.1**. In a supplemental terrestrial field dissipation study that focused on residues in prairie dogs (MRID 45855101), no dissipation of chlorophacinone could be detected in grain samples for up to 10 days. Apparent concentrations increased over this time period, which was likely either due to insect consumption of the internal part of the grain or changes to bait water content. The ability of this study to follow the dissipation of chlorophacinone on grain samples was hampered by consumption of the grain samples. This suggests that the primary route of dissipation of chlorophacinone may be consumption of the treated grain.

2.2.3. Evaluation of Degradates

Chlorophacinone has two identified minor degradates: *o*-phthalic acid and *p*-chlorophenylphenyl acetic acid (**Table 2.2**). Both degradates were found in the hydrolysis study at pH 5 and the aerobic soil metabolism study. A comparison of the structures of these two degradates with those of the parent and other anticoagulant rodenticides suggest that the toxic moiety is no longer present in these degradates.

There were three major degradates, CO_2 and two that were not identified. The first unidentified degradate was observed at 11.7% in the pH 5 hydrolysis study, and 0.9% from aerobic soil metabolism study. The second unidentified degradate was material at the origin of the thin-layer chromatograms at 10.5%. Occurrence at the origin of the chromatogram suggests that material was either very polar, or very immobile. Often this material is composed of a mixture of compounds, so that it may not, in fact be, a single major degradate. Since the structures for these degradates are not known, the nature of their toxicity cannot be assessed.

Table 2.2 Major and minor chlorophacinone degradates and the maximum amounts found in degradation studies.

Compound	Hydrolysis	Aerobic Soil Metabolism
Chlorophacinone (parent) 		
o-phthalic acid 	0.7% @ 30 d	9.8% @70 d
p-chlorophenylphenyl acetic acid 	0.4% @ 14 d	5.4% @ 14 d
Unknown 1	11.7% @ 14 d (pH 5)	0.9% @ 30 d
Unknown 2	--	10.5% @ 30 d
CO_2	--	64% @ 70 d

2.2.4. Evaluation of Mixtures

The Agency does not routinely include, in its risk assessments, an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of active ingredients (that

is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively in accordance with the Agency's Overview Document and the Services' Evaluation Memorandum (USEPA, 2004a; USFWS/NMFS/NOAA, 2004).

Chlorophacinone does not have registered products that contain multiple active ingredients, so an analysis of available data with multiple active ingredients is not necessary. The risk assessment based on the toxicity of the single active ingredient, chlorophacinone, is appropriate.

2.2.5. Summary of Previous Assessments

Over the last 20 years, several ecological risk and endangered species assessments have been conducted by the Agency on chlorophacinone. In addition, a biological opinion was issued on several listed species. These assessments are described below.

The U.S. Fish and Wildlife Service (FWS) addressed the risk of chlorophacinone use on endangered species in a Biological Opinion (BO) issued in March of 1993. The FWS produced the BO in response to a 1991 request by the EPA for formal consultation on 16 registered vertebrate pest agents. Specific labels and application rates that were evaluated in the BO were not listed. The BO included an evaluation of the use of chlorophacinone for:

- Norway rats, roof rats and house mice in and around homes, industrial and agricultural buildings;
- pocket gophers applied as bait in underground runways;
- mice and voles in Idaho and Delaware;
- orchard mice in Delaware, Connecticut and Arizona;
- deer mice in non-crop areas in Florida;
- ground squirrels in Arizona;
- deer mice, house mice and pocket gophers in California; and
- nuisance bats in Georgia, Connecticut and Colorado in domiciles and other buildings.

The BO concluded that chlorophacinone will have no effect on listed aquatic species when used as bait. For terrestrial animals, the BO discussed concerns for primary and secondary poisoning. The FWS issued a jeopardy call for species listed in **Table 2.3**; further detail on individual species is provided in the BO (http://www.fws.gov/sacramento/es/programmatic_consultations.htm). The profile of registered chlorophacinone uses has changed since the 1993 BO was issued. For example, in 1993 at the time of the BO, several ground sprays (*i.e.*, broadcast spray not in a bait formulation) uses were registered and there were uses for registered for nuisance bats. Currently, no ground sprays are registered and there are no uses registered for nuisance bats as a target species.

Table 2.3 Jeopardy Calls for Species Evaluated in the 1993 FWS Biological Opinion on Chlorophacinone Use			
MAMMALS			
Alabama beach mouse	J	Jaguarundi	J
Amargosa vole	J	Louisiana black bear	NJ
Anastasia Island beach mouse	J	Morro Bay kangaroo rat	J
Carolina northern flying squirrel	J	Ocelot	J
Choctawhatchee beach mouse	J	Perdido Key beach mouse	J
Florida panther	J	Point Arena mountain beaver	J
Florida salt marsh vole	J	Salt marsh harvest mouse	J
Fresno kangaroo rat	J	San Joaquin kit fox	J
Giant kangaroo rat	J	Southeastern beach mouse	J
Gray wolf	NJ	Stephen's kangaroo rat	J
Grizzly bear	J	Tipton kangaroo rat	J
Hualapai Mexican vole	J	Utah prairie dog	NJ
BIRDS			
Audubon's crested caracara	J		
REPTILES			
Eastern indigo snake	NJ		
Puerto Rican boa	NJ		
Virgin Islands tree boa	NJ		
J= Jeopardy ; NJ = No Jeopardy			

The Reregistration Eligibility Decision (RED) for chlorophacinone was published in 1998 as part of the rodenticide cluster (USEPA, 1998b). For birds and mammals, the RED found that there was a high risk of primary and secondary poisoning, especially to mammals. Toxicity to aquatic organisms ranged from moderate to very high, but aquatic exposure was expected to be minimal. The RED did contain mitigation measures for all rodenticides, but these measures were modified after further analysis within OPP and collaboration with a stakeholder group.

Another OPP risk assessment, titled “Potential Risks of Nine Rodenticides to Birds and Non-target Mammals: a Comparative Approach” (USEPA 2004b), evaluated primary and secondary exposure of birds and mammals to chlorophacinone and eight other rodenticides. This document was developed to provide further guidance in developing mitigations for all rodenticides. This assessment determined that the greatest risk of chlorophacinone use to non-target animals is via primary and secondary exposure to mammals. Risk associated with primary and secondary exposure to birds was also of concern. The assessment also specified a number of factors contributing to uncertainty in assessing anticoagulant rodenticides. Those factors that contributed the most uncertainty were: (1) missing data, including acute, chronic, and secondary toxicity as well as data regarding retention of some active ingredients in the liver, blood, and other body tissues; (2) the variable quality and

quantity of existing data on metabolism and retention times in rodents and non-target species; (3) specific use information by formulation, including typical amounts applied by use site, seasonally, and annually; distances applied from buildings; amounts used in rural versus urban areas; use by Certified Applicators versus homeowners and other non-certified applicators; and other such relevant information; (4) information on the number and species of birds and non-target mammals frequenting baited areas and the likelihood of their finding and consuming bait or poisoned primary consumers in the various use areas; (5) methods to determine liver concentration(s) and total body burdens of rodenticide that would corroborate death or even if such a cause-effect relationship is appropriate (e.g., the "threshold of toxicity" concentration); (6) not accounting for the impacts of sub-lethal effects on reproduction and non-target mortality (e.g., clotting abnormalities, hemorrhaging, stress factors including environmental stressors, such as adverse weather conditions, food shortages, and predation); (7) not accounting for bioaccumulation of repeated sub-lethal exposures to bait or poisoned rodents utilized as food by predators and scavengers; and (8) lack of incident reporting. All of the above issues remain as uncertainties for this assessment. Based on the conclusions of this document for the rodenticide cluster were finalized. (USEPA 2008).

EFED has completed several more recent assessments for chlorophacinone in the last five years. In 2007, EFED assessed (D334201) Rozol Vole Bait (EPA Registration No. 7173-242). This Section 3 assessment was for the expansion of the Special Local Needs (SLN) labels for vole control in fruit crops and non-crop areas including tree farms, commercial nurseries, and/or tree plantations to a national scale. The evaluated label also added outdoor non-crop sites for control of rats and mice, which has not previously been registered for any chlorophacinone product. Proposed application methods for this use included ground and aerial application of bait. The assessment indicated that the new and expanded uses would vastly increase exposure and risk to listed and non-listed non-target animals, including local and migratory birds, mammals, reptiles and possibly amphibians and that take of listed species was likely to occur. The assessment concluded that 0.005% chlorophacinone food baits pose low to moderate acute risk to birds but high primary and secondary risks to non-target mammals. Risks to aquatic organisms were not assessed.

Another new use application in 2008 (D351036) proposed an expanded use for Rozol Vole Bait (EPA Registration No. 7173-242). The added uses were for broadcast applications for the control of pine, meadow and mountain voles in pome fruit and stone fruit tree orchards, commercial nurseries, tree and forestry plantations and Christmas tree farms for 36 additional states where it was not previously registered, broadcast applications to forestry plantations where hand, spot baiting was previously required, and allow application via bait stations and hand spot baiting in nurseries, forestry, lawns, golf courses, parks, other ornamental turf areas, ornamental flower and shrub gardens, commercial nurseries, Christmas Tree farms and crop fence lines and borders and buffer strips adjacent to crops. The assessment found that dietary RQs exceed the Agency's LOC for listed and non-listed birds and non-target mammals that eat bait. Risks to aquatic species were found to be low. Special concern was noted for three federally listed species: the Amargosa vole (*Microtus californicus scirpensis*), Florida salt marsh vole (*Microtus pennsylvanicus dukecampbelli*) and the Hualapai Mexican vole (*Microtus mexicanus hualpaiensis*). The

assessment noted that particular care should be taken so that these species are not mistaken for target species.

In 2008, EFED assessed a new used of chlorophacinone to control chipmunks (D336220) for JT Eaton AC Formula Ready-To-Use Rodenticide. The proposed label change specifies the placement of up to three packets of this rodenticide on a securing rod inside a tamper resistant bait stations to be spaced every 10 to 15 feet around the outside or a house or building, on an as needed basis. This use was found to pose direct and indirect risks to birds, mammals and possibly reptiles, including Federally Listed species protected under the Endangered Species Act.

In November 2008, EFED evaluated a proposed expansion of uses of chlorophacinone for black-tailed prairie dogs (DP350010). Risks were identified for listed and non-listed birds and mammals that eat bait. In addition, secondary and tertiary risk is likely for listed and non-listed predators and scavengers as chlorophacinone residues will be present in body tissues of target and nontarget primary consumers for days or weeks after consuming bait. Chlorophacinone is highly toxic to fish and aquatic invertebrates but EECs in the water column were expected to be low; therefore, risks to fish and aquatic invertebrates were presumed minimal. An endangered species of special concern (black-footed ferret, *Mustela nigripes*) was noted. Black-footed ferret may consume poisoned prairie dogs or non-target animals that contain chlorophacinone residue in body tissues (secondary exposure). The black-footed ferret are most likely found residing near prairie dog towns as they depend on prairie dogs for food and utilize prairie dog borrows for shelter (USFWS 2000). The assessment offered the following recommendations for risk mitigation: (1) requiring carcass searches at 1-to-2 day intervals; (2) requiring non-target animal carcasses be provided to proper authorities for identification and tissue-residue analysis; (3) requiring a discrete application interval so that full monitoring and carcass removal from the initial application may be completed; and (4) taking into consideration the black-footed ferret because it is an endangered species, preys on the target species as a primary food source and utilizes their burrows. The resulting product label for the black-tailed prairie dog use reflected recommendations from the assessment in the following ways: (1) requiring an initial carcass search 5 to 10 days after application and a second carcass search 14 to 21 days after application; (2) allowing reapplication "several weeks" after initial application; and (3) stating: "[d]o not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office."

An endangered species risk assessment for chlorophacinone was completed in 2010 (USEPA 2010b). This ecological risk assessment and effects determination was specific to Rozol Prairie Dog Bait (EPA Reg. No. 7173-286) to address potential product-specific risks raised in pending litigation, Defenders of Wildlife v. U.S. EPA[1]. In this assessment, a "may affect, and likely to adversely affect" (LAA) determination was made for the following federally listed species: grizzly bear (*Ursus arctos horribilis*), American burying beetle (*Nicrophorus americanus*), Salt Creek tiger beetle (*Cicindela nevadica lincolniana*), California condor (*Gymnogyps californianus*), whooping crane (*Grus americana*), Eskimo curlew (*Numenius borealis*), northern Aplomado falcon (*Falco femoralis septentrionalis*), black-footed ferret (*Mustela nigripes*), Chiricahua leopard frog (*Rana chiricahuensis*), jaguar (*Panthera onca*), Gulf Coast jaguarundi (*Herpailurus*

[1] Defenders of Wildlife v. U.S. EPA, Case No. 09-1199 (D.C. Cir., 2009); Defenders of Wildlife v. Jackson, Case No. 09-cv-1814 (D.D.C., 2009); NRDC v. U.S. EPA, Case No. 10-cv-1063, (D.D.C., 2010).

yagouaroundi cacomitli), Canada lynx (*Lynx Canadensis*), Preble's meadow jumping mouse (*Zapus hudsonius preblei*), ocelot (*Leopardus pardalis*), Mexican spotted owl (*Strix occidentalis lucida*), piping plover (*Charadrius melodus*), New Mexican ridge-nosed rattlesnake (*Crotalus willardi obscurus*), Sonora tiger salamander (*Ambystoma tigrinum stebbinsi*) black-capped vireo (*Vireo atricapilla*), golden-cheek warbler (*Dendroica chrysoparia*), and gray wolf (*Canis lupus*). In addition, the assessment found the action was expected to result in modification of designated critical habitat for the Salt Creek tiger beetle, whooping crane, Canada lynx, Preble's meadow jumping mouse, Mexican spotted owl, piping plover, and New Mexican ridge-nosed rattlesnake because these critical habitats overlap with the use area of Rozol Prairie Dog Bait.

In 2011, a proposed new use for control of California ground squirrels was evaluated by EFED. A final decision regarding the registration of this use is still pending. This risk assessment (D377940) indicates that chlorophacinone will directly and indirectly impact both listed and non-listed terrestrial animals including birds, mammals, reptiles, amphibians and invertebrates. The risks posed by chlorophacinone include both primary exposure (consumption of bait) and secondary exposure (consumption of chlorophacinone-contaminated carcasses). The proposed use also presents a high level of indirect risk to terrestrial plants that rely on animals for pollination and seed dispersal through the potential for reduction in the animals that perform those functions. Risks to aquatic organisms, as well as to aquatic plants, are not expected. The lines of evidence supporting the conclusion of risk include: 11 incidents in the US reported in EIIS that were considered probably or highly probable for death due to chlorophacinone. Mortality through primary exposure to chlorophacinone, mammalian mortality through secondary exposure, and avian mortality through secondary exposure to chlorophacinone were documented in the assessment. Empirical data (whole body residue concentrations of chlorophacinone from field and laboratory trials) were used in the estimation of secondary exposure for carnivores and scavengers. Use of these data in the risk estimation process did result in the exceedance of LOCs.

2.2.6. Use Characterization

2.2.6.a. Label Summaries

Analysis of labeled use information is the critical first step in evaluating the federal action. The current labels for chlorophacinone 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.

There are currently 20 active registrations for chlorophacinone end-use products that may be used in California. Eight are restricted to indoor use (**Table 2-4**) and the remaining 12 products have registered outdoor uses (**Table 2-5**). The basic types of use patterns for chlorophacinone are indoor, outdoor bait station, outdoor spot baiting, and outdoor broadcast baiting.

Table 2-4. Chlorophacinone end use products with only indoor use.		
Registration Number	**Product Name**	**%ai**
56-56	Answer For Mice	0.005
56-69	Answer for Rats	0.005
7173-113	Rozol Tracking Powder	0.2
7173-172	Rozol Blue Tracking Powder	0.2
7173-287	Chlorophacinone Bait Station	0.005
7173-289	Chlorophacinone Block 0803 Bait Station	0.005
7173-293	Chlorophacinone Refillable Bait Station	0.005
7173-295	Chlorophacinone Block 0803 Bait Station II	0.005

Table 2-5. California Chlorophacinone end use products with outdoor uses				
Reg. Num. (date stamped)	**Product Name**	**% a.i.**	**Target species**	**Use patterns applicable to CA**
56-58 (Apr 4, 2011)	AC Formula 90	0.005	Norway rat Roof rat House mouse	- In and around (within 50 ft) homes, industrial buildings, commercial buildings, and public buildings - bait station mandatory for above ground, outdoor use
56-70 (Apr 4, 2011)	AC Formula 90 Ready To Use	0.005	Norway rat Roof rat House mouse	- In and around (within 50 ft) homes, industrial buildings, commercial buildings, and public buildings - Inside transport vehicles - bait station mandatory for above ground, outdoor use
7173-151 (Aug 17, 2010)	Rozol Pellets	0.005	Norway rat Roof rat House mouse	- In and around (within 50 ft) homes, industrial buildings, commercial buildings, and public buildings - Inside transport vehicles - bait station mandatory for above ground, outdoor use
7173-242 (Jan 19, 2010)	Rozol Vole Bait	0.005	Voles	-pome fruit (apple, pear) and stone fruit (peach, cherry, apricot, plum, prune, and nectarine), nurseries, tree and forestry plantations, Christmas tree farms, buffer strips adjacent to crops application: ground broadcast (10 lbs bait/acre/app and 20 lbs/acre/year) or hand spot bait (1.5 oz bait per hole, trail or runway; max 10 lbs bait/acre) -lawns, parks, ornamental flower and shrub gardens (do not apply to golf courses or turfgrass) application: hand spot bait (1.5 oz bait per hole, trail or runway; max 10 lbs bait/acre/app and 20 lbs/acre/year)

Table 2-5. California Chlorophacinone end use products with outdoor uses				
Reg. Num. (date stamped)	**Product Name**	**% a.i.**	**Target species**	**Use patterns applicable to CA**
			Norway rat Roof rat House mouse	- In and around (within 50 ft) homes, industrial buildings, commercial buildings, and public buildings - Inside transport vehicles - bait station mandatory for above ground, outdoor use
7173-243 (Jan 13, 2011)	Rozol Mini Blocks	0.005	Norway rat Roof rat House mouse	- In and around (within 50 ft) homes, residential buildings, food processing facilities, industrial, commercial, agricultural and public buildings - Inside transport vehicles and in and around (within 50 ft) port and terminal buildings. - In alleys and sewers. - bait station mandatory for above ground, outdoor use
7173-184 (Jun 18, 2007)	Rozol Pocket Gopher Bait	0.005	Pocket gopher	-must be applied within pocket gopher runways (underground)
7173-244 (Mar 2, 2005)	Rozol Pocket Gopher Bait II	0.005	Pocket gopher	-must be applied within pocket gopher runways (underground)
7173-294 (Feb 11, 2011)	Rozol Pocket Gopher Bait III	0.005	Pocket gopher	-must be applied within pocket gopher runways (underground) - use only on lawns, golf courses, alfalfa fields, rangeland, orchards and groves, and non-crop areas.
CA-060006 (May 22, 2009) *SLN for 7173-151	Rozol Pellets	0.005	California voles (*Microtus californicus*)	-use restricted to artichoke fields from October to March if artichoke bracts are not available -apply 3-5 gms bait/plant on bare ground. Repeat for max of 3 trts at 21 days apart. -can repeat entire regimen after 60 days if necessary.
CA-930022 (May 12, 2011)	Rodent Bait Chlorophacinone Treated Artichoke Bracts	0.01	California voles (*Microtus californicus*)	-use restricted to artichoke fields -apply 1 oz bait (4-5 bracts) per plant on bare ground -repeat for max of 3 trts at 21 day intervals -do not exceed 3 applications in one 12-month interval

Table 2-5. California Chlorophacinone end use products with outdoor uses				
Reg. Num. (date stamped)	**Product Name**	**% a.i.**	**Target species**	**Use patterns applicable to CA**
CA-890023 (Mar 25, 2011)	Rodent Bait Chlorophacinone Treated Grain (0.005%)	0.005	California ground squirrel (*Spermophilus beecheyi*)	**Bait stations:** in and around livestock buildings; around (but not within) livestock pens; in and around vineyards, orchards, and groves; in rangelands, noncrop borders and fallow lands; outsides of fence rows adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities; and in campgrounds, recreational areas, horticultural nurseries, and forest tree plantations. **Spot-baiting:** vineyards, orchards, and groves during dormant season and in rangeland. Do not graze livestock or plant food or feed crops in spot-treated areas while bait is present.
			Chipmunks (*Eutanias* spp.)	**Bait stations:** in and around campgrounds and recreational areas; along non-crop borders; in fallow lands; outsides of fence rows adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities; horticultural nurseries, and forest tree plantations.
			California and montane voles *(Microtus californicus, M. montanus*)	**Spot-baiting:** vineyards, orchards, and groves during dormant season, in rangelands, noncrop borders and fallow lands; outsides of fence rows adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities; and in campgrounds, recreational areas, horticultural nurseries, and forest tree plantations. Do not graze livestock or plant food or feed crops in spot-treated areas while bait is present.
			Black-tailed jackrabbits (*Lepus californicus*)	**Bait stations:** borders of agricultural crops; rangeland and fallow lands; outsides of fence rows adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities; and in campgrounds, recreational areas, horticultural nurseries, and forest tree plantations.

Table 2-5. California Chlorophacinone end use products with outdoor uses				
Reg. Num. (date stamped)	**Product Name**	**% a.i.**	**Target species**	**Use patterns applicable to CA**
			Muskrat (*Ondatra zibethicus*)	**Floating bait station secured to bank or bottom of waterway**: natural and manmade waterways and wetlands adjacent to agricultural crops, rangelands, noncrop borders, uncultivated agricultural areas and rights-of-way.
CA-890024 (Apr 18, 2011)	Rodent Bait Chlorophacinone Treated Grain (0.01%)	0.01	California ground squirrel (*Spermophilus beecheyi*) California and montane voles *(Microtus californicus, M. montanus*) House mice (*Mus musculus*)	**Broadcast (aerial and ground):** vineyards, orchards, and groves (non-bearing season only); non-crop borders and fallow lands; outsides of fence rows adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities; campgrounds; recreational areas; horticultural nurseries; forest tree plantations; pastures; and rangeland. Apply up to 10 lbs bait/swath acre/application; make a second application 4 days after first treatment. Do not graze livestock or plant food or feed crops in areas while bait is present.
			Deer mice (*Peromyscus* spp.)	**Broadcast (aerial and ground):** vineyards, orchards, and groves (non-bearing season only); non-crop borders and fallow lands; outsides of fence rows adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities; campgrounds; recreational areas; horticultural nurseries; forest tree plantations; pastures; and rangeland. Apply at 2-6 lbs bait/swath acre/application; make a second application 4 days after first treatment. Do not graze livestock or plant food or feed crops in areas while bait is present.

Table 2-5. California Chlorophacinone end use products with outdoor uses				
Reg. Num. (date stamped)	**Product Name**	**% a.i.**	**Target species**	**Use patterns applicable to CA**
			Pocket gopher (*Thomomus* spp.)	**Underground burrow baiting:** orchards, groves, vineyards, agricultural crops (forage crops, grain and edible seed crops, oil crops, fiber crops, fruits, and vegetable crops), rangeland, and non-crop areas (fallow lands, campgrounds, recreational areas, horticultural nurseries, rights-of-way adjacent to canal banks, ditch banks, highways, levees, railroad lines, and utilities). Apply bait underground in tunnels using a burrow probe. Do not use a burrow-builder machine.

2.2.6.b. Reported Usage Data

The Agency's Biological and Economic Analysis Division (BEAD) provides county-level usage information using California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database[2]. CDPR PUR is considered a more comprehensive source of usage data than USDA-NASS or EPA proprietary databases, and thus the usage data reported for chlorophacinone by county in this California-specific assessment were generated using CDPR PUR data. Eleven years (1999-2009) of usage data were included in this analysis. Data from CDPR PUR were obtained for every agricultural pesticide application made on every use site at the section level (approximately one square mile) of the public land survey system.[3] BEAD summarized these data to the county level by site, pesticide, and unit treated. Calculating county-level usage involved summarizing across all applications made within a section and then across all sections within a county for each use site and for each pesticide. The county level usage data that were calculated include: average annual pounds applied, average annual area treated, and average and maximum application rate across all eleven years. The units of area treated are also provided where available.

The average number of pounds of chlorophacinone in California over the eleven year period was 44 lbs. The highest usage was 105 lb in 2005 and the lowest 13 lb in 2009. The county with the highest was Monterey County with17.4 lb. There were about 80 listed use sites in the California PUR data. However, over half of all documented use in California in 1999-2009 was on two use sites, artichokes with 10.7 lb/year and rights-of-way with 12.5 lb/year. Another 10.4 lb of use was listed non-specifically as 'vertebrate pest control'.

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

[3] Most pesticide applications to parks, golf courses, cemeteries, rangeland, pastures, and along roadside and railroad rights of way, and postharvest treatments of agricultural commodities are reported in the database. The primary exceptions to the reporting requirement are home-and-garden use and most industrial and institutional uses (http://www.cdpr.ca.gov/docs/pur/purmain.htm).

2.3. Assessed Species

Table 2-6 provides a summary of the current distribution, habitat requirements, and life history parameters for the listed species being assessed. More detailed life-history and distribution information can be found in **Attachment III**. See **Figure 2-2 to 2-5** for maps of the current range and designated critical habitat, if applicable, of the assessed listed species. A brief overview of each species is provided below:

- **Alameda Whipsnake (AW):** The AW was listed as threatened in 1997 by the USFWS. The species occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties in California.
- **Salt Marsh Harvest Mouse (SMHM):** The SMHM was listed by the USFWS as an endangered species in 1970. The species is found in tidal and non-tidal salt marshes along the San Francisco, San Pablo, and Suisun Bays in California.
- **California Tiger Salamander (CTS):** There are currently three CTS Distinct Population Segments (DPSs): the Sonoma County (SC) DPS, the Santa Barbara (SB) DPS, and the Central California (CC) DPS. Each DPS is considered separately in the risk assessment as they occupy different geographic areas. The main difference in the assessment will be in the spatial analysis. The CTS-SB and CTS-SC were downlisted from endangered to threatened in 2004 by the USFWS, however, the downlisting was vacated by the U.S. District Court. Therefore, the Sonoma and Santa Barbara DPSs are currently listed as endangered while the CTS-CC is listed as threatened. CTS utilize vernal pools, semi-permanent ponds, and permanent ponds, and the terrestrial environment in California. The aquatic environment is essential for breeding and reproduction and mammal burrows are also important habitat for estivation.
- **San Joaquin Kit Fox (SJKF):** The SJKF was listed as endangered in 1967 by the USFWS. The species is found in a variety of habitats in the Central Valley area of California.

Table 2-6. Summary of Current Distribution, Habitat Requirements, and Life History Information for the Assessed Listed Species[1]						
Assessed Species	**Size**	**Current Range**	**Habitat Type**	**Designated Critical Habitat?**	**Reproductive Cycle**	**Diet**
Salt Marsh Harvest Mouse (SMHM) (*Reithrodontomys raviventris*)	Adult 8 – 14 g	Northern subspecies can be found in Marin, Sonoma, Napa, Solano, and northern Contra Costa counties. The southern subspecies occurs in San Mateo, Alameda, and Santa Clara counties with some isolation populations in Marin and Contra Costa counties.	Dense, perennial cover with preference for habitat in the middle and upper parts of the marsh dominated by pickleweed and peripheral halophytes as well as similar vegetation in diked wetlands adjacent to the Bay	No	Breeding: March – November Gestation period: 21 – 24 days	Leaves, seeds, and plant stems; may eat insects; prefers "fresh green grasses" in the winter and pickleweed and saltgrass during the rest of the year; drinks both salt and fresh water
San Joaquin Kit Fox (SJKF) (*Vulpes macrotis mutica*)	Adult ~2 kg	Alameda, Contra Costa, Fresno, Kern, Kings, Madera, Merced, Monterey, San Benito, San Joaquin, San Luis Obispo, Santa Barbara, Santa Clara, Stanislaus, Tulare and Ventura counties	A variety of habitats, including grasslands, scrublands (*e.g.*, chenopod scrub and sub-shrub scrub), vernal pool areas, oak woodland, alkali meadows and playas, and an agricultural matrix of row crops, irrigated pastures, orchards, vineyards, and grazed annual grasslands. Kit foxes dig their own dens, modify and use those already constructed by other animals (ground squirrels, badgers, and coyotes), or use human-made structures (culverts,	No, but has designated core areas	Mating and conception: late December - March. Gestation period: 48 to 52 days. Litters born: February - late March Pups emerge from their dens at about 1-month of age and may begin to disperse after 4 – 5 months usually in Aug. or Sept.	Small animals including blacktailed hares, desert cottontails, mice, kangaroo rats, squirrels, birds, lizards, insects and grass. It satisfies its moisture requirements from prey and does not depend on freshwater sources.

Table 2-6. Summary of Current Distribution, Habitat Requirements, and Life History Information for the Assessed Listed Species[1]						
Assessed Species	**Size**	**Current Range**	**Habitat Type**	**Designated Critical Habitat?**	**Reproductive Cycle**	**Diet**
			abandoned pipelines, or banks in sumps or roadbeds). They move to new dens within their home range often (likely to avoid predation by coyotes)			
Alameda Whipsnake (AW) (*Masticophis lateralis euryxanthus*)	3 – 5 ft	Contra Costa and Alameda Counties in California (additional occurrences in San Joaquin and Santa Clara Counties)	Primarily, scrub and chaparral communities. Also found in grassland, oak savanna, oak-bay woodland, and riparian areas. Lands containing rock outcrops, talus, and small mammal burrows.	Yes	Emerge from hibernation and begin mating from late March through mid-June. Females lay eggs in May through July. Eggs hatch from August through November. Hibernate during the winter months.	Lizards, small mammals, nesting birds, other snakes including rattlesnakes
California Tiger Salamander (CTS) (*Ambystoma californiense*)	Adult 14.2-80.5 g^2	CTS-SC are primarily found on the Santa Rosa Plain in Sonoma County. CTS-CC occupies the Bay Area (central and southern Alameda, Santa Clara, western Stanislaus, western Merced, and the majority of San Benito Counties), Central Valley (Yolo, Sacramento, Solano, eastern Contra Costa, northeast Alameda, San Joaquin, Stanislaus, Merced, and northwestern Madera Counties), southern San Joaquin Valley (portions of Madera, central Fresno, and northern Tulare and Kings Counties), and the Central	Freshwater pools or ponds (natural or man-made, vernal pools, ranch stock ponds, other fishless ponds); Grassland or oak savannah communities, in low foothill regions; Small mammal burrows	Yes	Emerge from burrows and breed: fall and winter rains Eggs: laid in pond Dec. – Feb., hatch: after 10 to 14 days Larval stage: 3-6 months, until the ponds dry out, metamorphose late spring or early summer, migrate to small mammal burrows	Aquatic Phase: algae, snails, zooplankton, small crustaceans, and aquatic larvae and invertebrates, smaller tadpoles of Pacific tree frogs, California red-legged frogs, toads; Terrestrial Phase: terrestrial invertebrates, insects, frogs, and worms

Table 2-6. Summary of Current Distribution, Habitat Requirements, and Life History Information for the Assessed Listed Species[1]						
Assessed Species	**Size**	**Current Range**	**Habitat Type**	**Designated Critical Habitat?**	**Reproductive Cycle**	**Diet**
		Coast Range (southern Santa Cruz, Monterey, northern San Luis Obispo, and portions of western San Benito, Fresno, and Kern Counties). CTS-SB are found in Santa Barbara County.				

[1] For more detailed information on the distribution, habitat requirements, and life history information of the assessed listed species, see Attachment II.
[2] See Page 369 of Trenham *et al.* (Trenham *et al.*, 2000).

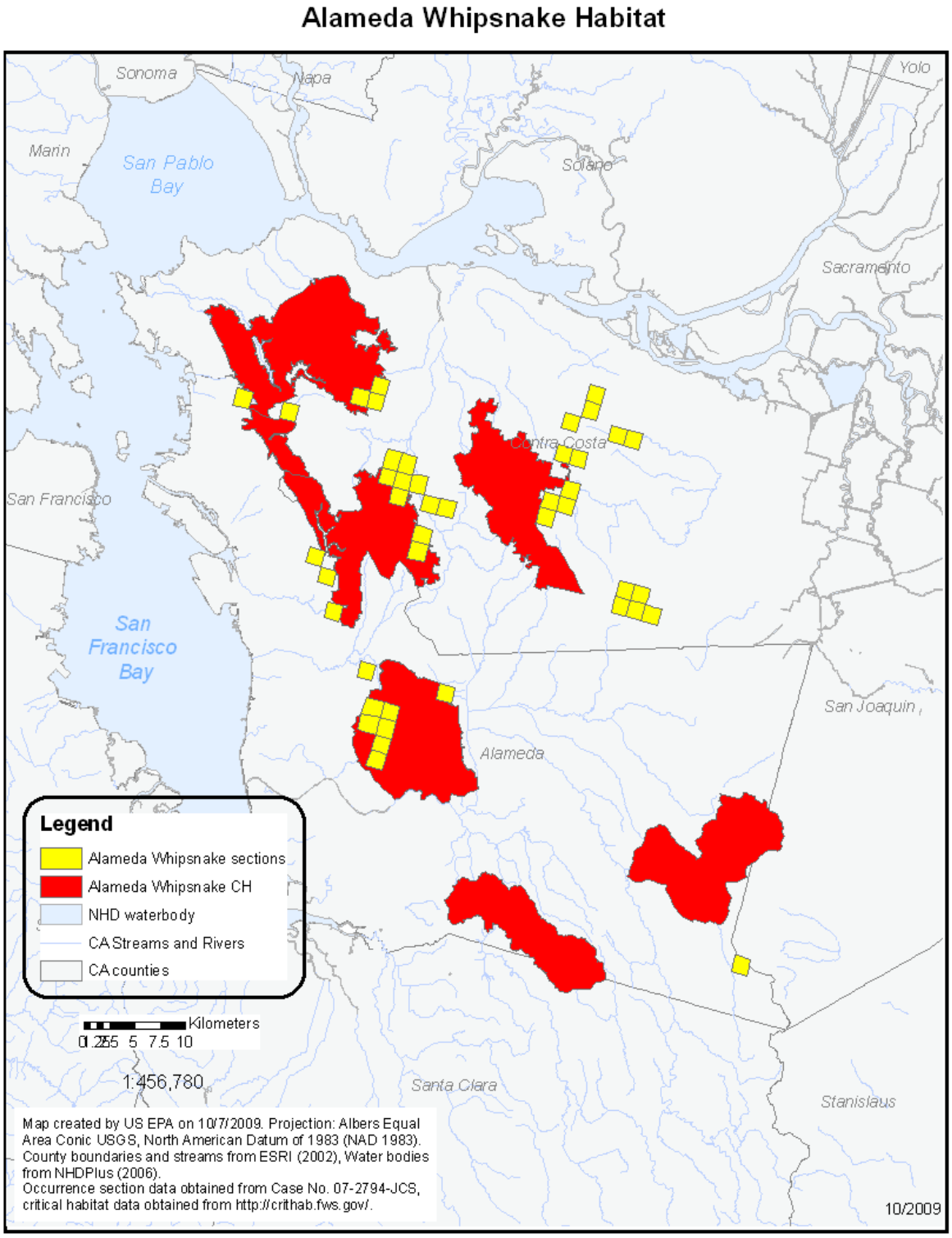


Figure 2-2. Critical habitat (CH) and occurrence sections of the Alameda Whipsnake, as identified in Case No. 07-2794-JCS

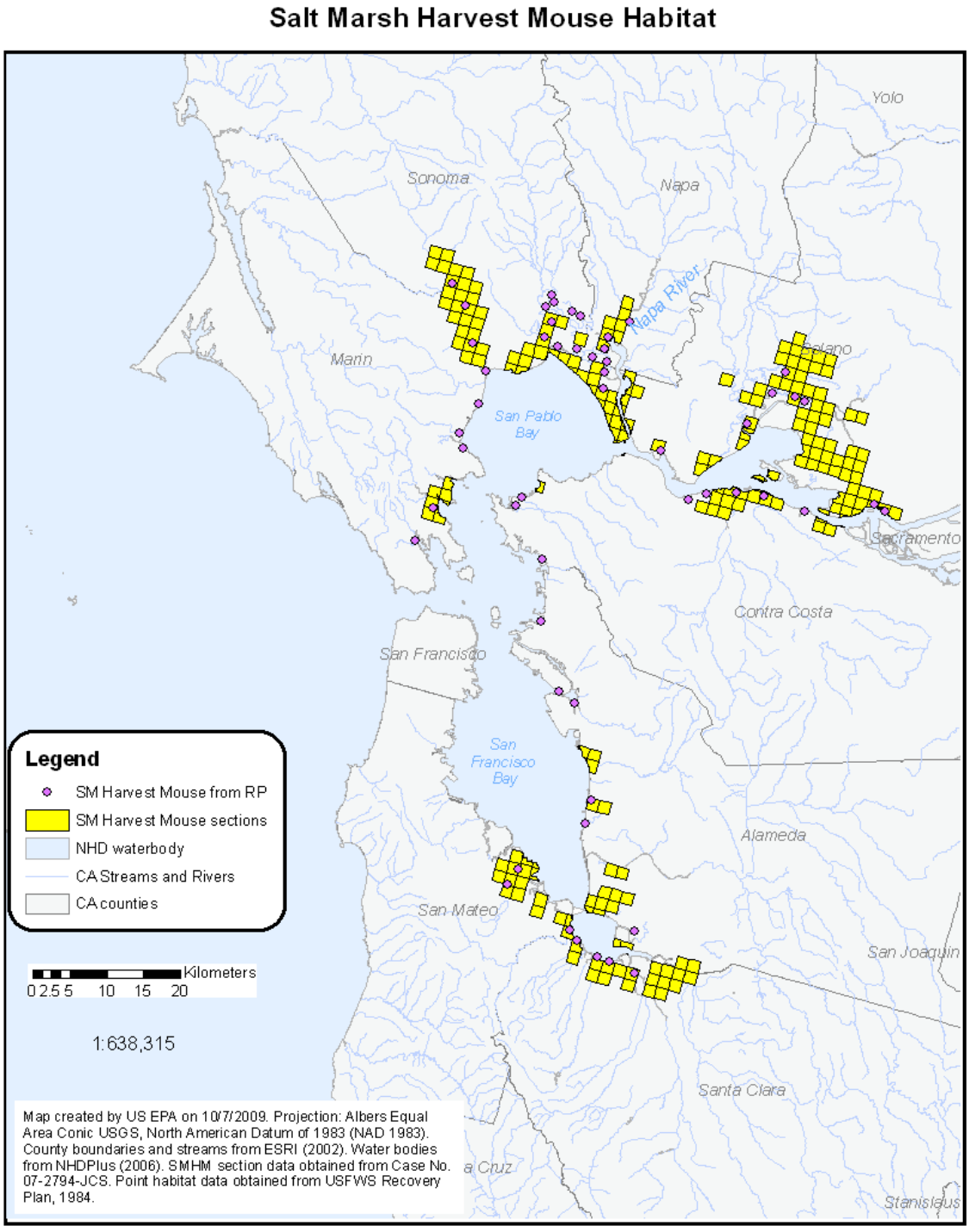


Figure 2-3. Occurrences and occurrence sections of the salt marsh harvest mouse, as identified in Case No. 07-2794-JCS. (RP is Recovery Plan)

CA Tiger Salamander Habitat

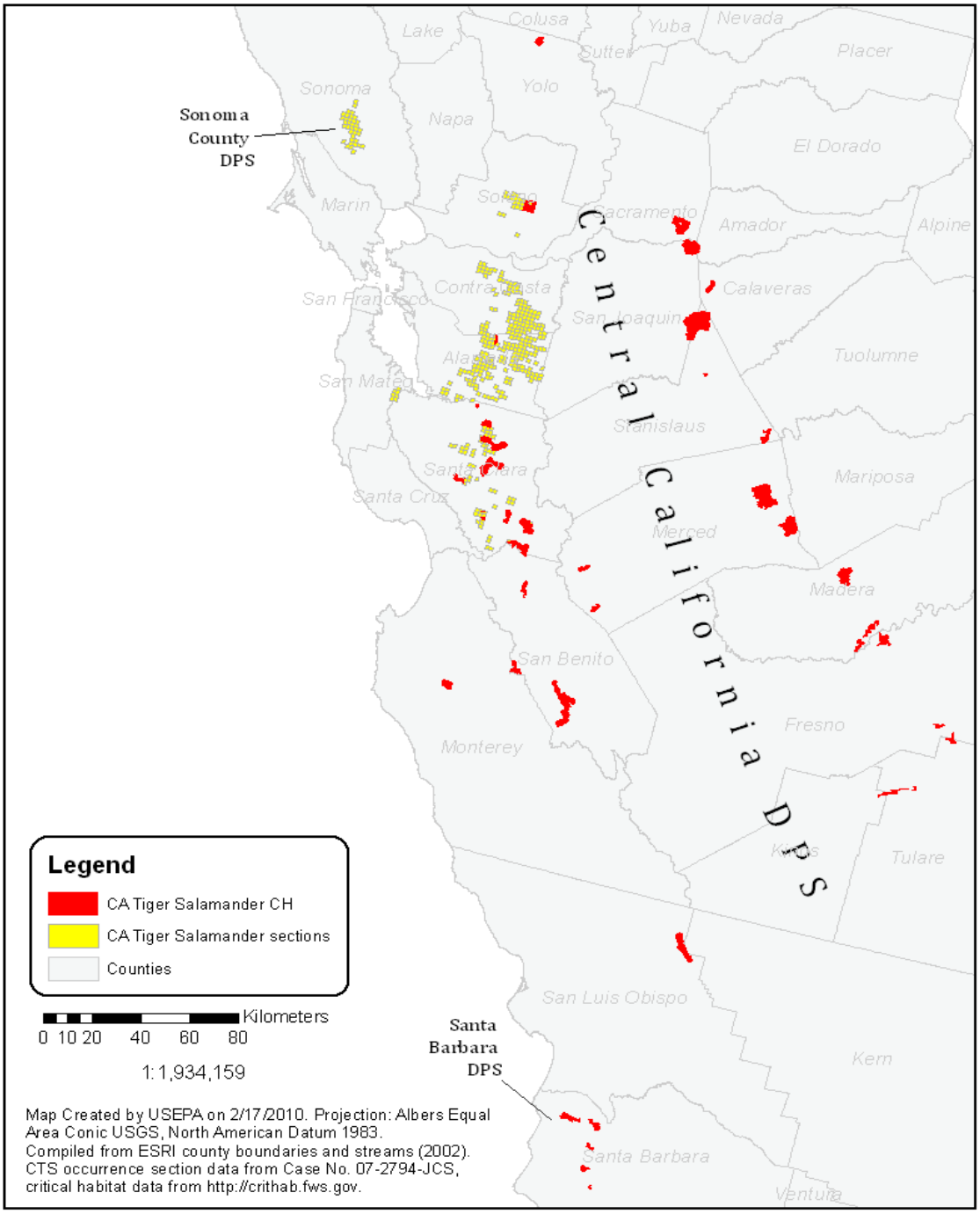


Figure 2-4. Critical habitat (CH) and occurrence sections of the CA Tiger Salamander, as identified in Case No. 07-2794-JCS.

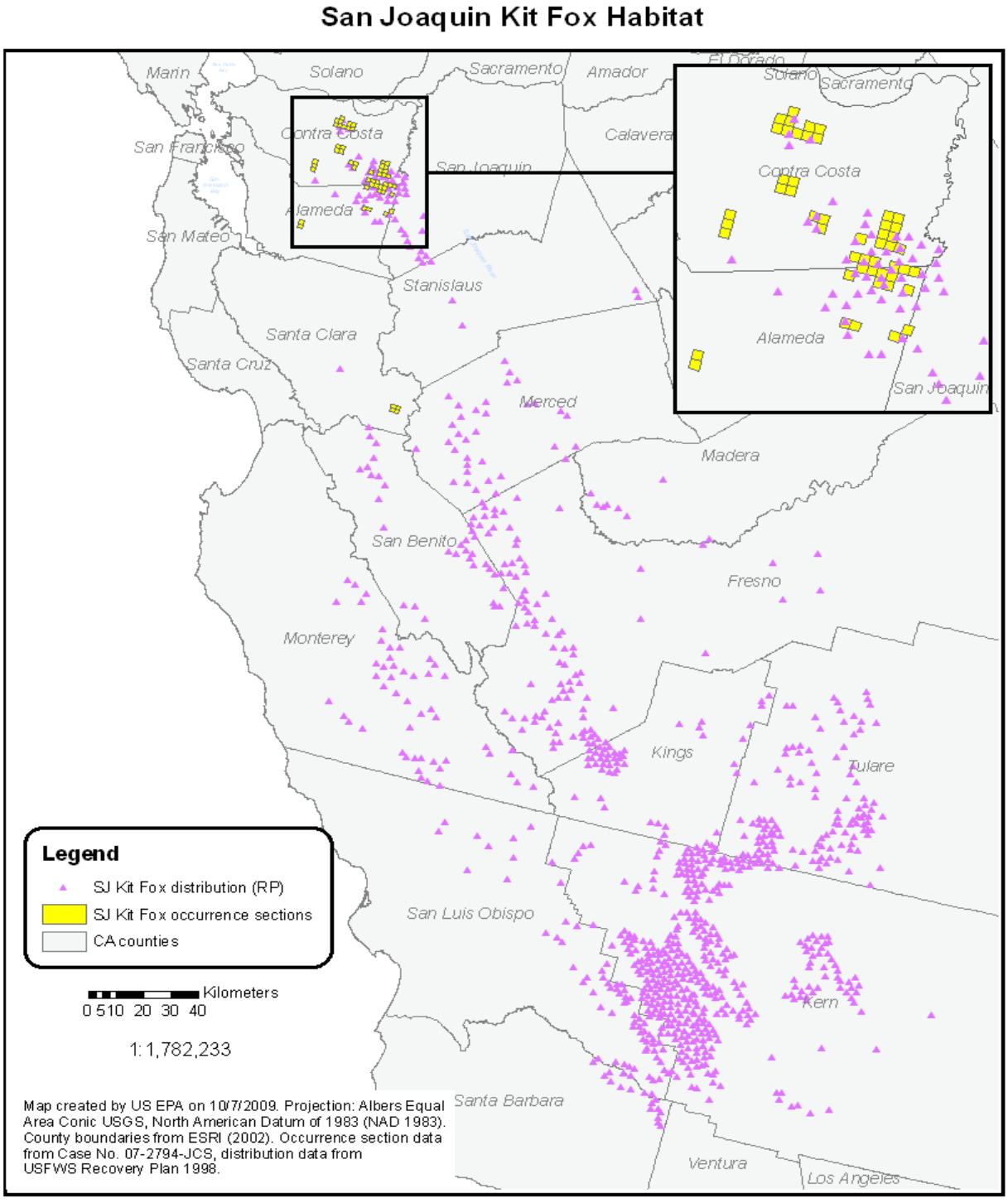


Figure 2-5. Occurrences and occurrence sections of the San Joaquin Kit Fox, as identified in Case No. 07-2794-JCS. (RP is the Recovery Plan).

2.4. Designated Critical Habitat

Critical habitat has been designated for the CTS and the AW. Risk to critical habitat is evaluated separately from risk to effects on the species. 'Critical habitat' is defined in the ESA as the geographic area occupied by the species at the time of the listing where the physical and biological features necessary for the conservation of the species exist, and there is a need for special management to protect the listed species. It may also include areas outside the occupied area at the time of listing if such areas are 'essential to the conservation of the species. Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species or areas that contain certain primary constituent elements (PCEs) (as defined in 50 CFR 414.12(b)). **Table 2-7** describes the PCEs for the critical habitats designated for the CTS and AW.

Table 2-7. Designated Critical Habitat PCEs for the California tiger salamander and the Alameda whipsnake[1].

Species	PCEs	Reference
California tiger salamander	Standing bodies of fresh water, including natural and man-made (*e.g.*, stock) ponds, vernal pools, and dune ponds, and other ephemeral or permanent water bodies that typically become inundated during winter rains and hold water for a sufficient length of time (*i.e.*, 12 weeks) necessary for the species to complete the aquatic (egg and larval) portion of its life cycle[2]	FR Vol. 69 No. 226 CTS, 68584, 2004
	Barrier-free uplands adjacent to breeding ponds that contain small mammal burrows. Small mammals are essential in creating the underground habitat that juvenile and adult California tiger salamanders depend upon for food, shelter, and protection from the elements and predation	
	Upland areas between breeding locations (PCE 1) and areas with small mammal burrows (PCE 2) that allow for dispersal among such sites	
Alameda whipsnake	Scrub/shrub communities with a mosaic of open and closed canopy	71 FR 58175 58231, 2006
	Woodland or annual grassland plant communities contiguous to lands containing PCE 1	
	Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2	

[1] These PCEs are in addition to more general requirements for habitat areas that provide essential life cycle needs of the species such as, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

[2] PCEs that are abiotic, including, physical-chemical water quality parameters such as salinity, pH, and hardness are not evaluated.

More detail on the designated critical habitat applicable to this assessment can be found in **Attachment II**. 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 chlorophacinone that may alter the PCEs of the designated critical habitat for the CTS and AW form the basis of the critical habitat impact analysis.

As previously noted in **Section 2.1**, the Agency believes that the analysis of direct and indirect effects to listed species provides the basis for an analysis of potential effects on the designated critical habitat. Because chlorophacinone is expected to directly impact living organisms within the action area, critical habitat analysis for chlorophacinone 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.

2.5. Action Area and LAA Effects Determination Area

2.5.1. Action Area

The action area is used to identify areas that could be affected by the Federal action. The Federal action is the authorization or registration of pesticide use or uses as described on the label(s) of pesticide products containing a particular active ingredient. The action area is defined by the Endangered Species Act as, "all areas to be affected directly or indirectly by the Federal action and not merely the immediate are involved in the action" (50 CFR §402.2). Based on an analysis of the Federal action, the action area is defined by the actual and potential use of the pesticide and areas where that use could result in effects. Specific measures of ecological effect for the assessed species that define the action area include any direct and indirect toxic effect to the assessed species and any potential modification of its critical habitat, including reduction in survival, growth, and fecundity as well as the full suite of sublethal effects available in the effects literature. It is recognized that the overall action area for the national registration of chlorophacinone is likely to encompass considerable portions of the United States based on the large array of agricultural and non-agricultural uses. However, the scope of this assessment limits consideration of the overall action area to those portions that may be applicable to the protection of the AW, SMHM, CTS, and SJKF and their designated critical habitat within the state of California. For this assessment, the entire state of California is considered the action area. The purpose of defining the action area as the entire state of California is to ensure that the initial area of consideration encompasses all areas where the pesticide may be used now and in the future, including the potential for off-site transport via drift and downstream dilution that could influence the San Francisco Bay Species. Additionally, the concept of a state-wide action area takes into account the potential for direct and indirect effects and any potential modification to critical habitat based on ecological effect measures associated with reduction in survival, growth, and reproduction, as well as the full suite of sublethal effects available in the effects literature.

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

2.5.2. LAA Effects Determination Area

A stepwise approach is used to define the Likely to Adversely Affect (LAA) Effects Determination Area. An LAA effects determination applies to those areas where it is expected that the pesticide's use will directly or indirectly affect the species and/or modify its designated critical habitat using EFED's standard assessment procedures (see Attachment I) and effects endpoints related to survival, growth, and reproduction. This is the area where the "Potential Area of LAA Effects" (initial area of concern + drift distance or downstream dilution distance) overlaps with the range and/or designated critical habitat for the species being assessed. If there is no overlap between the potential area of LAA effects and the habitat or occurrence areas, a no effect determination is made. The first step in defining the LAA Effects Determination Area is to understand the federal action. The federal action is defined by the currently labeled uses for chlorophacinone. An analysis of labeled uses and review of available product labels was completed. Several of the currently labeled uses are special local needs (SLN) uses not specified for use in California or are restricted to specific states and are excluded from this assessment. In addition, a distinction has been made between food use crops and those that are non-food/non-agricultural uses. For those uses relevant to the assessed species, the analysis indicates that, for chlorophacinone, the following agricultural uses are considered as part of the federal action evaluated in this assessment: orchards/groves, artichokes, forage crops, oil crops, fiber crops, grain, vegetables, fruits, rangeland, pasture, natural and manmade water bodies and wetlands near agricultural areas, non-crop areas, outside of fence rows, agricultural buildings, forest tree plantations, and fallow land. In addition, the following non-food and non-agricultural uses are considered: horticultural nurseries, commercial/industrial/residential/public buildings, transport vehicles, recreational areas, campgrounds, rights-of-way, and ornamental plantings.

Following a determination of the assessed uses, an evaluation of the potential "footprint" of chlorophacinone use patterns (*i.e.*, the area where pesticide application may occur) is determined. This "footprint" represents the initial area of concern, based on an analysis of available land cover data for the state of California. The initial area of concern is defined as all land cover types and the stream reaches within the land cover areas that represent the labeled uses described above. For chlorophacinone, these land cover types include all possible land cover types.

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

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

Generally, the Agency conducts analysis of the spatial extent of potential LAA effects whenever LOCs are exceeded. This analysis typically is needed to determine where adverse effects may occur in relation to the treated site. This spatial analysis typically determines if the potential area of usage, and the subsequent Potential Area of LAA Effects, overlaps with areas of occurrence and/or critical habitat of the species. However, because chlorophacinone is a vertebrate pest control that may be used in a wide variety of urban and non-urban areas, the spatial extent of chlorophacinone cannot be limited to defined areas. The Agency assumes that chlorophacinone potentially may be used in any area of the state. Therefore, a spatial analysis was not conducted to identify this overlap. All areas where these species occur, and all areas of the critical habitat of the AW and CTS, are assumed to lie within the potential use area of chlorophacinone.

2.6. Assessment Endpoints and Measures of Ecological Effect

For more information on the assessment endpoints, measures of ecological effect, see **Attachment I**.

2.6.1. Assessment Endpoints

A complete discussion of all the toxicity data available for this risk assessment, including resulting measures of ecological effect selected for each taxonomic group of concern, is included in **Section 4** of this document. **Table 2-8** identifies the taxa used to assess the potential for direct and indirect effects from the uses of chlorophacinone for each listed species assessed here. The specific assessment endpoints used to assess the potential for direct and indirect effects to each listed species are provided in **Table 2-9**.

Table 2-8. Taxa Used in the Analyses of Direct and Indirect Effects for the Assessed Listed Species.

Listed Species	Birds	Mammals	Terr. Plants	Terr. Inverts.	FW Fish	FW Inverts.	Aquatic Plants
Salt marsh harvest mouse	Indirect (rearing sites)	Direct Indirect (rearing sites)	Indirect (food, habitat)	Indirect (prey)	n/a	n/a	Indirect (habitat)
San Joaquin kit fox	Indirect (prey)	Direct Indirect (prey)	Indirect (food/ habitat)	Indirect (prey)	n/a	n/a	n/a
Alameda whipsnake	Direct Indirect (prey)	Indirect (prey/habitat)	Indirect (habitat)	Indirect (prey)	n/a	n/a	n/a
California tiger salamander	Direct Indirect (prey)	Indirect (prey/ habitat)	Indirect (habitat)	Indirect (prey)	Direct Indirect (prey)	Indirect (prey)	Indirect (food/ habitat)

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

Table 2-9. Taxa and Assessment Endpoints Used to Evaluate the Potential for Use of Chlorophacinone to Result in Direct and Indirect Effects to the Assessed Listed Species or Modification of Critical Habitat.

Taxa Used to Assess Direct and Indirect Effects to Assessed Species and/or Modification to Critical Habitat or Habitat	Assessed Listed Species	Assessment Endpoints	Measures of Ecological Effects
1. Freshwater Fish and Aquatic-Phase Amphibians	Direct Effect – -CA Tiger Salamander	Survival, growth, and reproduction of individuals via direct effects	1a. Most sensitive fish acute LC_{50} (guideline or ECOTOX) 1b. Most sensitive fish chronic NOAEC (guideline or ECOTOX) 1c. Most sensitive fish early-life stage NOAEC (guideline or ECOTOX)
2. Freshwater Invertebrates	Indirect Effect (prey) - CA Tiger Salamander	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on aquatic prey food supply (*i.e.,* freshwater invertebrates)	2a. Most sensitive freshwater invertebrate EC_{50} (guideline or ECOTOX) 2b. Most sensitive freshwater invertebrate chronic NOAEC (guideline or ECOTOX)
5. Aquatic Plants (freshwater/marine)	Indirect Effect (food/habitat) -Salt Marsh Harvest Mouse -CA Tiger Salamander	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on habitat, cover, food supply, and/or primary productivity (*i.e.,* aquatic plant community)	5a. Vascular plant acute EC_{50} (duckweed guideline test or ECOTOX vascular plant) 5b. Non-vascular plant acute EC_{50} (freshwater algae or diatom, or ECOTOX non-vascular)
6. Birds	Direct Effect -Alameda Whipsnake -CA Tiger Salamander	Survival, growth, and reproduction of individuals via direct effects	6a. Most sensitive bird[a] or terrestrial-phase amphibian acute LC_{50} or LD_{50} (guideline or ECOTOX) 6b. Most sensitive bird[a] or terrestrial-phase amphibian chronic NOAEC (guideline or ECOTOX)
	Indirect Effect (prey/rearing sites) -Salt Marsh Harvest Mouse - San Joaquin Kit Fox -Alameda Whipsnake	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey (birds)	
7. Mammals	Direct Effect -Salt Marsh Harvest Mouse -San Joaquin Kit Fox	Survival, growth, and reproduction of individuals via direct effects	7a. Most sensitive laboratory mammalian acute LC_{50} or LD_{50} (guideline or ECOTOX) 7b. Most sensitive laboratory mammalian chronic NOAEC (guideline or ECOTOX)
	Indirect Effect (prey/habitat from burrows/rearing sites) -Salt Marsh Harvest Mouse -San Joaquin Kit Fox	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey (mammals) and/or	

Table 2-9. Taxa and Assessment Endpoints Used to Evaluate the Potential for Use of Chlorophacinone to Result in Direct and Indirect Effects to the Assessed Listed Species or Modification of Critical Habitat.			
Taxa Used to Assess Direct and Indirect Effects to Assessed Species and/or Modification to Critical Habitat or Habitat	**Assessed Listed Species**	**Assessment Endpoints**	**Measures of Ecological Effects**
	- Alameda Whipsnake -CA Tiger Salamander	burrows/rearing sites	
8. Terrestrial Invertebrates	Indirect Effect (prey) -Salt Marsh Harvest Mouse -San Joaquin Kit Fox -Alameda Whipsnake -CA Tiger Salamander	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey (terrestrial invertebrates)	8a. Most sensitive terrestrial invertebrate acute EC_{50} or LC_{50} (guideline or ECOTOX) 8b. Most sensitive terrestrial invertebrate chronic NOAEC (guideline or ECOTOX)
9. Terrestrial Plants	Indirect Effect (food/habitat) (non-obligate relationship) -Salt Marsh Harvest Mouse -San Joaquin Kit Fox -Alameda Whipsnake -CA Tiger Salamander	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on food and habitat (*i.e.*, riparian and upland vegetation)	9a. Distribution of EC_{25} for monocots (seedling emergence, vegetative vigor, or ECOTOX 9b. Distribution of EC_{25} (EC_{05} or NOAEC for the BCB and the VELB) for dicots (seedling emergence, vegetative vigor, or ECOTOX)
[a] Birds are used as a surrogate for terrestrial-phase amphibians and reptiles.			

2.6.2. Assessment Endpoints for Designated Critical Habitat

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of chlorophacinone that may alter the PCEs of the assessed species' designated critical habitat. PCEs for the assessed species were previously described in **Section 2.4.** Actions that may modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the assessed species. Therefore, these actions are identified as assessment endpoints. It should be noted that evaluation of PCEs as assessment endpoints is limited to those of a biological nature (*i.e.*, the biological resource requirements for the listed species associated with the critical habitat) and those for which chlorophacinone effects data are available.

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

2.7. Conceptual Model

2.7.1. Risk Hypotheses

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

The labeled use of chlorophacinone within the action area may:

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

2.7.2. Diagram

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

Potential transport mechanisms to aquatic ecosystems include pesticide surface water runoff, drift, and secondary drift of volatilized or soil-bound residues leading to deposition onto nearby

or more distant ecosystems. Surface water runoff and spills of muskrat floating bait stations are expected to be the major routes of aquatic exposure for chlorophacinone.

The conceptual model assumes that chlorophacinone will be available to non-target organisms, and as toxic food bait, it will adversely affect terrestrial species. The major sources of exposure of non-target terrestrial animals are expected to be ingestion of the formulated food bait and consumption of vertebrate body tissues or invertebrates that have eaten the food bait (USEPA 2004b). Exposure via these routes is expected primarily for birds and mammals, though it is likely that other terrestrial animals such as reptiles and terrestrial amphibians are at risk if they consume invertebrates or tissues of vertebrates that have eaten bait. Chlorophacinone may also be consumed by target and non-target animals through ingestion of fecal material (coprophagy).

Terrestrial species may ingest chlorophacinone by drinking contaminated water. Chlorophacinone is applied on a bait, and it tends to bind strongly to organic matter, little is expected to partition into drinking water source (*e.g.* puddles) compared to that which is available for direct consumption on the bait itself; therefore, this route of exposure was not assessed. Since chlorophacinone is not sprayed directly onto plants, and because so little is expected to leach from the bait and then be available for plant uptake, consumption of chlorophacinone on plants is not also being considered as a route of exposure. Aquatic species may ingest some bait and may be exposed to chlorophacinone via uptake through gills/integument. Dermal and inhalation routes of exposure occur for some pesticides (*e.g.*, foliar sprays). However, these are not expected to be important routes of exposure for grain-based, rodenticide food bait because chlorophacinone is not volatile and is not expected to absorb appreciably through the skin.

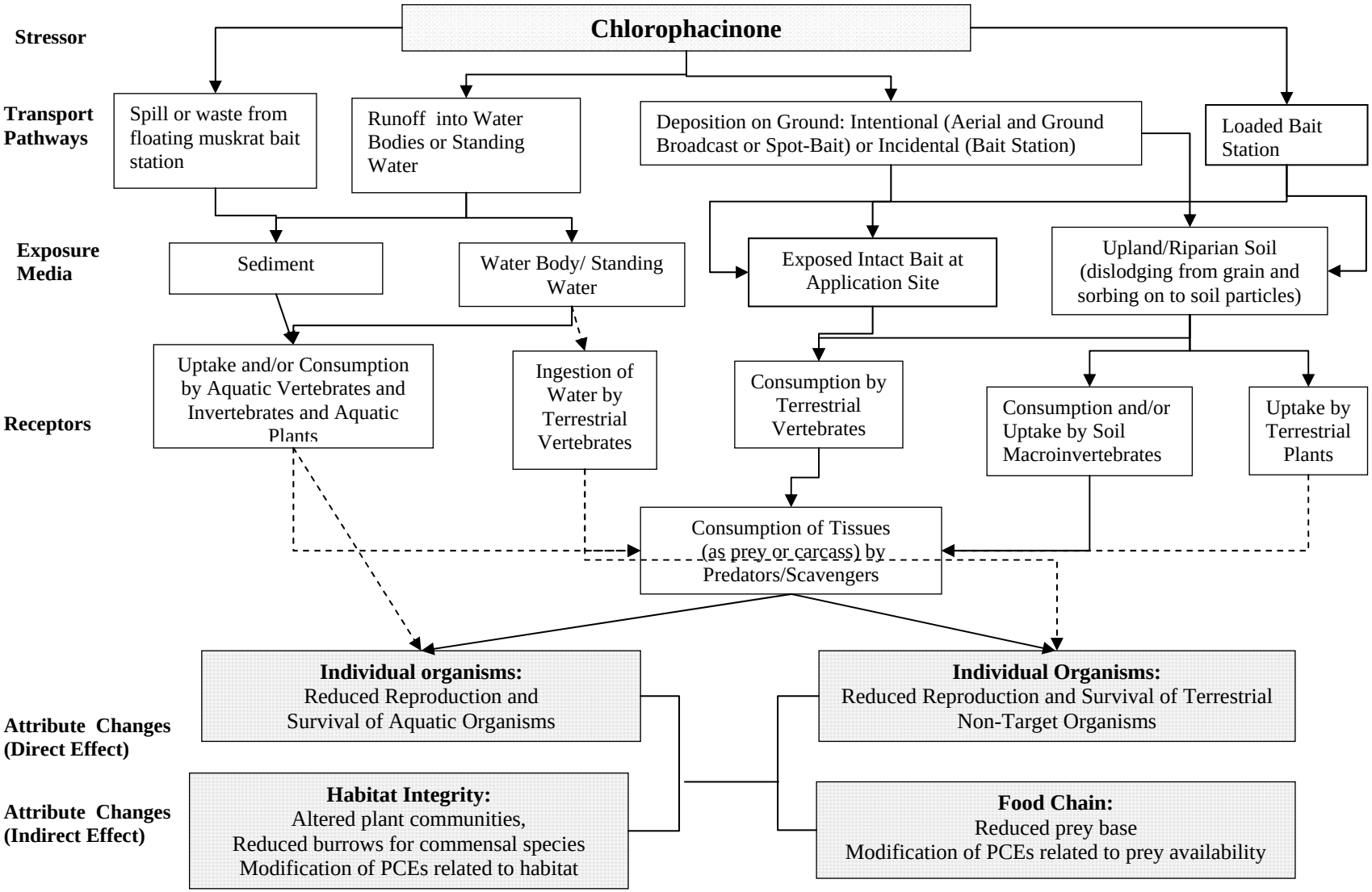


Figure 2-6. Conceptual Model Diagram of Chlorophacinone Exposure and Effects in Nontarget Species. Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk.

2.8. Analysis Plan

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

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

2.8.1. Measures of Exposure

In this assessment, transport of parent chlorophacinone through runoff to water bodies is considered in deriving quantitative estimates of chlorophacinone. With a vapor pressure of 3.58 x 10^{-6} torr and a calculated Henry's Law constant 5.12 x 10^{-7} atm·m^3·mol^{-1}, volatilization and atmospheric transport are very unlikely. In addition, primary exposure to bait and secondary exposure to chlorophacinone poisoned carcasses will be considered for measures of exposure to terrestrial organisms. This assessment only considered exposure and toxicity to parent chlorophacinone as the identified degradates do contain the structural moieties associated with the anticoagulant mode of action. An unidentified major degradate in the hydrolysis study is unlikely to be of concern because hydrolysis is slow compared to aerobic soil metabolism and the same degradate is only a minor degradate in the metabolism study. A second unidentified 'major degradate' only occurred at the origin of the chromatography plates. This material is unlikely to be similar in structure to the parent and is certainly of much lower environmental mobility (as it did not move on the chromatography plate) than the parent.

2.8.1.a. Estimating Aquatic Exposure

In general, deposition of drifting pesticides is expected to be greatest close to the site of application. Computer models of spray drift (AGDRIFT and AGDISP) are used to determine potential exposures to aquatic and terrestrial organisms via spray drift. There are aerial applications of chlorophacinone. However, the aerially applied products are grain-based. While, one of these models can simulate aerially applied granular applications, the chlorophacinone product which is aerially applied is not well characterized for use in these types of model. Due to these model limitations, it is not be possible to provide a quantitative estimate of exposure with known uncertainty. Consequently, distance estimates for terrestrial risks from this use will not be made. The standard drift assumption of 5% for aquatic assessment will be used. This is likely an overestimate as grain size is considerable bigger than droplet sizes used in making the 5% drift assumption.

Given that aquatic risks have not been exceeded in previous risk assessments, the exposure assessment for this use is being conducted at the first tier using the GENEEC model, version 2.0, dated August 1, 2001. GENEEC is a metamodel of the Tier 2 models PRZM and EXAMS and as such mimics the output of these models. However, GENEEC is hard-wired to a single, high exposure scenario which is intended to be protective of aquatic environments for all crops on a national basis. While application to control mammalian pests is not *per se* to an agricultural crop, the similarities are sufficient that EECs generated by GENEEC would still be expected to be protective of applications of chlorophacinone on a national basis. Rather than the time-series of concentration that is the output at Tier 2, GENEEC produces point estimates of 1-in-10 year peaks and means of specified duration (*e.g.* 4 day mean, 21-day mean) based on a more limited set of input data. If risks are above levels of concern at Tier 1 using GENEEC, more refined modeling at Tier 2 can be conducted which considers crop specific location information and additional fate data such as vapor pressure.

While the specific scenario built into GENEEC is a 10 ha field draining into a 1 ha pond, 2 meters deep, with no outlet, this scenario is intended to serve as a surrogate for a wide variety of small vulnerable water bodies that occur near the top of watersheds. These include prairie potholes, swamps, bogs, and other wetlands, playa lakes, and zero and first-order streams. Larger water bodies such as second-order and higher streams and rivers, and lakes reservoirs, are expected to be less vulnerable (lower EECs) than the standard pond built into GENEEC as they large dilution ratios, and they are unlikely to have 100% of the watershed committed to one use pattern.

There are no standard methods to estimate exposure from uses such as application to control muskrats. There is a reasonable expectation that at least some bait will be spilled into the water body during consumption by the target pest. Furthermore it is not unreasonable to think that in some case, the bait canister could get spilled into the water or sunk. Exposure from this use will be estimated by assuming that a full bait can with 5 lb pounds of bait is spilled into the standard pond. In addition, a calculation will be made to estimate how much would need to enter the standard pond in order to reach the level of concern. While it is likely that these two calculations will significantly overestimate exposure, they should provide an adequate screen. They are likely to be an overestimate because most of the chlorophacinone is likely to stay bound to the grain and not desorb into the water. If LOCs are not exceeded and/or an inordinately large amount of bait is required to exceed the LOC, the risks to endangered species are unlikely from this route.

2.8.1.b. Estimating Primary Terrestrial Exposure

EFED's exposure assessment for the rodenticides differs from that for most other pesticides. For a rodenticide, the bait itself is the potential food item of concern. Thus, the amount of active ingredient in the formulated bait is used as an EEC. This information is used to estimate the amount of grain bait that birds and mammals of various sizes need to consume to obtain a dose expected to be lethal to 50% of the individuals in the population (i.e., LD_{50} dose). Estimates of food-ingestion rates (g dry matter per day) are determined from established allometric equations presented in the Wildlife Exposure Factors Handbook (USEPA 1993). The concentration of chlorophacinone in grain bait is also used to estimate initial dietary exposure (mg a.i. per kg in bait) which in turn is used to calculate avian and mammalian dietary RQs.

2.8.1.c. Estimating Secondary Terrestrial Exposure

Secondary exposure analysis (from carcass) requires consideration of residues in tissues of target and non-target organisms that are commonly consumed by predators and scavengers. Moreover, it is important to know how long the residue persists in body tissues. Residue concentrations for non-target animals fed chlorophacinone were submitted by the registrant and are available in open literature. Additionally, a number of laboratory tests using avian and mammalian predators and scavengers are available to assess mortality from secondary exposure resulting from consumption of prey animals that had been exposed to chlorophacinone. Design and methodology vary among studies, adding unknown variability to the results and analysis. Pending development of standard methods and testing requirements for such studies, these tests provide the best data available.

2.8.2. Measures of Effect

Data identified in **Section 2-4** are used as measures of effect for direct and indirect effects. Data were obtained from registrant submitted studies or from literature studies identified by ECOTOX. More information on the ECOTOXicology (ECOTOX) database and how toxicological data is used in assessments is available in **Attachment I**.

2.8.2.a. Integration of Exposure and Effects

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

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

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

Individual effect probabilities are calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) developed by the U.S. EPA, OPP, Environmental Fate and Effects Division (June 22, 2004). The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the acute RQ is entered as the desired threshold.

2.8.4. Data Gaps

Data gaps were assigned a low or high potential to add value to the ecological risk assessment. Data gaps listed below were requested as part of an EFED risk assessment conducted for a new use of chlorophacinone with the target species of California ground squirrels (D377940). While still considered data gaps according to 40 CFR Part 158, low potential studies are unlikely to change risk determinations because alternate methods and weights of evidence (*i.e.*, acute-to-chronic ratio, scaling factors, or consideration of environmentally relevant concentrations relative to effects thresholds) may possibly be used in the absence of data. High potential studies would enable the Agency to better characterize potential risks by eliminating uncertainties for both non-listed and listed species that cannot be accounted for using alternate methods or weights of evidence. It is important to note that a study that is currently assigned a low potential to add value could be changed to high potential based on future proposed uses, submitted data, and/or incidents.

Data that were requested with **high potential** to add value to the ecological risk assessment were:

- A data gap is identified for *Field Testing for Terrestrial Wildlife* (850.2500). EPA originally specified a Field Testing for Terrestrial Wildlife Study in May 2009, as a condition of registration for Rozol Prairie Dog Bait, EPA Reg. No. 7173-286. The purpose of this study is to provide quantitative data on the availability of poisoned/incapacitated prairie dogs and ***non-target animals*** to predators and scavengers, the effect of carcass collection on mitigating exposure, and carcass collection efficacy (per label directions).
- A data gap is identified for the *Avian Reproduction Study* (850.2300), both waterfowl and upland game bird species. One avian reproduction study conducted using Japanese quail (MRID 473232-01). This study was reviewed and classified as supplemental; it can be used for risk assessments but it does not meet guideline requirements as there were a significant number of uncertainties (*e.g.*, no raw data, no GLP statement, not all endpoints reported, limited summary data available, and not conducted using a recommended species).
- A data gap is identified for an *Avian Acute Oral Toxicity Test (850.2100*) conducted using a passerine species. Under 40 CFR Part 158, data are required for one passerine species and either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses. The current method of calculating a weight-adjusted LD_{50} using bobwhite quail or mallard duck data may over- or under-estimate risks to passerines because these birds may metabolize the chemical differently. Because of the documented high toxicity to birds through submitted studies and the

reported incidents, information regarding relative toxicity to passerines is essential for further characterization of the avian risks of chlorophacinone.

Other data that were requested to satisfy existing data requirement were:

- *Seedling Emergence, Tier II (850.4225), ten species*
- *Vegetative Vigor, Tier II (850.4250), ten species*
- *Soil photolysis (835.2410)*
- *Aqueous photolysis (835.2240*
- *Aerobic aquatic metabolism (835.4300)*
- *Anaerobic aquatic metabolism (835.4400)*
- *Freshwater Fish Early Life-Stage Toxicity Test (850.1400)*
- *Freshwater Invertebrate Life Cycle Toxicity Test (850.1300)*
- *Estuarine/Marine Fish Acute Toxicity Test (850.1075*)
- *Estuarine/Marine Fish Early-life Stage Toxicity Test (850.1400)*
- *Aquatic Plant Toxicity Test Using* Lemna *spp., Tiers I and II (850.4400)*
- *Algal Toxicity, Tiers I and II (850.5400), four species*

3. Exposure Assessment

Chlorophacinone is formulated as on grain, or as granules and mini-block baits. These baits may be sold in bait stations, or placed into pre-existing bait stations, for spot-baiting, or broadcast. Broadcast applications can be made from ground equipment or from aircraft, depending upon the product and the use site. Labels allowing aerial applications are only for treated grain (0.010% chlorophacinone).

3.1. Label Application Rates and Intervals

Chlorophacinone labels may be categorized into two types: labels for manufacturing uses (including technical grade chlorophacinone) and end-use products. While technical products, which contain chlorophacinone of high purity, are not used directly in the environment, they are used to make formulated products, which can be applied in specific areas to control pest mammals. The formulated product labels legally limit chlorophacinone's potential use to only those sites that are specified on the labels. The uses being assessed are summarized in **Table 3-1**. All mitigation required as part of the reregistration process was completed as of April 2011 (**Appendix A**).

Table 3-1. Modeled Chlorophacinone Uses, Scenarios, and Application Information[1]					
Scenario	**% a.i.**	**Application Rate (per application)**	**Maximum Number of Applications**	**Application Interval**	**Evaluated Exposure Pathways**
Aerial broadcast in agriculture and non-ag	0.010	10 lbs bait/acre 0.001 lbs a.i./acre	2	4 days	-Aquatic -Terrestrial primary -Terrestrial secondary
Ground broadcast and spot-bait in agriculture and non-ag	0.005	10 lbs bait/acre 0.0005 lbs a.i./acre	2	4 days	-Terrestrial primary -Terrestrial secondary
Ground broadcast and spot-bait in agriculture and non-ag	0.010	10 lbs bait/acre 0.001 lbs a.i./acre	2	4 days	-Terrestrial primary -Terrestrial secondary
Rozol pellets in artichoke fields	0.005	3-5 gms bait/plant .003 lb a.i./acre	3	21 days * can repeat after 60 days	-Terrestrial primary -Terrestrial secondary
Artichoke bracts in artichoke fields[2]	0.010	1 oz bait (4-5 bracts)/plant 0.03 lbs a.i./acre	3	21	-Aquatic -Terrestrial primary -Terrestrial secondary
Muskrat	0.005	1-5 lbs bait/station	NA	NA	-Aquatic -Terrestrial primary -Terrestrial secondary
Bait stations	0.010 0.005	varies	varies	varies	-Terrestrial primary -Terrestrial secondary
Below ground (*e.g.*, burrows, runways)	0.010 0.005	varies	varies	varies	-Terrestrial primary -Terrestrial secondary

1-Uses assessed based on memorandum from Pesticide Re-evaluation Division (PRD) dated [April 24, 2011] and EFED Label Data report and associated Draft Label Use Information Reports.
2-There are two products registered for control of voles in artichoke fields. Label states bait (treated artichoke bracts) are placed on bare ground around each artichoke plant. Applications can be made up to three times per year at a minimum of 21 day intervals. Typical planting densities for annual artichokes are 40 inch beds with spacing at 30 to 36 inches in the bed (Bari, Sances, and Wingett, 1999). For the 30 inch spacing, this is a planting density of 5190 plants per acre. Assuming 1 oz bait/plant, label application rates convert to 0.03 lbs a.i./acre/application.

3.2. Aquatic Exposure Assessment

The aquatic exposure assessment consists of simulation modeling only. No monitoring data for chlorophacinone in air or water have been identified.

3.2.1. Runoff Modeling for Chlorophacinone (GENEEC)

Based on the application patterns of chlorophacinone described above, two use patterns are being simulated for the assessment of aquatic exposure from broadcast uses:

- the use of the treated artichoke bract product for control of voles in artichoke fields and
- a general agricultural use pattern for all other broadcast uses of chlorophacinone.

These two use patterns are expected to be protective of all use sites except the aquatic use for control of muskrats, which is assessed below. The general agriculture use is meant to represent all broadcast uses of chlorophacinone. Uses which are based on spot baiting or in bait stations are not assessed for aquatic exposure and are assessed using a dose based approach for terrestrial exposure. The aquatic exposure assessment of the broadcast uses is expected to be protective of spot baiting and bait station uses, as there is a much reduced availability to runoff for these types of applications. The simulated application patterns are in **Table 3.2**. The aerial application sub-model in GENEEC is intended to simulate spray applications. A course spray was chosen to simulate aerial application of grain-based bait. No incorporation and no watering-in were assumed for both simulations.

Table 3.2. Simulated use patterns for the assessing aquatic risks to endangered species from chlorophacinone in the San Francisco Bay watershed.

Use site	Maximum Single Application Rate (lb a.i./ acre)	No. of Apps.	Application Intervals (days)	Application Method
artichokes	0.03	3	21	ground (no drift)
general ag.	0.001	2	4	aerial*
* aerial application simulated assuming a course spray to simulate application of treated grain by aircraft				

3.2.1.a. Chemistry Input Parameters

The chemistry input parameters used to simulate chlorophacinone are in **Table 3.3**. As discussed above, these input parameters representative of the properties of parent chlorophacinone only as chlorophacinone degradates are not likely to have anticoagulant activity. The chemistry input parameters are the same as those used in the previous assessment (D377940). The solubility in water at 25°C value is 3.4 $mg \cdot L^{-1}$ (MRID 42237401). The aerobic aquatic metabolism half-life was estimated as the upper 90% confidence bound on two measured values, as per current guidance (USEPA, 2009). As no aquatic metabolism data was available, the water column half-life input parameter was estimated by doubling the aerobic soil metabolism half-life.

Table 3.3. Chemistry input parameters for simulation of chlorophacinone use with GENEEC.		
Property	**Value**	**Comment**
Solubility	3.4 ppm	
Photolysis in Water	0	Assume that chlorophacinone is stable to photolysis. An unacceptable study was used previously.
Aerobic Soil Degradation	37 d	Upper 90% confidence bound on 2 values
Aerobic aquatic metabolism	74 d	2 x aerobic soil metabolism used in absence of data
K_{oc}	20,299 $l \cdot kg^{-1}$	Slope of line regression on K_d on OC%
Incorporation depth	0 in	Surface applications

3.2.1.b. Aquatic EECs

The EECs for these use patterns are in **Table 3.4**. The peak EEC value represents the maximum concentration in a year that would be expected to recur once every 10 years. The 4 day, 21 day, 60 day and 90 day values represent the maximum mean value of that duration that is expected to recur once every ten years. A GENEEC output file is provided in **Appendix C**.

Table 3.4. Tier 1 EECs ($\mu g \cdot L^{-1}$) for use of chlorophacinone in the San Francisco Bay Watershed.					
Use Pattern	**Peak**	**4 d**	**21d**	**60 d**	**90 d**
Artichokes	0.275	0.256	0.176	0.091	0.064
General agriculture	0.011	.010	0.007	0.004	0.003

3.2.2. Aquatic EEC Estimation for Muskrat Control

One product, Rodent Bait Chlorophacinone Treated Grain (0.005%) (SLN 890023). For this use, 1 to 5 lb of bait is placed in floating bait station containing 1 to 5 lb bait anchored to shore or the bottom. Two methods are being used to assess this use. First, we can assume that one full bait station was spilled into the standard pond. Five pound of bait contains 0.113 grams of chlorophacinone. The volume of the pond is 20 million liters, and if we dissolve the chlorophacinone in the pond, the resulting concentration is 5.7 $ng \cdot L^{-1}$. Alternatively we can estimate the amount of product that would be required to raise the concentration to the level of concern. The most sensitive aquatic species with a measured endpoint is rainbow trout which has an LC_{50} of 452 $\mu g \cdot L^{-1}$. The associated endangered species LOC is $1/20^{th}$ this value or 22.6 $\mu g \cdot L^{-1}$. To reach this concentration in the pond would require 19,960 lb of product (22.6 $\mu g \cdot L^{-1}$ X $1x10^{-6}$ $g \cdot \mu g^{-1}$ X $2x10^{7}$ L / 453 g·lb / 0.00005 lb-chlorophacinone/lb-product).

3.3. Bioconcentration in fish and aquatic organisms

Because of its known propensity for secondary poisoning, it is worthwhile to assess the amount of chlorophacinone that may occur in exposed fish. Based on the measured octanol water partition coefficient of 97 (MRID 42237401), the bioconcentration factor for chlorophacinone can be estimated at 2.408 using the regression method in EPISuite 4.0. Based on the peak EEC estimated with GENEEC for the artichoke use, 0.275 ug/L, the concentration found in fish tissue

would be 0.543 ug/kg-fish tissue. The concentration that would be found in a daphnid which was exposed at the LC50 of 640 ppb (highly unlikely given the above exposure assessments), the concentration in tissue would be 2.7 mg/kg-body weight.

3.4. Terrestrial Animal Exposure Assessment

For assessing exposure of pesticides to terrestrial animals, the Agency typically uses T-REX to calculate EECs for dietary exposure of terrestrial wildlife, and T-HERPS to calculate refined EECs for dietary exposure to reptiles and amphibians. However, these models only calculate EECs (and risk quotient based on the EECs) for natural wildlife food items such as plants, seeds, and insects that are exposed from foliar application of pesticides. These models are not appropriate for calculating EECs for animals that directly consume bait products, or that consume other animals which consume the bait products. These models also calculate risk quotients (RQs) for application of granular pesticides and seed treatment uses, but cannot be used to calculate RQs for bait products. Therefore, terrestrial animal exposure to chlorophacinone was calculated without use of T-REX and T-HERPS.

For this assessment, it was assumed that terrestrial animals could be exposed in two different pathways. Animals may directly consume bait (primary consumption), or animals may consume contaminated carcasses either killed or scavenged by the consumer (secondary consumption). Both approaches and the expected exposure levels are detailed below. It is important to note that these methods are not typically used in EFED risk assessments.

3.4.1. Expected Chlorophacinone Ingestion through Bait Consumption

Exposure through bait consumption will be calculated using two methodologies. For the first method, chlorophacinone exposure is calculated as mg a.i./kg-bwt, where kg-bwt is the kilograms of the consuming individual for three standard weight classes of passeriforms and rodents and for typical weights of the SMHM and the SJKF. Exposure (food dry weight consumption) estimates were derived using allometric equations from USEPA (1993). The allometric equations for passeriform birds and rodent mammals were used as these would best approximate those individuals with high potential for consuming grain and they would give the most conservative exposure estimates. Food dry weight was converted to wet weight assuming the bait contained 10% water, similar to the assumption that seeds for wildlife consumption contain 10% water (USEPA 1993). Formulas for calculation of dose estimates are provided in **Table 3.5**, and chlorophacinone exposure estimates (on a dose basis) are provided in **Table 3.6**. The default weight classes of birds are small (20 g), medium (100 g), and large (1000 g), and the default weight classes for mammals are small (15 g), medium (35 g), and large (1000 g).

EECs for direct effects to the SMHM and the SJKF are calculated based on estimated average body weights. EECs for indirect effects of reduction in prey (birds, reptiles, terrestrial amphibians, and mammals) and habitat (*e.g.*, use of nests and burrows by the listed species) are also calculated. RQs are generated by dividing these exposure estimates of chlorophacinone (mg a.i./kg-bwt) for a given weight class by the most conservative toxicity endpoint for the relevant taxa adjusted for the default body weights. RQs using these exposure estimates were generated for acute bird and mammal (using LD_{50} data) and chronic mammal (using the NOAEL from a developmental study).

Table 3.5 Formulas for Calculation of Chlorophacinone Intake based on Consumption of Bait.

Passeriform bird food intake (g, dry weight): FI (g dry-wt/day) = 0.398 * $Wt(g)^{0.850}$

**Rodent mammal food intake (g, dry weight*): FI (g dry-wt/day) = 0.621 * $Wt(g)^{0.564}$

***Mammal food intake (g, dry weight*): FI (g dry-wt/day) = 0.235 * $Wt(g)^{0.822}$

Food intake (g, wet weight): FI (g wet-wt/day) = FI (g dry-wt/day) / 0.90

Chlorophacinone intake (mg a.i./kg-bwt/day) = FI (g wet-wt/day) * **C** mg a.i./kg-bait / Wt(g)

Where: Wt(g) = weight (in grams) of the bird or mammal consumer
C(mg a.i./kg-bait) = concentration of chlorophacinone in bait

*Equation for SMHM and generic bait-consuming rodents
**Equation for SJKF food consumption

Table 3.6 Expected Chlorophacinone Intake for SMHM, SJKF, and Generic Bird and Mammal Weights based on Consumption of Bait.

Species or Taxa	% a.i. in bait	Weight (g)	Food intake (g dry-wt/day)	Food intake (g wet-wt/day)	Chlorophacinone intake (mg a.i./kg-bwt/day)
SMHM	0.005	10	2.3	2.5	12.6
	0.010	10	2.3	2.5	25.3
SJKF	0.005	2300	136	151	3.3
	0.010	2300	136	151	6.6
Passeriform Birds*	0.005	20	5.1	5.6	14.1
		100	19.9	22.2	11.1
		1000	141.2	156.9	7.8
	0.010	20	5.1	5.6	28.2
		100	19.9	22.2	22.2
		1000	141.2	156.9	15.6
Rodent Mammals	0.005	15	2.9	3.2	10.6
		35	4.6	5.1	7.3
		1000	30.6	34.0	1.7
	0.010	15	2.9	3.2	21.2
		35	4.6	5.1	14.6
		1000	30.6	34.0	3.4

*surrogate for reptiles and terrestrial-phase amphibians

The second exposure method for primary consumption of bait results in a diet concentration of 50 mg a.i./kg-bait (concentration of chlorophacinone as packaged in bait) and a diet concentration of 100 mg a.i./kg-bait. Since these EECs are not dependent on body weight or food consumption rates, they can be used for both direct effects to the SMHM and SJKF and indirect effects to all four evaluated species. RQs are calculated using this estimate of dietary concentration and the LC_{50} (mg a.i./kg-diet) available from dietary toxicity studies. RQs using

these exposure estimates were generated for acute bird and mammal (using LC_{50} data) and chronic bird (using the NOAEC from reproduction study).

3.4.2. Expected Chlorophacinone Ingestion through Consumption of Contaminated Carcasses

Exposed mammals, birds, amphibians and reptiles, have the potential to consume chlorophacinone bait. The determination of chlorophacinone intake for individuals consuming chlorophacinone poisoned animals or carcasses is calculated in a manner similar to the approach for individuals consuming bait (**Section 3.3.1**). Empirical residue data are used instead of bait concentration of chlorophacinone (**Table 3.7**). Chlorophacinone body burdens in deceased field and laboratory studies were determined in mammals, after exposure to chlorophacinone bait. Data are available for a variety of small and medium sized mammalian granivores and omnivores, with the majority of data from ground squirrels. No data were identified for other exposed taxonomic groups (*e.g.*, birds, herptiles, and invertebrates). For all studies, it was assumed the concentrations were reported using wet weights of the mammals. In field studies, mean concentrations ranged from 0.13 to 1.58 mg a.i./kg-bw, with reported individual values ranging from <LOD to 4.1 mg a.i./kg-bw. Field collected data are subject to a number of uncertainties including, but not limited to:

- possible partial decomposition of bodies in field,
- collection may miss carcasses with highest body burdens, and
- collection may miss individuals that were rapidly predated, died off site, or died underground.

In laboratory studies, mean chlorophacinone concentrations ranged from 0.45 to 0.47 mg a.i./kg-bw. Because of the lack of data on chlorophacinone residues in birds, amphibians and reptiles, it was assumed the mammal body burden data would be relevant for all the evaluated taxonomic groups. Due to the uncertainties regarding adequate sampling to capture the full distribution of carcass residue values, the maximum reported individual value, 4.1 mg a.i./kg-carcass, will be used for this assessment.

Some previous assessments used a mean residue concentration of 3.2 mg a.i./kg-carcass (MRID 42760901, MRID 40751402, E73126). This study provided information on residues in chlorophacinone-fed voles and secondary toxicity of chlorophacinone to raptors who ate the chlorophacinone-fed voles. While this study is useful for investigating secondary toxicity of chlorophacinone, the reported residue concentrations of the voles and raptors are not scientifically valid as the carcasses were received by the chemical analysis laboratory in a "thawed and rotten" condition.

Table 3.7 Chlorophacinone Residue Levels in Mammalian Primary Consumers					
Exposure information	**Carcass species**	**Sample size**	**mg ai/kg bait**	**Mean whole-carcass residue (mg a.i./kg-bw)**	**Reference**
Field, spot bait; active burrows treated 2 day interval for 4 applications. Daily carcass searches, first 10 carcasses collected after trt began	California ground squirrel	10	100	1.27 ± 0.56 (sd) range (0.237 – 2.24)	MRID 43922201 Baroch 1996 (Supplemental)
Field, spot bait; active burrows treated 2 day interval for 4 applications. Daily carcass searches, first 10 carcasses collected after trt began	California ground squirrel	10	50	0.52 + 0.31(sd) range (0.244 – 1.29)	
Field, bait stations. Daily carcass searches, first 10 carcasses collected after trt began	California ground squirrel	10	50	0.57 ± 0.27 (sd) range (0.123 – 0.896)	MRID 43922202 Baroch 1996 (Supplemental)
Field, spot bait. Daily carcass searches for 15 days after trt began	Belding's ground squirrel	38	100	6 carcasses<LOD=0.025 32 carcasses: 0.159+0.141(sd) range (0.025 – 0.546)	Ramey et al. 2007 Primus et al. 2001 (E0165) (Quantitative)
Field, bait station. Daily carcass searches for 15 days after trt began	Belding's ground squirrel	16	50	0.122 range (<LOD, 0.265)	Primus et al. 2001 (E0165) Matschke, 1999 (Quantitative)
	Microtus sp. vole	3	50	1.58 range(0.26-4.1)	
Field, bait applied in burrow systems. Radio-collared animals followed for 13 days after application. Collared animals with no movement for 3 days were excavated.	Valley pocket gopher	8	50 and 100	0.357 range (<LOD, 1.21)	Primus et al. 2001 (E0165) Stewart et al 2000 Quantitative

Table 3.7 Chlorophacinone Residue Levels in Mammalian Primary Consumers					
Exposure information	**Carcass species**	**Sample size**	**mg ai/kg bait**	**Mean whole-carcass residue (mg a.i./kg-bw)**	**Reference**
Field, spot bait; Collected daily 2-15 days after first application	California ground squirrel	21	50	0.28 range (0.02 – 0.71)	MRIDs 45855101 and 46117303 Salmon et al 2002 Goodall et al. 2002 (supplemental)
Field, spot bait; Collected daily 2-15 days after first application	California ground squirrel	16	100	1.41 range (0.30 – 2.72)	
Field, broadcast; Collected daily 2-15 days after first application	California ground squirrel	16	50	0.26 range (<LOD, 1.01)	
Field, broadcast; Collected daily 2-15 days after first application	California ground squirrel	20	100	0.51 range (<LOD – 1.31)	
Field, in-burrow; Collected daily 2-15 days after first application	Black tailed prairie dogs (8) and one cottontail rabbit	9	50	0.58 range (0.01, 1.25)	MRIDs 47333602, 47333603 and 48294401 (supplemental)
Field, bait application and collection methods unknown	Black-tailed prairie dog	8	NA	1.48 range(0.85, 2.24)	
Laboratory, 5 days bait consumption	Laboratory rat	5	50	0.47 range(0.21-0.93)	MRID 44631402 Baroch 1997 (supplemental)
Laboratory, 5 days bait consumption	Laboratory rat	4	50	0.45 range(0.18-0.81)	MRID 44631401 Ahmed et al. 1996 (supplemental)

Chlorophacinone exposure through carcass consumption is calculated as mg a.i./kg-bwt, where kg-bwt is the kilograms of the consuming individual for three weight classes of birds and mammals. For this analysis, bird weight classes of 50, 1000, and 2000 g individuals and mammal weight classes of 50, 1000, and 3000 g individuals were used to better represent the larger size of carnivores and scavengers relative to the full range of bird and mammal weights. Exposure (food dry weight consumption) estimates were derived using the generic bird and mammal allometric equations from (EPA 1993). Food dry weight was converted to wet weight assuming the consumed prey/carcass contained 68 % water (USEPA 1993). Formulas for calculation of dose estimates are provided in **Table 3.8**, and chlorophacinone exposure estimates (on a dose basis) are provided in **Table 3.9**.

EECs for direct effects to the SJKF, CTS, and AW are calculated based on estimated average body weights. EECs for indirect effects of reduction in prey (birds, reptiles, terrestrial amphibians, and mammals) and habitat (*e.g.*, use of nests and burrows by the listed species) are also calculated.

Secondary exposure was also evaluated for assessing risk to the AW. This species may be exposed if it consumes a vertebrate animal that has eaten chlorophacinone bait. Lizards in particular are believed to be the most important prey item of whipsnakes (USFWS 2005), but lizards generally feed upon insects and other terrestrial arthropods and would not likely consume rodent bait. Therefore, secondary exposure was based on consumption of small mammals, which are also a component of the diet of the AW. For assessing secondary exposure for the AW, scenarios were considered in which a snake preyed upon a house mouse, a broad-footed mole, or a Norway rat after they prey had consumed chlorophacinone bait. The maximum size of the prey consumed by snakes may be estimated using the following allometric equation developed by King (2002).

$$\text{Prey Size (g)} = \text{Snake body weight (g)}^{1.071}$$

To make this assessment protective, the exponent used in this equation is the upper limit of the 95% confidence interval that King (2002) reported for this parameter. The weight of the AW was not available, but the Agency has estimated body weight of this species from its length using the method presented in USEPA (1993). The body weights of this species were estimated to range from 2.5 to 176 g for juveniles and 46 to 897 g for adults (USEPA 2010a). Using the upper bounds of these ranges, and the allometric equation given above, the maximum prey size for the AW was estimated to be 254 g for juvenile snakes and 1450 g for adult snakes. Reported body weights of house mice, eastern mole (similar to the broad-footed mole), and Norway rat are 18-23 g, 82-140 g, and 195-485 g, respectively (Whitaker, 1996). Therefore, the AW is predicted to be able to consume all three of these prey species, including the Norway rat. In this assessment, the upper limit of the reported ranges was used for the body weight of each prey (23 g for the house mouse, 140 g for the broad-footed mole, and 485 g for the Norway rat.)

The size of the AW was set at the minimum size animal that could consume prey of the size assumed for the three prey species. This was done by setting the prey size in the allometric equation for maximum prey size, given above, and solving for snake body weight. The minimum snake size to consume the mouse, mole, and rat was calculated to be 18.6, 101, and

322 g, respectively. The 18.6-g snake is plausible for a juvenile AW, the 322-g snake is plausible for an adult AW, and the 101-g snake is plausible for either an adult or large juvenile AW.

Secondary exposure was also evaluated for assessing risk to the CTS. This species may be exposed if it consumes a vertebrate animal that has eaten chlorophacinone bait. Secondary exposure was based on consumption of small mammals, which are also a component of the diet of the CTS. CTS weights of 15 and 80 g and the allometric equation for insectiviorous iguanids (USPEA 1993) was used to establish prey sizes (**Table 3-8**).

RQs are generated by dividing these exposure estimates of chlorophacinone (mg a.i./kg-bwt) for a given weight class by the most conservative toxicity endpoint for the relevant taxa adjusted for the default body weights. RQs using these exposure estimates were generated for acute bird and mammal (using LD_{50} data) and chronic mammal (using the NOAEL from a developmental study) toxicity.

Table 3-8 Formulas for Calculation of Chlorophacinone Intake based on Consumption of Carcasses.

Bird food intake (g, dry weight): FI (g dry-wt/day) = $0.648 * Wt(g)^{0.651}$

**Mammal food intake (g, dry weight*): FI (g dry-wt/day) = $0.235 * Wt(g)^{0.822}$

***Snake food intake (g, wet weight):* FI (g wet-wt/day) = $Wt(g)^{1.071}$

**** Insectivorous iguanid (g, wet weight):* FI (g dry-wt/day) = $0.013 * Wt(g)^{0.773}$

Food intake (g, wet weight): FI (g wet-wt/day) = FI (g dry-wt/day) / 0.32

Chlorophacinone intake (mg a.i./kg-bwt/day) = FI (g wet-wt/day) * 4.1 mg a.i./kg-carcass / Wt(g)

Where: Wt(g) = weight (in grams) of the bird or mammal consumer

*Equation for SJKF and generic carnivorous mammals
**Equation for AW
***Equation for CTS

Table 3-9 Expected Chlorophacinone Intakes for SJKF, AW, Carnivorous Birds and Mammals based on Consumption of Contaminated Carcasses				
Species or Taxa	**Weight (g)**	**Food intake (g dry-wt/day)**	**Food intake (g wet-wt/day)**	**Chlorophacinone intake (mg a.i./kg-bwt/day)[1]**
SJKF	2300	136	426	0.76
AW	18.6	-	23	5.05
	101	-	140	5.69
	322	-	485	6.18
CTS	15	0.1	0.3	0.09
	80	0.4	1.2	0.06
Birds*	50	8.3	25.8	2.12
	1000	58.2	181.7	0.75
	2000	91.3	285.4	0.59
Mammals	50	5.9	18.3	1.86
	1000	68.7	214.7	1.50
	3000	169.5	529.8	0.72

*surrogate for reptiles and terrestrial-phase amphibians
[1] See Table 3-8 for derivation.

The second exposure method for consumption of contaminated carcasses results in a carcass concentration of 4.1 mg a.i./kg-carcass (maximum measured concentration of chlorophacinone in carcasses). RQs are calculated using this estimate of dietary concentration and the LC_{50} (mg a.i./kg-diet) available from dietary toxicity studies. RQs using these exposure estimates were generated for acute bird and mammal (using LC_{50} data) and chronic bird (using the NOAEC from reproduction study).

3.4.3. Exposure to Terrestrial Invertebrates

Exposure to invertebrates can occur through consumption and contact with bait. These individuals could then either be negatively affected or be available to be consumed by any of the four evaluated species as well as other animals. EFED does not currently have methodology for estimation of terrestrial invertebrate exposure through contact with a treated bait. In addition, EFED does not currently have any chlorophacinone data to enable the estimation of invertebrate body burden of chlorophacinone. Therefore, for this assessment, it was assumed that dietary chlorophacinone exposure through the consumption of contaminated invertebrates was comparable to consumption of contaminated mammals (**Section 3.3.2**).

4. Effects Assessment

This assessment evaluates the potential for chlorophacinone to directly or indirectly affect AW, SMHM, CTS, and SJKF or modify their designated critical habitat. Assessment endpoints for the effects determination for each assessed species include direct toxic effects on the survival, reproduction, and growth, as well as indirect effects, such as reduction of the prey base or modification of its habitat. In addition, potential modification of critical habitat is assessed by evaluating effects to the PCEs, which are components of the critical habitat areas that provide essential life cycle needs of each assessed species. Direct effects to the aquatic-phase CTS are based on toxicity information for freshwater fish, while terrestrial-phase amphibian effects (CTS)

and reptiles (AW) are based on avian toxicity data, given that birds are generally used as a surrogate for terrestrial-phase amphibians and reptiles.

As described in the Agency's Overview Document (USEPA, 2004a), the most sensitive endpoint for each taxon is used for risk estimation. For this assessment, evaluated taxa include freshwater fish (used as a surrogate for aquatic-phase amphibians), freshwater invertebrates, aquatic plants, birds (used as a surrogate for terrestrial-phase amphibians and reptiles), mammals, terrestrial invertebrates, and terrestrial plants. 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 chlorophacinone.

4.1. Ecotoxicity Study Data Sources

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (USEPA, 2004a). Open literature data presented in this assessment were obtained from previous risk assessments as well as ECOTOX information obtained on 30 November 2010. In order to be included in the ECOTOX database, papers must meet the following minimum criteria:

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

Open literature toxicity data on the effects of chlorophacinone to "target" rodent species (the house mouse, the Norway rat, and the wood rat), which include efficacy studies, were not considered in deriving the most sensitive endpoint for terrestrial mammals. In the case of rodenticides, adequate data on the toxicity to rats and mice are already provided by acute mammalian toxicity studies that the rodenticide registrants are required to submit for product registration. Therefore, toxicological data on target species of rats and mice were not included in the ECOTOX open literature search that the Agency conducted, and are not included in the summary table provided in **Appendix G**. Citations of open literature papers that provide toxicological data for target rodent species are listed in **Appendix F** with the code "TARGET" given after the citation. While toxicological findings were not included in the summary of acute and chronic toxicity endpoints in this document, some of these papers which were deemed useful were obtained and used to provide supplemental information for characterizing the toxicity of chlorophacinone, such as information on the sublethal effects and the mode of action of chlorophacinone.

Data that pass the ECOTOX screen are evaluated along with the registrant-submitted data, and may be incorporated qualitatively or quantitatively into this endangered species assessment. In general, effects data in the open literature that are more conservative than the registrant-submitted data are considered. The degree to which open literature data are quantitatively or

qualitatively characterized for the effects determination is dependent on whether the information is relevant to the assessment endpoints (*i.e.*, survival, reproduction, and growth) identified in **Section 2.8**. For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, because quantitative relationships between modifications and reduction in species survival, reproduction, and/or growth are not available. Although the effects determination relies on endpoints that are relevant to the assessment endpoints of survival, growth, or reproduction, it is important to note that the full suite of sublethal endpoints potentially available in the effects literature (regardless of their significance to the assessment endpoints) are considered, as they are relevant to the understanding of the area with potential effects, as defined for the action area.

Citations of all open literature not considered as part of this assessment because they were either rejected by the ECOTOX screen or accepted by ECOTOX but not used (*e.g.*, the endpoint is less sensitive) are included in **Appendix F**. **Appendix F** also includes a rationale for rejection of those studies that did not pass the ECOTOX screen and those that were not evaluated as part of this endangered species risk assessment. A detailed spreadsheet of the available ECOTOX open literature data, including the full suite of lethal and sublethal endpoints is presented in **Appendix G**. Reviews of open literature data are included in **Appendix H**. **Appendix E** includes a summary of the human health effects data for chlorophacinone excerpted from the 1998 Rodenticide Cluster RED.

In addition to registrant-submitted and open literature toxicity information, other sources of information, including use of the acute probit dose response relationship to establish the probability of an individual effect and reviews of ecological incident data, are considered to further refine the characterization of potential ecological effects associated with exposure to chlorophacinone. A summary of the available aquatic and terrestrial ecotoxicity information and the incident information for chlorophacinone are provided in **Sections 4.2** and **4.3**.

4.2. Toxicity of Chlorophacinone to Aquatic Organisms

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

Chlorophacinone is highly toxic to freshwater fish and invertebrates on an acute basis. No acceptable or supplemental data are available to characterize chronic toxicity to freshwater fish and invertebrates, acute and chronic toxicity to estuarine/marine fish and invertebrates, and toxicity to aquatic plants. The available acute toxicity data for freshwater fish and invertebrates will be used to represent effects of acute exposures of estuarine/marine fish and invertebrates to chlorophacinone.

Table 4-1 Aquatic Toxicity Profile for Chlorophacinone				
Assessment Endpoint	**Tested Species**	**Toxicity Value (95% CI) Used in Risk Assessment**	**Source Citation**	**Status/Comments**
Freshwater Organisms				
Acute Toxicity to Fish and Aquatic-phase Amphibians	Rainbow trout *(Oncorhynchus mykiss)*	96-hr LC_{50} = 452 µg/L (416, 494) Slope = 16.3 (9.3, 23.2)	42356103 (Machado 1992)	Acceptable, highly toxic
Acute Toxicity to Aquatic Invertebrates	Water flea (*Daphnia magna)*	48-hr EC_{50} = 640 µg/L (538, 808) Slope = 5.1 (2.8, 7.4)	42356101 Putt (1992)	Acceptable, highly toxic

Toxicity to fish and aquatic invertebrates is categorized using the system shown in **Table 4-2** (USEPA, 2004a). Toxicity categories for aquatic plants have not been defined.

Table 4-2. Categories of Acute Toxicity for Fish and Aquatic Invertebrates	
LC_{50} (mg/L)	**Toxicity Category**
< 0.1	Very highly toxic
> 0.1 - 1	Highly toxic
> 1 - 10	Moderately toxic
> 10 - 100	Slightly toxic
> 100	Practically nontoxic

4.3. Toxicity of Chlorophacinone to Terrestrial Organisms

Table 4-3 summarizes the most sensitive terrestrial toxicity endpoints, based on an evaluation of both the registrant-submitted studies and the open literature. A brief summary of submitted and open literature data considered relevant to this ecological risk assessment is presented below. Data on toxicity of chlorophacinone to terrestrial plants are not available. Additional information is provided in **Appendix D**.

Table 4-3. Terrestrial Toxicity Profile for Chlorophacinone					
Taxa	**Study Type**	**Species Tested**	**Toxicity Value Used in Risk Assessment**	**Citation or MRID**	**Classification and Comments**
Bird	Gavage (single dose)	Northern bobwhite *Colinus virginianus*	LD_{50} = 258 mg a.i./kg-bw Slope = 2.88	41513101	Acceptable (mortalities occurred ≤ 5 days after gavage, observed 30 days)
	Dietary (5-day exposure)	Northern bobwhite *Colinus virginianus*	LC_{50} = 56 mg a.i./kg-diet Slope = 1.49	41513102	Acceptable (mortalities occurred ≤ 9 days after test start, observed 30 days)
	13-week subchronic	Japanese quail *Coturnix c. japonica*	NOAEC = 1 mg/kg-diet	47323201	Supplemental (non-guideline reproduction study, no raw data submitted, non-GLP)
Mammal	Gavage (single dose)	Black-tailed Prairie Dogs *Cynomys ludovicianus*	LD_{50} = 1.94 mg a.i./kg-bw	47333601	Supplemental (Single dose, mortalities occurred 9 to 22 days after dosing)
	Gavage (5-day exposure, multiple dose)	Norway Rat *Rattus norvegicus*	5-day LD_{50} = 0.8 mg a.i./kg-bw	Ashton, *et al.* (1986)	Qualitative (multiple dose; doses of 0.16 mg a.i./kg-bw were administered daily for 5 consecutive days equal the LD_{50} dose)
	Dietary (5-day exposure)	Laboratory Rat *Rattus norvegicus*	LC_{50} = 1.14 mg a.i./kg-diet Slope = 7.19	Teeters 1981 (TNM 117)*	Supplemental (mortalities occurred 4-9 days after test start, observed 9 days)
	Developmental Gavage (daily from days 7 to 19 of gestation)	Rabbit	Developmental NOAEL = 10 µg/kg-bw/day	MRID 43570801	Acceptable (endpoint based lack of sufficient fetuses/litters at the higher dose levels as high maternal mortality was observed)
*Teeters, W.R. (1981) Chlorophacinone technical: Toxicity to Laboratory Rat: Test No. 117. (U.S. Environmental Protection Agency, Pesticides Regulation Div., Agricultural Research Center, Animal Biology Laboratory, unpublished report.)					

Acute toxicity to terrestrial animals is categorized using the classification system shown in **Table 4-4** (USEPA, 2004a). Toxicity categories for terrestrial plants have not been defined.

Table 4-4. Categories of Acute Toxicity for Avian and Mammalian Studies		
Toxicity Category	**Oral LD_{50}**	**Dietary LC_{50}**
Very highly toxic	< 10 mg/kg	< 50 mg/kg-diet
Highly toxic	10 - 50 mg/kg	50 - 500 mg/kg-diet
Moderately toxic	51 - 500 mg/kg	501 - 1000 mg/kg-diet
Slightly toxic	501 - 2000 mg/kg	1001 - 5000 mg/kg-diet
Practically non-toxic	> 2000 mg/kg	> 5000 mg/kg-diet

4.3.1. Toxicity to Birds

4.3.1.a. Primary Toxicity: Acute and Chronic Studies

Chlorophacinone is moderately acutely toxic to birds with the most sensitive endpoints being an acute LD_{50} of 258 mg a.i./kg bw and a 5-day sub-acute LC_{50} of 56 mg a.i./kg-diet (MRID 41513101 and 41513102). Sublethal effects noted in the gavage study in all test groups (MRID 41513101) included lethargy, subcutaneous, intramuscular, and internal hemorrhaging, piloerection, diarrhea, bloody diarrhea, and anorexia. Sublethal effects noted in the dietary study in all test groups (MRID 41513102) included subcutaneous, intramuscular, and internal hemorrhaging, and swollen, bloody feet. Previous assessments included an LD_{50} = 430 mg a.i./kg-bw (red-winged blackbird, Clark 1994); however, this value will not be used in this assessment as data were not available to verify that value.

One sub-chronic study conducted with Japanese quail was submitted to the Agency (MRID 47323201, supplemental). Young breeding pairs were fed diets containing chlorophacinone for 13 weeks, and resulting eggs were collected and hatched. A NOAEC of 1 mg a.i./kg-diet (NOAEC of 2 mg a.i./kg-diet) was established due to adult mortality. The study authors also reported that reproduction was not affected until dose levels are reached in which the physiological changes (blood coagulation changes, microcytic anemia at 4 and 8 mg a.i./kg-diet) and mortality are already manifested.

4.3.1.b. Secondary Toxicity: Acute Studies

The effects of chlorophacinone poisoned carcasses on predatory and scavenging birds have been evaluated in many studies (**Table 4-5**). This information was previously compiled (USEPA 2004b, USEPA 2010b). In this assessment, some studies were excluded due to lack of sufficient information to conduct a review. Though no mortalities were reported in these studies, sublethal effects including external bleeding and internal hemorrhaging were reported. Though these studies do not allow for quantification of effect, they confirm that secondary exposure can result in effect.

Table 4-5 Secondary Hazards of Chlorophacinone to Birds in Laboratory Studies						
Predator/ scavenger species	**Prey offered to birds**	**No. prey offered daily per bird**	**No. days Birds exposed**	**Mortality outcome**	**Signs of toxicity**	**Reference**
Barn owl	rats fed choice of 0.005% bait or untreated bait for 5 days	1-2	1 owl for 1 day 1 owl for 6 days 2 owls for 3 days 2 owls for 10 days All owls followed 20 days	No mortalities out of the 6 barn owls exposed	none	MRID 46750931 (Mendenhall and Pank 1980) Qualitiative
Black-billed magpie	rats fed 0.005% bait for 5 days	One rat offered day 1 and day 3.	Fed treated rats for 5 days, birds observed for total of 21 days	No mortalities out of the 20 birds exposed	No overt signs of tox. Yellowing of liver in 4 birds, spleen color not uniform in one bird.	MRID 44631402 (Supplemental) (Baroch 1997)
American kestrel	mice fed 0.01% bait until dead	Grp 1: 1 treated mouse daily for 21 days, then untreated mouse daily till day 61 Group 2: 1 treated mouse every 3 days, untreated mouse on other days. Exposure time: 61 days.		None of the 10 birds in either group died.	All treated birds exhibited hemorrhaging in one or more organs	E39765 Radvanyi et al. 1988 Qualitiative
Red-tailed hawk	voles fed 10 g 0.005% bait daily for up to 9 days	2	Feed treated voles for 6 days, then untreated voles; total test length was 34 days	None of the 4 birds died	No signs of adverse behavior. No signs of discomfort or stress or bleeding.	Askham 1988, E73126 Askham and Poché 1992 Qualitative
Great horned owl				The 1 owl did not die		

4.3.2. Toxicity to Mammals

4.3.2.a. Primary Toxicity: Acute and Chronic Studies

Chlorophacinone is very highly acutely toxic to mammals with the most sensitive endpoints being an acute LD_{50} of 1.94 mg a.i./kg-bw and an LC_{50} = 1.14 mg a.i./kg-diet (MRID 41875301 and Teeters, 1981(TNM117)). In the prairie dog gavage study (MRID 41875301), sublethal effects included reduced reaction to external stimuli, reduced appetite, lethargy, hunched posture, comatose state, cold to the touch, reduced grooming, dull/closed/swollen eyes, reduced feces, bloody feces, and external bleeding. In the laboratory rat dietary study (TNM117), reductions in feed consumption and weight gain were recorded; clinical signs of toxicity were not reported.

A multiple-dose gavage study on rats resulted in a 5-day LD_{50} of 0.8 mg a.i./kg-bw (0.16 mg a.i./kg-bw dose daily for five days); however, this open literature study was classified as Qualitative as control animals were not used (Ashton *et al*., 1986). Previous assessments used an LD_{50} = 0.49 mg a.i./kg-bw (deer mouse, Clark 1994); however, this value will not be used in this assessment as data were not available to verify that value.

No two-generation reproduction studies were submitted to the Agency, but two developmental studies were submitted and can be used to assess chronic effects of chlorophacinone. The most sensitive study investigated rabbit developmental toxicity (MRID 43570801, Acceptable). Doses were administered by oral gavage daily from gestation days 7 to 19, inclusive. The maternal NOAEL=5 µg/kg-bw/day (LOAEL = 10 µg/kg-bw/day) was based on increased prothrombin and activated partial thromboplastin times in the preliminary range-finding study at gestation day 20. The developmental NOAEL=10 µg/kg-bw/day (LOAEL = 25 µg/kg-bw/day) was based on lack of sufficient fetuses/litters at higher dose levels as high maternal mortality was observed (13/16 rabbits at 25 µg/kg-bw/day and 16/16 rabbits at 75 µg/kg-bw/day) in definitive test. In addition, external bleeding and internal hemorrhage were observed in the 25 µg/kg-bw/day and 75 µg/kg-bw/day dose groups. For this assessment, the developmental NOAEL = 10 µg/kg-bw/day (LOAEL = 25 µg/kg-bw/day) will be used for risk estimation as the effected endpoint is directly linked to survival, growth, and/or reproduction. It should be noted that the observed increase in prothrombin and activated partial thromboplastin times is an indication of an increase in clotting time and a decrease in clotting ability. These effects may result in animals more prone to hemorrhaging, thus injury and death.

4.3.2.b. Secondary Toxicity: Acute Studies

The effects of chlorophacinone poisoned carcasses on predatory and scavenging mammals have been evaluated in many studies (**Table 4-6**). This information was previously compiled (USEPA 2004b, USEPA 2010b). In this assessment, some studies were excluded due to lack of sufficient information to conduct a review. Mortalities and sublethal effects, including external bleeding and internal hemorrhaging, were reported. Though these studies do not allow for quantification of effect, they confirm that secondary exposure can result in effect.

Table 4-6 Secondary Hazards of Chlorophacinone to Mammals in Laboratory Studies

Predator/ scavenger species	Prey offered to mammal	No. prey offered daily per mammal	No. days Mammal exposed	Mortality outcome	Signs of toxicity	Reference
Mongoose	rats fed 0.005% bait for 5 days	1	Each mongoose fed 1 to 10 rats during 1st 5 days, followed for 20 days	7 of the 8 mongoose died between 5 and 20 days on test	Increased blood coagulation times, no other indicators reported	MRID 2467 Pank and Hirata 1976 Qualitative
Coyote	ground squirrels fed 15 g of 0.01% bait for 6 days	1	Fed treated squirrel for 5 days, followed for 30 more days	3 of the 7 coyotes died	3 deaths due to internal hemorrhaging. No other signs of toxicity.	MRID 42760902 Marsh and Howard 1986 (Supplemental)
European ferret	rats fed 0.005% bait for 5 days	As needed, each ate 1-5 rats	5, followed for 21 more days	11 of 20 ferrets died between 5 and 12 days on test	Hemorrhaging from nose, moribund; liver chlorophacinone concentrations in two of the deceased ferrets were 0.600 and 0.483 µg/g	MRID 44631401 Ahmed et al. 1996 (Supplemental)
European ferret	prairie dogs fed 25 g of 0.0025% bait daily for 6 days	4 (1 every other day)	8, followed for 30 more days	5 of 6 ferrets died	Internal hemorrhaging in dead ferrets, not reported in the surviving ferret.	Fisher and Timm 1987 Qualitative

4.3.3. Toxicity to Terrestrial Invertebrates

A two-phase study on a burying beetle, *Nicrophorus orbicollis*, was performed to assess the impacts of chlorophacinone on the survival and larval growth of burying beetles (MRID 47383001). The first phase investigated effects of chlorophacinone on the emergence (number of beetles produced), growth, and sex ratio of burying beetles raised on chlorophacinone-dosed rat carcasses. Concentrations of chlorophacinone in the rat carcasses were not available. Significant differences between control and treatment groups were found for carcass weight, number of beetles produced, and estimated total brood weight (g). The second phase of the study investigated effects on the survival and reproductive success of burying beetle adults fed chlorophacinone-dosed ground beef (3.0 mg a.i./kg-beef) for 28 days prior to being provided an undosed quail carcass for brooding of young. No significant differences were found between the

treatment and control groups (subsequent ability of adults fed no-choice diets to brood and produce normal progeny). Based on this two-phase study, the most sensitive phase of the beetle life-cycle was brooding/reproduction; however, the chlorophacinone exposure estimates for this phase were not available.

A 14-day toxicity test on the earthworm (*Eisenia foetida*) resulted in an LC_{50} > 1000 mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (MRID 47383002). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil. These are preliminary results, as Agency review of this study has not been completed.

4.4. Incident Database Review

A review of the Ecological Incident Information System (EIIS, version 2.1), the 'Aggregate Incident Reports' (v. 1.0) database, and the Avian Monitoring Information System (AIMS) for ecological incidents involving chlorophacinone was completed on March 10, 2011. The results of this review for terrestrial incidents are in **Tables 4-7 and 4-8** and in **Appendix I**. No plant or aquatic incidents were reported.

Eighteen incident reports are included in **Table 4-7**. Of these 18 incidents, 11 were considered to be probable or highly probable for death due to chlorophacinone. Mortalities included species that were likely primary consumers of the bait (*e.g.,* grey squirrel and wild turkey) and carnivorous species (*e.g.,* badger and red-tailed hawk) likely to have preyed upon the granivorous individuals. Six endangered San Joaquin kit fox mortalities were included in the EIIS database.

Table 4-7 Reported EIIS Incident Summaries for chlorophacinone					
Incident ID/ Year/ Legality	**Formulation/ Product**	**Location**	**Certainty #**	**Species (number of individuals)**	**Certainty Discussion**
B0000-501-41 1990 Misuse (intentional)	bait	San Luis Obispo, CA	3	San Joaquin kit fox (4)	Cholorphacinone was known to be the active ingredient in the bait that was used. Chemical analysis results were one fox had liver chlorophacinone residues of 1.24 ppm, a second fox had residues of 0.4 ppm. Concentrations in the other two foxes were unknown
I009063-001 1999 Undetermined	bait	New York, NY	2	grey squirrel (1)	Cause of mortality was listed as predation. However, chemical analysis revealed 0.44 ppm chlorophacione and trace diphacinone in the liver. Analyst surmised this may have compromised the squirrel's health.
I009111-001 1999 Undetermined	N/R	New York, NY	4	grey squirrel (1)	Of the 15 anticoagulants screened, only chlorophacinone was present in the liver (0.465 ppm). Squirrel had abundant fat, but muscle and liver was anemic, and hemorrhage was observed.
I009118-001 1999 Undetermined	N/R	New York, NY	3	grey squirrel (1)	Chlorophacinone was present in the liver at 0.29 ppm. In addition, the squirrel had a bacterial infection covering the skull, pale muscles and liver. The investigator concluded the infection was the primary cause of death, but blood loss had also occured from the anticoagulant.
I012972-001 2002 Undetermined	Rozol Pocket Gopher Bait	Cheyenne, KS	3	wild turkey (2)	Chlorophacinone was found in the livers of both birds at 0.40 and 0.69 ppm. Both birds exhibited symptoms of anticoagulant poisoning.
I013810-013 1999 Undetermined	N/R	New York, NY	3	red-tailed hawk (1)	Chlorophacinone was found in the liver at 0.18 ppm. Trichomoniasis was also present.
I016100-001 between 1999-2003 Undetermined	N/R	San Joaquin, CA	3	San Joaquin kit fox (1)	Trapping and radiotelemetry study identified 36 kit foxes with cause of death of hemorrhaging between 1999 and 2003. Of those 36 kit foxes, one had chlorophacinone residues in the liver (0.03 ppm). The remaining 35 kit foxes had liver residues of other anticoagulants.
I019311-001 2008 Undetermined	Rozol Pocket Gopher Bait	Milwaukee, WI	4	badger (1)	The National Fish and Wildlife Forensics Lab determined that mortality was caused by anticoagulant poisoning and found chlorophacinone in stomach (0.320 ppm) and liver (2.0 ppm) of the badger.
I019968-001 2008 Undetermined	Pelleted Rozol	Monterey, CA	4	Canadian geese (70) turkey vulture (2) red-tailed hawk (1) barn owl (1) bobcat (1)	Chlorophacinone was tested for in 47 liver or stomach samples of the geese (concentrations ranged from <LOD to 2.2 ppm). Chlorophacinone resides in the turkey vulture livers were 0.004 and 0.005 ppm. No chemical analysis was done on the red-tailed hawk. The barn owl had a chlorophacinone liver concentration of 0.03 ppm. The bobcat had a chlorophacinone liver concentration of 0.340 ppm. Some samples did test postive for other anticoagulant pesticides

Table 4-7 Reported EIIS Incident Summaries for chlorophacinone

Incident ID/ Year/ Legality	Formulation/ Product	Location	Certainty #	Species (number of individuals)	Certainty Discussion
I020607-001 2009 Undetermined	Rozol	Logan, KS	4	badger (1)	Badger exhibited severe hemorrhaging and had a chlorophacinone liver concentration of 4.4 ppm. The badger was found approximately 1/2 mile from a black-footed ferret release site.
I020996-001 2009 Undetermined	N/R	Logan, KS	2	wild turkey (45)	Phosphine gas (indicator of zinc phosphide poisoning) was detected in all 45 turkey crops. Chlorophacione was detected in the crop of one turkey. Concentrations were not provided.
I020996-003 2009 Undetermined	N/R	Logan, KS	2	raccoon (1)	Chlorophacinone, brodifacoum, and bromodiolone were found in the liver (concentrations unknown).
R000-02-002 1994 Undetermined	N/R	Nevada, CA	1	wild turkey (1)	The judgment of the pathologist was that it was unlikely that chlorophacinone was the cause of death. Chlorphacinone was detected in the blood at 5.5 ppm.
R000-02-003 1995 Undetermined	N/R	Marin, CA	3	bobcat (1)	The pathologist called it a "likely" cause of death; liver concentration was 0.4 ppm.
R000-02-005 1997 Undetermined	N/R	Los Angeles, CA	4	coyote (1)	In the pathologist's judgment, chlorophacinone was the Highly Likely cause of death; concentration in liver = 1.2 ppm, blood = 0.04 ppm, and gut contents = 0.24 ppm.
R000-02-007 1998 Undetermined	N/R	Los Angeles, CA	2	coyote (1)	The coyote was trapped and euthanized; body condition was not reported. Chemical analysis resulted in liver concentrations of 0.08 ppm brodifacoum, 0.081 ppm diphacinone, and 0.43 ppm chlorophacinone.
R000-02-015 1999 Undetermined	N/R	Santa Clara, CA	0	coyote (1)	The coyote was trapped and euthanized; body condition was not reported. Chemical analysis resulted in liver concentrations of 0.36 ppm brodifacoum and a trace of chlorophacinone.
R000-02-030 1999 Undetermined	N/R	Kern, CA	1	San Joaquin kit fox (1)	The kit fox was found dead; body condition was not reported. Chemical analysis resulted in liver concentrations of 0.27 chlorophacinone and 0.07 ppm brodifacoum. Pathologist did not determine cause of death.

Certainty Code: 0=Unrelated, 1=Unlikely, 2=Possible, 3=Probable, 4=Highly Probable.

Incident number I-016476 (Berny *et al*., 1997) reported the results of a four year survey (1991-1994) in France based on the activity of a wildlife disease surveillance network (SAGIR). Livers from wildlife suspected of anticoagulant poisoning were subjected to chemical analysis to determine concentrations of the eight anticoagulants available in Europe during the time of the study (chlorophacinone, difenacoum, bromadiolone, warfarin, coumachlor, coumatetralyl, difethailone, and brodifacoum). Berny *et al*. (1997) only reported animals with detectable concentrations of chlorophacinone and bromadiolone, the two most commonly detected chemicals. In France, bromadiolone can only be applied by official Pest Control Operators, and wet baits are buried 15 cm underground. Chlorophacinone in France is sold as 75 ppm bait (against field voles), 50 ppm bait (domestic uses), and as a concentrated formula (2.5 g/L) for farmers to make their own bait. Species with any positive detections of chlorophacinone were included in **Table 4-8**. For the foxes, buzzards, hares, rabbits, and boars reported in **Table 4-8**, some individuals may have positive concentrations of both chlorophacinone and bromadiolone, and some may only have positive concentration of one of the two chemicals. This detailed information was not provided in the journal article.

Table 4-8 Chlorophacinone poisoning in wild animals in France as reported by Berny *et al* (1997), Incident # I016476.

	Animals suspected[1]	Animals submitted for chemical analysis (confirmed positive)[2]	Anticoagulant detected in liver (number)[3]	Median concentration (mg/kg-liver)	Range of concentrations (mg/kg-liver)
Red fox (*Vulpes vulpes*)	34	31 (31)	Broma (22) Chloro (7)	1.5 0.3	0.8 – 6.9 0.2 – 0.6
Buzzard (*Buteo buteo*)	16	16 (15)	Broma (15) Chloro (6)	0.4 0.3	0.2 – 1.3 0.2 – 0.5
Hare (*Lepus capensis*)	59	15 (13)	Broma (2) Chloro (12)	1.4 2.3	1.2 – 1.6 0.2 – 8.3
Rabbit (*Oryct. cuniculus*)	16	13 (12)	Broma (2) Chloro (8)	1.35 2.9	1.3 – 1.4 1.1 – 14.3
Wild boar (*Sus scrofa*)	8	6 (6)	Broma (3) Chloro (3)	0.6 1.2	0.4 – 3.6 0.6 – 1.4
Pigeon (*Columba livia*)	22	4 (4)	Chloro (3)	3.4	1.7 – 3.5
Eagle (*Aquila* sp.)	1	1 (1)	Chloro (1)	6.2	6.2
Barn owl (*Tyto alba*)	7	1 (1)	Chloro (1)	0.3	0.3

[1] Suspected animals included those with clinical/necropsy finding compatible with anticoagulant poisoning.
[2] Submitted (animals sent for chemical analysis); Confirmed (clinical/necropsy compatible and liver anticoagulant concentration ≥ 0.2 mg/kg).
[3] Anticoagulant and number of detects (LOD = 0.2 mg/kg-liver); Broma= Bromadiolone; Chloro = Chlorophacinone

Two chlorophacinone incidents are reported in the EFED Aggregate Incident database (packages 015803 and 020127). One 2004 incident involved Rozol Pocket Gopher Bait (no additional information available), and one 2008 incident involved Rozol pellets (no additional information available).

As reported in EPA (2010b), FWS recorded mortality of a bald eagle (FWS 2007600155R003) that was attributed to chlorophacinone used to control black-tailed prairie dogs. Primary indication of anticoagulant poisoning (*i.e.*, internal hemorrhaging) was reported and chlorophacinone liver concentration was measured at 0.30 mg a.i./kg-bwt.

One additional incident (FWS 2009600498), involving a ferruginous hawk and a great horned owl, is not attributed to chlorophacinone although residues were detected below the level of quantification (LOQ) of 0.25 mg a.i./kg-bw. The ferruginous hawk mortality is attributed to interspecific/intraspecific fighting and the great horned owl mortality is attributed to a car collision. However, both animals appeared anemic during examination indicating blood loss, possibly accelerated by chlorophacinone, as cause of death. Further, hemorrhaging that may have occurred may not have been detectable due to the freezing of carcasses prior to examination. Some evidence indicates that micro-hemorrhaging can be detected prior to carcass freezing but cannot be detected otherwise (personal communication, Scott Larson, USFWS, June 25, 2010 as reported in USEPA 2010b).

5. Risk Characterization

Risk characterization is the integration of the exposure and effects characterizations. Risk characterization is used to determine the potential for direct and/or indirect effects to the SMHM, SJKF, AW, and CTS or for modification to their designated critical habitat from the use of chlorophacinone in CA. The risk characterization provides an estimation (**Section 5.1**) and a description (**Section 5.2**) of the likelihood of adverse effects; articulates risk assessment assumptions, limitations, and uncertainties; and synthesizes an overall conclusion regarding the likelihood of adverse effects to the assessed species or their designated critical habitat (*i.e.*, "no effect," "likely to adversely affect," or "may affect, but not likely to adversely affect"). In the risk estimation section, risk quotients are calculated using standard EFED procedures and models. In the risk description section, additional analyses may be conducted to help characterize the potential for risk.

5.1. Risk Estimation

Risk is estimated by calculating the ratio of exposure to toxicity. This ratio is the risk quotient (RQ), which is then compared to pre-established acute and chronic levels of concern (LOCs) for each category evaluated (**Appendix B**). For acute exposures to the aquatic animals, as well as terrestrial invertebrates, the LOC is 0.05. For acute exposures to the birds (and, thus, reptiles and terrestrial-phase amphibians) and mammals, the LOC is 0.1. The LOC for chronic exposures to animals is 1.0.

Acute and chronic risks to aquatic organisms are estimated by calculating the ratio of exposure to toxicity using 1-in-10 year EECs based on the label-recommended chlorophacinone usage

scenarios summarized in **Table 3-1** and the appropriate aquatic toxicity endpoints from **Table 4-1**. Acute and chronic risks to terrestrial animals are estimated based on primary and secondary exposures resulting from application of chlorophacinone (**Section 3.4**) and the appropriate toxicity endpoints from **Table 4-3**.

5.1.1. Exposures in the Aquatic Habitat

5.1.1.a. Freshwater Fish and Aquatic-phase Amphibians

Acute risk to fish and aquatic-phase amphibians and reptiles is based on 1 in 10 year peak EECs in the standard pond and the lowest acute toxicity value for freshwater fish. Risk quotients for freshwater fish are shown in **Table 5-1**. There were no exceedences of acute LOCs for freshwater fish (RQ <0.001).

Chronic toxicity data for aquatic organisms were not available; however, chronic risks were presumed negligible. For freshwater fish, the NOAEC would have to exceed 0.09 µg a.i./L and the Acute-to-Chronic ratio would have to be at least 5,022 for the chronic LOC to be exceeded.

Based on the above analysis, chlorophacinone does not have the potential to directly affect the aquatic phase of the CTS. Additionally, since the acute and/or chronic RQs are not exceeded, there is not a potential for indirect effects to those listed species that rely on fish during at least some portion of their life-cycle (*i.e.*, CTS).

Table 5-1 Freshwater fish acute RQs

Use Scenario	Species	Peak EEC (µg a.i./L)	Toxicity endpoint (µg a.i./L)	RQ
Artichokes, bracts, 0.03 lbs a.i./acre	Rainbow trout	0.275	452	<0.001
General ag., aerial, 0.001 lbs a.i./acre	Rainbow trout	0.011	452	<0.001

* = LOC exceedances (acute RQ $\geq$ 0.05) are bolded and shaded. Acute RQ = use-specific peak EEC /452 µg a.i./L .

5.1.1.b. Freshwater Invertebrates

Acute risk to freshwater invertebrates is based on 1-in-10 year peak EECs in the standard pond and the lowest acute toxicity value for freshwater invertebrates. Risk quotients for freshwater invertebrates are shown in **Table 5-2**. There were no exceedences of acute LOCs for freshwater invertebrates (RQ <0.001).

Chronic toxicity data for aquatic organisms were not available; however, chronic risks were presumed negligible. For freshwater invertebrates, the NOAEC would have to exceed 0.176 µg a.i./L and the Acute-to-Chronic ratio would have to be at least 3,636 for the chronic LOC to be exceeded.

Based on the above analysis, chlorophacinone does not have the potential to indirectly affect to those listed species that rely on freshwater invertebrates during at least some portion of their life-cycle (*i.e.*, CTS).

Table 5-2 Freshwater invertebrate acute RQs				
Use Scenario	**Species**	**Peak EEC (µg a.i./L)**	**Toxicity endpoint (µg a.i./L)**	**RQ**
Artichokes, bracts, 0.001 lbs a.i./acre	Daphnid	0.275	640	<0.001
General ag., aerial, 0.001 lbs a.i./acre	Daphnid	0.011	640	<0.001
* = LOC exceedances (acute RQ ≥ 0.05) are bolded and shaded. Acute RQ = use-specific peak EEC /640 µg a.i./L .				

5.1.1.c. Non-vascular and Vascular Aquatic Plants

RQs were not calculated for aquatic vascular and non-vascular plants as toxicity data were not available. EFED presumed risks were low to aquatic plants given the expected low concentrations in water and the mode of action of chlorophacinone.

Since risks were presumed low, there is not a potential for indirect effects to those listed species that rely on non-vascular and/or vascular aquatic plants during at least some portion of their life-cycle (*i.e.*, SMHM and CTS).

5.1.2. Exposures in the Terrestrial Habitat: Birds (surrogate for Reptiles and Terrestrial-phase Amphibians)

Potential direct acute effects to the AW are evaluated by considering dose- and dietary-based EECs based on the consumption of chlorophacinone-contaminated prey (**Sections 5.1.2.c and 5.1.2.d**).

Potential for indirect effects to the SJKF, AW, and CTS may result from direct acute effects to birds and/or amphibians due to a reduction in prey. Potential indirect effects to the SMHM may result from direct acute effects to birds due to a reduction in rearing sites. RQs for indirect effects are calculated from dose- and dietary-based EECs based on the consumption of bait (**Sections 5.1.2.a and 5.1.2.b**) and chlorophacinone-contaminated prey (**Sections 5.1.2.c and 5.1.2.d**). These RQs are calculated for a range of bird body weights.

5.1.2.a. Risks from Direct Bait Consumption (based on gavage toxicity)

In the case of primary exposure, it is assumed the bait containing chlorophacinone is ingested by non-target animals and evokes a toxic response. For toxic response elicited from gavage exposure route, exposure is measured as mg a.i./kg-bw (**Section 3.3.1** and **Table 3-3**). Toxicity is measured by the LD_{50} obtained from the single-gavage studies for birds. The LD_{50}'s are adjusted for the weight of the assessed animals (birds: 20, 100, 1000 g) (**Table 5-3**). Avian RQs based on acute single-dose gavage studies are provided in **Table 5-4**; the Listed Species LOC was exceeded for small birds consuming bait with 100 mg a.i./kg-bait.

Table 5-3 Formulas for Calculation of Weight-adjusted Avian Chlorophacinone LD_{50}s.

Adjusted avian LD_{50}: $Adj.LD_{50} = LD_{50}\left(\frac{AW}{TW}\right)^{(x-1)}$ where:

Adj. LD_{50} = adjusted LD_{50} (mg/kg-bw)
LD_{50} = endpoint reported from bird study (mg/kg-bw)
TW = body weight of tested animal (178g bobwhite)
AW = body weight of assessed animal (20g, 100g, and 1000g)
x = Mineau scaling factor for birds; EFED default 1.15

Table 5-4 Bird Acute RQs based on a Single-dose of Chlorophacinone through consumption of bait

	Chlorophacinone concentration in bait (mg a.i./kg-bait)	Weight (g)	Chlorophacinone intake (mg a.i./kg-bwt/day)[1]	Adjusted LD_{50} (mg a.i./kg-bw)[2]	RQ[3]
Passeriform Birds*	50	20	14.1	185.9	0.08
		100	11.1	236.6	0.05
		1000	7.8	334.2	0.02
	100	20	28.2	185.9	**0.15***
		100	22.2	236.6	0.09
		1000	15.7	334.2	0.05

*surrogate for reptiles and terrestrial-phase amphibians
[1] See Table 3-5 and 3-6 for derivation.
[2] See Table 5-3 for derivation.
[3] Bolded (*) RQs exceed Listed Species LOCs.

5.1.2.b. Risks from Direct Bait Consumption (based on dietary toxicity)

For toxic response elicited from the dietary exposure route extended over several days, exposure is measured as mg a.i./kg-bait (**Section 3.3.1**). Toxicity is measured by the LC_{50} obtained from the dietary studies (5 days on treated diet) for birds. Avian RQs based on dietary studies are provided in **Table 5-5**; the Listed Species, Restricted Use, and Acute LOCs were exceeded for both bait concentrations.

Table 5-5 Bird Acute RQs based on a 5-day Exposure to Chlorophacinone in the Diet (consumption of bait)

	Chlorophacinone concentration in bait (mg a.i./kg-bait)	LC_{50} (mg a.i./kg-diet)	RQ[1]
Birds*	50	56	**0.89*** **
	100	56	**1.78*** **

*surrogate for reptiles and terrestrial-phase amphibians
[1] Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.

For avian chronic exposure, expected concentration of chlorophacinone in the diet is compared to the NOAEC obtained in the sub-chronic (non-guideline reproduction study). Avian RQs based on sub-chronic exposure are provided in **Table 5-6**. For birds, the Chronic LOC was exceeded (RQ = 50 and 100).

Table 5-6 Bird RQs based on a Sub-chronic Exposure to Chlorophacinone in the Diet			
	Chlorophacinone concentration in bait (mg a.i./kg-bait)	**NOAEC (mg a.i./kg-diet)**	**RQ[1]**
Birds*	50	1	**50*** **
	100	1	**100*** **
*surrogate for reptiles and terrestrial-phase amphibians [1] Bolded (***) RQs exceed Chronic Risk LOCs.			

5.1.2.c. Risks from Consumption of Chlorophacinone-contaminated Carcasses (based on gavage toxicity)

To determine secondary exposure EECs, available literature concerning carcass residue concentrations were considered. Previous assessments (USEPA 2004b, USEPA 2010b) compiled available mammalian residue data. No bird residue data for primary consumption of chlorophacinone were located. For this assessment, a carcass concentration of 4.1 mg a.i./kg-carcass was used to estimate exposure (**Section 3.3.2**). Expected chlorophacinone intake (mg a.i./kg-bwt/day) was calculated in **Table 3.9**. As in the direct consumption risk estimation, the LD_{50}'s are adjusted for the weight of the assessed birds (50, 1000, 2000 g). These heavier weights are used to better represent carnivores and scavengers which tend to be larger individuals. Listed Species, Restricted Use, and Acute Risk LOCs were not exceeded for the AW, CTS, or generic weight classes of birds consuming contaminated carcasses using a gavage-based LD_{50} (**Table 5-7**).

Table 5-7 AW, CTS, and Carnivorous/Scavenger Bird Acute RQs based on a Single-dose of Chlorophacinone by Gavage, consumption of contaminated carcasses				
Species or Taxa	**Weight (g)**	**Chlorophacinone intake (mg a.i./kg-bwt/day)[1]**	**Adjusted LD_{50} (mg a.i./kg-bwt)[2]**	**RQ[3]**
AW	18.6	5.05	183.9	0.03
	101	5.69	237.0	0.02
	322	6.18	282.0	0.02
CTS	15	0.09	178.0	<0.01
	80	0.06	228.8	<0.01
Birds*	50	2.12	213.3	0.01
	1000	0.75	334.2	<0.01
	2000	0.59	370.9	<0.01
*surrogate for reptiles and terrestrial-phase amphibians [1] See Tables 3.8 and 3.9 for derivation. [2] See Table 5.2 for derivation with assessed body weights used in this table. [3] Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.				

5.1.2.d. Risks from Consumption of Chlorophacinone-contaminated Carcasses (based on dietary toxicity)

For toxic response elicited from the dietary exposure route extended over several days, exposure is measured as mg a.i./kg-carcass. Toxicity is measured by the LC_{50} obtained from the dietary studies (5 days on treated diet) for birds and mammals. Avian and mammalian RQs based on dietary studies are provided in **Table 5-8**; carnivore/scavenger bird LOCs were not exceeded.

Table 5-8 AW, CTS, and Bird Acute RQs based on a 5-day Exposure to Chlorophacinone in the Diet, consumption of contaminated carcasses			
Species or Taxa	**Chlorophacinone concentration in carcass (mg a.i./kg-carcass)**	**LC_{50} (mg a.i./kg-diet)**	**RQ[1]**
AW and CTS	4.1	56	0.07
Birds*	4.1	56	0.07
*surrogate for reptiles and terrestrial-phase amphibians [1] Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.			

For avian chronic exposure, expected concentration of chlorophacinone in consumed carcasses is compared to the NOAEC obtained in the sub-chronic (non-guideline reproduction study). The avian RQ based on sub-chronic exposure is provided in **Table 5-9**. For AW, CTS, and birds, the Chronic LOC was exceeded (RQ = 4.1).

Table 5-9 AW, CTS, and Bird RQs based on a Sub-chronic Exposure to Chlorophacinone in the Diet, consumption of contaminated carcasses			
Species or Taxa	**Chlorophacinone concentration in bait (mg a.i./kg-bait)**	**NOAEC (mg a.i./kg-diet)**	**RQ[1]**
AW and CTS	4.1	1	**4.1*** **
Birds*	4.1	1	**4.1*** **
*surrogate for reptiles and terrestrial-phase amphibians [1] Bolded (***) RQs exceed Chronic Risk LOCs.			

Based on the above analysis, chlorophacinone does have the potential to directly affect the AW. Additionally, since the acute and chronic LOCs are exceeded, there is a potential for indirect effects to those listed species that rely on birds (and, thus, reptiles and/or terrestrial-phase amphibians) during at least some portion of their life-cycle (*i.e.*, SMHM, SJKF, CTS and AW).

5.1.3. Exposures in the Terrestrial Habitat: Mammals

Potential direct acute effects to the SMHM are evaluated by considering dose- and dietary-based EECs based on the consumption of chlorophacinone-treated bait (**Sections 5.1.3.a and 5.1.3.b**).

Potential direct acute effects to the SJKF are evaluated by considering dose- and dietary-based EECs based on the consumption of chlorophacinone-treated bait and chlorophacinone-contaminated prey (**Sections 5.1.3.a through 5.1.3.d**).

Potential for indirect effects to the SJKF and AW may result from direct acute effects to mammals due to a reduction in prey. Potential indirect effects to the SMHM may result from direct acute effects to mammals due to a reduction in rearing sites. RQs for indirect effects are calculated from dose- and dietary-based EECs based on the consumption of bait (**Sections 5.1.3.a and 5.1.3.b**) and chlorophacinone-contaminated prey (**Sections 5.1.3.c and 5.1.3.d**). These RQs are calculated for a range of mammal body weights.

5.1.3.a. Risks from Direct Bait Consumption (based on gavage toxicity)

In the case of primary exposure, it is assumed the bait containing chlorophacinone is ingested by non-target animals and evokes a toxic response. For toxic response elicited from gavage exposure route, exposure is measured as mg a.i./kg-bw (**Section 3.3.1** and **Table 3-3**). Toxicity is measured by the LD_{50} obtained from the single-gavage studies for mammals. The LD_{50}'s are adjusted for the weight of the assessed mammals (15, 35, 1000 g) (**Table 5-10**). Mammalian RQs based on an acute single-dose gavage study and a developmental study are provided in **Table 5-11**; the Listed Species, Restricted Use, Acute Risk, and Chronic LOCs were exceeded for all scenarios.

Table 5-10 Formulas for Calculation of Weight-adjusted Mammalian Chlorophacinone LD_{50}s and NOAELs.

Adjusted mammalian LD_{50}: $Adj.LD_{50} = LD_{50}\left(\frac{TW}{AW}\right)^{(0.25)}$ where:

Adj. LD_{50} = adjusted LD_{50} (mg/kg-bw)
LD_{50} = endpoint reported from mammal study (mg/kg-bw)
TW = body weight of tested animal (938g black tailed prairie dog)
AW = body weight of assessed animal (15g, 35g, 1000g)

Adjusted mammalian NOAEL: $Adj.NOAEL = NOAEL\left(\frac{TW}{AW}\right)^{(0.25)}$ where:

Adj. NOAEL = adjusted NOAEL (mg/kg-bw)
NOAEL = endpoint reported from mammal study (0.01 mg/kg-bw)
TW = body weight of tested animal (3490g New Zealand rabbit)
AW = body weight of assessed animal (15g, 35g, 1000g)

Table 5-11 SMHM, SJKF, and Mammalian Acute and Chronic RQs based on a Single-dose of Chlorophacinone through consumption of bait

Species or Taxa	Chlorophacinone concentration in bait (mg a.i./kg-bait)	Weight (g)	Chlorophac-inone intake (mg a.i./kg-bwt/day)[1]	Adjusted LD_{50} (mg a.i./kg-bw)[2]	Acute RQ[3]	Adjusted NOAEL (mg a.i./kg-bw)[2]	Chronic RQ[4]
SMHM	50	10	12.6	6.0	**2.09*** **	0.043	**292***
	100	10	25.3	6.0	**4.19*** **	0.043	**585***
SJKF	50	2300	3.3	1.6	**2.12*** **	0.011	**297***
	100	2300	6.6	1.6	**4.25*** **	0.011	**593***
Rodent mammals	50	15	10.6	5.5	**1.94*** **	0.039	**271***
		35	7.3	4.4	**1.66*** **	0.032	**232***
		1000	1.7	1.9	**0.89*** **	0.014	**124***
	100	15	21.2	5.5	**3.88*** **	0.039	**542***
		35	14.6	4.4	**3.32*** **	0.032	**463***
		1000	3.4	1.9	**1.78*** **	0.014	**248***

[1] See Table 3-5 and 3-6 for derivation.
[2] See Table 5-2 for derivation.
[3] Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.
[4] Bolded (*) RQs exceed Chronic LOCs.

5.1.3.b. Risks from Direct Bait Consumption (based on dietary toxicity)

For toxic response elicited from the dietary exposure route extended over several days, exposure is measured as mg a.i./kg-bait (**Section 3.3.1**). Toxicity is measured by the LC_{50} obtained from the dietary studies (5 days on treated diet) for mammals. Mammalian RQs based on dietary studies are provided in **Table 5-12**; the Listed Species, Restricted Use, and Acute LOCs were exceeded for both bait concentrations.

Table 5-12 Mammalian Acute RQs based on a 5-day Exposure to Chlorophacinone in the Diet (consumption of bait)

	Chlorophacinone concentration in bait (mg a.i./kg-bait)	LC_{50} (mg a.i./kg-diet)	RQ[1]
Mammals	50	1.14	**43.9*** **
	100	1.14	**87.7*** **

[1] Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.

5.1.3.c. Risks from Consumption of Chlorophacinone-contaminated Carcasses (based on gavage toxicity)

To determine secondary exposure EECs, available literature concerning carcass residue concentrations were considered. Previous assessments (USEPA 2004b, USEPA 2010b) compiled available mammalian residue data. No bird residue data for primary consumption of chlorophacinone were located. For this assessment, a carcass concentration of 4.1 mg a.i./kg-carcass was used to estimate exposure (**Section 3.3.2**). Expected chlorophacinone intake (mg a.i./kg-bwt/day) was calculated in **Table 3.9**. As in the direct consumption risk estimation, the LD_{50}'s are adjusted for the weight of the assessed mammals (50, 1000, 3000 g). These heavier body weights are used to better represent carnivores and scavengers which tend to be larger individuals. Listed Species and Restricted Use LOCs as well as the Chronic LOC were exceeded for the SJKF and all mammal weight classes. The Acute Risk LOC was also exceeded for the largest mammal weight class (3000 g) (**Table 5-13**).

Table 5-13 SJKF and Carnivorous/Scavenger Mammal Acute and Chronic RQs based on a Single-dose of Chlorophacinone by Gavage, consumption of contaminated carcasses

Species or Taxa	Weight (g)	Chlorophacinone intake (mg a.i./kg-bwt/day)[1]	Adjusted LD_{50} (mg a.i./kg-bw)[2]	Acute RQ[3]	Adjusted NOAEL (mg a.i./kg-bw)[2]	Chronic RQ[4]
SJKF	2300	0.76	1.6	**0.49****	0.011	**68***
Mammals	50	1.50	4.0	**0.37****	0.029	**52***
	1000	0.88	1.9	**0.46****	0.014	**64***
	3000	0.72	1.5	**0.50*****	0.010	**70***

[1] See Table 3-5 and 3-6 for derivation.
[2] See Table 5-2 for derivation.
[3] Bolded (**) RQs exceed Listed Species and Restricted Use LOCs.
Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.
[4] Bolded (*) RQs exceed Chronic LOCs.

5.1.3.d. Risks from Consumption of Chlorophacinone-contaminated Carcasses (based on dietary toxicity)

For toxic response elicited from the dietary exposure route extended over several days, exposure is measured as mg a.i./kg-carcass. Toxicity is measured by the LC_{50} obtained from the dietary studies (5 days on treated diet) for birds and mammals. SJKF and mammalian RQs based on dietary studies are provided in **Table 5-14**; Listed Species, Restricted Use, and Acute Risk LOCs were exceeded.

Table 5-14 SJKF and Mammal Acute RQs based on a 5-day Exposure to Chlorophacinone in the Diet, consumption of contaminated carcasses

Species or Taxa	Chlorophacinone concentration in carcass (mg a.i./kg-carcass)	LC_{50} (mg a.i./kg-diet)	RQ[1]
SJKF	4.1	1.14	**3.6*** **
Mammals	4.1	1.14	**3.6*** **

*surrogate for reptiles and terrestrial-phase amphibians
[1] Bolded (***) RQs exceed Listed Species, Restricted Use, and Acute Risk LOCs.

Based on the above results, chlorophacinone does have the potential to directly affect the SMHM and the SJKF. Additionally, since the acute and chronic LOCs are exceeded, there is a potential for indirect effects to those listed species that rely on mammals during at least some portion of their life-cycle (*i.e.*, SMHM, SJKF, and AW).

5.1.4. Exposures in the Terrestrial Habitat: Terrestrial Invertebrates

Toxicity to listed terrestrial invertebrates was evaluated qualitatively (as chlorophacinone residues in the dosed rat carcasses for the reproduction phase in the study discussed in **Section 4.2.3** (MRID 47383001) were not available). The study demonstrated larval survival effects for *N. orbicollis*; however, chlorophacinone exposure concentrations were not available for this phase of the study. In addition to this study, an earthworm toxicity study resulted in an LC_{50} > 1000 mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (MRID 47383002). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil. Based on the effects seen in these studies and lack of quantifiable exposure estimates, risks to terrestrial invertebrates are presumed.

Since the risks to terrestrial invertebrates are presumed, there is a potential for indirect effects to those listed species that rely on terrestrial invertebrates during at least some portion of their life-cycle (*i.e.*, SMHM, SJKF, CTS, AW).

5.1.5. Exposures in the Terrestrial Habitat: Terrestrial Plants

RQs were not calculated for terrestrial plants as toxicity data were not available. EFED presumed direct risks were low to terrestrial plants given the mode of action of chlorophacinone and the lack of any reported incidents. Since chlorophacinone is not sprayed directly onto plants, and because so little is expected to leach from the bait and then be available for plant uptake, exposure is expected to be minimal.

Based on this analysis, there is not a potential for indirect effects to those listed species that rely on terrestrial plants during at least some portion of their life-cycle (*i.e.* SMHM, SJKF, CTS, and the AW).

5.1.6. Primary Constituent Elements of Designated Critical Habitat

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

5.2. Risk Description

The risk description synthesizes overall conclusions regarding the likelihood of adverse impacts leading to a preliminary effects determination (*i.e.*, "no effect," "may affect, but not likely to adversely affect," or "likely to adversely affect") for the assessed species and the potential for modification of their designated critical habitat based on analysis of risk quotients and a comparison to the Level of Concern. The spatial extent of potential effects is discussed for each of the listed species including any potential overlap between areas where potential usage may result in LAA effects and areas where species are expected to occur (including any designated critical habitat). The final No Effect/May Affect determination is made after the spatial analysis is completed at the end of the risk description for each species. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a No Effect determination is made.

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

Table 5-15. Risk Estimation Summary for Chlorophacinone - Direct and Indirect Effects

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
Freshwater Fish and Aquatic-phase Amphibians	Non-listed Species (No)	No LOCs exceeded	Indirect Effects: CTS
	Listed Species (No)	No LOCs exceeded	Direct Effects: CTS
Freshwater Invertebrates	Non-listed Species (No)	No LOCs exceeded	Indirect Effects: CTS
Vascular Aquatic	Non-listed Species (No)	RQs not calculated, minimal risk	Indirect Effects: SMHM

Table 5-15. Risk Estimation Summary for Chlorophacinone - Direct and Indirect Effects			
Taxa	**LOC Exceedances (Yes/No)**	**Description of Results of Risk Estimation**	**Assessed Species Potentially Affected**
Plants		based on mode of action and lack of incidents	and CTS
Non-Vascular Aquatic Plants	Non-listed Species (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	Indirect Effects: SMHM and CTS
Birds, Reptiles, and Terrestrial-Phase Amphibians	Non-listed Species (Yes)	Acute and Chronic LOCs exceeded for primary toxicity (direct bait consumption). Chronic LOCs exceeded for secondary toxicity (contaminated carcass consumption).	Indirect Effects: SMHM, SJKF, AW, and CTS
	Listed Species (Yes)	AW: Chronic LOC exceeded for consumption of contaminated prey CTS: Chronic LOC exceeded for consumption of contaminated prey	Direct Effects: AW and CTS
Mammals	Non-listed Species (Yes)	Acute and Chronic LOCs exceeded for primary toxicity (direct bait consumption). Acute and Chronic LOCs exceeded for secondary toxicity (contaminated carcass consumption).	Indirect Effects: SMHM, SJKF, AW, and CTS
	Listed Species (Yes)	SMHM: Acute and Chronic LOCs exceeded for primary toxicity (direct bait consumption). SJKF: Acute and Chronic LOCs exceeded for primary toxicity (direct bait consumption). Acute and Chronic LOCs exceeded for secondary toxicity (contaminated carcass consumption).	Direct Effects: SMHM and SJKF
Terrestrial Invertebrates	Listed Species (Yes)	RQs not calculated, presumed risk based on evidence of toxicity in burying beetle study	Direct/Indirect Effects: SMHM, SJKF, AW, and CTS
Terrestrial Plants – Monocots	Non-listed Species (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	Indirect Effects: SMHM, SJKF, AW, and CTS
Terrestrial Plants - Dicots	Non-listed Species (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	Indirect Effects: SMHM, SJKF, AW, and CTS

Table 5-16. Risk Estimation Summary for Chlorophacinone – Effects to Designated Critical Habitat. (PCEs)			
Taxa	**LOC Exceedances (Yes/No)**	**Description of Results of Risk Estimation**	**Species Associated with a Designated Critical Habitat that May Be Modified by the Assessed Action**
Freshwater Fish and Aquatic-phase Amphibians	Non-listed Species (No)	No LOCs exceeded	CTS
	Listed Species (No)	No LOCs exceeded	
Freshwater Invertebrates	Non-listed Species (No)	No LOCs exceeded	CTS
Vascular Aquatic Plants	Non-listed Species (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	CTS
Non-Vascular Aquatic Plants	Non-listed Species (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	CTS
Birds, Reptiles, and Terrestrial-Phase Amphibians	Non-listed Species (Yes)	Acute and Chronic LOCs exceeded for primary toxicity (direct bait consumption). Chronic LOCs exceeded for secondary toxicity (contaminated carcass consumption).	AW and CTS
	Listed Species (Yes)	AW and CTS: Chronic LOC exceeded for consumption of contaminated prey	
Mammals	Non-listed Species (Yes)	Acute and Chronic LOCs exceeded for primary toxicity (direct bait consumption). Acute and Chronic LOCs exceeded for secondary toxicity (contaminated carcass consumption).	AW and CTS
Terrestrial Invertebrates	Listed Species (Yes)	RQs not calculated, presumed risk based on evidence of toxicity in burying beetle study	AW and CTS
Terrestrial Plants - Monocots	Non-listed Species[1] (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	AW and CTS
Terrestrial Plants - Dicots	Non-listed Species[1] (No)	RQs not calculated, minimal risk based on mode of action and lack of incidents	AW and CTS

[1] Only non-listed LOCs were evaluated because none of the assessed species have an obligate relationship with terrestrial monocots and dicots.

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

The criteria used to make determinations that the effects of an action are "not likely to adversely affect" the assessed species or modify its designated critical habitat include the following:

- Significance of Effect: Insignificant effects are those that cannot be meaningfully measured, detected, or evaluated in the context of a level of effect where "take" occurs for even a single individual. "Take" in this context means to harass or harm, defined as the following:
    - Harm includes significant habitat modification or degradation that results in death or injury to listed species by significantly impairing behavioral patterns such as breeding, feeding, or sheltering.
    - Harass is defined as actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding, or sheltering.
- Likelihood of the Effect Occurring: Discountable effects are those that are extremely unlikely to occur.
- Adverse Nature of Effect: Effects that are wholly beneficial without any adverse effects are not considered adverse.

A description of the risk and effects determination for each of the established assessment endpoints for the assessed species and their designated critical habitat is provided in **Sections 5.2.1** through **5.2.4**. The effects determination section for each listed species assessed will follow a similar pattern. Each will start with a discussion of the potential for direct effects, followed by a discussion of the potential for indirect effects. These discussions do not consider the spatial analysis. For those listed species that have designated critical habitat, the section will end with a discussion on the potential for modification to the critical habitat from the use of chlorophacinone. Finally, a discussion of any potential overlap between areas of concern and the species (including any designated critical habitat) is presented. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a No Effect determination is made.

5.2.1. Salt-Marsh Harvest Mouse

5.2.1.a. Direct Effects

The SMHM is at risk from uses of chlorophacinone. The labels include directions for broadcast and spot-baiting; therefore, treated bait will be easily acceptable and attractive to non-target mammals, including the SMHM, for consumption. Based on bait concentrations of 50 mg a.i./kg-bait and 100 mg a.i./kg-bait, acute RQs (2.09 to 4.19) for SMHM consuming a single-dose of chlorophacinone in bait (**Table 5.3**) and the acute RQ (44 to 88) for SMHM based on a 5-day dietary study exceeds the Listed Species LOC (0.1). Therefore, there is potential for mortality to the SMHM through consumption of bait for a single day or over a several day period.

In the rabbit developmental study (MRID 43570801), significant mortality of dams occurred at exposure levels greater than 0.01 mg a.i./kg-bwt. Using the NOAEC = 0.01 mg a.i./kg-bwt, chronic RQs ranged from 292 to 585, both exceeding the chronic LOC (1.0). Other observed

effects in this study included increased prothrombin and activated partial thromboplastin times at dose level of 0.005 mg a.i./kg-bwt. These measures of reduced blood clotting ability indicate an increased likelihood of hemorrhage, which may be followed by death.

Incidents were reported in the United States and in France (**Tables 4.5 and 4.6**) of non-carnivorous/non-scavenger mammals that died that of chlorophacinone poisoning. The known species include squirrels, rabbits, and hares. The presence of confirmed incidents of chlorophacinone poisoning under the currently registered labels corroborates the risk estimation process that identified risks to grain-consuming mammals based on the current label rate and directions.

The Agency uses the probit dose-response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (USEPA 2004a). For these calculations, the highest RQs for SMHM from the primary exposure to bait (direct consumption) were used. The probability of an individual effect to SMHM was calculated based on a gavage study with a probit slope of 3.45 with 95% confidence bounds of (0.8, 6.1) and a dietary study with a probit slope of 7.2 with 95% confidence bounds of (3.8, 10.6). For the gavage exposure and baits containing 100 mg a.i./kg-bait, the corresponding estimated chance of an individual acute mortality to the SMHM at an RQ of 4.19 is 1 in 1.0 (with respective upper and lower bounds of 1 in 1.0 to 1 in 1.5). For the dietary exposure and baits containing 100 mg a.i./kg-bait, the corresponding estimated chance of an individual acute mortality to the SMHM at an RQ of 88 is 1 in 1.0 (with respective upper and lower bounds of 1 in 1.0 to 1 in 1.0).

Using a weight-of-evidence approach, the following pieces of evidence were considered to conclude that there **is** a potential for direct effects to the SMHM from the registered uses of chlorophacinone:

- the listed species and chronic LOCs are exceeded for the SMHM based on consumption of bait (both concentrations of 50 mg a.i./kg-bait and 100 mg a.i./kg-bait),
- the likelihood of an individual effect (mortality) is approximately 1 in 1.0 based on gavage and dietary exposure,
- mortality through primary exposure to chlorophacinone was documented through low LD_{50} and LC_{50} values obtained in toxicity studies, high mortality percentages observed in field efficacy trials, and mortality of the rodents when fed chlorophacinone for the secondary exposure trials, and
- reported incidents for small non-target herbivorous mammals in the EIIS database.

5.2.1.b. Indirect Effects

Indirect effects on the SMHM may occur through the potential for chlorophacinone impacts on birds and mammals that provide rearing sites and terrestrial invertebrates that are prey of the SMHM. Indirect effects on the SMHM are not expected from terrestrial plants that provide food and habitat and aquatic plants that provide habitat, as risks to these taxa from chlorophacinone are low.

For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the probability of an individual mortality occurrence is very high for both birds and mammals (**Table 5-17**), thus there is a high likelihood that the availability of burrows for SMHM use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing burrows and rearing sites for the SMHM.

Table 5-17 Chlorophacinone (50 mg a.i./kg-bait exposure) Probit Dose Response Analysis for Birds and Mammals

Taxa (study type)[1]	Acute Effect Slope (95% C.I.)	Chance of Individual Effect at Derived Acute RQ (95% C.I.)
Bird oral dose (max RQ = 0.08)	Mortality Slope = 2.88 (1.3,4.4)	1 in 1.26E+03 (1 in 13, 1 in 1.44E+06)
Bird dietary (max RQ = 0.89)	Mortality Slope = 1.49 (0.8, 2.2)	1 in 2.13 (1 in 2.07, 1 in 2.19)
Mammal oral dose (max RQ = 1.94)	Mortality Slope = 3.45 (0.8, 6.1)	1 in 1.19 (1 in 1.04, 1 in 1.69)
Mammal dietary (max RQ = 44)	Mortality Slope = 7.2 (3.8, 10.6)	1 in 1

[1] Reported RQs are the maximum values based on primary exposure (bait consumption).

Toxicity to terrestrial invertebrates was evaluated qualitatively (as chlorophacinone residues in the dosed rat carcasses in the study discussed in **Section 4.2.3** (MRID 47383001) were not available); larval survival effects to *N. orbicollis* were observed. In addition to this study, an earthworm toxicity study resulted in an LC_{50} > 1000 mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (MRID 47383002). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil. Based on the effects seen in these studies and lack of quantifiable exposure estimates, risks to terrestrial invertebrates are presumed.

RQs were not calculated for terrestrial and aquatic plants as toxicity data were not available. EFED presumed direct risks were low to terrestrial and aquatic plants given the mode of action of chlorophacinone and the lack of any reported incidents. Since chlorophacinone is not sprayed directly onto plants, and because so little is expected to leach from the bait and then be available for plant uptake, exposure is expected to be minimal. Based on this analysis, there is not a potential for indirect effects to the SMHM due to impacts to terrestrial and aquatic plants.

5.2.1.c. Spatial Extent of Potential Effects

Generally, the Agency conducts analysis of the spatial extent of potential LAA effects whenever LOCs are exceeded. This analysis typically is needed to determine where adverse effects may occur in relation to the treated site. This spatial analysis typically determines if the potential area of usage, and the subsequent Potential Area of LAA Effects, overlaps with areas of occurrence and/or critical habitat of the species. However, because chlorophacinone is a vertebrate pest control agent that may be used in a wide variety of urban and non-urban areas, the spatial extent of chlorophacinone cannot be limited to defined areas. The Agency assumes that chlorophacinone potentially may be used in any area of the state that that use may occur in any

of the land use categories that are identified in the NLCD. Therefore, a spatial analysis was not conducted to identify this overlap. All areas where the SMHM occurs are assumed to lie within the potential use area of chlorophacinone.

5.2.1.d. Effects Determination

The results of this risk assessment indicates that use of chlorophacinone in baits for vertebrate pest control poses a risk of direct effects to the SMHM resulting from acute and chronic toxicity. This species has the potential to come into contact with chlorophacinone bait placed for control of a variety of rodent species. Ingestion of this bait is likely to be lethal to the SMHM. Even if the ingested dose of chlorophacinone is not lethal, sublethal behavioral and neurological effects may adversely affect the survival of individuals of this species. Finally, some risk of indirect effects is possible because use of chlorophacinone may reduce the abundance of small mammals and birds, which may reduce the availability of nest sites. Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determinations for the SMHM based on the potential for direct and indirect effects to this species.

5.2.2. San Joaquin Kit Fox

5.2.2.a. Direct Effects

The SJKF is at risk from uses of chlorophacinone. The labels include directions for broadcast and spot-baiting; therefore, treated bait will be easily acceptable and attractive to non-target mammals for consumption. Based on bait concentrations of 50 mg a.i./kg-bait and 100 mg a.i./kg-bait, acute RQs (2.12 to 4.25) for SJKF consuming a single-dose of chlorophacinone in bait and the acute RQs (44 to 88) for SJKF based on a 5-day dietary study exceeds the Listed Species LOC. In addition, the listed species LOCs are exceeded for SJKF when consuming chlorophacinone-contaminated carcasses. Assuming a prey concentration of 4.1 mg a.i./kg-carcass, acute RQs ranged from 0.49 (gavage LD_{50}) and 3.9 (dietary LC_{50}). Therefore, for SJKF consuming chlorophacinone through bait or carcass exposure routes, mortality is expected.

Based toxicity in the 5-day dietary study, in order for there to be no exceedence of the Acute Risk LOC for carnivore/scavenger mammals, the exposure concentration would need to be less than 0.57 mg a.i./kg-carcass. For those field studies in which the bait contained 0.005% chlorophacinone (**Table 3.7**), the study average carcass concentration of chlorophacinone was 0.56 mg a.i./kg-carcass. All of the six field studies in which 0.005% chlorophacinone bait was used had at least one individual carcass with whole body concentrations of chlorophacinone greater than 0.57 mg a.i./kg-carcass. Therefore, it is likely that carnivores and scavengers feeding in or near treated fields would encounter and consume carcasses containing sufficient concentrations of chlorophacinone to cause mortality.

In addition to the mammalian toxicity data used to calculate RQs, data were available from four studies in which carnivorous mammals were fed prey that had been poisoned with chlorophacinone (*i.e.*, fed treated bait) (**Table 4.4**). Many of the exposed carnivorous mammals 43% to 88%) died in these studies. In addition, many of the individuals experienced hemorrhaging. Actual chlorophacinone exposure (concentration in the fed carcasses) was not

available in any of the studies. Exposure time ranged from 5 to 8 days and all individuals were followed for a total of 21 to 30 days after the start of the test.

In the rabbit developmental study (MRID 43570801), significant mortality of dams occurred at exposure levels greater than 0.01 mg a.i./kg-bwt. Using the NOAEC = 0.01 mg a.i./kg-bwt, chronic RQs for bait consumption ranged from 297 to 593, and the chronic RQ for prey consumption was 68; all exceeded the chronic LOC = 1.0. Other observed effects in this study included increased prothrombin and activated partial thromboplastin times at dose level of 0.005 mg a.i./kg-bwt. These measures of reduced blood clotting ability indicate an increased likelihood of hemorrhage, which may be followed by death.

Incidents were reported in the United States and in France (**Tables 4.5 and 4.6**) of non-carnivorous/non-scavenger and carnivorous/scavenger mammals that died that of chlorophacinone poisoning. The presence of confirmed incidents of chlorophacinone poisoning under the currently registered labels corroborates the risk estimation process that identified risks to mammals based on the current label rate and directions. Take of the subject species was reported as six endangered San Joaquin kit fox mortalities were included in the incident database. Four of these kit foxes had documented concentrations of chlorophacinone in the liver.

The Agency uses the probit dose-response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (USEPA 2004a). For these calculations, the highest RQs for SJKF from the primary exposure to bait (direct consumption) were used. The probability of an individual effect to SJKF was calculated based on a gavage study with a probit slope of 3.45 with 95% confidence bounds of (0.8, 6.1) and a dietary study with a probit slope of 7.2 with 95% confidence bounds of (3.8, 10.6). For the gavage exposure and baits containing 100 mg a.i./kg-bait, the corresponding estimated chance of an individual acute mortality to the SJKF at an RQ of 4.25 is 1 in 1.02 (with respective upper and lower bounds of 1 in 1.0 to 1 in 1.44). For the dietary exposure and baits containing 100 mg a.i./kg-bait, the corresponding estimated chance of an individual acute mortality to the SJKF at an RQ of 88 is 1 in 1.0 (with respective upper and lower bounds of 1 in 1.0 to 1 in 1.0). The probability of an individual mortality occurrence is high and chlorophacinone is likely to cause direct adverse effects to the SJKF.

Using a weight-of-evidence approach, the following pieces of evidence were weighed:

- the listed species and chronic LOCs are exceeded for the SJKF based on consumption of bait (both concentrations of 50 mg a.i./kg-bait and 100 mg a.i./kg-bait),
- the likelihood of an individual effect (mortality) is approximately 1 in 1.0 based on gavage and dietary exposure,
- mortality through primary exposure to chlorophacinone was documented through low LD_{50} and LC_{50} values obtained in toxicity studies, high mortality percentages observed in field efficacy trials, and mortality of the rodents when fed chlorophacinone for the secondary exposure trials, and
- mortality through secondary exposure to chlorophacinone was documented for the secondary exposure trials where 43% to 88% of the secondary consumers died, and

- eleven incidents in the US reported in EIIS that were considered probable or highly probable for death due to chlorophacinone. Mortalities included species that were likely primary consumers of the bait (*e.g.*, grey squirrel and wild turkey) and carnivorous species (*e.g.*, badger and red-tailed hawk) likely to have preyed upon the granivorous individuals. These incidents included take of an endangered species as six endangered San Joaquin kit fox mortalities were included in the incident database. Four kit foxes had documented concentrations of chlorophacinone in the liver.

From these lines of evidence, there **is** a potential for direct effects to the SJKF from the registered uses of chlorophacinone.

5.2.2.b. Indirect Effects

Indirect effects on the SJKF may occur through the potential for chlorophacinone impacts on birds, mammals, and terrestrial invertebrates that are prey of the SJKF. Indirect effects on the SJKF are not expected from terrestrial plants that provide food and habitat, as risks to this taxa from chlorophacinone are low.

For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the probability of an individual mortality occurrence is very high for both birds and mammals (**Table 5.13**), thus there is a high likelihood that the availability of prey for SJKF use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the SJKF.

Toxicity to terrestrial invertebrates was evaluated qualitatively (as chlorophacinone residues in the dosed rat carcasses in the study discussed in **Section 4.2.3** (MRID 47383001) were not available); larval survival effects to *N. orbicollis* were observed. In addition to this study, an earthworm toxicity study resulted in an LC_{50} > 1000 mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (MRID 47383002). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil. Based on the effects seen in these studies and lack of quantifiable exposure estimates, risks to terrestrial invertebrates are presumed.

RQs were not calculated for terrestrial plants as toxicity data were not available. EFED presumed direct risks were low to terrestrial plants given the mode of action of chlorophacinone and the lack of any reported incidents. Since chlorophacinone is not sprayed directly onto plants, and because so little is expected to leach from the bait and then be available for plant uptake, exposure is expected to be minimal. Based on this analysis, there is not a potential for indirect effects to the SJKF due to impacts to terrestrial plants.

5.2.2.c. Spatial Extent of Potential Effects

Generally, the Agency conducts analysis of the spatial extent of potential LAA effects whenever LOCs are exceeded. This analysis typically is needed to determine where adverse effects may occur in relation to the treated site. This spatial analysis typically determines if the potential area of usage, and the subsequent Potential Area of LAA Effects, overlaps with areas of occurrence

and/or critical habitat of the species. However, because chlorophacinone is a vertebrate pest control agent that may be used in a wide variety of urban and non-urban areas, the spatial extent of chlorophacinone cannot be limited to defined areas. The Agency assumes that chlorophacinone potentially may be used in any area of the state that that use may occur in any of the land use categories that are identified in the NLCD. Therefore, a spatial analysis was not conducted to identify this overlap. All areas where the SJKF occurs are assumed to lie within the potential use area of chlorophacinone.

5.2.2.d. Effects Determination

The results of this risk assessment indicates that use of chlorophacinone in baits for vertebrate pest control poses a risk of direct effects to the SJKF resulting from acute and chronic toxicity. This species has the potential to come into contact with chlorophacinone bait placed for control of a variety of rodent species. Primary exposure (ingestion of this bait) and secondary exposure (consumption of contaminated small mammal or other vertebrate carcasses) are likely to be lethal to the SJKF. Even if the ingested dose of chlorophacinone is not lethal, sublethal behavioral and neurological effects may adversely affect the survival of individuals of this species. Finally, some risk of indirect effects is possible because use of this product may reduce the abundance of small mammals and birds and invertebrates, thus reducing the available prey base. Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determinations for the SJKF based on the potential for direct and indirect effects to this species.

5.2.3. Alameda Whipsnake

5.2.3.a. Direct Effects

The AW is at risk from uses of chlorophacinone. The AW is directly exposed to chlorophacinone through consumption of chlorophacinone-contaminated prey. Although there were no listed species LOC exceedances (acute RQs ranged from 0.02 to 0.07), the chronic LOC was exceeded (RQ = 4.1). The LD_{50} and LC_{50} used to calculate the RQs were based on granivorous species. These species prefer to eat a relatively consistent quantity of food on a daily basis. Carnivores and scavengers may consume a large meal (an entire carcass) once every several days. Given this feeding strategy, the AW may get a larger single-dose exposure of chlorophacinone than is currently estimated in the risk quotient methodology.

As discussed in **Section 4.3.1**, significant mortality of adults occurred at exposure levels greater than 1 mg a.i./kg-diet in the Japanese quail reproduction study. Using the NOAEC = 1 mg a.i./kg-diet, a chronic RQ = 4.1 was attained for carnivorous/scavenger birds, which exceeds the chronic LOC = 1.0. For both adult males and females, 17% mortality was reported at the dietary concentration of 2 mg a.i./kg-diet. Other observed effects in this study included increased relative liver mass and prothombin time at 4 mg a.i./kg-diet and greater for females in addition to increased liver mass, relative liver mass and prothombin time at 8 mg a.i./kg-diet and greater for males. No effects on progeny were reported. Even with uncertainties discussed above, the effects seen in this study are significant and indicate risk to herptiles consuming chlorophacinone.

In order for there to be no exceedences of the chronic LOC for the AW, the exposure concentration would need to be less than 1.0 mg a.i./kg-carcass. For those field studies in which the bait contained 0.005% chlorophacinone, the study average carcass concentration of chlorophacinone was 0.56 mg a.i./kg-carcass. Four of the six field studies in which 0.005% chlorophacinone bait was used had at least one individual carcass with whole body concentrations of chlorophacinone greater than 1.0 mg a.i./kg-carcass.

In addition to the avian toxicity data used to calculate RQs, data were available from four studies in which carnivorous birds were fed prey that had been poisoned with chlorophacinone (fed treated bait) (**Table 4.3**). None of the exposed carnivorous birds died in these studies; however, some did exhibit signs of toxicity (hemorrhaging, yellowing of spleen, pale liver). Actual chlorophacinone exposure (concentration in the fed carcasses) was not available in any of the studies. Exposure time varied among the studies (1 day to 2 months). The birds with longer exposure times exhibited the most severe symptoms (hemorrhaging in organs). If these birds were exposed to chlorophacinone under natural conditions, these signs of reduced fitness combined with natural stressors could potentially reduce fitness of the affected individuals and, thus, make them more prone to mortality.

The Agency uses the probit dose-response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (USEPA 2004a). For these calculations, the highest RQs for AW from the secondary exposure to chlorophacinone (carcass consumption) were used. The probability of an individual effect to AW was calculated based on a gavage study with a probit slope of 2.88 with 95% confidence bounds of (1.3, 4.4) and a dietary study with a probit slope of 1.49 with 95% confidence bounds of (0.8, 2.2). For the gavage exposure, the corresponding estimated chance of an individual acute mortality to the AW at an RQ of 0.03 is 1 in 1.7E+05 (with respective upper and lower bounds of 1 in 42 to 1 in 9.6E+10). For the dietary exposure, the corresponding estimated chance of an individual acute mortality to the AW at an RQ of 0.07 is 1 in 24 (with respective upper and lower bounds of 1 in 5.6 to 1 in 181). The probability of an individual mortality occurrence is moderately high and chlorophacinone is likely to cause direct adverse effects to the AW.

Using a weight-of-evidence approach, the following pieces of evidence were weighed:

- the chronic LOCs are exceeded for the AW based on consumption of chlorophacinone-contaminated prey,
- the likelihood of an individual effect (mortality) is approximately 1 in 24 based on dietary exposure,

From these lines of evidence, there **is** a potential for direct effects to the AW from the registered uses of chlorophacinone.

5.2.3.b. Indirect Effects

Indirect effects on the AW may occur through the potential for chlorophacinone impacts on birds, mammals, and terrestrial invertebrates that are prey of the AW. Mammals also provide habitat (burrows). Indirect effects on the AW are not expected from terrestrial plants that provide habitat, as risks to this taxa from chlorophacinone are low.

For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the probability of an individual mortality occurrence is very high for both birds and mammals (**Table 5.13**), thus there is a high likelihood that the availability of prey for AW use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the AW.

Toxicity to terrestrial invertebrates was evaluated qualitatively (as chlorophacinone residues in the dosed rat carcasses in the study discussed in **Section 4.2.3** (MRID 47383001) were not available); larval survival effects to *N. orbicollis* were observed. In addition to this study, an earthworm toxicity study resulted in an LC_{50} > 1000 mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (MRID 47383002). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil. Based on the effects seen in these studies and lack of quantifiable exposure estimates, risks to terrestrial invertebrates are presumed.

RQs were not calculated for terrestrial plants as toxicity data were not available. EFED presumed direct risks were low to terrestrial plants given the mode of action of chlorophacinone and the lack of any reported incidents. Since chlorophacinone is not sprayed directly onto plants, and because so little is expected to leach from the bait and then be available for plant uptake, exposure is expected to be minimal. Based on this analysis, there is not a potential for indirect effects to the AW due to impacts to terrestrial plants.

5.2.3.c. Spatial Extent of Potential Effects

Generally, the Agency conducts analysis of the spatial extent of potential LAA effects whenever LOCs are exceeded. This analysis typically is needed to determine where adverse effects may occur in relation to the treated site. This spatial analysis typically determines if the potential area of usage, and the subsequent Potential Area of LAA Effects, overlaps with areas of occurrence and/or critical habitat of the species. However, because chlorophacinone is a vertebrate pest control agent that may be used in a wide variety of urban and non-urban areas, the spatial extent of chlorophacinone cannot be limited to defined areas. The Agency assumes that chlorophacinone potentially may be used in any area of the state that that use may occur in any of the land use categories that are identified in the NLCD. Therefore, a spatial analysis was not conducted to identify this overlap. All areas where the AW occurs are assumed to lie within the potential use area of chlorophacinone.

5.2.3.d. Modification of designated critical habitat

Critical habitat has been defined for the AW. As discussed above, the potential for chlorophacinone use to adversely modify the critical habitat of the AW stems primarily from reduction of prey species and potential reduction of small mammal burrows. Use of rodenticide bait certainly has the potential to adversely affect the abundance of small mammals and other vertebrates within the critical habitat. Since the AW prey on small mammals (along with other types of terrestrial vertebrates and invertebrates), adverse effects on these communities could

adversely affect the habitat by reducing the abundance of prey. Birds, reptiles, terrestrial-phase amphibians, and terrestrial arthropods are also prey of the AW. Reductions in the abundance of these types of prey are also possible, although less certain because the likelihood that these types of animals would consume bait designed for rodents and moles is uncertain. In addition to prey effects, the AW makes use of small mammal burrows for refuge and foraging. Therefore, reduction of small mammal abundance could adversely affect the critical habitat by reducing the availability of this important habitat resource.

As discussed in **Section 5.1.5**, use of chlorophacinone in bait products to is not expected to result in significant effects on plants. Bait can be broadcast, thus exposure will occur. However, due to the mode of action of chlorophacinone, effects to plants are not expected.

5.2.3.e. Effects Determination

The results of this risk assessment indicates that use of chlorophacinone in baits for vertebrate pest control poses a risk of chronic toxicity to the AW resulting from secondary exposure. Further risk to this species would be posed by sublethal behavioral and neurological effects which may result from acute or chronic exposure to chlorophacinone. Finally, indirect effects are also possible from use of this product reducing the abundance of vertebrate and invertebrate prey, and possibly reducing the availability of small mammal burrows. Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determinations for the AW, and a **habitat modification determination** for its designated critical habitat, based on the potential for direct and indirect effects and effects to the PCEs of critical habitat.

5.2.4. California Tiger Salamander

5.2.4.a. Direct Effects

The CTS is at risk from uses of chlorophacinone. The CTS is directly exposed to chlorophacinone through consumption of chlorophacinone-contaminated prey. Although there were no listed species LOC exceedances (acute RQs ranged from <0.01 to 0.07), the chronic LOC was exceeded (RQ = 4.1). The LD_{50} and LC_{50} used to calculate the RQs were based on granivorous species. These species prefer to eat a relatively consistent quantity of food on a daily basis. Carnivores and scavengers may consume a large meal (an entire carcass) once every several days. Given this feeding strategy, the CTS may get a larger single-dose exposure of chlorophacinone than is currently estimated in the risk quotient methodology.

As discussed in **Section 4.3.1**, significant mortality of adults occurred at exposure levels greater than 1 mg a.i./kg-diet in the Japanese quail reproduction study. Using the NOAEC = 1 mg a.i./kg-diet, a chronic RQ = 4.1 was attained for carnivorous/scavenger birds, which exceeds the chronic LOC = 1.0. For both adult males and females, 17% mortality was reported at the dietary concentration of 2 mg a.i./kg-diet. Other observed effects in this study included increased relative liver mass and prothombin time at 4 mg a.i./kg-diet and greater for females in addition to increased liver mass, relative liver mass and prothombin time at 8 mg a.i./kg-diet and greater for males. No effects on progeny were reported. Even with uncertainties discussed above, the effects seen in this study are significant and indicate risk to herptiles consuming chlorophacinone.

In order for there to be no exceedences of the chronic LOC for the CTS, the exposure concentration would need to be less than 1.0 mg a.i./kg-carcass. For those field studies in which the bait contained 0.005% chlorophacinone, the study average carcass concentration of chlorophacinone was 0.56 mg a.i./kg-carcass. Four of the six field studies in which 0.005% chlorophacinone bait was used had at least one individual carcass with whole body concentrations of chlorophacinone greater than 1.0 mg a.i./kg-carcass.

In addition to the avian toxicity data used to calculate RQs, data were available from four studies in which carnivorous birds were fed prey that had been poisoned with chlorophacinone (fed treated bait) (**Table 4.3**). None of the exposed carnivorous birds died in these studies; however, some did exhibit signs of toxicity (hemorrhaging, yellowing of spleen, pale liver). Actual chlorophacinone exposure (concentration in the fed carcasses) was not available in any of the studies. Exposure time varied among the studies (1 day to 2 months). The birds with longer exposure times exhibited the most severe symptoms (hemorrhaging in organs). If these birds were exposed to chlorophacinone under natural conditions, these signs of reduced fitness combined with natural stressors could potentially reduce fitness of the affected individuals and, thus, make them more prone to mortality.

The Agency uses the probit dose-response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (USEPA 2004a). For these calculations, the highest RQs for CTS from the secondary exposure to chlorophacinone (carcass consumption) were used. The probability of an individual effect to CTS was calculated based a dietary study with a probit slope of 1.49 with 95% confidence bounds of (0.8, 2.2). The corresponding estimated chance of an individual acute mortality to the CTS at an RQ of 0.07 is 1 in 24 (with respective upper and lower bounds of 1 in 5.6 to 1 in 181). The probability of an individual mortality occurrence is moderately high and chlorophacinone is likely to cause direct adverse effects to the CTS.

Using a weight-of-evidence approach, the following pieces of evidence were weighed:

- the chronic LOCs are exceeded for the CTS based on consumption of chlorophacinone-contaminated prey,
- the likelihood of an individual effect (mortality) is approximately 1 in 24 based on dietary exposure,

From these lines of evidence, there **is** a potential for direct effects to the CTS from the registered uses of chlorophacinone.

5.2.4.b. Indirect Effects

Indirect effects on the CTS may occur through the potential for chlorophacinone impacts on herptiles, mammals, and terrestrial invertebrates that are prey of the CTS. Mammals also provide habitat (burrows). Indirect effects on the CTS are not expected from fish and invertebrates that are prey, from terrestrial plants that provide habitat, or from aquatic plants that provide food and habit as risks to these taxa from chlorophacinone are low.

For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the probability of an individual mortality occurrence is very high for both birds and mammals (**Table 5.13**), thus there is a high likelihood that the availability of prey for CTS use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the CTS.

Toxicity to terrestrial invertebrates was evaluated qualitatively (as chlorophacinone residues in the dosed rat carcasses in the study discussed in **Section 4.2.3** (MRID 47383001) were not available); larval survival effects to *N. orbicollis* were observed. In addition to this study, an earthworm toxicity study resulted in an LC_{50} > 1000 mg ai/kg-soil and a mortality NOAEC = 309 mg ai/kg-soil (MRID 47383002). Weight change was significantly affected at all treatment levels resulting in a NOAEC < 95 mg ai/kg-soil. Based on the effects seen in these studies and lack of quantifiable exposure estimates, risks to terrestrial invertebrates are presumed.

RQs were calculated for freshwater fish and invertebrates as they are prey of the aquatic-phase CTS. There were no exceedances of any LOCs; therefore, there is not a potential for indirect effects to the CTS due to reduction in the prey items of freshwater fish and invertebrates.

RQs were not calculated for terrestrial and aquatic plants as toxicity data were not available. EFED presumed direct risks were low to terrestrial and aquatic plants given the mode of action of chlorophacinone and the lack of any reported incidents. Since chlorophacinone is not sprayed directly onto plants, and because so little is expected to leach from the bait and then be available for plant uptake, exposure is expected to be minimal. Based on this analysis, there is not a potential for indirect effects to the CTS due to impacts to terrestrial and aquatic plants.

5.2.4.c. Spatial Extent of Potential Effects

Generally, the Agency conducts analysis of the spatial extent of potential LAA effects whenever LOCs are exceeded. This analysis typically is needed to determine where adverse effects may occur in relation to the treated site. This spatial analysis typically determines if the potential area of usage, and the subsequent Potential Area of LAA Effects, overlaps with areas of occurrence and/or critical habitat of the species. However, because chlorophacinone is a vertebrate pest control agent that may be used in a wide variety of urban and non-urban areas, the spatial extent of chlorophacinone cannot be limited to defined areas. The Agency assumes that chlorophacinone potentially may be used in any area of the state that that use may occur in any of the land use categories that are identified in the NLCD. Therefore, a spatial analysis was not conducted to identify this overlap. All areas where the CTS occurs are assumed to lie within the potential use area of chlorophacinone.

5.2.4.d. Modification of designated critical habitat

Critical habitat has been defined for the CTS. As discussed above, the potential for chlorophacinone use to adversely modify the critical habitat of the CTS stems primarily from reduction of prey species and potential reduction of small mammal burrows. Use of rodenticide

bait certainly has the potential to adversely affect the abundance of small mammals and other vertebrates within the critical habitat. Since the CTS preys on small mammals (along with other types of terrestrial vertebrates and invertebrates), adverse effects on these communities could adversely affect the habitat by reducing the abundance of prey. Reptiles, terrestrial-phase amphibians, and terrestrial arthropods are also prey of the CTS. Reductions in the abundance of these types of prey are also possible, although less certain because the likelihood that these types of animals would consume bait designed for rodents and moles is uncertain. In addition to prey effects, the CTS makes use of small mammal burrows for refuge and foraging. Therefore, reduction of small mammal abundance could adversely affect the critical habitat by reducing the availability of this important habitat resource.

As discussed in **Section 5.15**, use of chlorophacinone in bait products to is not expected to result in significant effects on plants. Bait can be broadcast, thus exposure will occur. However, due to the mode of action of chlorophacinone, effects to plants are not expected.

5.2.4.e. Effects Determination

The results of this risk assessment indicates that use of chlorophacinone in baits for vertebrate pest control poses a risk of chronic toxicity to the CTS resulting from secondary exposure. Further risk to this species would be posed by sublethal behavioral and neurological effects which may result from acute or chronic exposure to chlorophacinone. Finally, indirect effects are also possible from use of this product reducing the abundance of vertebrate and invertebrate prey, and possibly reducing the availability of small mammal burrows. Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determinations for the CTS, and a **habitat modification determination** for its designated critical habitat, based on the potential for direct and indirect effects and effects to the PCEs of critical habitat.

5.2.5. Addressing the Risk Hypotheses

In order to conclude this risk assessment, it is necessary to address the risk hypotheses defined in **Section 2.5.1**. Based on the conclusions of this assessment, many of the hypotheses cannot be rejected, meaning that the stated hypotheses represent concerns in terms of direct and indirect effects of chlorophacinone on the AW, SMHM, SJKF, and CTS and the designated critical habitat of the AW and CTS.

The labeled use of chlorophacinone within the action area may:

- directly affect AW, SMHM, CTS, and SJKF by causing mortality or by adversely affecting growth or fecundity;
- indirectly affect AW, SMHM, CTS, and SJKF and/or modify their designated critical habitat by reducing or changing the composition of food supply;
- indirectly affect SMHM, AW, and CTS and/or modify their designated critical habitat by reducing or changing terrestrial habitat in their current range (via reduction in small burrowing mammals leading to reduction in underground refugia/cover).

The risk assessment did indicate that three of the risk hypothesis may be rejected. The hypotheses which were rejected are that use of chlorophacinone may:

- indirectly affect SMHM and CTS and/or modify their designated critical habitat by reducing or changing the composition of the aquatic plant community in the species' current range, thus affecting primary productivity and/or cover;
- indirectly affect SMHM and CTS and/or modify their designated critical habitat by reducing or changing aquatic habitat in their current range (via modification of water quality parameters, habitat morphology, and/or sedimentation);
- indirectly affect AW, SMHM, CTS, and SJKF and/or modify their designated critical habitat by reducing or changing the composition of the terrestrial plant community in the species' current range.

6. Uncertainties

6.1. Fate and Transport Properties

The most significant uncertainty regarding the fate and transport properties of chlorophacinone are regarding the nature of the major degradates. At least one and potentially two major degradates are seen in the hydrolysis and aerobic soil metabolism studies whose structures are not unknown. Since the nature of the compounds is not known, the fate and toxicological properties cannot be determined. In addition, there are two known minor degradates, *o*-phthalic acid and *p*-chlorophenylphenyl acetic acid. While the specific toxicological and fate properties of these compounds are not known, a comparison of the structures of these compounds to that of parent chlorophacinone and other anticoagulant rodenticides suggests that neither of the compounds has the structural moiety associated with this mode of action still present. While acceptable information is lacking on aerobic metabolism and aqueous photolysis processes, these two processes would only decrease the amount of chlorophacinone present and aquatic risks are already below the level of concern. It is unlikely that these degradation processes would produce degradates more toxic than the parent and thus increase the risk.

6.2. Effects

While there are currently no chronic aquatic toxicity data for chlorophacinone, the very low risk quotients for acute aquatic effects indicate that little risk would also be expected for chronic risk. The assessment of risks to mammals was based, in part, on acute dose study (MRID 41875301). However, another 5 day – multiple dose study (Ashton, *et al*., 1987) was not of sufficient quality to use for a quantitative assessment endpoint but does indicate that effects can be seen at lower daily dosing levels if the treated bait is consumed over several days, which is the intended strategy for the use of the pesticide. This indicates that the risks are greater than that estimated using the RQ from the single dose study. Since risks are exceeded using the single dose study, this does not change the overall interpretation of the risk.

6.2.1. Use of Surrogate Species Effects Data

Guideline toxicity tests and open literature data on chlorophacinone are not available for aquatic-phase amphibians; therefore, freshwater fish are used as surrogate species for aquatic-phase amphibians and the CTS. In addition, birds are used as surrogate species for terrestrial phase amphibians as well as the CTS and AW. Endpoints based on freshwater fish ecotoxicity data are assumed to be protective of potential direct effects to aquatic-phase amphibians including the

CTS, and extrapolation of the risk conclusions from the most sensitive tested species to the aquatic-phase CTS is likely to overestimate the potential risks to those species. Similar assumptions are made for risk conclusions for the terrestrial-phase CTS and the AW. Efforts are made to select the organisms most likely to be affected by the type of compound and usage pattern; however, there is an inherent uncertainty in extrapolating across phyla. In addition, the Agency's LOCs are intentionally set very low, and conservative estimates are made in the screening level risk assessment to account for these uncertainties.

6.2.2. Sublethal Effects

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

6.3. Data Gaps

Data gaps were assigned a low or high potential to add value to the ecological risk assessment. . High potential studies will allow for better characterization of potential risks by eliminating uncertainties for both non-listed and listed species that cannot be accounted for using alternate methods or weights of evidence (*i.e.*, acute-to-chronic ratio, scaling factors, or consideration of environmentally relevant concentrations relative to effects thresholds). Low potential studies are unlikely to change risk determinations because alternate methods and weights of evidence may possibly be used in the absence of data. Data gaps are listed below; details for each data gap are discussed in **Section 2.9.4.** Studies with a **high potential** to add value to the risk assessment are:

- *Field Testing for Terrestrial Wildlife (850.2500)*
- *Avian Reproduction Study (850.2300), two species*
- *Avian Acute Oral Toxicity Test (850.2100), one passerine species.*

Other studies which were requested to satisfy existing data requirements were:

- *Seedling Emergence, Tier II (850.4225), ten species*
- *Vegetative Vigor, Tier II (850.4250), ten species*
- *Soil photolysis (835.2410)*
- *Aqueous photolysis (835.2240)*
- *Aerobic aquatic metabolism (835.4300)*
- *Anaerobic aquatic metabolism (835.4400)*
- *Freshwater Fish Early Life-Stage Toxicity Test (850.1400)*
- *Freshwater Invertebrate Life Cycle Toxicity Test (850.1300)*
- *Estuarine/Marine Fish Acute Toxicity Test (850.1075*)
- *Estuarine/Marine Fish Early-life Stage Toxicity Test (850.1400)*
- *Aquatic Plant Toxicity Test Using* Lemna *spp.,Tiers I and II (850.4400)*
- *Algal Toxicity, Tiers I and II (850.5400), four species*

7. Risk Conclusions

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

Based on the best available information, the Agency makes a **May Affect, and Likely to Adversely Affect** determination for the SMHM, SJKF, AW, and CTS from the all uses of chlorophacinone. Additionally, the Agency has determined that there is the potential for modification of designated critical habitat for the AW and CTS from the use of chlorophacinone. A summary of the risk conclusions and effects determinations for each listed species assessed here and their designated critical habitat is presented in **Table 7-1** and in **Table 7-2**. Use-specific determinations are provided in **Table 7-3** and **Table 7-4**. Given the LAA determination for the SMHM, SJKF, AW, and CTS and potential modification of designated critical habitat for the AW and CTS, a description of the baseline status and cumulative effects for the SMHM, SJKF, AW, and CTS is provided in **Attachment II**.

Table 7-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.

Species	Effects Determination	Basis for Determination
Salt marsh harvest mouse (SMHM) (*Reithrodontomys raviventris*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects** Risk assessment indicates use of chlorophacinone will potentially result in direct effects to the SMHM from acute and chronic toxicity. Lines of evidence include: • the listed species and chronic LOCs are exceeded for the SMHM based on consumption of bait , • the likelihood of an individual effect (mortality) is approximately 1 in 1.0 based on gavage and dietary exposure, • mortality through primary exposure to chlorophacinone was documented through low LD_{50} and LC_{50} values obtained in toxicity studies, high mortality percentages observed in field efficacy trials, and mortality of the rodents when fed chlorophacinone for the secondary exposure trials, and • reported incidents of mortality of small non-target herbivorous mammals after consumption of chlorophacinone bait. **Potential for Indirect Effects** ***Food sources*** Risk assessment indicates vegetative food sources are not expected to be affected by chlorophacinone application; however, terrestrial invertebrate prey populations may be reduced. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Adverse effects to birds and mammals may result in a reduction of abandoned bird and mammal nests, which are used as nest sites by the SMHM. Acute RQs for birds and mammals, and acute and chronic RQs for mammals, exceed LOCs. Therefore, use of chlorophacinone may adversely modify the habitat of the SMHM by reducing the availability of nest sites.

Table 7-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.

Species	Effects Determination	Basis for Determination
San Joaquin Kit Fox (SJKF) (*Vulpes macrotis mutica*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects** Risk assessment indicates use of chlorophacinone will potentially result in direct effects to the SJKF from acute and chronic toxicity. Lines of evidence include: • the listed species and chronic LOCs are exceeded for the SJKF based on consumption of bait, • the likelihood of an individual effect (mortality) is approximately 1 in 1.0 based on gavage and dietary exposure, • mortality through primary exposure to chlorophacinone was documented through low LD_{50} and LC_{50} values obtained in toxicity studies, high mortality percentages observed in field efficacy trials, and mortality of the rodents when fed chlorophacinone for the secondary exposure trials, and • mortality through secondary exposure to chlorophacinone was documented for the secondary exposure trials where 43% to 88% of the secondary consumers died, and • EIIS contains reports of eleven incidents in the US that were considered probable or highly probable for death due to chlorophacinone. Mortalities included species that were likely primary consumers of the bait (*e.g.*, grey squirrel and wild turkey) and carnivorous species (*e.g.*, badger and red-tailed hawk) likely to have preyed upon the granivorous individuals. • incident reports included six endangered San Joaquin kit fox mortalities were included in the incident database. Four kit foxes had documented concentrations of chlorophacinone in the liver.
		Potential for Indirect Effects ***Food sources*** This risk assessment indicates vegetative food sources are not expected to be affected by chlorophacinone application; however, terrestrial vertebrate and invertebrate prey populations may be reduced. For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the chance of an individual mortality occurrence is very high for both birds and mammals (greater than 1 in 3 at the acute RQ), thus there is a high likelihood that the availability of prey for SJKF use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the SJKF. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Risk assessment indicates use of chlorophacinone is not expected to adversely modify the habitat of this species by reducing the availability of nest sites. This conclusion is based on acute RQs for birds and mammals, and acute and chronic RQs for mammals, that exceed the LOC. Adverse effects to birds and mammals may result in a reduction of abandoned bird and mammal nests, which are used as nest sites by this species.
		Potential for Direct Effects

Table 7-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.		
Species	**Effects Determination**	**Basis for Determination**
Alameda Whipsnake (AW) (*Masticophis lateralis euryxanthus*)	May Affect, Likely to Adversely Affect (LAA)	This risk assessment indicates use of chlorophacinone will potentially result in direct effects to the AW from chronic toxicity. Lines of evidence include: • the chronic LOCs are exceeded for the AW based on consumption of chlorophacinone-contaminated prey, • the likelihood of an individual effect (mortality) is approximately 1 in 24 based on dietary exposure.
		Potential for Indirect Effects
		Food sources Risk assessment indicates terrestrial vertebrate and invertebrate prey populations may be reduced. For birds and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the chance of an individual mortality occurrence is very high for both birds and mammals (greater than 1 in 3 at the acute RQ), thus there is a high likelihood that the availability of prey for AW use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence of mortality of potential prey animals exposed to chlorophacinone. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study. ***Habitat Modifications*** Risk assessment indicates use of chlorophacinone may adversely modify the habitat of this species by reducing the availability of burrows. This conclusion is based on acute and chronic RQs for mammals that exceed the LOC. Adverse effects to mammals may result in a reduction of available burrows, which are used as shelters by this species.
California Tiger Salamander (CTS) (*Ambystoma californiense*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects**
		This risk assessment indicates use of chlorophacinone will potentially result in direct effects to the CTS from chronic toxicity. Lines of evidence include: • the chronic LOCs are exceeded for the CTS based on consumption of chlorophacinone-contaminated prey, • the likelihood of an individual effect (mortality) is approximately 1 in 24 based on dietary exposure.
		Potential for Indirect Effects
		Food sources Risk assessment indicates terrestrial vertebrate and invertebrate prey populations may be reduced. For birds (surrogate for herptiles) and mammals consuming bait directly and/or consuming chlorophacinone-contaminated carcasses, acute and/or chronic LOCs are exceeded. With the exception of avian gavage exposure, the chance of an individual mortality occurrence is very high for both birds and mammals (greater than 1 in 3 at the acute RQ), thus there is a high likelihood that the availability of prey for CTS use may decrease due to reductions in the populations of other birds and mammals. Reported incidents for a variety of birds and mammals also provide evidence to the likelihood of mortality for animals providing food sources for the CTS. Risks to terrestrial invertebrates were presumed based on reduced larval survival in a burying beetle study.

Table 7-1. Effects Determination Summary for Effects of Chlorophacinone on the SMHM, SJKF, AW, and CTS.		
Species	**Effects Determination**	**Basis for Determination**
		Habitat Modifications Risk assessment indicates use of chlorophacinone may adversely modify the habitat of this species by reducing the availability of burrows. This conclusion is based on acute and chronic RQs for mammals that exceed the LOC. Adverse effects to mammals may result in a reduction of available burrows, which are used as shelters by this species.

Table 7-2. Effects Determination Summary for the Critical Habitat Impact Analysis		
Designated Critical Habitat for:	**Effects Determination**	**Basis for Determination**
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	Habitat Modification	This risk assessment indicates use of chlorophacinone may adversely modify the critical habitat of this species by reducing the availability of small mammal burrows. This may result in modification of PCE 3: "Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2." In addition, the availability of prey may be reduced in the critical habitat by toxicity to small birds, mammals, reptiles, and terrestrial-phase amphibians.
California Tiger Salamander (*Ambystoma californiense*)	Habitat Modification	This risk assessment indicates use of chlorophacinone may adversely modify the critical habitat of this species by reducing the availability of small mammal burrows. This may result in modification of PCE 3: "Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2." In addition, the availability of prey may be reduced in the critical habitat by toxicity to small mammals, reptiles, and terrestrial-phase amphibians.

Table 7-3. Use Specific Summary of The Potential for Adverse Effects to Aquatic Taxa						
Uses	**Potential for Effects to Identified Taxa Found in the Aquatic Environment:**					
	CTS-CC, CTS-SC, and CTS-SB, and Freshwater Vertebrates[1]		**Freshwater Invertebrates[2]**		**Vascular Plants[3]**	**Non-vascular Plants[3]**
	Acute	**Chronic**	**Acute**	**Chronic**		
0.005% a.i. bait (broadcast, spot, station)	No	No	No	No	No	No
0.010% a.i. bait (broadcast, spot, station)	No	No	No	No	No	No
0.005% a.i. in floating bait station (muskrat use)	No	No	No	No	No	No

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

Table 7-4. Use Specific Summary of The Potential for Adverse Effects to Terrestrial Taxa													
Uses	**Potential for Effects to Identified Taxa Found in the Terrestrial Environment:**												
	SMHM and Small Mammals[1]		**SJKF and Large Mammals [2]**		**Small Birds[3]**		**CTS-CC, CTS-SC, CTS-SB and Amphibians[4]**		**AW and Reptiles[5]**		**Invertebrates (Acute)[6]**	**Dicots[7]**	**Monocots[7]**
	Acute	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**			
0.005% a.i. bait (broadcast, spot, station)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
0.010% a.i. bait (broadcast, spot, station)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
0.005% a.i. in floating bait station (muskrat use)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No

1 A yes in this column indicates a potential for direct effects to SMHM and indirect effects to SMHM, SJKF, AW, CTS-CC, CTS-SC, and CTS-SB.
2 A yes in this column indicates a potential for direct and indirect effects to SJKF.
3 A yes in this column indicates a potential for indirect effects to the SMHM, SJKF, AW, CTS-CC, CTS-SC, and CTS-SB.
4 A yes in this column indicates a potential for direct effects to CTS-CC, CTS-SC, CTS-SB, and indirect effects to CTS-CC, CTS-SC, CTS-SB, and AW.
5 A yes in this column indicates the potential for direct and indirect effects to AW, and other reptiles.
6 A yes in this column indicates a potential for indirect effects to SMHM, SJKF, AW, CTS-CC, CTS-SC, and CTS-SB.
7 A yes in this column indicates a potential for indirect effects to SMHM, CTS-CC, CTS-SC, CTS-SB.

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

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

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

8. Bibliography

Ashton, A.D., W.B. Jackson and H. Peters. 1986. Comparative evaluation of LD_{50} values for various anticoagulant rodenticides in Control of Mammal Pests (eds. C.G.J. Richards and T.Y. Ku) Tropical Pest Management 32 (supplement) 1: 187-197.

Berny, P.J., T. Buronfosse, F. Buronfosse, F. Lamarque, and G. Lorgue. 1997. Field evidence of secondary poisoning of foxes (*Vulpes vulpes*) and buzzards (*Buteo buteo*) by bromadiodiolone, a 4-year survey. Chemosphere. 35:8. pp. 1817-1829.

Bari, M. A., F.V. Sances, and J.T. Wingett. 1999. *Crop Profile for Artichokes in California.* (http://www.ipmcenters.org/cropprofiles/docs/caartichokes.pdf)

Clark, J.P. 1994. Vertebrate Pest Control Handbook. (4th ed.) California Dept. Food and Agriculture, Sacramento. 803 pp. (http://www.vpcrac.org/about/handbook.php)

Cox, P. and R.H. Smith. 1992. Rodenticide ecotoxicology: pre-lethal effects of anticoagulants on rat behavior. Proc. Vertebr. Pest Conf. 15:165-170.

Dowding, C.V.; R.F. Shore, A. Worgan, P.J. Baker and S. Harris. 2010. Accumulation of anticoagulant rodenticides in a non-target insectivore, the European hedgehog (*Erinaceus eropaeus*). Environmental Pollution. 158. 161-166.

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

Matschke, G. 1999. Chlorophacinone in bait stations for Beldings Ground Squirrel. (completed project report). National Wildlife Research Center. 2pp. (http://www.vpcrac.org/research/documents/COMPLETED%20PROJECT%20REPORTmatschkebeldings.pdf)

Merson, M. H. and R. E. Byers. 1985. Weathering and the field efficacy of pelletized rodenticide baits in orchards Crop Protection Volume 4, Issue 4, December 1985, Pages 511-519

Ramey, C., G. Matschke, and R. Engeman. 2007. Chlorophacinone baiting for Belding's ground squirrels. Proceedings of the 12th Wildlife Damage Management Conference (D.L. Nolte, W.M. Arjo, D.H. Stalman, Eds).

Stewart, W.B., G.H. Matschke, G.R. McCann, J.B. Bourassa, and C.A. Ramey. 2000. Hand baiting efficacy of chlorophacinone and diphacinone grain baits to control valley pocket gophers. Proc. Vertebr. Pest Conf. 19:393-397.

Trenham, P. C., Shaffer, H. B., Koenig, W. D., & Stromberg, M. R. 2000. Life history and demographic variation in the California Tiger Salamander (*Ambystoma californiense*). *Copeia, 2,* 365-377.

U.S. Environmental Protection Agency. 1993. *Wildlife Exposure Factors Handbook.* Office of Research and Development. December. EPA/600/R-93/187

U.S. Environmental Protection Agency. 1998a. *Guidelines for Ecological Risk Assessment.* United States Environmental Protection Agency (USEPA). Risk Assessment Forum. Office of

Research and Development. Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460 (Accessed June 19, 2009).

U.S. Environmental Protection Agency.1998b. *Reregistration Eligibility Decision (RED): Rodenticide Cluster*. July 1998. EPA 738-R-98-007.

U.S. Environmental Protection Agency. 2004a. *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs*. US EPA Office of Pesticide Programs, Environmental Fate and Effects Division.

U.S. Environmental Protection Agency. 2004b. Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach. July 2004. US EPA Office of Pesticide Programs, Environmental Fate and Effects Division.

U.S. Environmental Protection Agency. 2009. Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Version 2.1. Office of Pesticide Programs. Environmental Fate and Effects Division. October 22, 2009.

U.S. Environmental Protection Agency. 2010a. Guidance on calculating risk quotients (RQs) for San Francisco Bay species litigation assessments, uncertainty language for the terrestrial exposure assessment, and release of an updated version of T-HERPS. Memorandum from Donald Brady to the Environmental Fate and Effects Division. February 5, 2010.

U.S. Environmental Protection Agency. 2010b. Risks of Chlorophacinone Use on Black Tailed Prairie Dogs to Federally Endangered and Threatened Species. http://www.epa.gov/oppfead1/endanger/litstatus/effects/index.htm#chlorophacinone (Accessed 01 April 2011)

U.S. Fish and Wildlife Service (USFWS). 2007. Red Willow County Bald Eagle. Office of Law Enforcement. Report #: 2007600155R003.

U.S. Fish and Wildlife Service (USFWS). 2009. Logan County Raptor Deaths. Office of Law Enforcement. Report #: 2009600498.

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

Whitaker, J. O., Jr. 1996. National Audubon Society® Field Guide to North American Mammals. Alfred A. Knopf, New York. 937 pp.

World Health Organization. Data Sheets on Pesticides No. 62: Chlorophacinone. Food and Agriculture Organization. http://www.inchem.org/documents/pds/pds/pest62_e.htm. Accessed 01 April 2010.