Risks of Brodifacoum Use to the Federally Threatened

Alameda Whipsnake (*Masticophis lateralis euryxanthus*),

and the Federally Endangered

Salt Marsh Harvest Mouse (*Reithrodontomys raviventris*)

and San Joaquin Kit Fox (*Vulpes macrotis mutica*)

Pesticide Effects Determinations
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List of Commonly Used Abbreviations and Nomenclature

µg/kg	Symbol for "micrograms per kilogram"
µg/L	Symbol for "micrograms per liter"
ºC	Symbol for "degrees Celsius"
AAPCO	Association of American Pesticide Control Officials
a.i.	Active Ingredient
AIMS	Avian Monitoring Information System
Acc#	Accession Number
amu	Atomic Mass Unit
AW	Alameda Whipsnake
BCB	Bay Checkerspot Butterfly
BCF	Bioconcentration Factor
BEAD	Biological and Economic Analysis Division
bw	Body Weight
CAM	Chemical Application Method
CARB	California Air Resources Board
CBD	Center for Biological Diversity
CCR	California Clapper Rail
CDPR	California Department of Pesticide Regulation
CDPR-PUR	California Department of Pesticide Regulation Pesticide Use Reporting Database
CFWS	California Freshwater Shrimp
CI	Confidence Interval
CL	Confidence Limit
CTS	California Tiger Salamander
CTS-CC	California Tiger Salamander Central California Distinct Population Segment
CTS-SB	California Tiger Salamander Santa Barbara County Distinct Population Segment
CTS-SC	California Tiger Salamander Sonoma County Distinct Population Segment
DS	Delta Smelt
EC	Emulsifiable Concentrate
EC_{05}	5% Effect Concentration
EC_{25}	25% Effect Concentration
EC_{50}	50% (or Median) Effect Concentration

ECOTOX	EPA managed database of Ecotoxicology data
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division
e.g.	Latin *exempli gratia* ("for example")
EIM	Environmental Information Management System
EPI	Estimation Programs Interface
ESU	Evolutionarily significant unit
et al.	Latin *et alii* ("and others")
etc.	Latin *et cetera* ("and the rest" or "and so forth")
EXAMS	Exposure Analysis Modeling System
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FQPA	Food Quality Protection Act
ft	Feet
GENEEC	Generic Estimated Exposure Concentration model
HPLC	High Pressure Liquid Chromatography
IC_{05}	5% Inhibition Concentration
IC_{50}	50% (or median) Inhibition Concentration
i.e.	Latin for *id est* ("that is")
IECV1.1	Individual Effect Chance Model Version 1.1
KABAM	K_{OW} (based) Aquatic BioAccumulation Model
kg	Kilogram(s)
kJ/mole	Kilojoules per mole
km	Kilometer(s)
K_{AW}	Air-water Partition Coefficient
K_d	Solid-water Distribution Coefficient
K_F	Freundlich Solid-Water Distribution Coefficient
K_{OC}	Organic-carbon Partition Coefficient
K_{OW}	Octanol–water Partition Coefficient
LAA	Likely to Adversely Affect
lb a.i./A	Pound(s) of active ingredient per acre
LC_{50}	50% (or Median) Lethal Concentration
LD_{50}	50% (or Median) Lethal Dose
LOAEC	Lowest Observable Adverse Effect Concentration
LOAEL	Lowest Observable Adverse Effect Level
LOC	Level of Concern
LOD	Level of Detection

LOEC	Lowest Observable Effect Concentration
LOQ	Level of Quantitation
m	Meter(s)
MA	May Affect
MATC	Maximum Acceptable Toxicant Concentration
m^2/day	Square Meters per Days
ME	Microencapsulated
mg	Milligram(s)
mg/kg	Milligrams per kilogram (equivalent to ppm)
mg/L	Milligrams per liter (equivalent to ppm)
mi	Mile(s)
mmHg	Millimeter of mercury
MRID	Master Record Identification Number
MW	Molecular Weight
n/a	Not applicable
NASS	National Agricultural Statistics Service
NAWQA	National Water Quality Assessment
NCOD	National Contaminant Occurrence Database
NE	No Effect
NLAA	Not Likely to Adversely Affect
NLCD	National Land Cover Dataset
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NOAEC	No Observable Adverse Effect Concentration
NOAEL	No Observable Adverse Effect Level
NOEC	No Observable Effect Concentration
NRCS	Natural Resources Conservation Service
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides and Toxic Substances
ORD	Office of Research and Development
PCE	Primary Constituent Element
pH	Symbol for the negative logarithm of the hydrogen ion activity in an aqueous solution, dimensionless
pKa	Symbol for the negative logarithm of the acid dissociation constant, dimensionless
ppb	Parts per Billion (equivalent to µg/L or µg/kg)

ppm	Parts per Million (equivalent to mg/L or mg/kg)
PRD	Pesticide Re-Evaluation Division
PRZM	Pesticide Root Zone Model
ROW	Right of Way
RQ	Risk Quotient
SFGS	San Francisco Garter Snake
SJKF	San Joaquin Kit Fox
SLN	Special Local Need
SMHM	Salt Marsh Harvest Mouse
TG	Tidewater Goby
T-HERPS	Terrestrial Herpetofaunal Exposure Residue Program Simulation
T-REX	Terrestrial Residue Exposure Model
UCL	Upper Confidence Limit
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
VELB	Valley Elderberry Longhorn Beetle
WP	Wettable Powder
wt	Weight

1. Executive Summary

1.1. Purpose of Assessment

The purpose of this assessment is to evaluate potential direct and indirect effects on the federally threatened Alameda Whipsnake (AW, *Masticophis lateralis euryxanthus*), the federally endangered salt marsh harvest mouse (SMHM, *Reithrodontomys raviventris*), and the federally endangered San Joaquin kit fox (SJKF, *Vulpes macrotis mutica*) arising from FIFRA regulatory actions regarding use of brodifacoum 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. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998), procedures outlined in the Agency's Overview Document (USEPA, 2004), and consistent with a suit in which brodifacoum was alleged to be of concern to the AW, SMHM and SJKF (*Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 07-2794-JCS).

Brodifacoum is a second generation anticoagulant pesticide for rodent control against commensal rats and mice (See **Section 2.3** for a more detailed discussion of the different classes of rodenticides). There are 26 product labels for this chemical; however, at the time this review is prepared, four of them do not comply with the risk mitigation decision required for ten rodenticides (**Table 2-5**). All compliant and non-compliant labels were evaluated in this assessment.[1]

The AW, a subspecies of the California whipsnake (*Masticophis lateralis*), was listed as threatened in 1997 by the USFWS. A recovery plan for this and other threatened and endangered species of the chaparral and scrub community east of San Francisco Bay, California was approved by the USFWS in 2003. Critical habitat was designated for this subspecies in 2006. 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. The subspecies occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties in California.

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.

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] According to the Risk Mitigation Decision for Ten Rodenticides (RMD) (EPA-HQ-OPP-2006-0955-0764, June 2008), to reduce wildlife exposures and ecological risks, the Agency is requiring sale and distribution limits intended to prevent general consumers from purchasing residential use bait products containing the second generation rodenticide brodifacoum for labels of bait products sold after June 4, 2011. However, not all labels are in compliance with this requirement at the time this assessment is completed. A Notice of Intent to Cancel (NOIC) has been issued for the non-compliant products.

1.2. Scope of Assessment

1.2.1. Uses Assessed

Brodifacoum is a rodenticide for control of Norway rats (*Rattus norvegicus)*, roof rats (*Rattus rattus*) and house mice (*Mus musculus*). Formulation types registered include meal, pellets, blocks and paste. Currently, labeled uses of brodifacoum that are considered as part of the federal action evaluated in this assessment include sites in and around homes, and agricultural, industrial and commercial buildings, transport vehicles and associated ports, alleys and sewers. Uses that occur indoors are not expected to result in any primary exposure to the AW, SMHM, or SJKF. However, indoor use could result in secondary exposure to the AW or SJKF if a rodent ingests bait indoors and then moves outside and is consumed by the AW or SJKF. In addition, many label uses classified as "indoor" actually refer to uses that take place indoors and/or within 50 ft of residences or other structures. Therefore, all of the uses listed above (both indoor and outdoor) are considered as part of the federal action evaluated in this assessment.

1.2.2. Environmental Fate Properties of Brodifacoum

It appears that the primary route of dissipation/transport for brodifacoum might be through consumption of bait product by target animals (*e.g.*, rats and mice) as well as non-target birds and mammals that consume brodifacoum bait. However, these animals do not die immediately after feeding; therefore, movement of the intact chemical in the bodies of the affected animals to distant places is expected. This distance is species-specific to the home range of the animal that ingested brodifacoum bait. Brodifacoum kills non-target birds, target mammals (commensal rodents), and possibly other non-target mammals eating bait within a period of days; therefore, movement of the chemical might be substantial during that period.

Brodifacoum (CAS Chemical Name: 3-[3-(4′-bromo[1,1′-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2*H*-1-benzopyran-2-one) shows a low solubility (solubility of 0.240 mg/L at pH 7.4 and 20°C) and non-volatile (vapor pressure of 1.11×10^{-18} mmHg at 25^0C; calculated Henry's Law Constant of 2.0×10^{-16} atm-m^3/mole). The compound is relatively stable to hydrolysis (no evidence of degradation during the test at pHs 5, 7 and 9). However, the UV/Visible spectrum of the compound has a peak within the visible region at around 310 nm, which suggests photolysis by sunlight in aqueous media is potentially important, should exposure to aquatic environments actually occur. In a sandy clay loam soil, brodifacoum degraded slowly (half-life 157 days, with no further identification data about the major degradate). In an aged soil column study, the compound was immobile in four soils tested. Based on its low vapor pressure and Henry's Law Constant, this compound should not volatilize readily. Based on an estimated log K_{OW} value of 8.5, bioconcentration in fish is anticipated should water exposure occur. The low application rates of brodifacoum per placement and its high tendency to be adsorbed to soils indicate a low likelihood of runoff towards adjacent surface waters except when carried by eroded sediment. The applications of brodifacoum as bait products will not cause the chemical to drift. No aquatic monitoring data has been found for this chemical. Rodenticide test substances are not typically considered in surface or groundwater

monitoring studies. For further details about this chemical's physicochemical and fate characteristics, refer to **Tables 2-2** and **2-3**, respectively.

1.2.3. Evaluation of Degradates and Stressors of Concern

In this assessment, brodifacoum is the stressor of concern. There is no information about possible degradates of brodifacoum that could be derived from the available environmental fate studies. The only exception is that one degradate was observed in the aerobic soil metabolism study at around 17% of the applied radioactivity (AR) but it was not identified. Brodifacoum is relatively persistent in studies performed to assess its half-life in livers of mice. Thus, it remains intact for several months if taken at sublethal levels (6.44 µg a.i/mouse, Vandenbroucke et al, 2008) and it appears unlikely that major (≥10% AR) metabolites would be formed in animal tissues.

1.3. Assessment Procedures

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

1.3.1. Exposure Assessment

1.3.1.a. Aquatic Exposures

There are no aquatic species that are relevant to the assessment of the AW and SJKF, based on their life history and feeding preferences. The aquatic plant taxon is relevant to the SMHM for the potential of indirect effects. However, brodifacoum is a bait formulation with low application rates. This rodenticide should be applied per placements at least 8 ft away from each other (for mice), and when applied at the maximum rate per placement, 15 ft from each other (for rats). The maximum rate per placement is small compared to conventional agricultural pesticides (0.000050 lb or 23 mg/placement). In addition, except for four products included in the Notice of Intent to Cancel (NOIC), placements should occur within 50 ft of urban and agricultural structures and for above ground applications, bait stations should be used. Thus, applications appear to be highly localized. Furthermore, its strong affinity to sorb to soil suggests that it is likely to strongly sorb to bait material itself; consequently, off-field runoff and exposures in aquatic environments are expected to be negligible. Finally, labels have certain requirements to avoid substantive exposure to water when brodifacoum is applied to sewers (see **Section 2.4.3**). Therefore, concentrations of brodifacoum in both freshwater and saltwater marshes are expected to be negligible and not impact aquatic vegetation. There is no surface water monitoring data available for brodifacoum. Based on this information, the aquatic habitat is not assessed in this document.

1.3.1.b. Terrestrial Exposures

Brodifacoum exposures to the AW and SJKF resulting from application of brodifacoum baits were evaluated by assuming the AW and SJKF consume prey species that directly consumed

baits of various types (*e.g.*, pellets, blocks) which are defined as direct effects (through secondary exposure). This assumption was made on the basis of snakes rarely consuming anything but live prey and the fact that all above ground placements of brodifacoum are required to be in bait stations, which would preclude primary exposure to the SJKF. Direct effects through primary exposure would only be applicable to the SMHM via direct consumption of brodifacoum bait from outdoors bait applications. Indoors, applied bait is unlikely to be consumed by the SMHM.

Indirect effects to the AW and SJKF in this assessment are defined as direct effects to birds, mammals, and reptiles that directly ingest brodifacoum bait and serve as prey for the AW and SJKF. Since exposure occurs via consumption of organisms that have ingested baits, standard EFED models of terrestrial exposure (*e.g.*, T-REX, T-HERPS) are not considered in this assessment. The concentration of active ingredient in food was simply assumed to be the concentration of active ingredient in the bait. The Agency does not have a standard model or method of predicting secondary exposure of terrestrial animals that eat other animals which have ingested bait. As a Tier 1 (screening) risk assessment, conservative assumptions included:

1. The amount of active ingredient ingested by the AW and SJKF from secondary exposure was assumed to be equal to the amount of active ingredient that a prey item would ingest if it consumed brodifacoum bait at its daily ingestion rate.
2. The prey was assumed to be a house mouse, roof rat or Norway rat (the target species for which brodifacoum is currently registered), as well as birds and reptiles, and the amount of bait these species ingested was assumed based on their body weights. It is noted, however, that non-target animals such as other small mammals, birds, and reptiles can ingest the bait directly as well.
3. The weights of these prey species were assumed to be the maximums of the reported body weight ranges to maximize secondary exposure to the AW and SJKF.
4. All of the brodifacoum ingested by the prey was assumed to be available to and assimilated by the AW and SJKF that eats it.

Effects to terrestrial plants are not considered in this assessment due primarily to the nature of the bait placements and mode of action of brodifacoum. The mode of action of brodifacoum is to block the activity of Vitamin K epoxide reductase. This enzyme is needed for the reconstitution of Vitamin K in its cycle from Vitamin-K epoxide; therefore, brodifacoum steadily reduces the amount of active Vitamin K in the blood. Vitamin-K is required for the synthesis of prothrombin, which is involved in blood clotting. Since plants do not have a circulatory system, this mode of action is not relevant to plants as it is to animals. Furthermore, terrestrial plants are not expected to be exposed to brodifacoum given its method of application. Therefore, effects to terrestrial plants and resulting indirect effects to the assessed species are not considered in this assessment.

1.3.2. Toxicity Assessment

The assessment endpoints include direct toxic effects on survival, reproduction, and growth of individuals (through primary exposure) to the SMHM, direct toxic effects on survival, reproduction, and growth of individuals (through secondary exposure) for the AW and SJKF,

and indirect effects, such as reduction of the food source and/or modification of habitat for the AW, SJKF, and SMHM. Federally-designated critical habitat has been established for the AW but not for the SMHM and SJKF. Primary constituent elements (PCEs) were used to evaluate whether brodifacoum has the potential to modify designated critical habitat. The Agency evaluated registrant-submitted studies and data from the open literature to characterize brodifacoum toxicity. The most sensitive toxicity value available from acceptable or supplemental registrant submitted studies as well as ECOTOX and OPP accepted open literature studies for each taxon relevant for estimating potential risks to the assessed species and/or their designated critical habitat was used.

Section 4 summarizes the ecotoxicity data available on brodifacoum. Brodifacoum is very highly toxic to birds and mammals on an acute oral and subacute dietary exposure basis. In the acute oral studies, brodifacoum was observed to cause several sublethal effects in birds including hemorrhaging body weight changes fresh and digested blood in the feces, severe and extensive bruising, subcutaneous hemorrhage, and excessive, prolonged bleeding from damaged feathers or small wounds in the skin of the face, comb, and wattles.

In the avian dietary toxicity studies, sublethal effects were noted; however, the levels at which the sublethal effect occurred were not indicated. Both studies conducted a 5-day exposure followed by a 35-day observation period due to the delayed toxicity of brodifacoum. For the bobwhite quail dietary study, clinical signs of toxicity included, depression, wing droop, loss of coordination, prostration, and hemorrhage. Control mortality in this study was 12% which was attributed to toe and nostril picking. Toe and nostril picking also occurred in the treated birds, and in combination with the anticoagulant properties of the test material, may have been a partial cause for the mortality according to the study authors. In the mallard duck dietary study, clinical signs of toxicity included lethargy, weakness, loss of coordination, and prostration (extreme exhaustion). Most birds, but not all had internal hemorrhage detected during necropsies.

In an acute oral toxicity studies with mammals, clinical signs of toxicity in the study with the laboratory rat included pallor, subdued behavior, decreased activity, bruising and bleeding from the nose and/or rectum. Necropsy finings of free or clotted blood in the thoracic and/or abdominal cavity, kidney, esophagus, and subcutaneous tissues are consistent with the anticoagulant mode of action of brodifacoum. In an acute oral toxicity study with minks, brodifacoum was administered in five treatment groups and the minks were monitored for 5 weeks post dose administration due to the delayed toxicity of brodifacoum. Clinical sings of toxicity included bloody droppings. The LD_{50} for this study was determined to be 9.2 mg a.i/kg-bw. It was reported by the study authors that the increased LD_{50} for the mink to brodifacoum relative to other species could possibly be attributed to the very rapid transit of food through the intestinal tract which has been reported by other studies to be approximately 2 hours.

An acute oral toxicity study with Richardson's ground squirrel (*Spermophilus richardsonii*), (MRID 48638401) had brodifacoum administered to test animals via gavage at five treatment groups. After exposure, the animals were observed for 21 days or until death due to the delayed toxicity of brodifacoum. The combined (male and female) LD_{50} was determined to be 0.13 mg a.i/kg-bw (0.063 – 0.188 mg a.i/kg-bw confidence interval). Necropsy findings showed all but

two treated ground squirrels at all test concentrations had internal or external hemorrhaging. All other test animals appeared to have died from hemorrhages.

In a series of dietary studies conducted with technical brodifacoum and albino rats, animals were exposed for five days with a 9 day observation period due to the delayed toxicity of brodifacoum. The most sensitive LC_{50} (0.53 mg a.i./kg-diet) was very similar to the LC_{50}s attained in three of the additional tests (LC_{50}s ranged from 0.55 to 0.57 mg a.i./kg-diet). One study indicated less sensitivity to brodifacoum with an LC_{50} = 0.84 mg a.i./kg-diet). No control animals died during the study. Animals were followed for 14 days after starting the treated diet (5 days treated diet, followed by 9 days clean diet). All mortalities occurred between days 4 and 14 after the feeding of treated diet started. The majority of mortalities were between days 4 and 8.

There are no available data to characterize toxicity of brodifacoum to the honey bee. No data are available to characterize chronic toxicity to birds and mammals.

1.3.3. Measures of Risk

Acute and chronic risk quotients (RQs) are compared to the Agency's Levels of Concern (LOCs) to identify instances where brodifacoum use has the potential to adversely affect the assessed species or 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 brodifacoum use "may affect," the assessed species, and/or may cause effects to designated critical habitat, the best available additional information is considered to refine the potential for exposure and effects, and distinguish actions that are Not Likely to Adversely Affect (NLAA) from those that are Likely to Adversely Affect (LAA).

1.4. Summary of Conclusions

Based on the best available information, the Agency makes a May Affect, and Likely to Adversely Affect determination for AW, SMHM and SJKF from the use of brodifacoum. Additionally, the Agency has determined that there is the potential for modification of designated critical habitat for the AW from the use of the chemical. A summary of the risk conclusions and effects determinations for the listed species assessed here and their designated critical habitat is presented in **Table 1-1** and **Table 1-2**. Use-specific determinations are provided in **Table 1-3.** Further information on the results of the effects determination is included as part of the Risk Description in **Section 5.2**. Given the LAA determination for the AW, SMHM, and SJKF and potential modification of designated critical habitat for the AW, a description of the baseline status and cumulative effects for AW, SMHM, and SJKF is provided in **Attachment III**.

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

Species	Effects Determination	Basis for Determination

Species	Effects Determination	Basis for Determination
Alameda whipsnake (AW) (*Masticophis lateralis euryxanthus*)	*May Affect* and *Likely to Adversely Affect* (LAA)	**Potential for Direct Effects**
		Use of brodifacoum may result in direct effects to the AW from acute toxicity through secondary exposure. Dietary exposure estimates and acute toxicity to reptiles (based on acute toxicity data for birds) result in acute RQs that exceed the LOC for secondary exposure. Secondary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Additionally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).
		Potential for Indirect Effects
		Terrestrial prey items Use of brodifacoum may reduce the abundance of terrestrial vertebrates which serve as prey for this species. This conclusion is based on acute RQs for birds, mammals, and reptiles which exceed the LOCs. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving small mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%). ***Habitat Modification*** Use of brodifacoum may modify the habitat of this species by reducing the availability of small mammal burrows. This conclusion is based on acute RQs for mammals that exceed the LOCs. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed.
Salt Marsh Harvest Mouse (SMHM) (*Reithyodontomys raviventris*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects**
		Use of brodifacoum may result in direct effects to the SMHM from acute toxicity via primary exposure. Exposure estimates and acute toxicity to mammals result in acute RQs that exceed the LOCs for primary exposure to the SMHM. Primary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity, however since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving small mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).
		Potential for Indirect Effects
		Terrestrial Habitat Use of brodifacoum may reduce SMHM rearing sites by adversely affecting small mammals. Estimated acute RQs for primary exposure to mammals exceeded acute LOCs for the small mammalian weight class considered.

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**
		Use of brodifacoum may result in direct effects to the SJKF from acute toxicity via secondary exposure. Secondary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).
		Potential for Indirect Effects
		Terrestrial prey items Use of brodifacoum may reduce the abundance of terrestrial vertebrates which serve as prey for this species. Dietary exposure estimates and acute toxicity to reptiles (based on acute toxicity data for birds), birds, and mammals result in acute RQs that exceed the LOC for secondary exposure. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving birds and mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).

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

Designated Critical Habitat for:	Effects Determination	Basis for Determination
Alameda whipsnake (AW) (*Masticophis lateralis euryxanthus*)	Habitat Modification	Use of brodifacoum may 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.

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

Uses	Potential for Effects to Identified Taxa Found in the Terrestrial Environment									
	SMHM and Small Mammals[1]		SJKF and Large Mammals[2]		AW and Reptiles[3]		Small Birds[4]		Terrestrial – phase Amphibians[5]	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
Rodent Control	Yes	Yes[6]	Yes	Yes[6]	Yes	Yes[6]	Yes	Yes[6]	Yes	Yes[6]

1 A yes in this column indicates a potential for direct effects to the SMHM and indirect effects to the AW and SJKF.

2 A yes in this column indicates a potential for direct and indirect effects to SJKF.

3 A yes in this column indicates the potential for direct (through secondary exposure) to the AW and indirect (through prey reduction) effects to the AW.
4 A yes in this column indicates a potential for direct effects to the AW, SMHM and SJKF.
5 A yes in this column indicates a potential for indirect effects to the AW.
6 Chronic toxicity data are not available to assess this species; however chronic risk is assumed based upon the high acute risks.

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated to seek concurrence with the LAA determinations for AW, SMHM, and SJKF and to determine whether there are reasonable and prudent alternatives and/or measures to reduce and/or eliminate potential incidental take.

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

determination of the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual species and potential modification to critical habitat.

2. Problem Formulation

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

2.1. Purpose

The purpose of this endangered species assessment is to evaluate potential direct and indirect effects on individuals of the federally threatened Alameda Whipsnake (AW), and the federally endangered Salt Marsh Harvest Mouse (SMHM) and San Joaquin Kit Fox (SJKF), arising from FIFRA regulatory actions regarding use of brodifacoum for rodent control. 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) entered in Federal District Court for the Northern District of California on May 17, 2010.

In this assessment, direct and indirect effects to the AW, SMHM and SJKF, and potential modification to designated critical habitat for the AW are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA, 2004).

The AW, a subspecies of the California whipsnake, was listed as threatened in 1997 by the USFWS. A recovery plan for this and other threatened and endangered species of the chaparral and scrub community east of San Francisco Bay, California was approved by the USFWS in 2003. Critical habitat was designated for this subspecies in 2006. The subspecies occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties in California.

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.

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.

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 brodifacoum 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 brodifacoum 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, and SJKF and the designated critical habitat of the AW 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 brodifacoum 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 of the AW, a "No Effect," or a "Habitat Modification," determination is made.

A description of routine procedures for evaluating risk to the San Francisco Bay Species is 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 brodifacoum in accordance with the approved product labels for California is "the action" relevant to this ecological risk assessment.

Brodifacoum is a rodenticide (against Norway rats, roof rats and house mice) for use in and around homes, and agricultural, industrial and commercial buildings, ports associated with transport vehicles (*e.g.*, trains, aircraft, ships), and sewers. There are 26 labels approved for this chemical. Of these 26 labels, four of these labels are subject to the Notice of Intent to Cancel (NOIC) for Twenty Rodenticide products (further detailed in **Section 2.3**). However, for this assessment, all currently registered uses are considered. Formulation types registered include meal, pellets, blocks and paste.

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

2.2.1. Evaluation of Degradates

Information about environmental fate degradates of brodifacoum is very limited. The only exception is that one degradate was observed in one aerobic soil metabolism study; however, it was not identified. Furthermore, risk from exposure to degradation products was not considered a major concern because the majority of risk to the AW and SJKF is expected to be from acute secondary exposure from consumption of prey which feed on the intact bait. Similarly, risk from exposure to degradation products was not considered a major concern for the SMHM because the majority of the risk is expected to be from direct consumption of the bait. Contamination of soil and water from use of the bait products is expected to be minimal. Therefore, should there be formation of degradation products in soil and/ or in water, it would not be a major concern in this assessment because of minimal exposure expected from its use in bait stations. Labels have certain requirements to avoid substantive exposure to water when brodifacoum is applied to sewers (see **Section 2.4.3**).

2.2.2. Evaluation of Mixtures

The Agency does not routinely include, in its risk assessments, an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively in accordance with the Agency's Overview Document and the Services' Evaluation Memorandum (USEPA, 2004; USFWS/NMFS/NOAA, 2004). However there are currently no registered products containing brodifacoum and another active ingredient.

2.3. Previous Assessments

Biological Opinion

The USFWS addressed the risk of brodifacoum use on endangered species in a Biological Opinion (BO) issued in March of 1993 (USFWS, 1993). The USFWS issued the BO in response to a 1991 request by the EPA for formal consultation on 16 registered vertebrate control agents. Particular labels and application rates evaluated in the BO were not specified. The BO included an evaluation of the use of brodifacoum for control of Norway rats, roof rats, and house mice in urban areas in and around the periphery of homes, industrial, commercial and public buildings and cargo areas of ships, trains, and aircraft and related port buildings, but not in sewers.

The BO concluded that normal use of brodifacoum would not likely harm aquatic fauna because its formulations, application methods, and relative water insolubility should limit its susceptibility to runoff, leaching, or drift and thus preclude aquatic exposure. For terrestrial animals, the BO discussed concerns for primary and secondary poisoning of listed scavengers

and predators. The FWS issued a jeopardy or no jeopardy call for species listed in **Table 2-1**; further detail on individual species is provided in the BO.[2].

Table 2-1. **Jeopardy Calls for Species Evaluated in the 1993 FWS Biological Opinion on Brodifacoum Use.**

Species	N/NJ[1]
MAMMALS	
Alabama beach mouse (*Peromyscus polionotus ammobates)*	J
Anastasia Island beach mouse (*Peromyscus polionotus phasma)*	J
Carolina northern flying squirrel (*Glaucomys sabrinus coloratu)*	J
Choctawhatchee beach mouse *(Peromyscus polionotus allphrys)*	J
Florida salt marsh vole (*Microtus pennsylvanicus dukecampbelli)*	J
Fresno kangaroo rat (*Dipodomys nitrotoides exilis)*	J
Giant kangaroo rat (*Dipodomys ingens)*	NJ
Louisiana black bear (*Ursus americanus luteolus)*	NJ
Morro Bay kangaroo rat (*Dipodomys heermanni morroensis)*	J
Perdido Key beach mouse (*Peromyscus polionotus trissyllepsis)*	J
Point Arena mountain beaver (*Aplodontia rufa nigra)*	NJ
Salt marsh harvest mouse[3] (*Reithrodontomys raviventris)*	J
San Joaquin kit fox[4] (*Vulpes macrotis mutica)*	NJ
Southeastern beach mouse (*Peromyscus polionotus niveiventris)*	J
Stephen's kangaroo rat (*Dipodomys stephensi*)	NJ
Tipton kangaroo rat (*Dipodomys nitrotoides nitrotoides*)	NJ
BIRDS	
Audubon's crested caracara (*Polyborus plancus auduboni)*	J
Hawaiian hawk (*Buteo solitaries)*	NJ
San Clemente loggerhead shrike (*Lanius ludovicianus)*	J
REPTILES	
Eastern indigo snake (*Drymarchon couperi)*	NJ

1. J = Jeopardy; NJ = No Jeopardy

The BO included Reasonable and Prudent Alternatives (RPAs) or Reasonable and Prudent Measures (RPMs) for species with jeopardy calls. For example, for the SMHM (and Fresno kangaroo rat, *Dipodomys nitrotoides exilis*), RPAs included "[P]rohibit outdoor brodifacoum use within 100 yards of these species' occupied habitat." Furthermore, RPMs included that "EPA must establish a monitoring enforcement program." For the SJKF, there were no established RPAs (note there was a no jeopardy call because it "has a relatively large range and many of its habitats are far removed from anticipated brodifacoum uses"), but RPMs were included as follows, "[O]utdoor application of brodifacoum baits within the range of the San Joaquin kit fox

[2] Available at: http://www.fws.gov/sacramento/ES/Consultation/Programmatic-Consultations/Documents/EPA_Rodenticide_BO_March_1993_Sec_1_intro.pdf, http://www.fws.gov/sacramento/ES/Consultation/Programmatic-Consultations/Documents/EPA_Rodenticide_BO_March_1993_Sec_2_chemicals_A-M.pdf, http://www.fws.gov/sacramento/ES/Consultation/Programmatic-Consultations/Documents/EPA_Rodenticide_BO_March_1993_Sec_2_chemicals_P-Z.pdf, http://www.fws.gov/sacramento/ES/Consultation/Programmatic-Consultations/Documents/EPA_Rodenticide_BO_March_1993_Sec_3_species.pdf

[3] SMHM is one of the species evaluated in this review.

[4] SJKF is one of the species evaluated in this review.

shall be placed in tamper resistant bait boxes and shall not be placed in areas accessible to wildlife." The AW was not included among the list of species evaluated but one reptile species was included, the Eastern indigo snake. For the species a NJ call was indicated because "the snake's potential for exposure to poisoned prey is considered minimal…it is the Service's opinion that the use of brodifacoum is not likely to jeopardize the continued existence of the eastern indigo snake."

Reregistration Eligibility Decision (RED)

The Agency assessed the risks of rodenticide uses of several rodenticides, which included brodifacoum, in the *Reregistration Eligibility Decision (RED): Rodenticide Cluster* that was published in July 1998 (USEPA, 1998b).

This RED document included an ecological effects risk assessment that was based on environmental fate and ecotoxicological studies that had been submitted by the rodenticide registrants at the time. The assessment concluded that primary risk to mammals was very high for all the covered rodenticides. Furthermore, primary risk to birds was found to be high to very high for the single-feeding compounds (brodifacoum, bromadiolone, bromethalin). In addition, there was data on the secondary risk for avian and mammalian predators and/or scavengers for some (chlorophacinone and diphacinone), but not for all of the rodenticides involved. Thus, registrant-submitted secondary toxicity data was required for rodenticides used in the field, and around buildings in non-urban (*i.e.*, rural, suburban areas). Based on the environmental fate characteristics of the rodenticides involved, it was broadly concluded at the time, that they were unlikely to result in contamination of surface or ground waters. Even though they are persistent chemicals, they tend to be relatively immobile in soils and fairly insoluble in water. In the RED, it was further concluded that since they are primarily applied as bait stations outdoors, their aquatic risk appeared to be negligible. Risk mitigation measures were imposed on these rodenticides in two phases: short and long term risk reduction and subsequently, certain labeling requirements were implemented.

Examples of mitigation measures imposed at the time include the addition of an environmental hazard statement regarding contamination of water. Additionally, all rodenticide products labeled for field use, except those to be applied manually against pocket gophers and moles, were classified as restricted use. Finally, applications to control mice and rats were labeled for applications "indoors and along the outside walls of buildings" and the environmental hazard statement was modified to read "predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait."

Rodenticide Comparative Assessment

An assessment of the risks of brodifacoum to terrestrial wildlife was included in the 2004 assessment *Potential Risks of Nine Rodenticides to Birds and Non-target Mammals: a Comparative Approach* (USEPA 2004b). Among the general conclusions in the document, it was found that brodifacoum was one of the two rodenticides that pose the greatest risk to non-target birds and mammals (with difethialone, another second generation anticoagulant rodenticide being the other). When exposure and toxicity were evaluated, brodifacoum was one

of the three rodenticides that posed the greatest risk to birds that eat bait. Also, brodifacoum was one of the two rodenticides that posed the greatest potential risks to avian predators and scavengers that feed on target or non-target animals poisoned with bait. It was indicated that rodenticide baits are formulated to be lethal to small mammals, and they are not selective to non-target species. The document stressed that all baits pose a high potential for primary risk to birds and non-target mammals that eat bait. Avian and mammalian predators and scavengers are at risk from feeding on animals poisoned with anticoagulant baits.

The overall risk to birds from primary exposure was found to be high for brodifacoum and comparable to difethialone and zinc phosphide. For non-target mammals, a comparative analysis found that brodifacoum posed less risk from primary exposure than zinc phosphide, and it was comparable to difethialone, bromadialone, diphacinone and warfarin.

Anticoagulant rodenticides are generally divided into two classes, first generation and second generation anticoagulants. Both classes have the same mode of action but second generation anticoagulants (including brodifacoum) are characterized by being more acutely toxic than first generation anticoagulants (*e.g.* warfarin) and having a significantly longer liver retention time.

Second generation anticoagulants appear not to be readily metabolized and are mostly excreted through the feces. After absorption, high concentrations circulate in the blood and are rapidly established in the liver and other tissues. Risk to wildlife from secondary exposure to brodifacoum was evaluated based upon the liver retention time of the chemical. In various studies, the liver retention of brodifacoum was greater than 80 days and as high as 350 days (in a rat study). Overall, the available toxicokinetic data indicates that the second-generation anticoagulants like brodifacoum, are considerably more persistent in animal tissues than are the first-generation anticoagulants, and bioaccumulation may increase whole-body residues with repeat feedings. Brodifacoum was among the top two rodenticides posing the greatest secondary risk to birds and mid range for secondary risk to non-target mammals. This assessment therefore concluded that brodifacoum poses a higher secondary risk to wildlife than non-anticoagulant rodenticides.

A total of 244 reported wildlife incidents associated with brodifacoum were documented that attest to the extensive exposure of birds and non-target mammals, including endangered species. **"Brodifacoum residues have been detected in liver tissue of 27 of 32 endangered kit foxes screened for rodenticide residues from 1999 to 2003**. Birds in which rodenticides are most frequently detected include owls, hawks, eagles, and crows; mammals include wild canids and felids, tree squirrels, raccoons, deer, and others."[5]

Scientific Advisory Panel (SAP) and Notice of Intent to Cancel (NOIC) Non-Compliant Rodenticides

In November 2011, the Agency issued background papers to the FIFRA Science Advisory Panel (SAP) on a Notice of Intent to Cancel (NOIC) non-RMD (Risk Mitigation Decision, US EPA, 2008b) compliant rodenticide products. The meeting was held in November – December, 2011. The focus of this section is on the document titled "Risks of Non-Compliant Rodenticides to

[5] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0718-0006

Non-target Wildlife" which was essentially an update of the "…previous risk assessment findings conducted in support of the May 2008 RMD through the evaluation of additional effects and exposure data, use of additional exposure modeling, and quantitative risk assessment for products of four rodenticides subject to the NOIC (brodifacoum, difethialone, warfarin and bromethalin)…".[6] Concerns were raised for both primary and secondary exposure to the products subject to the NOIC. Lines of evidence included the following:

- An assessment of the risks to non-target animals associated with primary exposure to rodenticides;
- An assessment of the risks of non-target animals through secondary exposure to rodenticides;
- An evaluation of available feeding studies as they relate to secondary exposure risks; and
- An evaluation of reported wildlife incidents.

Among the highlighted conclusions, it was indicated that:

- "[P]rimary exposure risk to mammals is above concern levels and is similar across the assessed rodenticides, which is consistent with their use as rodenticides";
- "[P]rimary exposure risk to birds is above concern levels for brodifacoum, difethialone, and bromethalin, and less than a single day of feeding could result in a median lethal dose";
- For mammals "a greater opportunity for secondary exposure to result in median lethal doses was estimated to be greater for brodifacoum and difethialone relative to the other assessed rodenticides";
- "[S]econdary exposure risk to birds is above concern levels for brodifacoum and difethialone under all assessed scenarios, and consumption of less than a single contaminated prey animal could result in a median lethal dose"; and
- Wildlife incidents have been reported for rodenticides to birds and mammals through primary and secondary routes of exposure in urban/suburban and rural areas.

In response to the Agency's presentation, in December 2011, the FIFRA SAP issued the report of the scientific conclusions on the above mentioned background paper and presentation relative to the NOIC.[7] Regarding the Agency's conclusion that use of non-conforming rodenticide products can cause adverse effects to non-target wildlife, the SAP commented that it concurred with the conclusion and that "[B]ait in the form of pellets or forms otherwise not contained within a bait station undoubtedly enhance the likelihood of ingestion by non-target primary consumers. In turn, the more primary consumers that contain residues, the more widespread contamination of the food chain will be through secondary and possibly tertiary exposures in predators and scavengers." Furthermore, "[T]he Panel believed it is reasonable to expect that rodenticides placed inside tamper resistant bait stations will reduce the likelihood of wildlife (*e.g.*, grey squirrels, chipmunks, passerine birds) accessing the bait." Regarding secondary exposure, "[T]he case for a high risk to non-target wildlife from brodifacoum exposure is well supported." "The incident data and exposure data provide strong evidence that SGAR[8] use,

[6] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0718-0006
[7] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0718-0086
[8] Second generation anticoagulant rodenticides (SGAR).

particularly brodifacoum, in urban and suburban areas has the potential to impact non-target wildlife, and that brodifacoum contamination of the terrestrial food chain is widespread." However, according to the SAP, regarding the uncertainties, "[I]n general, the analysis presented by the EPA did not include real numerical quantifications of risk, and there seems to be a great degree of uncertainty for some components of the risk assessment." These uncertainties are further discussed in **Section 4.4.2.**

2.4. Environmental Fate Properties

Table 2-2 lists various important physicochemical properties of brodifacoum. **Table 2-3** lists available environmental fate properties of brodifacoum, from the submitted environmental fate and transport studies. The structure of brodifacoum is provided in **Figure 2-1**. In this assessment many of the physical/chemical properties of brodifacoum were obtained using the quantitative structure-activity relationship (QSAR) estimation software EPI Suite (USEPA 2011). For complete EPI Suite v.4.1 output file see the **Appendix F**.

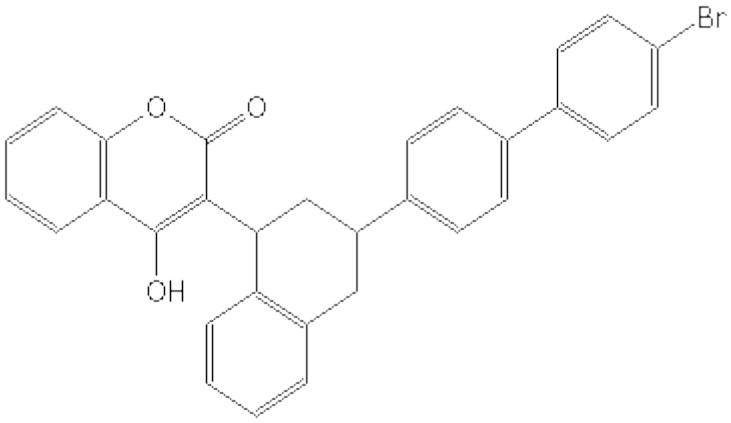

Figure 2-1. Structure of Brodifacoum

Table 2-2. Physicochemical Properties of Brodifacoum

Property	Parent Compound	
	Value and units	MRID or Source
Molecular Weight	523.43 g/mole	EPI Suite v.4.1 (USEPA 2011)
Chemical Formula	$C_{31}H_{23}BrO_3$	EPI Suite v.4.1 (USEPA 2011)
CAS Name	3-[3-(4′-bromo[1,1′-biphenyl]-4-yl)-1,2,3,4-tetrahydro-1-naphthalenyl]-4-hydroxy-2*H*-1-benzopyran-2-one	Brodifacoum's data sheet[1]
IUPAC Name	3-[(1*RS*,3*RS*;1*RS*,3*SR*)-3-(4′-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	Brodifacoum's data sheet[1]
CAS No.	56073-10-0	41892202
Color/Physical State	Cream colored, fine, powdery solid	41892201
Density	1.42 g/cm^3 at 25^{0}C	41892201
pH	3.8 in a 1% v/v dispersion in water at approx. 20^{0}C	41892201
Melting Point	232^{0}C	41892202
Water Solubility	0.0038 mg/L at 20^{0}C and pH 5.2; 0.240 mg/L at pH 7.4; 10.0 mg/L at pH 9.3 buffered water and 20^{0}C	41892202; only the pH 5.2 solubility appears in EPI Suite 4.1's database (USEPA 2011)

Property	Parent Compound	
	Value and units	MRID or Source
Vapor Pressure	$1.11x10^{-18}$ mmHg (torr) at 25^0C <<10^{-8} torr at 20^0C „Non-volatile from a field condition'	EPI Suite v.4.1 Estimate (USEPA 2011) 41892202 USEPA, 2008a
Henry's Law Constant	2.012×10^{-16} atm-m^3/mole at 25^0C <<10^{-8} atm-m^3/mole at pH 7.4 and 20^0C	EPI Suite v.4.1 calculated from WS and VP estimate (USEPA 2011) 41892202
n-Octanol-water partition coefficient (log K_{OW})	3.16×10^8 (log K_{OW} = 8.5) (Estimated based on SARs)	MRID 41892202; solubility too low to obtain experimental value
Dissociation Constant (pK_a)	4.44 (Temperature not specified)	EPI Suite 4.1 database (USEPA 2011) (Tomlin, C. 1997)
Air-water partition coefficient (K_{AW})	$K_{AW} = C_{air}/C_{water}$ = HLC/RT $K_{AW} = 8.23 \times 10^{-15}$ „Non-volatile' (from a water surface)	Calculated Value, USEPA, 2008a
$C_{water+soil}/C_{air}$	$C_{water+soil}/C_{air} = (1/K_{AW})\ (1/r + K_d) =$ 9.58×10^{18} „Non-volatile from moist soil'	Assuming $K_d \approx 0.02 \times K_{OC}$ Calculated value USEPA, 2008a
n-Octanol-air partition coefficient (K_{OA})	$K_{OA} = \frac{K_{OW}}{K_{AW}} = \frac{K_{OW} RT}{\text{Henry's Law Constant}}$ $K_{OA} = 3.84 \times 10^{22}$	Calculated value, using EPI Suite v.4.1's K_{OW} (USEPA 2011)
UV/visible light absorption	Maxima at around 205, 265 and 310 nm.	41892202
Volatization Flux	Not available	Not Applicable
1. The structure of the chemical was obtained from the brodifacoum data sheet available at http://www.alanwood.net/pesticides/brodifacoum.html (accessed 01/18/2012).		

Brodifacoum has a high molecular weight ≥523 g/mol (**Table 2-2**), with a relatively small solubility (0.240 ppm at near neutral pH) and a high octanol/ water partition coefficient (K_{OW} = $3.16x10^8$). Based on it octanol/ water partition coefficient, it appears that brodifacoum has the potential to bioaccumulate/bioconcentrate. Brodifacoum has a very small vapor pressure of 1.11×10^{-18} mmHg, and a relatively little solubility, and therefore its calculated Henry's Law Constant is very small (2.012×10^{-16} atm-m^3/mol). In addition, its K_{AW} is 8.23×10^{-15}, which classifies it as "non-volatile from a water surface" (USEPA 2008a). Brodifacoum has very little potential to volatilize from wet surfaces. The potential to volatilize may be attenuated by its tendency to bind to organic matter (*e.g.*, soils, sediments, or organic matter and particulate in natural water), as indicated by high estimated K_{OC} and K_{OW} values.

For brodifacoum, the log K_{OA} is 22.5, the log K_{OW} is 8.5, the rate of transformation is relatively slow in the environment, and the rate of transformation appears to be relatively slow in fish (with an EPIWEB v.4.1 estimated half-life of 351 days) (**Table 2-3**); based on this information, it appears that brodifacoum has *a potential* to biomagnify in terrestrial food chains, based on the presumption made by Gobas *et al.* (2003) and Armitage & Gobas (2007). Their presumption is that if log K_{OA} > 5, log K_{OW} >2 and the rate of chemical transformation is low, the chemical may biomagnify in terrestrial food chains. Even though an official reference or guideline to distinguish chemicals that biomagnify has not been established, Gobas *et al.* and Armitage & Gobas' presumption was utilized here as a broad reference to identify the potential for

biomagnification in terrestrial food chains. Evidence of brodifacoum in the terrestrial food chains and information on its liver retention half-lives support the above mentioned presumption.

Brodifacoum is stable to hydrolysis at pH 5, 7, and 9, relatively persistent in soil ($t_{½}$ = 157 days), and immobile in soil columns. Aged column leaching studies indicated that parent brodifacoum is immobile in soil columns of UK sand, sandy clay loam, silty clay and clay. In the study ~78-94% of the applied radioactivity remained in the uppermost layer (of unaged soil) and < 0.32 % was recovered in the leachate. Valid K_ds or K_{OC}s were not obtained, but they are expected to be relatively high because of the low mobility observed in the column leaching studies for parent and possible degradates and the EPI Suite v.4.1 estimated K_{OC}s are on the order of 10^5 to 10^6 L/Kg_{OC}. Brodifacoum is persistent, but little, if any, contamination of surface and ground waters is expected because of its use pattern and immobility in soil. It is noted that the degradates and their accumulation and decline patterns were not identified in the aerobic soil metabolism study. However, because brodifacoum is typically applied in bait stations and/or only in and around structures, bait is only 25 or 50 ppm (0.0025 or 0.005%) a.i., and brodifacoum is immobile in soil, potential contamination of surface and ground water is expected to be low. Therefore, degradate identification, accumulation and decline, unaged column leaching, field dissipation, and adsorption/desorption data were not required.

Table 2-3. Summary of Brodifacoum Environmental Fate Properties

Study	Value and Unit	Major Degradate *Minor Degradates*	MRID No. or Citation	Study Classification
Hydrolysis	Half-life = No evidence of degradation at pHs 5, 7 and 9, considered relatively stable	N/A	42237701, 44021706	Acceptable
Atmospheric Oxidation	Half-life = 2.2 hours, hydroxyl radical reaction 2.0 hours, for ozone reaction	NA	EPIWEB v.4.1 Estimate	N/A
Aerobic Soil Metabolism	Half-life = 157 days, sandy clay loam at 21^0C; No organic volatiles, and $^{14}CO_2$ at 36% AR. Only one soil is available.	Up to 11 degradates at up to 17.34% AR were not identified.	42579401	Acceptable
Organic-Carbon Normalized Distribution Coefficient (K_{OC})	K_{OC} = 7.745×10^6 L/kg_{OC} (estimate from Molecular Connectivity Index) 1.411×10^5 L/kg_{OC} (estimate from K_{OW}) Immobile (FAO 2000)	NA	EPIWEB v.4.1 Estimate	N/A
Aged Soil Column Leaching	Brodifacoum was aged for 30 days. Shows low mobility in sand, sandy clay loam, silty clay and clay soil columns. ≤0.32% was recovered in the leachates.	No major degradates were observed in soil or leachate.	42568301	Acceptable
Bioconcentration Factor (BCF)	Regression based BCF= 2450 L/kg wet-wt Biotransformation $t_{1/2}$ = 351 days (normalized to 10 g fish at 15^0C)	NA	EPIWEB v.4.1 Estimate	N/A

Abbreviations: wt=weight, NA=Not Available, N/A=Not Applicable, AR = Applied Radioactivity

There is no evidence of hydrolysis of brodifacoum at pHs 5 to 9. The available study was considered acceptable (MRID 42237701). Another available hydrolysis study (MRID 44021706) also shows relative stability to hydrolysis at pHs 5 to 9.

Brodifacoum is relatively persistent. It degraded with a half-life of 157 days in sandy clay loam soil incubated in the dark at 21^0C and 75% of ⅓ bar moisture capacity. No volatile degradates other than $^{14}CO_2$ were identified; $^{14}CO_2$ comprised 36% of the applied radioactivity at 52 weeks post-treatment. Up to eleven [^{14}C] compounds other than [^{14}C]brodifacoum were isolated from the soil extracts at 2.07 to 17.34% of the applied (0.008 to 0.067 ppm), but none were identified. The identification, accumulation and decline of major metabolites (17.34% of applied) were not required at the time of the review.

An adsorption/desorption study was conducted for brodifacoum. Even though the data was considered of uncertain value due to the use of a co-solvent (acetone), it pointed towards very high sorption of the chemical to three soils. EPI Suite v.4.1's estimate of the K_{OC} for brodifacoum is on the order of 10^5 to 10^6 L/kg$_{OC}$ which confirms that brodifacoum is immobile in soils (FAO 2000). Based on column leaching experiments, aged 30 days, brodifacoum residues (89-97% as brodifacoum) were relatively immobile in columns of sand, sandy clay loam, silty clay, or clay soils from Great Britain that were leached with 20 inches of 0.01 M calcium chloride solution. Following leaching, 78.8 - 94.8% of the applied radioactivity remained in the layer of aged soil and ≤0.32% was recovered in the leachate. No degradates were identified in the soil or leachate. he test material for 30 days, there were no major brodifacoum degradates produced, and parent brodifacoum remained essentially intact. Therefore, the study was considered acceptable and represented also unaged column leaching rather than aged column leaching for which the study was originally designed.

EPIWEB v.4.1's estimate of the fish bioconcentration factor (BCF) is 2450 L/kg wet-wt, with a very slow biotransformation rate ($t_{1/2}$ = 351 days).

2.4.1. Environmental Transport Mechanisms

For most conventional pesticides, potential transport mechanisms typically include surface water runoff, spray drift, and secondary drift of volatilized or soil-bound residues leading to deposition onto nearby or more distant ecosystems. However, because the only use of brodifacoum is in bait for rodent control, no potential for spray drift exists, and exposure from volatilization is expected to be minimal. Because brodifacoum bait may be used outdoors, some potential exists for residues of brodifacoum to leach from the bait, if exposed to rainwater or runoff. However, due to the extremely low concentration of active ingredient in the bait (0.0025 or 0.005%), small amount applied per placement, and the hydrophobic nature of the compound (log K_{OW} = 8.5), leaching of dissolved brodifacoum from the bait would be so small that the potential for contaminating surface water is expected to be insignificant. Similarly, exposure of surface water via erosion of soils that sorb brodifacoum is also expected to be minimal. For the uses on sewers, instructions indicate to thread wire through blocks and securely attach to a stationary structure such as the bottom step of a manhole ladder or a sewer grate. Thus, aquatic exposure

due to sewer uses is not anticipated. The low vapor pressure for this chemical suggests volatilization from the bait is also expected to be insignificant.

Another possible route of transport is within the bodies of animals which feed on the brodifacoum bait. Because poisoned animals are not killed immediately, they would travel some distance before dying, thereby potentially exposing other animals away from the application site. This transport within animals is the major route of exposure for the AW and the SJKF since their diet includes small mammals, birds, and reptiles, and thus they are vulnerable to secondary exposure from consuming poisoned prey.

2.4.2. Mechanism of Action

According to the 2004 Comparative Assessment (USEPA 2004b), the anticoagulant rodenticides' mode of action is as follows: "The anticoagulant rodenticides are vitamin-K antagonists that disrupt normal blood-clotting mechanisms and induce capillary damage (Pelfrene 1991). Death results from hemorrhage, and exposed animals may exhibit increasing weakness prior to death. Behavior also may be affected (Cox and Smith 1992). The anticoagulants are typically grouped into "first-generation" (warfarin, chlorophacinone, diphacinone) and "second-generation" (brodifacoum, bromadiolone, difethialone) compounds. Second-generation anticoagulants tend to be more acutely toxic than are the first-generation anticoagulants, and they are retained much longer in body tissues of primary consumers. They generally provide a lethal dose after a single feeding, although death is usually delayed 5 to 10 days and animals continue feeding. In contrast, the first-generation compounds, because they are less acutely toxic and more rapidly metabolized and/or excreted, generally must be ingested for several days to provide a dose lethal to most individuals. Diphacinone and chlorophacinone may kill some animals in a single feeding, but multiple feedings are generally needed for sufficient population control (Timm 1994)."

2.4.3. Use Characterization

Label Use

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

Primary exposure of the SMHM to bait placed outdoors is likely. Nationwide, brodifacoum is registered for use only in baits for control of three commensal rodents: the Norway rat (*Rattus norvegicus*), the roof rat (*Rattus rattus*), and the house mouse (*Mus musculus*). All three of the commensal rodent species occur in the regions of California where the AW, SMHM, and SJKF occur. Therefore, registered products of brodifacoum in California could be used in the area inhabited by the assessed species. Rodent control baits containing brodifacoum are registered for use in and around buildings, inside transport and cargo vehicles (*e.g.*, trains, aircraft), alleys and in sewers. Brodifacoum products may be used in and around any type of building, including

residential, industrial, and commercial structures, as well as transportation ports and terminals, and agricultural buildings. Uses that occur indoors would not be expected to result in any primary exposure to the AW, SMHM, or SJKF. However, indoor use could result in secondary exposure to the AW or SJKF if a rodent ingests bait indoors and then is consumed outside by the AW or SJKF. For outdoor application, rodent control bait containing brodifacoum generally must be placed within 50 feet of buildings.

Product labels for brodifacoum generally do not limit the amount of product or active ingredient that may be applied per unit area, the number of applications that can be made per unit time, or the minimum interval between applications. Labels generally state the amount of bait (*e.g.*, number of blocks or mass of bait per placement) that may be placed in one location, and the linear distance between placements. The linear distance is generally 8 to 12 feet for mice, and 15 to 30 feet for rats. The concentration of brodifacoum in the bait is 0.0025% or 0.005% for all its products (*i.e.* 25 or 50 mg a.i./kg bait). The amount of active ingredient per placement, or the amount of active ingredient per linear feet, can be calculated for most of the products. The maximum known amount of active ingredient per placement for any product is 0.00005 lb a.i. or 23 mg a.i. when it is used to control Norway rats or roof rats. The amount of active ingredient per placement for mice control is usually smaller. According to the Risk Mitigation Decision for Ten Rodenticides (RMD) (Document ID EPA-HQ-OPP-2006-0955-0764, USEPA 2008b), which was issued in May 2008 and revised in June 2008, the sale of brodifacoum in California is limited to packages equal to or larger quantities than 16 pounds in an effort to restrict homeowner use, except for applications in agricultural sites. For some of the labels, however, this restriction has not been implemented at the time of this assessment.

Table 2-4 presents a summary of uses and corresponding application rates and methods of application for brodifacoum. This chemical has multiple use sites and application methods. In the row labeled „use sites and application methods,' sewer applications were placed separately from all other uses for the chemical. The reason is that it appears to have a higher potential to impact water quality than all the other uses. It is noted that the product labels for the uses in sewers include instructions that are intended to minimize potential exposure to water.

Table 2-4. Summary of Brodifacoum Use and Label Information

Target Species	Norway rats , roof rats, and house mice	
Use Sites and Application Methods	Rodent control bait for use in and around homes and residential buildings, industrial, commercial and public buildings, food processing facilities, transport vehicles (ships, trains, aircraft) and their related ports, and in and around agricultural buildings. Product should not be applied further than 50 ft from agricultural buildings. Bait stations are mandatory for outdoor above ground applications. For four products, the mandatory language is not included.	Sewers – thread wire through blocks and securely attach to a stationary structure such as the bottom step of a manhole ladder or a sewer grate. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of rat activity cease.
Bait Placement Interval	8-12 ft (mice) for 15 days or until activity ceases; 15-30 ft (rats) for 10 days or until activity ceases	One placement per manhole; 8-12 ft in infested areas for 15 days or until activity ceases.
Formulation	Meal, pellet, block, paste	
% A.I. in Bait	For all products 0.005% (50 mg a.i./kg bait) with the exception of three products at	

	0.0025% (25 mg a.i./kg bait), as described in the text of this section
Presentation	For all but the Notice of Intent to Cancel (NOIC) products, not less than 16 lb (Pest Control Operators, PCOs) and 8 lb (agricultural) of bait (appropriate presentations for products conforming with the Risk Mitigation Decision, RMD
App. Rate per Bait Placement	Varies for each product, maximum appears to be 16 oz (1 lb) product at 0.005%, equivalent to 0.00005 lb a.i. or 23 mg a.i./ placement. Similar for sewers
PCO Restrictions	For all but four NOIC products, restricted to Pest Control Operators except for use in agricultural sites

The vast majority of the products containing brodifacoum contain active ingredient at 0.005%. There are three exceptions, for which the amount of AI is 0.0025%. Of the three products, two are designed for the control or eradication of rats or mice on islands or grounded vessels or vessels in peril for grounding. These two products do not appear to have a potential for use in the areas where the assessed species occur. There is another product for which the amount of AI is also 0.0025% for commensal mice and rats of potential to be used in California, where the assessed species occur. Because the vast majority of the products for brodifacoum have 0.0050% AI, and the assessment of the higher concentration covers the lower one and is more conservative, in this assessment only the higher amount of active ingredient will be included.

Per the RMD (emphasis added), "To reduce wildlife exposures and ecological risks, the Agency will require sale and distribution limits intended to prevent general consumers from purchasing residential use bait products containing four of the ten rodenticides that pose the greatest risk to wildlife (the second generation anticoagulants – ***brodifacoum***, bromadiolone, difenacoum, and difethialone). Moreover, bait stations will be required for all outdoor, above-ground uses of these second generation-anticoagulants." For the above mentioned rodenticides, limits are being imposed in the package size, use sites, sales and distribution, and bait station requirements as outlined below.

1. Minimum package size: The Agency requires brodifacoum bait products to be sold in packages that contain ≥ 8 lb of bait for products that are labeled for use only inside of and within 50 ft of agricultural buildings and not for use in and around homes. For products intended for use by professional applicators, the minimum permissible amount of bait per package is 16 lb.
2. Use site restriction: For products in packages with at least 8 lb but not more than 16 lb of bait, labels are required to state that products may only be used in and around (within 50 ft) of agricultural buildings (*e.g.*, barns, hen houses), and bear the statement, "Do not use this product in homes or other human residences."
3. Sale and distribution restriction: The terms and conditions of registration for products containing brodifacoum are required to be amended to specify that the registrants will control distribution of the products so that they will only be distributed to or sold in agricultural, farm and tractor stores or directly to pest control operators (PCOs) and other professional applicators, and that registrants will not sell or distribute products containing brodifacoum in channels of trade likely to result in retail sale in hardware and home improvement stores, grocery stores, convenience stores, drug stores, club stores, big box stores, and other general retailers.
4. Bait stations required for outdoor above ground placements: All outdoor, above-ground placements of bait products containing brodifacoum are required to be contained in bait stations, in order to deny non-target animals, ready access to bait. According to the

RMD, most bait products are grain-based and are therefore attractive to many birds and non-target mammals; those baits with flavor enhancers (*e.g.* fish flavors) might also attract carnivores. Tamper-resistant bait stations are required if the bait placement are within reach of pets, domestic animals, non-target wildlife, or children under six years-of-age. Other types of bait stations may be constructed and used in settings, such as around livestock production buildings, where exposure to children and non-target wildlife is unlikely.

The requirements mentioned above were imposed for labels of all brodifacoum rodenticide bait products sold after June 4, 2011. However, not all labels of brodifacoum rodenticide products are in compliance with the RMD requirements at the time this assessment is being conducted. At the time of this assessment, all of the mitigation measures from the 2008 RMD have been incorporated into the labels of 22 of 26 brodifacoum products. The four non-conforming products were included in the Rodenticides Notice of Intent to Cancel (NOIC). Prior to finalizing the cancellation, the Agency sought independent scientific review on banning certain rat and mouse products, including the NOIC brodifacoum products. The four products that do not conform to the RMD (**Table 2-5**) may have been sold after the June 4, 2011 date and will likely remain on the market until the Agency completes the NOIC process and the registrant has exhausted all of its legal appeals. Thus, they are included in this assessment. Reasons why these products do not conform to the RMD include unapproved formulations (*e.g.*, pellets or crushed pellets), requirement for bait stations and/or missing the 50-ft restriction as described above. More information may be found at http://www.epa.gov/pesticides/mice-and-rats/consumer-prod.html and http://www.epa.gov/pesticides/mice-and-rats/ (both were accessed 01/24/2012). As per the websites mentioned above, "After June 4, 2011, any rodenticide manufacturers who distribute or sell rodenticide products that do not meet the new risk mitigation goals will face EPA actions to remove those products from the market."

Table 2-5. Products Failing to Comply with Risk Mitigation Decision for Brodifacoum

Reg. No.	Name	Pellets	Crushed Pellet	RMD Issues
3282-65	D- MOUSE PRUFE II	X		Unapproved formulation & AI, need of bait station and missing 50 ft restriction.
3282-66	D- PELLETS GENERATION II	X		
3282-74	D- BAIT PELLETS II	X (Pl. packs)		
3282-81	D- READY MIXED GENERATION II		X	

As mentioned above, brodifacoum should be applied per placements at least 8 ft away from each other (for mice), and when applied at the maximum rate per placement, 15 ft from each other (for rats). The maximum rate per placement is small compared to conventional agricultural pesticides (0.000050 lb or 23 mg/placement). In addition, except for four products included in the NOIC, placements should occur within 50 ft of structures and for above ground applications, bait stations should be used. Thus, applications appear to be highly localized.

Usage

The Agency's Biological and Economic Analysis Division (BEAD) provides an analysis of both national- and county-level usage information (USEPA 2012) using state-level usage data obtained from USDA-NASS[9], Doane (www.doane.com, the full dataset is not provided due to its proprietary nature), and the California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database[10]. 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 brodifacoum by county in this California-specific assessment were generated using CDPR PUR data. Twelve years (1999-2010) of usage data were included in this analysis.[11] 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.[12] 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 include: average annual pounds applied and number of records across all twelve years. The units of area treated are also provided where available.

A summary of brodifacoum usage for California is provided below in **Table 2-6.** CDPR PUR data show that brodifacoum is used in all of the 21 counties in California where the AW, SJKF and SMHM may occur (see rows shaded blue in **Table 2-6**). Due to its use as vertebrate control bait products, the pattern of use of brodifacoum is characterized as numerous applications of very small amounts of active ingredient. The average annual use per county was no more than 0.5 pounds for any county in California. Unlike conventional agricultural pesticides, the area treated was generally not reported in this database, and therefore the average application rate (*e.g.*, expressed in units lb a.i./A) could not be calculated. Of the counties where the AW, SJKF and SMHM may occur, those where the average annual pounds applied exceed 0.1 lb (which corresponds to over 2,000 placements at the maximum rate per placement) are Fresno, San Joaquin, Santa Barbara and Ventura. However, this threshold was set for illustration purposes only.

Table 2-6. Summary of California Department of Pesticide Registration (CDPR) Pesticide Use Reporting (PUR) Data from 1999 to 2010 for Current Brodifacoum Uses

County [A]	Ave. Annual Pounds Applied [B]	Number of Records
ALAMEDA	0.06302	3014
ALPINE	0.00020	13

[9] United States Department of Agriculture (USDA), National Agricultural Statistics Service (NASS) Chemical Use Reports provide summary pesticide usage statistics for select agricultural use sites by chemical, crop and state. See http://www.pestmanagement.info/nass/app_usage.cfm.

[10] 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 .

[11] Pesticide usage data for the same variables were also compiled for 1994 to 1998 but not merged with the newer data because error identification was not available for the older data.

[12] 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).

County [A]	Ave. Annual Pounds Applied [B]	Number of Records
AMADOR	0.00054	60
BUTTE	0.01766	1111
CALAVERAS	0.00127	149
COLUSA	0.01504	336
CONTRA COSTA	0.07116	3369
DEL NORTE	0.00066	82
EL DORADO	0.00851	1015
FRESNO	**0.11818**	2517
GLENN	0.01129	484
HUMBOLDT	0.01374	191
IMPERIAL	0.00236	349
INYO	0.00045	45
KERN	0.05085	1301
KINGS	0.00602	342
LAKE	0.00242	101
LASSEN	0.00021	47
LOS ANGELES	**0.47099**	10628
MADERA	0.01082	879
MARIN	0.00901	702
MARIPOSA	0.00508	243
MENDOCINO	0.00581	103
MERCED	0.04529	1101
MONO	0.00051	29
MONTEREY	0.03246	895
NAPA	0.01719	910
NEVADA	0.00658	562
ORANGE	**0.27795**	4812
PLACER	0.03371	1596
PLUMAS	0.00123	34
RIVERSIDE	**0.13130**	4259
SACRAMENTO	**0.11529**	2251
SAN BENITO	0.00966	371
SAN BERNARDINO	0.09839	3606
SAN DIEGO	**0.12865**	2258
SAN FRANCISCO	0.07088	1525
SAN JOAQUIN	**0.12070**	1979
SAN LUIS OBISPO	0.00673	628
SAN MATEO	0.04569	2583
SANTA BARBARA	0.01888	898
SANTA CLARA	**0.10116**	3248

County [A]	Ave. Annual Pounds Applied [B]	Number of Records
SANTA CRUZ	0.03957	649
SHASTA	0.00356	364
SIERRA	<0.00001	4
SISKIYOU	0.00239	83
SOLANO	0.01765	1224
SONOMA	0.03492	842
STANISLAUS	0.07304	1511
SUTTER	0.00472	469
TEHAMA	0.00772	311
TULARE	0.03368	1076
TUOLUMNE	0.00113	188
VENTURA	**0.10865**	1271
YOLO	0.01763	1256
YUBA	0.00398	514

A. Table is based on data supplied by BEAD (USEPA, 2012). All counties are included in this table; however, rows shaded blue are counties where the AW, SMHM and SJKF are known to inhabit. Results were rounded to five figures after the decimal.

B. **Bolded** values are pounds that exceed **0.1 lb**, which is an arbitrary value that was set for illustration purposes.

Table 2-7 shows a summary of the average (of twelve years) of pounds of active ingredient used per year for each site name. Use sites listed in the database in BEAD's report, for brodifacoum in California counties include structural pest control (average of 2.02 lb) and landscape maintenance (0.211 lb average), which were the top two use sites. Other uses which exceed an average of 0.01 lb are animal premise, poultry, public health, rights-of-way, vertebrate control and walnut. Brodifacoum does not appear to be used as a fumigant and on crops. It is used, however, around (within 50 ft of) agricultural buildings or structures. As noted above, this database does not include residential uses of brodifacoum. However, it is noted that the average pounds of active ingredient per county or per site name is relatively small, compared to typical broadcast applications of conventional agricultural pesticides.

Table 2-7. Average pounds of brodifacoum per year for all use sites

Site Name	Average Pounds [A]
AIRPORT	0.00004
ALFALFA	0.00000
ALMOND	0.00946
ANIMAL PREMISE	**0.05224**
APPLE	0.00000
AVOCADO	0.00001
CELERY	0.00019
CHERRY	0.00010
CHICKEN	0.00165
CITRUS	0.00392
COMMODITY FUMIGATION	0.00015
COUNTY AG COMM	0.00000
DAIRY EQUIPMENT	0.00001

Site Name	Average Pounds [A]
DITCH BANK	0.00000
DUCK	0.00102
EGGPLANT	0.00001
FOOD PROCRESSING PLANT	0.00458
FUMIGATION, OTHER	0.00029
GRAPE	**0.01617**
GRAPE, WINE	0.00251
GREENHOUSE FUMIGATION	<0.00001
INDUSTRIAL SITE	0.00004
LANDSCAPE MAINTENANCE	**0.21092**
LEMON	0.00216
LIME	0.00002
N-GRNHS FLOWER	0.00082
N-GRNHS PLANTS IN CONTAINERS	0.00292
N-GRNHS TRANSPLANTS	0.00010
N-OUTDR FLOWER	0.00001
N-OUTDR PLANTS IN CONTAINERS	0.00308
N-OUTDR TRANSPLANTS	0.00003
ORANGE	0.00236
PEACH	0.00001
PEPPER, FRUITING	0.00032
PEPPER, SPICE	0.00001
POULTRY	**0.03561**
PUBLIC HEALTH	**0.01002**
RASPBERRY	0.00000
REGULATORY PEST CONTROL	0.00508
RESEARCH COMMODITY	0.00014
RIGHTS OF WAY	**0.02286**
STRUCTURAL PEST CONTROL	**2.01668**
TOMATO, PROCESSING	0.00133
TURKEY	0.00043
UNCULTIVATED AG	0.00001
UNCULTIVATED NON-AG	0.00004
UNKNOWN or UNSPECIFIED	0.00107
VERTEBRATE CONTROL	**0.07728**
WALNUT	**0.01045**
WHEAT	0.00001

A. All averages were rounded to five figures after the decimal. The top two use sites are shaded **blue** and uses for which the average pounds exceed **0.01 lb** (an arbitrary value set for illustration purposes) are **bolded**.

2.5. Assessed Species

Table 2-8 provides a summary of the current distribution, habitat requirements, and life history parameters for the listed species being assessed. More detailed life-history and distribution information can be found in **Attachment III**. See **Figures 2-2** through **2-4** for maps of the current range and designated critical habitat, if applicable, of the AW, SMHM, and SJKF, respectively.

The AW, a subspecies of the California whipsnake, was listed as threatened in 1997 by the USFWS. A recovery plan for this and other threatened and endangered species of the chaparral and scrub community east of San Francisco Bay, California was approved by the USFWS in

2003. Critical habitat was designated for this subspecies in 2006. The subspecies occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and possibly Santa Clara Counties.[13]

Prior to 1930, SJKFs inhabited most of the San Joaquin Valley from southern Kern County north to eastern Contra Costa County and eastern Stanislaus County. Although no reason was given for the decline, it was believed that by 1930 the kit fox range had been reduced by more than half, with the largest remaining portion being in the western and southern portions of the Valley.

Although no extensive survey has been conducted of the historical range, kit foxes are thought to inhabit suitable habitat on the San Joaquin Valley floor and in the surrounding foothills of the coastal ranges, Sierra Nevada, and Tehachapi Mountains. Kit foxes have been found on all the larger, scattered islands of natural land on the Valley floor in Kern, Tulare, Kings, Fresno, Madera, San Benito, Merced, Stanislaus, San Joaquin, Alameda, and Contra Costa counties. They also occur in the interior basins and ranges in Monterey, San Benito, San Luis Obispo, and, possibly, Santa Clara counties; and in the upper Cuyama River watershed in northern Ventura and Santa Barbara counties and southeastern San Luis Obispo County.[14]

The SMHM is found in the marshes of Corte Madera, Richmond, and South San Francisco Bay. This species is generally restricted to saline (salty) or brackish (somewhat salty) marsh habitats around the San Francisco Bay Estuary, and is found in mixed saline/brackish areas in the Suisun Bay area and has been found in one brackish area in the southern South San Francisco Bay.[15]

Table 2-8. Summary of Current Distribution, Habitat Requirements, and Life History Information for the Assessed Listed Species [A]

Assessed Species	Size	Current Range	Habitat Type	Designated Critical Habitat?	Reproductive Cycle	Diet
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, terrestrial invertebrates, terrestrial-phase amphibians, other snakes including rattlesnakes
San Joaquin Kit Fox (SJKF) (*Vulpes macrotis mutica*)	Adult ~2 kg	Alameda, Contra Costa, Fresno, Kern, Kings, Madera, Merced,	A variety of habitats, including grasslands, scrublands (*e.g.*, chenopod scrub and sub-shrub scrub), vernal pool	No, but has designated core areas	Mating and conception: late December - March. Gestation period: 48 to 52	Small animals including blacktailed hares, desert cottontails, mice, kangaroo

[13] http://www.epa.gov/espp/factsheets/alameda-whipsnake.pdf
[14] http://esrp.csustan.edu/speciesprofiles/profile.php?sp=vuma
[15] http://ecos.fws.gov/docs/five_year_review/doc3221.pdf

Assessed Species	Size	Current Range	Habitat Type	Designated Critical Habitat?	Reproductive Cycle	Diet
		Monterey, San Benito, San Joaquin, San Luis Obispo, Santa Barbara, Santa Clara, Stanislaus, Tulare and Ventura counties	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, abandoned pipelines, or banks in sumps or roadbeds). They move to new dens within their home range often (likely to avoid predation by coyotes)		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.	rats, squirrels, birds, lizards, insects and grass. It satisfies its moisture requirements from prey and does not depend on freshwater sources.
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

[A] For more detailed information on the distribution, habitat requirements, and life history information of the assessed listed species, see Attachment II.

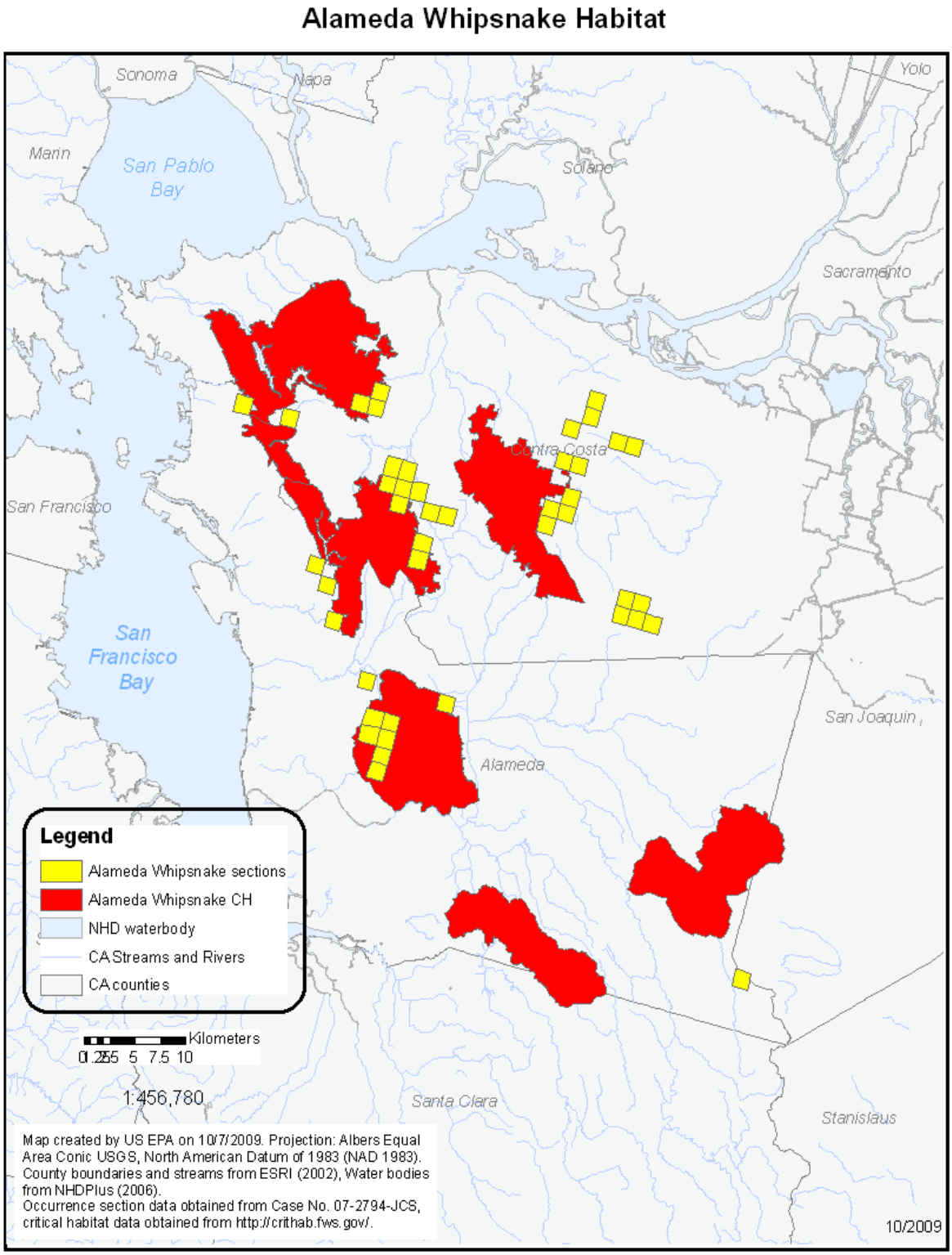

Figure 2-2. Alameda Whipsnake Critical Habitat and Occurrence Sections Identified in Case No. 07-2794-JCS

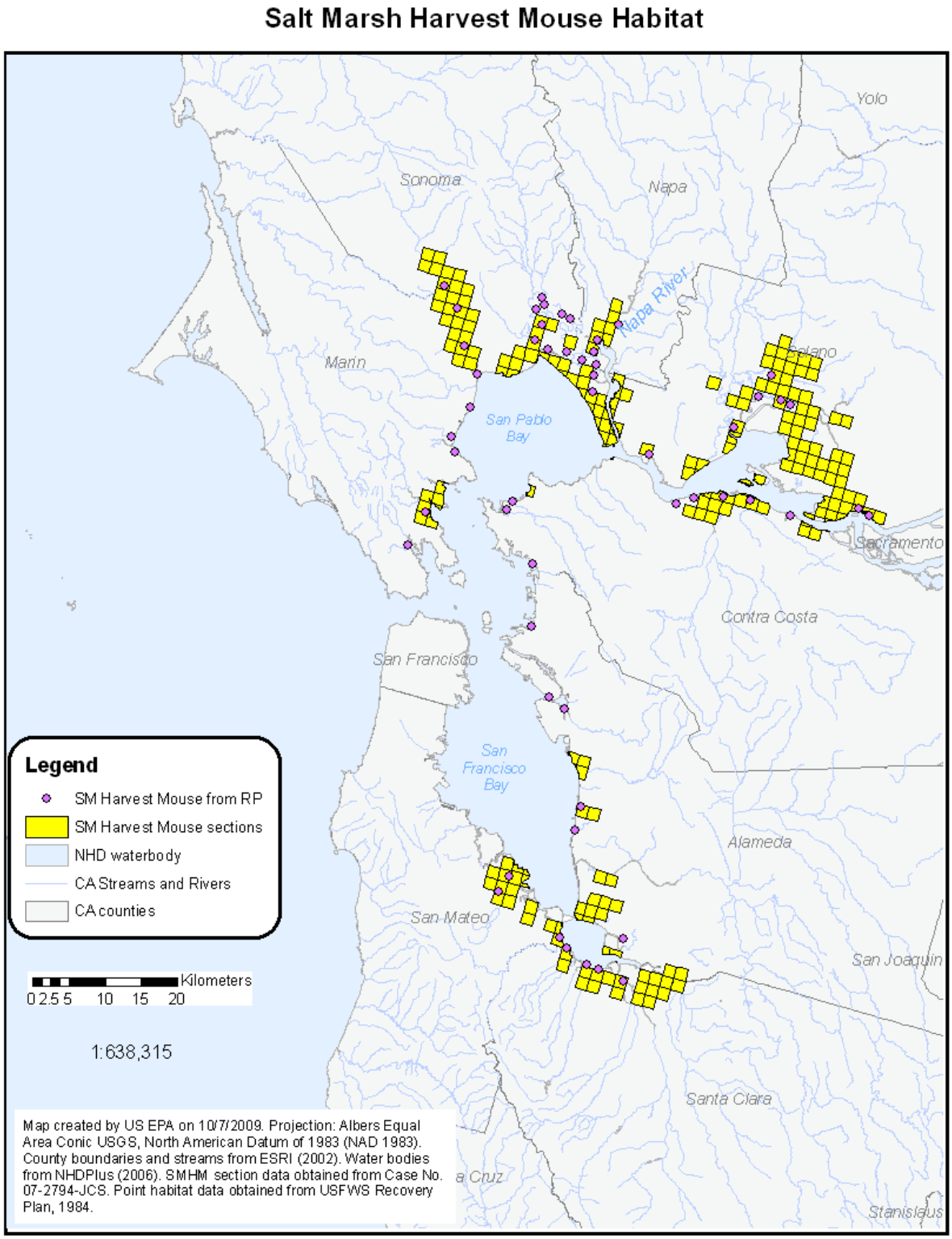

Figure 2-3. Salt Marsh Harvest Mouse Habitat and Occurrence Sections Identified in Case No. 07-2794-JCS

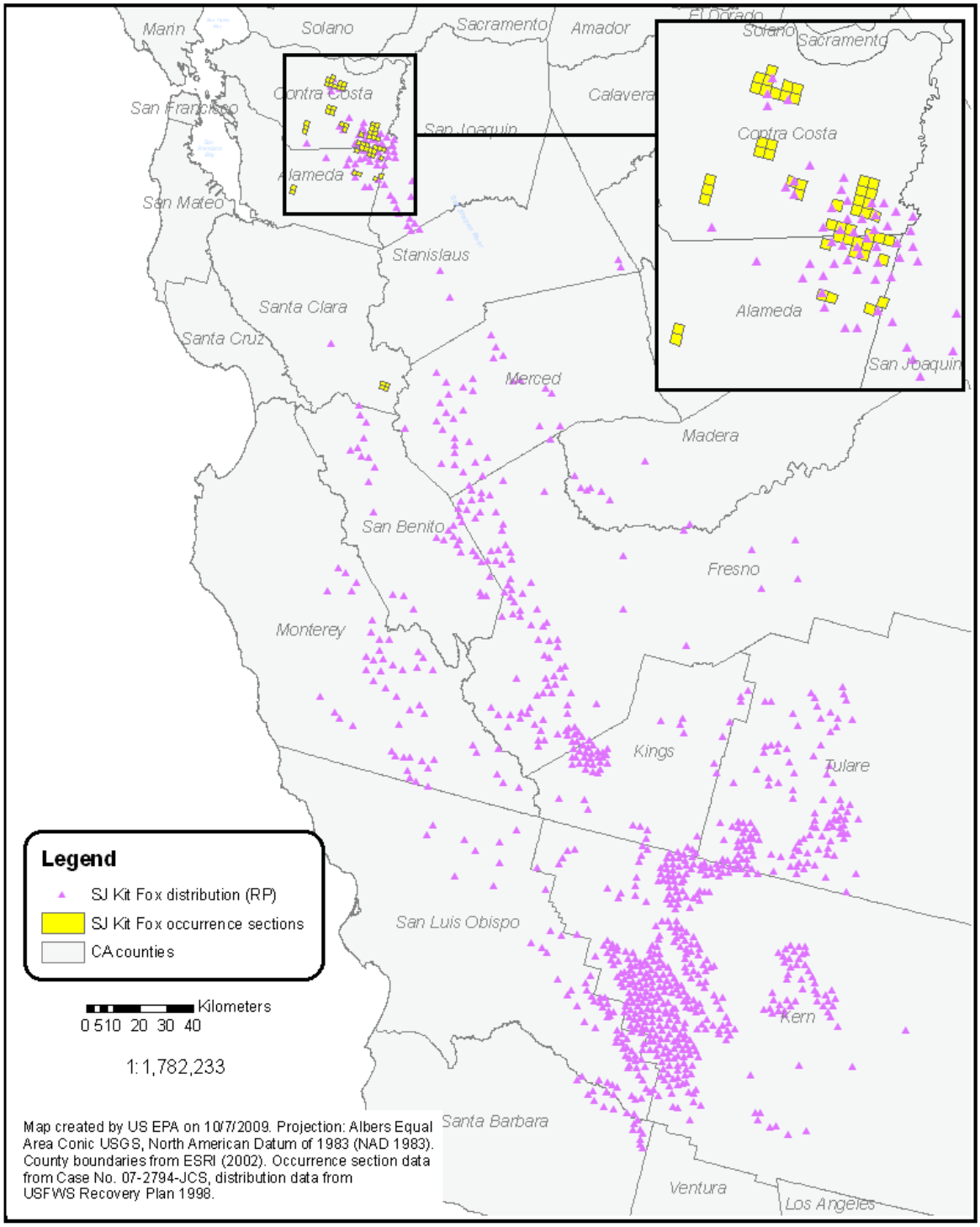

Figure 2-4. San Joaquin Kit Fox Habitat and Occurrence Sections Identified in Case No. 07-2794-JCS

2.6. Designated Critical Habitat

Critical habitat has been designated for 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 2-9** describes the PCEs for the critical habitats designated for the AW.

Table 2-9. Designated Critical Habitat PCEs for the Alameda Whipsnake (AW)[A]

Species	PCEs	Reference
Alameda whipsnake	PCE 1: Scrub/shrub communities with a mosaic of open and closed canopy	71 FR 58175 58231, 2006
	PCE 2: Woodland or annual grassland plant communities contiguous to lands containing PCE 1	
	PCE 3: Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2	

[A] 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.

More detail on the designated critical habitat applicable to this assessment can be found in **Attachment II**. Activities that may destroy or modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the species. Evaluation of actions related to use of brodifacoum that may alter the PCEs of the designated critical habitat for the 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 brodifacoum is expected to directly impact living organisms within the action area, critical habitat analysis for brodifacoum is limited in a practical sense to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes.

2.7. Action Area and LAA Effects Determination Area

2.7.1. 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 brodifacoum is likely to encompass considerable portions of the United States based on its widespread use for rodent control. 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, and SJKF and designated critical habitat for the AW, 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 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 SJKF, SMHM and AW, and designated critical habitat of the AW, may be affected or modified via endpoints associated with reduced survival, growth, or reproduction.

2.7.2. LAA Effects Determination Area

Typically, when assessing the potential for use of a pesticide to affect threatened or endangered species, the Agency determines a Likely to Adversely Affect (LAA) Effects Determination Area. This is the area where the pesticide's use is expected to directly or indirectly affect the species and/or modify its designated critical habitat, as determined by applying the Agency's standard assessment procedures (see **Attachment I**) based on effects endpoints related to survival, growth, and reproduction. The LAA Effects Determination Area is typically designated as the area where the land use corresponds with land use on which the pesticide is likely to be used (*e.g.* developed areas), plus the area outside this use area which could receive exposure at levels that are potentially toxic for the species of concern.

Brodifacoum is used in and around any type of building, including residential, commercial, industrial, and commercial structures, as well as transportation ports and terminals. For these uses, land cover classes include, developed high intensity, developed low intensity, developed medium intensity and possibly developed open space. Additionally, brodifacoum may be used in and around agricultural buildings; there are several land cover categories identified for this use including cultivated crops, orchards/vineyards, and pasture/hay. Therefore, multiple and diverse

land cover types applies to the use patterns for brodifacoum. In the case of this assessment, the area of potential use of brodifacoum does not appear to be restricted spatially. Considering the wide use pattern of rodent control baits, brodifacoum potentially could be used in most terrestrial land use cover types. Thus, any area of the state of California is considered an area of potential use of brodifacoum bait, and thus the assessed species potentially could be exposed to brodifacoum wherever they occur.

2.8. Assessment Endpoints and Measures of Ecological Effect

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

2.8.1. Assessment Endpoints

A complete discussion of all the toxicity data available for this risk assessment, including resulting measures of ecological effect selected for each taxonomic group of concern, is included in **Section 4** of this document. **Table 2-10** identifies the taxa used to assess the potential for direct and indirect effects from the uses of brodifacoum 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 2-11**.

Table 2-10. Taxa Used in the Analyses of Direct and Indirect Effects for the Assessed Listed Species.

Listed Species	Birds	Mammals	Terrestrial Invertebrates	Reptiles
Alameda Whipsnake	Indirect (prey)	Indirect (prey/habitat)	Indirect (prey)	Direct Indirect (Prey)
Salt Marsh Harvest Mouse	N/A	Direct Indirect (rearing sites)	Indirect (prey)	N/A
San Joaquin Kit Fox	Indirect (prey)	Direct Indirect (prey)	Indirect (prey)	Indirect (prey)

N/A = Not applicable to the assessed species.

Table 2-11. Taxa and Assessment Endpoints Used to Evaluate the Potential for Use of Brodifacoum 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
Birds*	Direct Effect - Alameda Whipsnake	Survival, growth, and reproduction of individuals via direct effects (secondary exposure, *i.e.* consuming prey that have ingested brodifacoum bait)	Acute: Most sensitive bird or terrestrial-phase amphibian acute LC_{50} or LD_{50} Chronic: Most sensitive bird or terrestrial-phase amphibian chronic NOAEC (No data available)
	Indirect Effect (prey) - Alameda Whipsnake - San Joaquin Kit Fox	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey	
Mammals	Direct Effect - Salt Marsh Harvest Mouse - San Joaquin Kit Fox Indirect Effect (prey/habitat from burrows) - Alameda Whipsnake - Salt Marsh Harvest Mouse (from rearing sites) - 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 burrows/rearing sites	Acute: Most sensitive laboratory mammalian acute LC_{50} or LD_{50} Chronic: Most sensitive laboratory mammalian chronic NOAEC (No data available)

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

2.8.2. Assessment Endpoints for Designated Critical Habitat

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of brodifacoum that may alter the PCEs of the assessed species' designated critical habitat. PCEs for the assessed species were previously described in **Section 2.6**. Actions that may modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the assessed species. Therefore, these actions are identified as assessment endpoints. It should be noted that evaluation of PCEs as assessment endpoints is limited to those of a biological nature (*i.e.*, the biological resource requirements for the listed species associated with the critical habitat) and those for which brodifacoum 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.

2.9. Conceptual Model

2.9.1. Risk Hypotheses

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

The labeled use of brodifacoum within the action area may:

- directly affect the AW and SJKF by causing mortality or by adversely affecting growth or fecundity via secondary poisoning from consumption of contaminated prey;
- directly affect the SMHM by causing mortality or by adversely affecting growth or fecundity via primary poisoning by direct consumption of brodifacoum bait
- indirectly affect AW and SJKF and/or modify the AW designated critical habitat by reducing or changing the composition of food supply;
- indirectly affect the SMHM by reducing the number of small mammalian rearing sites by direct effects on small mammals
- indirectly affect AW 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).

2.9.2. Diagram

The conceptual model is a graphic representation of the structure of the risk assessment. It specifies the brodifacoum release mechanisms, biological receptor types, and effects endpoints of potential concern. Typically, a separate diagram is created for terrestrial and aquatic exposure and effects. For this assessment, however, only a single diagram of terrestrial exposure and effects is depicted (**Figure 2-5**) because use of brodifacoum is not expected to result in significant exposure or effects to the AW, SMHM and SJKF through aquatic pathways. Although the conceptual models for direct/indirect effects and modification of designated critical habitat PCEs are shown on the same diagram, the potential for direct/indirect effects and modification of PCEs are evaluated separately in this assessment. Exposure routes shown in dashed lines are not quantitatively considered because the contribution of those exposure routes to potential risks to AW, SMHM and SJKF and modification to AW designated critical habitat is expected to be negligible.

As shown in the diagram, consumption of prey (small mammals, birds, and other reptiles) that have ingested brodifacoum from intact bait is considered to be the primary route of exposure to the AW and SJKF. Furthermore, small mammals, birds, and lizards are potential prey items for the AW, while small mammals and birds are potential prey items for the SJKF. For the SMHM, direct consumption of brodifacoum bait is considered as the primary route of exposure. The quantitative risk assessment therefore focuses on both the primary and secondary routes of exposure. Although terrestrial invertebrates are a potential prey item of the AW, SJKF, and the SMHM, exposure and indirect effects to these species are assumed to have a negligible contribution to overall risk, based on use practices and the specific mode of action of brodifacoum. Terrestrial plants, which may provide habitat for the assessed species, are also assumed to represent a negligible component of overall risk, given the same rationale. The presumed negligible exposure routes and indirect effects include:

- Consumption of terrestrial invertebrates which consume intact bait.
- Consumption of terrestrial invertebrates which ingest soil contaminated by dislodgement of brodifacoum from the intact bait.
- Consumption of plants which have taken up brodifacoum from residues dislodged from the bait into the soil.
- Indirect food chain effects resulting from brodifacoum reducing the abundance of plants and terrestrial invertebrates.
- Potential indirect effects to the SMHM based on direct effects to terrestrial and aquatic plants as habitat

Exposure routes through water and aquatic organisms are not considered in the assessment given the use pattern of brodifacoum. Aquatic exposure due to uses in sewers is not anticipated since the labels povide instructions to prevent such events. Thus, the sewer uses are not expected to result in exposure to aquatic receptors.

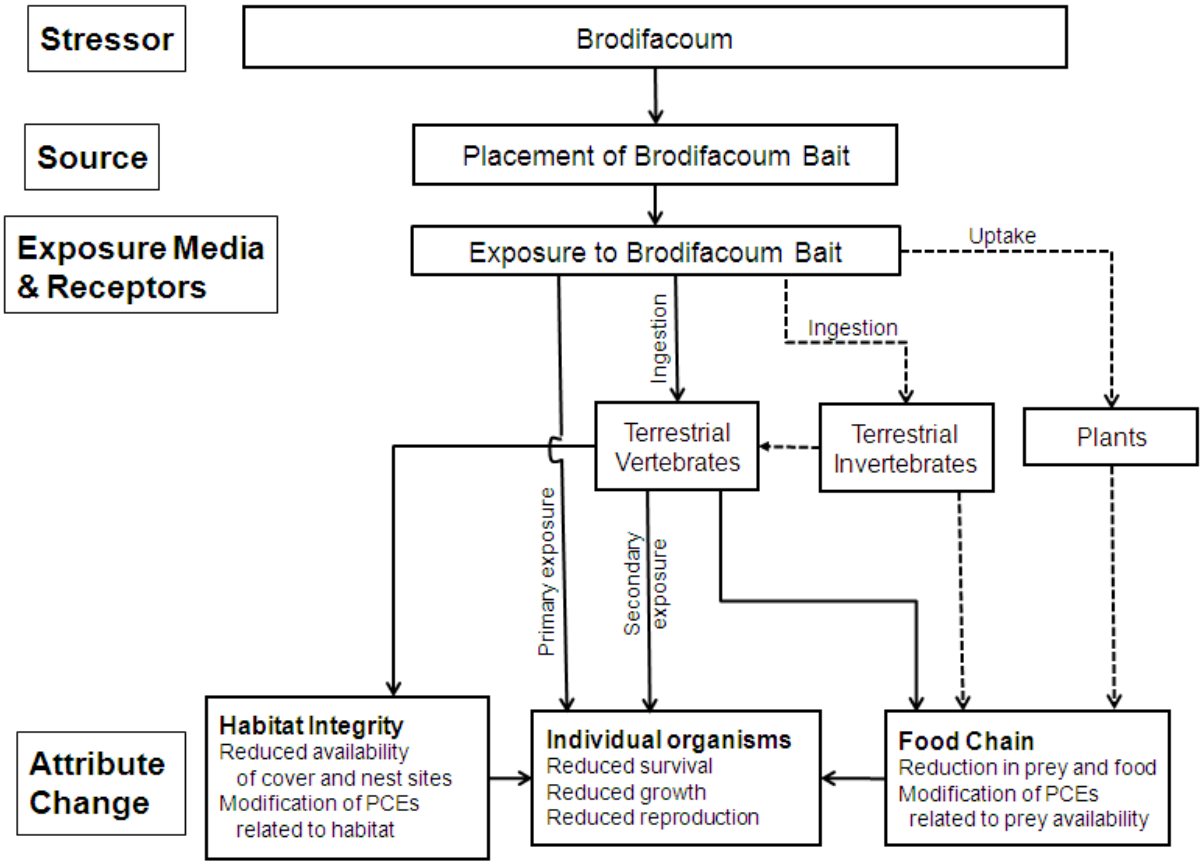

Figure 2-5. Conceptual model depicting stressors, exposure pathways, and potential effects to terrestrial organisms from the use of brodifacoum
Dotted lines indicate exposure pathways that are not assessed.

2.10. 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 brodifacoum are characterized and integrated to assess the risks. This is accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA, 2004), the likelihood of effects to individual organisms from particular uses of brodifacoum 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**.

2.10.1. Measures of Exposure

In this assessment, transport of brodifacoum through runoff and spray drift are not considered in deriving quantitative estimates of brodifacoum exposure to AW, SMHM, and SJKF, their prey and habitats because significant contributions of brodifacoum in water due to runoff are unlikely. Brodifacoum is applied as baits and spray drift does not occur. Based on the conceptual model, exposure from direct consumption of bait is considered for the SMHM. Consumption of the bait via secondary exposure is considered for the AW and SJKF in which these species consume prey that has previously ingested brodifacoum bait. These exposures constitute direct effects. Indirect effects include reduction of prey for the SJKF and SMHM, and a reduction in the potential rearing sites for the SMHM based on a reduction in other small mammals capable of building burrows. Because the aquatic exposure is not relevant to the AW and SJKF, and is believed to be negligible to the SMHM, it is also not included in this assessment. For brodifacoum, the vapor pressure and Henry's Law Constant are relatively low (1.11×10^{-18} mmHg and 2.0×10^{-16} atm-m^3/mole, respectively). Furthermore, its estimated atmospheric half-life is short (2.2 hours for hydroxyl radical reaction and 2.0 hours for ozone reaction, EPIWEB v.4.1). Thus, atmospheric transport appears to be unlikely.

A high K_{OW} value (log K_{OW} 8.5) suggests a potential for high bioaccumulation in aquatic and terrestrial receptors. Brodifacoum is relatively stable to hydrolysis at all pHs tested and the half-life in rat liver tissue was 307.4 days (Vandenbroucke et al. 2008).

For conventional pesticides, standard measures of exposure are based on aquatic and terrestrial models that predict estimated environmental concentrations (EECs) using maximum labeled application rates and methods of application as specified on the label. These models are parameterized using relevant reviewed registrant-submitted environmental fate data. More information on these models is available in **Attachment I**. However, for this assessment the primary pathway of brodifacoum exposure for terrestrial animals is through direct consumption of bait or through consumption of another animal that has directly ingested the bait.

With the persistence of brodifacoum in the liver and the propensity of the chemical to bioaccumulate, there exists the chance for multiple feedings on multiple prey items that have been poisoned by brodifacoum. This assessment however, assumes that a single day's exposure is most likely for the AW. Snakes in general, the AW included, generally consume large meals (often more than its own body weight) and do not eat again for several days, possibly weeks. This assessment considers single and multiple days of exposure for the SJKF consuming poisoned birds, but only a single day's exposure for the SJKF consuming poisoned mammals. These assumptions are based on available dietary studies for mammals.

2.10.1.a. Estimating Exposure in the Terrestrial Environment

Primary avian and mammalian consumers (pigeons, squirrels, and any other avian and mammalian organism that is not carnivorous) may consume brodifacoum bait if they encounter it. Therefore, terrestrial exposure for birds and mammals was based on dietary exposure to the bait itself. The concentration of brodifacoum in the diet was assumed to be equal to the maximum concentration of bait in products registered for rodent control uses (*i.e.*, 50 mg a.i./kg).

Indirect risks to AW and SJKF (through prey reduction) and SMHM (through decreased small mammal rearing sites) were assessed by assuming that mammals, birds, reptiles, and terrestrial-phase amphibians may directly consume the bait. Direct risk to the SMHM was also assessed by assuming direct consumption of brodifacoum bait itself. However, for the AW and SJKF, which are carnivorous species,[16] the primary route of exposure was assumed to be from secondary poisoning, that is from consumption of prey which fed directly on brodifacoum bait. For the SMHM, the primary route of exposure was from consumption of brodifacoum bait. The prey species were assumed to be one of the target species in the label including the Norway rat, roof rat and the house mouse, but also could include other mammals, birds, reptiles, and terrestrial-phase amphibians. The residues of brodifacoum in the prey were assumed to be the amount that the prey would consume in one day if it fed on the bait. All of the residues consumed by the prey were assumed to be available and assimilated by the AW and SJKF when it consumed the prey. All these assumptions are considered conservative.

2.10.2. Measures of Effect

Data identified in **Section 2.8** 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.**

2.10.2.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 brodifacoum, and the likelihood of direct and indirect effects to the assessed species. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. The risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs) (USEPA, 2004) (see **Appendix C**). More information on standard assessment procedures is available in **Attachment I**.

2.10.3. Data Gaps

From the ecological effects side of the assessment, there are no studies submitted to characterize chronic toxicity to avian species (avian reproduction studies) and mammalian species (2-generation mammalian reproduction). An acute contact toxicity study with the honey bee is also not available for this assessment. The environmental fate required studies were submitted and considered suitable for a deterministic risk assessment. Quantitative structure activity relationships (QSARs) (*e.g.*, EPI Suite v.4.1; USEPA 2007) were used to determine the K_{OC} and BCF for this chemical. The K_{OW} reported by the registrant was also based on QSAR because it was too high to be measured experimentally.

[16] http://www.fws.gov/desfbay/Archives/Whip/Whip.htm

3. Exposure Assessment

Formulation types registered for brodifacoum include meal, pellets, blocks and paste. There is no application equipment described in the label. Bait is applied by hand to specified places. Since there is no potential for spray drift and low potential for aquatic exposure, only terrestrial exposure is evaluated in this assessment.

3.1. Label Application Rates and Intervals

Brodifacoum labels may be categorized into two types: labels for manufacturing uses (including technical grade brodifacoum and its formulated products) and end-use products. While technical products, which contain brodifacoum 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 commensal rodents like Norway rats, roof rats and house mice. The formulated product labels legally limit brodifacoum's potential use to only those sites that are specified on the labels.

In May 2008 a Risk Mitigation Decision for Ten Rodenticides (RMD) was issued; this was followed by a revision in June 2008 (USEPA 2008b). According to the RMD, effective June 4, 2011, the Agency has been requiring sale and distribution limits intended to prevent general consumers from purchasing residential use bait products containing brodifacoum. Moreover, bait stations are required for all outdoor, above ground uses of brodifacoum. However, not all labels of brodifacoum rodenticide end-use products are in compliance with this requirement at the time this assessment is conducted. For the purposes of this assessment, all compliant and non-compliant uses of brodifacoum are assessed according to existing labels.

The RMD entails primarily two important provisions that relate to brodifacoum. First, for all second generation anticoagulants (the family to which brodifacoum belongs), application is restricted to tamper resistant bait boxes for all above ground uses. Second, package size restrictions on these second generation anticoagulants prevent the average consumer from purchasing any package size less than 16 lbs. Prior to the RMD, consumers (particularly homeowners looking for readily accessible rodent control options) were able to purchase brodifacoum-containing products in small packaging in grocery stores, warehouses and many other commercials establishments.

It is expected that the movement of brodifacoum to tamper resistant bait boxes will reduce primary exposure of brodifacoum to non-target organisms, but the potential for secondary exposure will still exist since brodifacoum is very acutely toxic to birds and mammals and has a long persistence in body tissues, making it available to secondary consumers, like the AW and SJKF. Even with labels not in full conformance with the RMD (*i.e.*, those not in bait stations), the RMD is not expected to have an impact on the primary or secondary exposure of brodifacoum to the AW and SJKF. The reason for this is that the AW and SJKF are not expected to directly consume brodifacoum bait, whether it is in a bait station or not, and the risk for secondary exposure likely remains the same as prey that are available to the AW and SJKF will still be at risk for exposure to brodifacoum. There is the possibility that

the removal of brodifacoum from the homeowner use market may reduce the total number of pounds of brodifacoum that is available for exposure; however, this type of analysis is beyond the scope of this assessment.

The movement of brodifacoum to tamper resistant bait boxes could reduce primary exposure of the chemical to the SMHM; however, this is uncertain. For larger mammals or birds that have the potential to consume loose brodifacoum bait not in stations, the risk of primary exposure is expected to be reduced by the movement into tamper resistant bait stations. For very small mammals, such as the SMHM, that would still be able to get into the bait boxes, as they are designed for small rodents, the risk of primary exposure still remains.

Currently registered urban and rural uses of brodifacoum within California include (a) bait for rat and mice control in and around buildings, transportation vehicles and associated ports, *etc.*, and (b) rat and mice control in sewers. The uses being assessed are summarized in **Table 3-1**.

Table 3-1. Brodifacoum Uses and Application Information

Use (App. Method)	Formulation	Max. % AI in Bait	Maximum App. Rate per Bait Placement (mg AI/placement)	Bait Placement Interval and Restrictions
Bait for rat and mouse control in and around buildings, transportation vehicles, ports, *etc.*	Meal, pellet, block paste	0.0050	23	8-12 ft (mice) 15-30 ft (rats) Bait generally should be placed within 50 ft of a building
Rodent control bait for use in sewers				8-12 ft in infested areas

Abbreviations: App. = application, NS = not stated, ft = feet.
1 Uses assessed based on memorandum from Pesticide Re-evaluation Division (PRD) dated 01/23/2012 (**Appendix A**) and EFED Label Data report and associated Label Use Information Reports prepared on 02/23/2012.

3.2. Aquatic Exposure Assessment

3.2.1. Modeling Approach

Aquatic exposure of the AW, SMHM, and SJKF is considered negligible in this assessment. Therefore, no aquatic exposure assessment was carried out for brodifacoum.

3.2.2. Existing Monitoring Data

No monitoring data in surface water or groundwater were found from the USGS NAWQA (United States Geological Survey National Water-Quality Assessment) program (http://water.usgs.gov/nawqa), or the California Department of Pesticide Regulation CDPR (http://www.cdpr.ca.gov/docs/emon/surfwtr/surfcont.htm). Water monitoring programs such as these generally monitor for conventional agricultural pesticides and typically do not include analysis for vertebrate control agents such as brodifacoum.

3.3. Terrestrial Animal Exposure Assessment

For this assessment, it is important to distinguish between primary and secondary exposure and its relation to direct or indirect effects to the species of concern. Primary exposure is defined as direct consumption of brodifacoum bait. This type of exposure is considered the chief route of exposure for the SMHM (resulting in direct effects) as well as for avian, mammalian and prey items for the AW and SJKF (which would result in indirect effects based on loss of prey items). Primary exposure (through ingestion of brodifacoum bait) is not considered the likely route of exposure for the AW and SJKF based on the carnivorous nature of these species and their preference for catching live prey. Secondary exposure is defined as an animal consuming another animal that has ingested brodifacoum bait. This is the chief route of exposure presumed for the AW and SJKF that results in direct effects to these species. Indirect effects to the AW and SJKF would be through loss of prey items (avian, mammalian, and reptilian) due to direct effects (primary exposure).

3.3.1. Exposure to Terrestrial Wildlife Prey from Primary Exposure

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. T-REX also models exposure from seed treatment and granular formulations. 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. Therefore, terrestrial animal exposure to brodifacoum was calculated without the use of these computer models.

For AW and SJKF that consume prey animals and for the SMHM that directly consumes brodifacoum bait (*i.e.*, primary exposure for prey), the EEC is simply the concentration of brodifacoum in the formulated bait. The assessment is based on the maximum concentration of brodifacoum in bait products used for rodent control. The maximum concentration is 0.005% (50 mg a.i./kg product) for products used to control rats and mice. For dietary-based risk, the concentration of brodifacoum in the bait was compared directly to the toxicity endpoint from dietary toxicity studies (*i.e.*, 40-day LC_{50} studies for birds and 14-day LC_{50} studies for mammals due to delayed toxicity of brodifacoum). For dosed-based risk, the brodifacoum concentration in bait had to first be converted to a daily ingestion rate. This was done using the allometric equations of Nagy (1987), as provided in USEPA's Wildlife Exposure Factor Handbook (USEPA, 1993). Ingested doses of brodifacoum (mg a.i./kg-BW) were calculated for birds and mammals of various assumed body weights. The doses calculated for birds were also used for reptiles and terrestrial-phase amphibians. This approach is consistent with other rodenticide risk assessments conducted by the Agency, most recently for the endangered species assessment for the chemical difethialone, which is closely related to brodifacoum.[17]

[17] http://www.epa.gov/espp/litstatus/effects/redleg-frog/2011/difethialone/assessment.pdf

Direct effects to the SMHM (through Primary Exposure)

The SMHM is likely to be exposed to brodifacoum residues from primary exposure that occurs from direct ingestion of brodifacoum bait. Bait with one concentration of brodifacoum was modeled, 0.005%. These small mammals were assumed to consume their average daily food intake in the form of the bait. The average daily food intake rate was estimated using the following allometric equation:

$$FI = 0.621\ W^{0.564}$$

Where FI is the food intake rate in g/d, and W is the body weight of the mammal in g.

This food ingestion rate was calculated for a 10-g mammal, which is representative of a typical SMHM. Food intake values for other mammals will be discussed later in the indirect effects section where reduction of mammalian prey to the AW and SJKF are discussed. These calculations yield a FI for the 10-g small mammal. The FI values were then converted into estimated daily doses using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

For dietary exposure, the EEC is assumed to be amount of bait a.i present in the bait. This approach is consistent with the Agency's other risk assessments for rodenticides. **Table 3-2** shows the dose and dietary based EECs expected for primary exposure to small mammals like the SMHM.

Table 3-2. Dose-based and Dietary EEC for Primary Exposure of Brodifacoum Bait.

	Formulation	% AI in Bait	Dose-based EEC for Primary Exposure (mg a.i/kg-bw)	Dietary EEC for Primary Exposure (mg ai/kg-diet)
Bait for rat and mouse control in and around buildings	Pellets, meal, blocks, paste	0.005	11.3	50

Indirect effects to the AW and SJKF (through Secondary Exposure Consuming Reptiles, Birds, and Mammals)

Direct acute effects from primary exposure to prey items for the AW and SJKF (mammals, birds, and reptiles) ingesting brodifacoum bait were evaluated by assuming an individual directly consumes a bait product containing brodifacoum at its daily ingestion rate. As the great majority of brodifacoum products are the same percent a.i, 0.005%, and this is also the highest

concentration of brodifacoum active ingredient in products registered, only one concentration of brodifacoum was assessed. The average daily food intake rate was estimated using the following allometric equation for insectivorous reptiles (Nagy, 1987 as cited in USEPA, 1993):

$$FI = 0.013\ W^{0.773}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the reptile in g.

Food ingestion rates were calculated for reptiles weighing 2, 20, and 800 g. These calculations yield FI values of 0.022, 0.13, and 2.3 g/d for small, medium and large reptiles, respectively. The FI values were then converted into estimated daily doses using the following equation:

$$Dose = FI \times \%A.I. \times (1/W) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

Finally, acute risk quotients were calculated by dividing the expected dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the mallard duck, 0.26 mg-a.i./kg-bw (surrogate for reptiles).

Indirect risk posed to the AW and SJKF (loss of prey items) mediated by toxic effects to birds was assessed using an approach similar to that used for reptiles, except the allometric equation for food ingestion rate (FI) was for birds rather than for reptiles. Risk was again assessed for bait with a brodifacoum concentration of 0.005%. The average daily food intake rate was estimated using the following allometric equation for birds (Nagy, 1987 as cited in USEPA, 1993):

$$FI = 0.648\ W^{0.651}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the bird in g.

Risk was assessed for birds of the standard default weights of 20, 100, and 1000 g, representing small, medium, and large birds, respectively. These calculated FI values for these weight classes were 4.56, 13.0, and 58.2 g/d, respectively. The FI values were then converted into estimated daily doses using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

Because the AW preys upon birds, it may be indirectly affected by adverse effects on bird populations. Dietary-based RQs for birds which consume brodifacoum bait were also calculated by dividing the concentration of brodifacoum in the bait by the subacute dietary LC_{50} value for the northern bobwhite (1.33 mg a.i./kg-diet). The brodifacoum concentrations in the bait, when expressed as parts-per-million (mg-a.i./kg), is 50 for rodenticide bait.

Risk quotients were calculated to assess risk to small mammals which directly consume brodifacoum bait and which may serve as prey for the AW and SJKF. These also apply to effects to small mammals that may provide rearing sites for the SMHM. Bait with one concentration of brodifacoum was modeled, 0.005%. The small mammals were assumed to consume their average daily food intake in the form of the bait. The average daily food intake rate was estimated using the following allometric equation:

$$FI = 0.621\ W^{0.564}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the mammal in g.

This food ingestion rate was calculated for 20-g mammal, which is representative of a typical small mammal on which the AW or SJKF might prey. These calculations yield a FI for the 20-g small mammal. The FI values were then converted into estimated daily doses using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

Finally, acute dose-based risk quotients were calculated by dividing the expected dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the most sensitive tested mammalian species (Richardson's ground squirrel), 0.13 mg-a.i./kg-bw.

3.3.2. Exposure to Terrestrial Animals from Secondary Exposure

Secondary exposure was also assessed for the AW and SJKF. These species may be exposed if they consume a vertebrate animal that has eaten brodifacoum 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, birds and other reptiles, which are likely to consume bait and are also a component of the diet of the AW and small mammals and birds for the diet of the SJKF. For assessing secondary exposure for the AW and SJKF, scenarios were considered in which both species preyed upon a house mouse or a Norway rat after the prey had consumed brodifacoum bait. The prey animal was assumed to

have consumed a quantity of bait equal to its daily ingestion rate. In one set of scenarios, the entire quantity of active ingredient ingested was assumed to remain in the animal at the time it was consumed. This could occur if the animal was consumed immediately after it ate the bait as the entire amount ingested would be present in the gastrointestinal tract of the prey animal. This scenario represents the high-end of possible secondary exposure. A second set of exposure scenarios was also evaluated to represent more typical conditions. In the typical scenarios, the prey animal was assumed to be eaten 24 hours after the prey had consumed brodifacoum bait. However, given the persistence of brodifacoum in the liver and other tissues of organisms, a length of 24 hours of prey consumption after prey had consumed brodifacoum bait would not likely result in degradation of brodifacoum in the prey before predatory consumption. As a result of the very long liver retention time of brodifacoum, consumption of prey that ingested brodifacoum immediately, or after a period of time, is not expected to impact the secondary risk of an organism.

Direct effects to the AW and SJKF (through Secondary Exposure Consuming Mammals)

The maximum size of the prey consumed by snakes was estimated using the following allometric equation developed by King (2002).

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

In order to provide a conservative measure of exposure, the exponent used in this equation is the upper limit or the 95% confidence interval that King (2002) reported for this parameter (*i.e.*, same relationship that is assumed in the T-HERPS model). Although the weight of the AW was not available, the Agency has estimated body weight of this species from its length using the method presented in USEPA (1993). The estimated body weight of this species ranges from 2.5 to 176 g for juveniles and 46 to 897 g for adults (USEPA 2010). 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 and Norway rat are 18-23 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 and 485 g for the Norway rat).

To provide a conservative measure of exposure, the size of the AW was set at the minimum size animal that could consume prey of the size assumed for the two 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 and rat was calculated to be 18.6 and 322 g, respectively. The 18.6-g snake is plausible for a juvenile AW while the 322-g snake is plausible for an adult AW.

For the SJKF, exposure through preying upon animals that consumed brodifacoum bait (secondary exposure) was assessed by estimating direct effects to the prey items that were later ingested by different size classes of mammal (the SJKF) using an allometric equation based on whether the prey item was another mammal, bird, or reptiles.

The AW and SJKF are likely to be exposed to brodifacoum residues from secondary exposure that occur from consumption of prey that has consumed brodifacoum bait. The AW and SJKF are capable of consuming all of the target small mammals species specified on the brodifacoum bait product labels, including rats and mice. Therefore, risk based on secondary exposure was conducted for AW and SJKF which feeds on a Norway rat, and a house mouse. These species were assumed to have consumed brodifacoum bait at their daily ingestion rate. The rat and the mouse were assumed to have consumed rodenticide bait with a brodifacoum concentration of 0.005%. Assumed body weights of these prey species were 485 g for the Norway rat and 23 g for the house mouse for the AW. These represent the high end of the range for these species to represent the highest potential exposure of brodifacoum from secondary exposure. The body weight of the snake was set at the weight of the minimum sized animal which would be predicted to be able to consume prey of the assumed size.

The average daily food intake rates of the two assumed prey species were estimated using the following allometric equation for mammals[18]:

$$FI = 0.621\ W^{0.564}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the rodent in g.

The calculated FI values for the Norway rat and house mouse were 20.3, 3.64 g/d, respectively. The FI values were then converted into estimated ingested doses of brodifacoum using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

To assess the maximum exposure that an AW could receive through secondary exposure, 100% of the active ingredient which was ingested by the small mammal prey was assumed to be present in the animal when it was consumed by the snake. This is plausible because a snake could prey upon the small mammal shortly after it has ingested the bait, with all of the brodifacoum contamination present in the ingesta within the gastrointestinal tract of the animal, before it has had a chance to metabolize or excrete any of it. Thus, the amount of active ingredient the prey was assumed to ingest was also the dose, in mg, which the AW was assumed to ingest. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg a.i./kg BW. Finally, the acute secondary exposure risk quotients for the AW were calculated by dividing the predicted dose of brodifacoum (mg-a.i./kg-bw) by the acute

[18] T-REX (v1.4.1) User's Guide. Environmental Fate and Effects Division, Office of Pesticide Programs, US EPA. (December 11, 2008)

oral LD_{50} value for the most sensitive bird species (mallard duck), 0.26 mg-a.i./kg-bw, which is a surrogate value to represent the snake.

For mammals consuming other mammals that have ingested brodifacoum bait (*i.e.*, the SJKF consuming rodents or other small mammals), a different method of estimating exposure was employed than for the AW. An equation for estimating the size of a mammal based on its prey size does not exist as it does for snakes; T-REX was used to estimate the ingestion rate for a given size mammal to consume to achieve its nutritional needs. Although there is some uncertainty in this method, specifically that this estimation is intended for insectivorous/ herbivorous mammals and not carnivores like the SJKF, there were no residue studies available to estimate the concentration of brodifacoum that a SJKF would ingest if it consumed a poisoned small mammal.

Using T-REX, the model estimates that a 2300 g mammal (average size for a SJKF) will ingest 11% of its body weight, or a 244 g small mammal. This weight represents an average sized Norway Rat since a larger Norway Rat (used for the AW) is assumed to be 485 g. This estimated body weight (244 g) was inputted into T-REX to estimate the food ingestion rate for a mammal of this size. This food ingestion rate (0.069 kg-diet/day) was multiplied by the amount of brodifacoum active ingredient (50 mg a.i./kg bait) to get an estimated dose for the small mammal of 3.45 mg a.i/day. This dose, divided by the weight of the 2.3 kg SJKF yields the dose-based EEC of 1.5 mg a.i/kg/day for a SJKF ingesting a poisoned 244 g mammal.

Direct effects to the AW and SJKF (through Secondary Exposure Consuming Birds)

The AW and SJKF are likely to be exposed to brodifacoum residues from secondary exposure that occurs from consumption of prey that has consumed brodifacoum bait. The AW and SJKF are capable of consuming birds as prey that may have directly ingested brodifacoum bait. Therefore, risk based on secondary exposure was conducted for a snake and mammal which feeds on birds. These species were assumed to have consumed brodifacoum bait at their daily ingestion rate. Birds were assumed to have consumed rodenticide bait with a brodifacoum concentration of 0.005%. Assumed body weights of these prey species were 20 g for a small bird, 100 g for a medium-sized bird, and 1000 g for a large-sized bird. The body weight of the snake was set at the weight of the minimum sized animal which would be predicted to be able to consume prey of the assumed size.

The average daily food intake rates of the two assumed prey species were estimated using the following allometric equation for birds[19]:

$$FI = 0.648\ W^{0.651}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the rodent in g.

[19] T-REX (v1.4.1) User's Guide. Environmental Fate and Effects Division, Office of Pesticide Programs, US EPA. (December 11, 2008)

The calculated FI values for the small bird, medium bird, and large bird were 4.55, 13.00, and 58.1 g/d respectively. The FI values were then converted into estimated ingested doses of brodifacoum using the following equation:

$$\text{Dose} = \text{FI} \times \%\text{AI} \times (1/\text{W}) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

To assess the maximum exposure that an AW could receive through secondary exposure, 100% of the active ingredient which was ingested by the bird prey was assumed to be present in the animal when it was consumed by the snake. This is plausible because a snake could prey upon a bird shortly after it has ingested the bait, with all of the brodifacoum contamination present in the ingesta within the gastrointestinal tract of the animal, before it has had a chance to metabolize or excrete any of it. Thus the amount of active ingredient the prey was assumed to ingest was also the dose, in mg, which the AW was assumed to ingest. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg a.i./kg BW. Finally, the acute secondary exposure risk quotients were calculated by dividing the predicted dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the most sensitive bird species (mallard duck), 0.26 mg-a.i./kg-bw, which is used as a surrogate for snake.

For mammals consuming birds that have ingested brodifacoum bait (*i.e.*, the SJKF consuming birds), a different method of estimating exposure was employed than for the AW. As an equation for estimating the size of a mammal based on its prey size does not exist as it does for snakes, T-REX was used to estimate the ingestion rate for a given size bird to consume to achieve its nutritional needs. Although there is some uncertainty in this method, specifically that this estimation is intended for insectivorous/ herbivorous mammals and not carnivores like the SJKF, there were no residue studies available to estimate the concentration of brodifacoum that a SJKF would ingest if it consumed a poisoned small mammal.

In the previous analysis for a 2300-g SJKF consuming a mammal, T-REX estimated that the SJKF would need to eat a 244-g small mammal to fulfill its nutritional needs. This same weight can be applied for a 244-g bird. This estimated body weight (244 g) was inputted into T-REX to estimate the food ingestion rate for a bird of this size. This food ingestion rate (0.116 kg-diet/day) was multiplied by the amount of brodifacoum active ingredient (50 mg a.i./kg bait) to get an estimated dose for the bird of 5.8 mg a.i/day. This dose, divided by the weight of the 2.3 kg SJKF yields the dose-based EEC of 2.52 mg a.i/kg/day for a SJKF ingesting a poisoned 244 g mammal.

Direct effects to the AW and SJKF (through Secondary Exposure Consuming Reptiles)

The AW is likely to be exposed to brodifacoum residues from secondary exposure that occurs from consumption of prey that has consumed brodifacoum bait. The AW is capable of consuming other reptiles such as lizards (their chief preference of food) as prey that may have directly ingested brodifacoum bait. Therefore, risk based on secondary exposure was conducted for a snake which feeds on lizards. These species were assumed to have consumed brodifacoum bait at their daily ingestion rate. Lizards and/or other reptiles were assumed to have consumed rodenticide bait with a brodifacoum concentration of 0.005%. Assumed body weights of these prey species were 2 g for a small reptile, 20 g for a medium-sized reptile, and 800 g for a large-sized reptile. The body weight of the snake was set at the weight of the minimum sized animal which would be able to consume prey of the assumed size.

The average daily food intake rates of the two assumed prey species were estimated using the following allometric equation for reptiles[20]:

$$FI = 0.013\ W^{0.773}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the reptile in g.

The calculated FI values for the small reptile, medium reptile, and large reptile were 0.02, 0.13, and 2.28 g, respectively. The FI values were then converted into estimated ingested doses of brodifacoum using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of brodifacoum (mg-a.i./kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

To assess the maximum exposure that an AW could receive through secondary exposure, 100% of the active ingredient which was ingested by the reptile prey was assumed to be present in the animal when it was consumed by the snake. This is plausible because a snake could prey upon a reptile very soon after it has ingested the bait, with all of the brodifacoum contamination present in the ingesta within the gastrointestinal tract of the animal, before it has had a chance to metabolize or excrete any of it. Thus the amount of active ingredient the prey was assumed to ingest was also the dose, in mg, which the AW was assumed to ingest. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg a.i./kg BW. Finally, the acute secondary exposure risk quotients were calculated by dividing the

[20] T-HERPS (v. 1.0) User's Guide. Environmental Fate and Effects Division, Office of Pesticides Programs, US EPA. September 4, 2008.

predicted dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the most sensitive bird species (mallard duck), 0.26 mg-a.i./kg-bw, used as a surrogate to the whipsnake.

Wildlife Monitoring Studies

There has also been literature suggesting that brodifacoum residues are prevalent and widespread throughout wildlife.

Of particular relevance to this assessment is a study conducted by McMillin et al (2008). In this study, the California Department of Fish and Game's Pesticide Investigations Unit (in conjunction with the Endangered Species Recovery Program's Urban Kit Fox Project), monitored San Joaquin Kit Foxes from the Bakersfield, CA population. This study corresponds with the EIIS incident number I016100-001. Necropsies and liver tissue samples were collected from kit fox carcasses. A non-urban population of kit foxes from Lokern Natural Area (a 40,000 acre habitat 30 miles west of Bakersfield) was used as a control. Between 1999 and 2007, tissue samples from various animals were analyzed for residues of anticoagulant rodenticides. The fox carcasses were part of an ongoing monitoring effort dating back to 1977 from which 10-20 carcasses were collected from both the Bakersfield and Lokern area per year. The compounds identified included brodifacoum and chlorophacinone. Out of the 30 San Joaquin Kit Foxes analyzed from the Bakersfield population, 27 contained at least one anticoagulant and the most commonly detected from that set was brodifacoum (26 out of 30 or 87%). Concentrations ranged from 0.2 to 11,000 ng/g fresh weight with a detection limit of 0.2 ng/g. Chlorophacinone residues were detected in one fox (3%). All control foxes from the Lokern population had no anticoagulant residues detected. The authors report that results from this study confirm that San Joaquin Kit Foxes are exposed to anticoagulants in urban environments.

In an article by Lima and Salmon (2010), environmental impacts to raptor populations were evaluated based on anticoagulant rodenticide use in California. In this study, 53 birds from San Diego County and 43 birds from 3 counties in the California Central Valley were recovered and tested for the presence of four first generation anticoagulants (chlorophacinone, diphacinone, coumachlor, and warfarin) and three second generation anticoagulants (difethialone, brodifacoum, and bromadiolone). The San Diego county birds were collected as part of a West Nile Virus surveillance program while the Central Valley birds were submitted by chance collection from the public. There were no active captures and all birds were presented dead. The findings of the study were that while most of the animals died from causes other than anticoagulant poisoning, the San Diego Country population had brodifacoum residues detected in 83% of the birds while this number was 12% in the Central Valley birds (no actual concentrations provided but only whether the chemical was detected or not; brodifacoum limit of detection was 0.01 ppm). The findings of this study indicate brodifacoum residues were detected in animals in both urban/suburban and rural environments. Also of note is the greater prevalence of brodifacoum detections in San Diego County, which may be associated with the greater use of second generation rodenticides (like brodifacoum) for rodent control in urban/suburban areas, versus agricultural areas. These finds are significant since the AW and SJKF both occur in developed areas of California.

Albert *et al.* (2009) presented rodenticide residue information on three species of owls in Western Canada from the time period of 1988 – 2003. Barn owls (*Tyto alba*), barred owls, (*Strix varia*), and great horned owls (*Bulbo virginianus*) were collected during this time period in the provinces of British Columbia and the Yukon Territory. Between 1988 and 2003, 164 dead owls (61 great horned, 25 barred, 78 barn) were collected from the study area. In the study, avian mortality was attributed to trauma, disease, anticoagulant rodenticide poisoning, or reported as undetermined. It was determined through chemical residue analysis and necropsy results that 6 of 164 birds died from anticoagulant poisoning while 113 out of 164 (68%) died from trauma (the remaining birds from disease and undetermined causes). Out of all the birds used in the study (regardless of the ultimate cause of death), 46% of the great horned owls, 76% of the barred owls, and 45% of the barn owls had residues of brodifacoum detected (concentrations of residues ranged from 0.001 to 0.927 mg/kg). This study, like the Lima and Salmon study confirm the presence of brodifacoum residues in wildlife, particularly in secondary consumers.

Riley *et al.* (2007) conducted a monitoring study in which bobcats and mountains lions in Southern California were tested for anticoagulant exposure and the correlation of exposure to the parasitic disease mange. A total of 39 bobcats and 4 mountain lions were tested. Out of the animals tested, 79% of bobcats and 100% of the mountain lions had detectable levels of brodifacoum present in their livers (concentrations of residues ranged from 0.01 to 0.56 ppm with the limit of detection for the assay being 0.01 ppm. The primary attributed cause of death for these bobcats was either being struck by a car or mange and not difethialone poisoning. Again, this study like those previously discussed, indicate bioaccumulation and the presence of sublethal levels of brodifacoum in wildlife are possible.

3.3.3. Exposure to Terrestrial Invertebrates

As described in **Section 2.9,** indirect effects to the AW, SMHM, and SJKF mediated through exposure to terrestrial invertebrates are expected to be negligible. It is possible that some terrestrial invertebrates could directly consume or be exposed via direct contact to brodifacoum bait resulting in mortality. However, given that the outdoor use of brodifacoum bait is restricted to areas adjacent to walls of buildings, any mortality of invertebrates is expected to be very localized. The impact to the invertebrate abundance throughout the range of the assessed species is expected to be negligible. Furthermore, although the AW, SMHM, and SJKF can consume terrestrial invertebrates that have potentially ingested or been exposed via direct contact to brodifacoum bait, their diet consists of many other non-invertebrate food items. These include lizards, small mammals, and birds for the AW and small mammals and birds for the SJKF. Furthermore, although brodifacoum has the propensity to bioaccumulate in the livers of terrestrial vertebrates and persist, it is unknown whether the fat body, a similar structure to the liver found in insects bioaccumulates brodifacoum in the same manner as it does in the liver. There are also no submitted ecotoxicity studies for terrestrial invertebrates, and no method is currently available to assess the consumption rate of brodifacoum bait by terrestrial invertebrates. Based on all of the available lines of evidence including mode of action, use patterns, and the dietary requirements of the assessed species, no exposure assessment was conducted for terrestrial invertebrates.

3.3.4. Exposure to Aquatic Plants

Brodifacoum is a bait product formulation with low application rates. It should be applied per placements at least 8 ft away from each other (for mice), and when applied at the maximum rate per placement, 15 ft from each other (for rats). The maximum rate per placement is small compared to conventional agricultural pesticides (0.000050 lb or 23 mg/placement). In addition, except for four products included in the Notice of Intent to Cancel (NOIC), placements should occur within 50 ft of structures and for above ground applications, and bait stations should be used. Thus, applications appear to be highly localized. Furthermore, its strong affinity to sorb to soil suggests that it is likely to strongly sorb to bait itself; consequently, runoff transport and exposures in aquatic environments are expected to be negligible. Concentrations of brodifacoum in both freshwater and saltwater marshes are expected to be negligible and not impact aquatic vegetation. Models that estimate concentrations in surface water or calculate spray drift deposition of brodifacoum on aquatic habitats were not applicable and not needed. No surface water monitoring data are readily available for brodifacoum. Based on this information, the aquatic habitat is not assessed in this document.

3.3.5. Exposure to Terrestrial Plants

The use of brodifacoum in bait for rodent control is not expected to result in significant exposure to terrestrial plants, and therefore the risk of indirect effects to the AW mediated through modification of vegetation is expected to be negligible. Given that there is no spray drift, exposure to terrestrial plants would be limited to absorption through the roots by plants growing in soil contaminated by the bait. Only plants growing in the immediate vicinity of placed bait would be expected to be exposed to contaminated soil. Thus, the area where terrestrial plants may be exposed and potentially adversely affected is expected to be very small relative to home range of the AW, SJKF, and SMHM. As brodifacoum is an anticoagulant rodenticide, its mode of action is not expected to cause adverse effects to terrestrial plants. Thus any damage that might occur to plants is not expected to cause significant vegetative damage which would significantly deteriorate the quality of the habitat of this species. Additionally, the amount of residues that would leach from brodifacoum bait applied at a maximum of 1 lb product/ placement or 0.00005 lb a.i./placement is expected to be small. Brodifacoum is immobile, based on the estimated K_{OC} range of $1.4x10^5$ to $7.7x10^6$ L/kg_{OC} (FAO 2000)]. Furthermore, bait products used for rodent control are oftentimes either placed within a plastic bait station that would minimize contact with rain water, or formulated into weather-resistant blocks which do not readily deteriorate. Finally, the log K_{OW} value for this chemical (log K_{OW} = 8.5) indicates that it binds to organic matter. It appears unlikely that brodifacoum would leach substantially from treated bait should exposure to rainwater occur.

As discussed in **Section 2.9.2**., use of brodifacoum in bait products to rodent pests is not expected to result in significant exposure to plants. Bait is generally placed by hand in specific bait stations around buildings. The products containing brodifacoum should not be broadcasted. Any exposure to plants would be minor and limited to the area immediately around the bait placement. Therefore, risk of indirect effects of brodifacoum to the AW, SJKF, and SMHM mediated through damage to terrestrial plants is considered negligible.

4. Effects Assessment

This assessment evaluates the potential for brodifacoum to directly or indirectly affect AW, SMHM, and SJKF or modify designated critical habitat of the AW. Assessment endpoints for the effects determination for each assessed species include direct toxic effects on the survival, reproduction, and growth (through secondary exposure for the AW and SJKF and through primary exposure to the SMHM) as well as indirect effects, such as reduction of the prey base, reduction of SMHM rearing sites or modification of habitat. In addition, potential modification of the AW 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 the AW. Direct effects to the reptiles are based on avian toxicity data, given that birds are generally used as a surrogate for terrestrial-phase reptiles.

As described in the Agency's Overview Document (USEPA, 2004), the most sensitive endpoint for each taxon is used for risk estimation. For this assessment, evaluated taxa include birds (which are used as a surrogate for reptiles) and mammals. Acute (short-term) toxicity information is characterized based on registrant-submitted studies and a comprehensive review of the open literature on brodifacoum. There were no registrant submitted avian or mammalian chronic studies available for brodifacoum. Additionally, there were no registrant submitted studies characterizing the toxicity of brodifacoum to terrestrial plant and invertebrates.

4.1. Ecotoxicity Study Data Sources

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (USEPA, 2004). Open literature data presented in this assessment were obtained from registrant submitted studies as well as ECOTOX information obtained in October, 2011. 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 brodifacoum to „target' rodent species (the house mouse, the Norway rat, and the roof 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 E**. Citations of open literature papers that provide toxicological data for target rodent species are listed in **Appendix B** 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 brodifacoum, such as information on the sublethal effects and the mode of action of brodifacoum.

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, 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 B**. The appendix 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 E.**

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 brodifacoum.

4.2. Toxicity of Brodifacoum to Terrestrial Organisms

Toxicity of brodifacoum to terrestrial species is relevant for the SMHM given expected direct effects due to ingestion of the bait material (primary exposure) and to the AW and SJKF given ingestion of prey that ingests bait material such as mammalian and avian species (secondary exposure). Furthermore, toxicity of brodifacoum for mammals and birds is important due to the indirect effects of related prey reduction associated with brodifacoum use. Finally, as highlighted by the design of many of the toxicity studies, brodifacoum, like other anticoagulants, may exhibit a delayed toxicity in which death can occur several days after ingestion. **Table 4-1** summarizes the available terrestrial toxicity endpoints, based on an evaluation of the registrant submitted studies. It is noted that a review of the acceptable ECOTOX studies did not yield a study with a lower endpoint that had acceptable test methods. Therefore the available submitted studies presented below will be used for this assessment.

Table 4-1. Terrestrial Toxicity Profile for Brodifacoum

Endpoint	Acute/ Chronic	Species	Toxicity Value Used in Risk Assessment (95% CI)	Citation/ MRID	Comment
Birds (surrogate for terrestrial-phase amphibians and reptiles)	Acute oral LD_{50}	Japanese quail (*Coturnix coturnix*)	11.6 mg (3.8 – 9.3) a.i/kg-bw	46351304	- Study classified as supplemental due to species not being recommended and because purity of formulation was not reported - Clinical signs of toxicity included fresh and digested blood in the feces, severe and extensive bruising, subcutaneous hemorrhage, and excessive, prolonged bleeding - Exposure was followed by a 30-day observation period due to the delayed toxicity of brodifacoum
	Acute oral LD_{50}	Ring-necked pheasant (*Phasianus colchicus*)	0.54 (not determined) mg a.i/kg-bw	46351303	- Study classified as supplemental due to species not being recommended - Clinical sings of toxicity included hemorrhaging - Significant decrease in body weight treatment group (0.155 mg/kg-bw) treatment group - Exposure was followed by a 30-day observation period due to the delayed toxicity of brodifacoum
	Acute oral LD_{50}	Mallard duck (*Anas platyrhynchos)*	0.26 (0.11 – 0.40) mg a.i/kg-bw	41563303	- Study was classified as acceptable - There were no clinical signs of toxicity noted during the study - Following the exposure, the birds were observed for 28 days due to the delayed toxicity of brodifacoum
	Acute dietary LC_{50}	Mallard duck (*Anas platyrhynchos)*	2.75 (0.07 – 7.93) ppm	00124476	- Study was classified as acceptable - There were no clinical signs of toxicity noted during the study After the 5-day exposure period, birds were observed for a 35-day period due to the delayed toxicity of brodifacoum
	Acute dietary LC_{50}	Northern bobwhite quail (*Colinus virginanus*)	1.33 (0 – 2.96) ppm	00124477	- Study was classified as acceptable - Control mortality was 12% due to toe and nostril picking - Clinical sings of toxicity included depression, wing droop, loss of coordination, prostration, and hemorrhage

Endpoint	Acute/ Chronic	Species	Toxicity Value Used in Risk Assessment (95% CI)	Citation/ MRID	Comment
					- After the five-day exposure, birds were observed for a further 35 days due to the delayed toxicity of brodifacoum
	Chronic	--	--	--	There are no avian reproduction studies available
Mammals	Acute oral LD_{50}	Richardson's ground squirrel (*Spermophilus richardsonii*)	0.13 (0.06-0.19)	48638401	- Study was classified as supplemental - Animals were observed for 21 days post exposure due to the delayed toxicity of brodifacoum - Necropsy findings showed internal or external hemorrhaging including in the liver, gall bladder, heart, caecum, small intestines, stomach, mesenteries, thoracic and abdominal walls, and the feet.
	Acute dietary LC_{50}	Albino rat	0.53 (0.45-0.68) mg a.i./kg-diet	Teeters, W.R. (1981) TMN 110	- Study classified as supplemental - Clinical signs of toxicity not noted during the study - 5 day exposure period, followed by 9 day observation period due to the delayed toxicity of brodifacoum
	Chronic	--	--	--	There are no mammalian reproduction studies available

bw = body weight

Data are not available to characterize the toxicity of brodifacoum to non-target invertebrates (*e.g.* honey bees) or to terrestrial or aquatic plants.

Acute toxicity to terrestrial animals is categorized using the classification system shown in **Table 4-2** (USEPA, 2004). Toxicity categories for terrestrial plants have not been defined. Toxicity data categorizes brodifacoum as *very highly toxic* to birds and mammals on an acute oral basis, and *very highly toxic* to birds on a subacute dietary basis.

Table 4-2. 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

4.2.1. Toxicity to Birds

As specified in the Overview Document, the Agency uses birds as a surrogate for reptiles and terrestrial-phase amphibians when toxicity data for each specific taxon are not available (USEPA, 2004). A summary of acute and chronic bird data is provided below.

Table 4-3 summarizes findings of studies on acute toxicity to birds when brodifacoum is administered as a single oral dose. These data classify brodifacoum as *very highly toxic* to birds. **Table 4-4** summarizes findings of studies on subacute toxicity to birds when brodifacoum is administered in the diet. The results for the northern bobwhite quail and mallard duck categorize brodifacoum as *very highly toxic* to birds when administered through the diet. There were no data available on the effects of chronic exposure of birds to brodifacoum.

Table 4-3. Acute Oral Toxicity of Brodifacoum to Birds

Species, Test substance	% AI	LD_{50} (mg/kg-bw) (95% confidence interval)	MRID	Classification
Japanese quail, brodifacoum administered in corn oil vehicle	Tech.	30-day LD_{50} = 11.6 mg (10– 13.6) a.i/kg-bw Probit Slope: 6.6	MRID 46351304	Supplemental
Ring-necked pheasant, administered via oral gavage	96	14-day LD_{50} = 0.59 (Not determined)	MRID 46351303	Supplemental
Mallard duck, brodifacoum administered in corn oil vehicle	97.6	28-day LD_{50} = 0.26* (0.11 – 0.40) mg a.i/kg-bw Probit slope: 3.0	MRID 41563303	Acceptable

*Endpoint used for quantitative assessment of risk.

Table 4-4. Subacute Dietary Toxicity of Brodifacoum to Birds

Species	% AI	LC_{50} (mg/kg-diet) (95% confidence interval)	MRID	Classification
Northern bobwhite	94	40-day LC_{50} = 2.75 (0.07 – 7.93) ppm	00124476	Acceptable
Mallard duck	94	40-day LC_{50} = 1.3* (0 – 2.96) ppm	00124477	Acceptable

*Endpoint used for quantitative assessment of risks.

In these studies, brodifacoum was observed to cause several sublethal effects in birds. In the oral studies hemorrhaging was observed at all doses but the lowest. In the ring necked pheasant study (MRID 46351303), body weight decreases were observed in themiddle treatment level for males and highest treatment level for females. Other sublethal effects observed in the acute oral toxicity studies at unspecified treatment levels were fresh and digested blood in the feces, severe and extensive bruising, subcutaneous hemorrhage, and excessive, prolonged bleeding from damaged feathers or small wounds in the skin of the face, comb, and wattles. In the Japanese quail study (MRID 46351304), all the treatment group birds that had died had extensive

hemorrhage of the lungs. A majority of treated birds had intramuscular and intestinal hemorrhage, and blood in the abdominal cavity. There were no other sublethal effects reported.

For the dietary toxicity studies, sublethal effects were noted in both studies (one with bobwhite quail and one with mallard duck) but the levels at which the sublethal effect occurred were not indicated. Both studies conducted a 5-day exposure followed by a 35-day observation period due to the delayed toxicity of brodifacoum. For the bobwhite quail dietary study, clinical signs of toxicity included, depression, wing droop, loss of coordination, prostration, and hemorrhage. Toe and nostril picking also occurred in treated birds as well as 12% of the control birds which was attributed to the observed mortality. In the mallard duck dietary study, clinical signs of toxicity included lethargy, weakness, loss of coordination, and prostration. Most birds, but not all, had internal hemorrhage detected during necropsies. There were no other clinical signs of toxicity noted for either study.

4.2.1.a. Birds: Secondary Toxicity Studies

Several secondary toxicity tests (i.e., feeding studies conducted with contaminated prey items) with avian species have been conducted using brodifacoum. In a secondary toxicity test conducted on raptorial species (MRID 00080243) four golden eagles (*Aguita chrysaetos*), four red-tailed hawks (*Buteo borealis colurus*), and two red-shouldered hawks (*Buteo lineatus*) were fed rat and mouse meat from those that had died during the exposure period. The test rodents were fed the bait in a no –choice test (with no other food) for 3 days with the daily amount of bait consumed being recorded. Following this 3-day period the rodents were put on normal laboratory diet and observed daily (rats for seven days, mice for nine days). Rats were then observed until death at which point they were fed to the raptorial birds. All four golden eagles survived after consuming a range of 3.45 – 4.71 mg a.i/kg-bw brodifacoum over the exposure period. Two of the four golden eagles exhibited external bleeding at days 11 and 13, and one bird appeared sluggish at day 9. All four red-tailed hawks in contrast, died after having consumed a range of 6.36 – 9.42 mg a.i/kg-bw brodifacoum. All birds showed symptoms of external bleeding from days 6 – 8. One of the two red-shouldered hawks died during the study. The concentration of brodifacoum consumed for the surviving and bird that suffered mortality was 10.60 and 8.41 mg a.i/kg-bw, respectively. Clinical sings of toxicity were blood in the droppings of the surviving bird at day 8 and external bleeding at day 18 for the dying bird. This study was not submitted to fulfill any guideline requirement and did not have a classification associated with it. This study however does demonstrate that raptorial species are sensitive to brodifacoum poisoned prey and for those birds that did not die, external bleeding was observed, which may have greater impacts in the wild, such as decreased fitness and ability to hunt and feed.

Barn owls (*Tyto alba)* were fed rats contaminated with 6 different rodenticides (including brodifacoum) in periods of 1, 3, 6, or 10 days in a secondary toxicity study (MRID 40077202). The exposure times correspond to the times that the contaminated rats were fed to the owls. The amount of chemical in the rats fed to the owls was not quantified, and there was an observation period of 10-19 days (depending on the dosing pattern of the owls). The test duration (exposure and observation) was 20 days total. The controls for the study were two control owls for each dosing group that were fed uncontaminated rats. Results of this study indicate that six of the

seven owls that were fed brodifacoum poisoned rats died. Clinical signs of toxicity included internal bleeding, bruises from normal activity, and in one case, bleeding from the wound where blood had been sampled 17 days prior to the start of the test. All dead birds showed hemorrhaging and heart lesions. This study was classified as supplemental due to the amount of brodifacoum fed to the owls being unclear as well as the small sample size (one to two owls) per doing regimen. Also not reported was the amount of bait consumed by the rats, the time to death, and residue analyses of similarly killed rats to evaluate the level of brodifacoum that causes lethality. Furthermore, as mentioned previously, the observation period varied depending on the treatment group.

Although only one of these studies was able to quantify the amount of bait that the animals received (MRID 00080243), all of these studies demonstrate that predators feeding on brodifacoum poisoned prey could suffer mortality or other sublethal effects such as external bleeding. At a minimum, these studies suggest that the secondary exposure for birds and mammals is a complete exposure pathway that is further supported by the terrestrial field monitoring studies (**Section 4.2.4**) and the wildlife incident reports (**Section 4.3**).

4.2.2. Toxicity to Mammals

A summary of acute mammalian data, including data published in the open literature, is provided below in **Sections 4.2.2.a**. The HED chapter for Rodenticide Cluster Reregistration Eligibility Decision (RED) has been the sole assessment for brodifacoum aside from the 2004 Comparative Assessment. The RED described in **Section 2.3** refers to a cluster of rodenticides that included brodifacoum among other rodenticides. There are no available chronic toxicity studies available to assess the effects of brodifacoum to mammals.

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

Table 4-6 summarizes findings of studies on the acute of brodifacoum to mammals. These data classify brodifacoum as *very highly toxic* to mammals. The lowest acute oral toxicity LD_{50} from a fully acceptable (MRID 42687501) study was 0.42 mg a.i./kg-bw. This value was used in the quantitative acute risk assessment for mammals. A survey of the ECOTOX and OPP accepted open literature found no studies that yielded endpoints lower than listed below that also had controls. A listing of the citations of these papers can be found in **Appendix E**.

Table 4-5. Summary of Findings of Acute Oral Toxicity of Brodifacoum to Mammals

Species, test substance	Test Material	% AI	LD_{50} [1]	MRID, Citation	Classification
Norway Rat, oral gavage	TGAI	96.1	Female: 0.42 (0.35 – 0.50) mg a.i/kg-bw Male: 0.56 (0.47 – 0.67) mg a.i/kg-bw Slope: N/R	42687501	Acceptable
Richardson's ground squirrel	TGAI	Technical	0.13 mg a.i/kg-bw* (0.06-0.19)	48638401	Supplemental

Species, test substance	Test Material	% AI	LD_{50} [1]	MRID, Citation	Classification
Mink, oral gavage	TGAI	2.5% w/w in propylene glycol	9.2 mg a.i/kg-bw	00080248	Supplemental

*Endpoint used for quantitative assessment of risks.
[1] 95% confidence intervals are given in parentheses when available.
N/R = Not reported

Table 4-6. Summary of Findings of Acute Dietary Toxicity of Brodifacoum to Mammals

Species	Test Material	% AI	LC_{50} [1]	MRID, Citation	Classification
Albino rat	TGAI	98	0.84 (0.67, 1.06) mg a.i./kg-diet Slope: 7.1 (3.2, 10.9)	Teeters, W.R. (1981) TMN 50	Supplemental
Albino rat	TGAI	98	0.55 (0.45-0.68) mg a.i./kg-diet Slope: N/A	Teeters, W.R. (1981) TMN 79	Supplemental
Albino rat	TGAI	98	0.57 (0.53-0.61) mg a.i./kg-diet Slope: 24.4 (10.3, 38.5)	Teeters, W.R. (1981) TMN 82	Supplemental
Albino rat	TGAI	98	0.53* (0.45-0.68) mg a.i./kg-diet Slope: N/A	Teeters, W.R. (1981) TMN 110	Supplemental
Albino rat	TGAI	98	0.55 (0.45-0.68) mg a.i./kg-diet Slope: N/A	Teeters, W.R. (1981) TMN 112	Supplemental

N/A – Not applicable
[1] 95% confidence intervals are given in parentheses when available.
*Indicates most sensitive endpoint to be used for risk assessment

In an acute oral toxicity study with the laboratory rat, TGAI brodifacoum was administered in treatment levels of 0.25 and 0.50 mg a.i/kg-bw for males and females as well as 5 males receiving a 0.35 mg a.i/kg-bw dose and 5 females receiving a 0.75 mg a.i/kg-bw dose. The rats were observed for 14 days post exposure. There were no mortalities or signs of toxicity at the two lowest treatment groups (0.25 and 0.35 mg a.i/kg-bw). Mortality occurred at the other two treatment groups with all animals dead by day 9. Clinical signs of toxicity in these treatment groups included pallor, subdued behavior, decreased activity, bruising and bleeding from the nose and/or rectum. Necropsy finings of free or clotted blood in the thoracic and/or abdominal cavity, kidney, esophagus, and subcutaneous tissues are consistent with the anticoagulant mode of action of brodifacoum. There were no treatment related effects on body weight. This study

was classified as acceptable and LD_{50} values of 0.42 mg a.i/kg-bw and 0.56 mg a.i/kg-bw were reported for females and males, respectively.

In an acute oral toxicity study with minks (MRID 00080428), brodifacoum was administered in five treatment groups and the minks were monitored for 5 weeks post dose administration due to the delayed toxicity of brodifacoum. It was not possible to calculate an LD_{50} with probit confidence limits as mortality occurred only that the highest treatment group. Clinical sings of toxicity included bloody droppings. The LD_{50} for this study was determined to be 9.2 mg a.i/kg-bw. It was reported by the study authors that the increased LD_{50} for the mink to brodifacoum relative to other species could possibly be attributed to the very rapid transit of food through the intestinal tract which has been reported by other studies to be approximately 2 hours. This study was determined to be supplemental based on its conductance with a non-guideline species.

In an acute oral toxicity study with Richardson's ground squirrel (*Spermophilus richardsonii*), (MRID 48638401), brodifacoum was administered to test animals via gavage at five treatment groups. After exposure, the animals were observed for 21 days or until death due to the delayed toxicity of brodifacoum. The combined (male and female) LD_{50} was determined to be 0.13 mg a.i/kg-bw (0.063 – 0.188 mg a.i/kg-bw confidence interval). Necropsy findings showed all but two treated ground squirrels at all test concentrations had internal or external hemorrhaging. All other test animals appeared to have died from hemorrhages. Areas of hemorrhage included the liver, gall bladder, heart, caecum, small intestines, stomach, mesenteries, thoracic and abdominal walls, and the feet. This study was determined to be supplemental based on its conductance with a non-guideline species.

In a series of dietary studies conducted with technical brodifacoum and albino rats, animals were exposed for five days with a 9 day observation period due to the delayed toxicity of brodifacoum. All five studies were conducted in the same lab (U.S. Environmental Protection Agency, Pesticides Regulation Div., Agricultural Research Center, Animal Biology Laboratory), and were done using very similar methodologies. The most sensitive LC_{50} (0.53 mg a.i./kg-diet) was attained in the Test Number 110. This value was very similar to the LC_{50}s attained in three of the additional tests (LC_{50}s ranged from 0.55 to 0.57 mg a.i./kg-diet). One study indicated less sensitivity to brodifacoum with an LC_{50} = 0.84 mg a.i./kg-diet). Animals were followed for 14 days after the starting the treated diet (5 days treated diet, followed by 9 days clean diet). All mortalities occurred between days 4 and 14 after the feeding of treated diet started. The majority of mortalities were between days 4 and 8. Although the study reports included data on body weight and food consumption, statistical analysis was not conducted for these parameters because of the high rate of mortality.

4.2.2.b. Mammals: Acute Exposure (Mortality) Studies

In a study that tested the brodifacoum product Talon®, fives foxes (four red, one grey), were fed ground rat meat contaminated with the chemical for 1, 3, or 4 days (MRID 00128422). The exposure period refers to the number of days the foxes were fed the contaminated rat meat. The rats were fed a diet of canned dog food for 12 days before being intubated with 600 g Talon on Day 13 and 400 g Talon on Day 14. The grey fox (*Urocyon cinereoargenteus*) died 9 days after the 3-day exposure period ended. One red fox (*Vulpes vulpes*) died 9 days after a 4-day exposure

period. The three remaining red foxes survived the treatment and observation period but showed slight to moderate hemorrhage as indicated by necropsy. Both foxes that died showed evidence of severe hemorrhage in necropsy. The study was classified as supplemental in that it provides an indication of secondary toxicity. Areas of uncertainty in the study were the unknown amount of Talon® ingested by the foxes as well as the possibly of further mortality in the study had the observation period been longer. Brodifacoum's mode of action is one where toxicity manifesting itself in clinical signs as well as mortality is delayed. Additionally, the test groups feeding for varying amounts of days consisted of differing numbers of animals species, and contaminated meat consumed (one fox consumed 154 g of meat in the 4-day treatment group while the other consumed 1600 g).

4.2.3. Toxicity to Terrestrial Invertebrates

No data are available on the toxicity of brodifacoum to terrestrial invertebrates.

4.2.4. Terrestrial Field Monitoring Studies

In a field monitoring study in which carcass searches were conducted for non-target animals resulting from the use of brodifacoum in the United Kingdom (MRID 00152102), Klerat® bait containing 50 ppm a.i brodifacoum was provided to 28 farmers (this product is not registered in the United States). They were given instructions on the use of the bait and the study conductors performed surveillance on 11 farms. The baiting instructions specified to keep placing bait until rodent activity ceased and provided distance intervals to place the bait. The surveillance efforts assessed the degree to which the bait was covered, the quantity of bait, the frequency of baiting, bait removal, how frequently non-target animals fed on bait, and locations of non-target corpses. These non-target corpses were collected and stored frozen until necropsy. The results of the study indicated that a total of 56 non-target animals (birds and mammals) suffered mortality during the study period. Although it was not clear from the study report when the baiting program began, the surveillance program was from December 1981 until January 1982. Two of the eleven farm use sites were in open fields while the remaining nine were around buildings. In all, 3 cats, 28 small birds of unknown species, 1 fox, 1 grey squirrel, 2 buzzards, 2 tawny owls, 1 rabbit, and 19 *Corvidae sp.* that includes crows, ravens, and magpies suffered mortality.

On one farm, the farmer reported three small bird mortalities while the study conductor did not find any carcasses. Furthermore, on three farms where the study conductor did not perform surveillance, 1 cat, 7 chickens, and 10 small birds of unknown species suffered mortality. Residues in the liver of animals found dead ranged from 0.04 (lower level of detection) to 3.8 ppm in birds and <0.04 to 2.1 ppm in mammals. The study, while demonstrating that both primary and secondary poisoning occurs to non-target birds and mammals, does not provide any analysis of potential population-level effects. The numbers of dead above ground rats were also significant (338 over the course of the study). While the rats were the target organisms, this substantial number would be available for scavenging and might also be attributed to some of the secondary poisonings observed in the study. This study was classified as supplemental as it does not fulfill any guideline requirements but does provide useful information.

In another field monitoring study conducted in the United Kingdom, (MRID 00152103), brodifacoum (Klerat®), was provided to farmers in a similar manner as the previously described study. This study followed 16 sites and involved the baiting of rats and mice. This study, unlike the previous one, instructed farmers to place the baits only in and close to infested buildings and not in the woods or open fields. The farmers were also instructed to conduct "pulsed baiting," which involves the placing of bait in small quantities at many points so that rodents are less likely to over consume the toxicant and more rodents can feed at once. During the surveillance visits, the treated areas were searched for carcasses and non-target animals were collected for later residue analysis.

Across the 16 farm sites, a total of 59 nontarget animas suffered mortality. These were categorized into 39 small birds (including domestic ducks, lapwing, pigeons, woodpigeons, robins, blackbirds, and jays, marions, and starlings), 1 magpie, 2 chickens, 2 pheasants, 3 rabbits, and 1 grey squirrel. The residues in the livers of the nontarget animals ranged from <0.05 (lower limit of detection) to 23 ppm. The conclusions from the study indicated that although primary and secondary poisoning occurred to nontarget birds and mammals in this study, very little secondary poisoning was observed following baiting around farm buildings compared to the rate of poisoning farther away from building and more in the field. The results of the study also do not adequately address population-level effects. This study is classified as supplemental in that it provides useful information but does not fulfill requirements for measuring population level effects.

A final related study to the (also conducted in the United Kingdom) two previously discussed field studies was a third field monitoring study (MRID 00152104) in which wax blocks with 50 ppm a.i were formed by pressing treated grains into blocks of wax. Ten farmers were supplied for use on 16 sites of which ten had surveillance performed by the study conductor. Pulsed baiting with the waxed blocks was performed and users were instructed to conceal bait and not to place it in wooded areas. Application took place starting November 11, 1983, and continued through the winter. The surveillance focused on placements of bait, the concealment of bait, the weathering of bait blocks, the frequency of feeding by non-target animals, the counts of non-target animals around the farm buildings, and carcass searches for target and non-target animals.

Results of the study suggest that primary and secondary poisoning occurred to birds and mammals, although not to extent observed for the previous two studies it was submitted with (MRID 00152102 and MRID 00152103). There were a total of 11 total nontarget animal deaths that amounted to 1 jay, 2 magpies, 2 carrion crows, 1 rabbit, 1 cat, 1 stoat, and 1 chaffinch. The residues of brodifacoum in animal livers ranged from 0.44 to 2.4 ppm for those birds and mammals considered to have died from anticoagulant effects. The conclusions from the study were that wax block formulations were of low palatability to non-target animals compared to the pelleted baits of the previous two field studies. This study was classified as supplemental as it does not fulfill any guideline requirements and not give an indication on population level effects.

4.3. Toxicity of Chemical Mixtures

Brodifacoum has no registered product that contains other active ingredients.

4.4. Incident Database Review

The following analysis of reported wildlife incidents for brodifacoum was presented as part of the previously mentioned Background Paper to the Science Advisory Panel (SAP).[21] Within that document, an extensive characterization, including categorization of incidents as primary or secondary exposure, where possible, of more than 260 reported wildlife incidents for brodifacoum was. Additionally, when possible, incidents were characterized by location, to determine whether they occurred in rural or urban/suburban areas. This approach was generally accepted by the SAP during the meeting that took place November – December 2011. The SAP noted uncertainties in characterizing exposure and location of incidents that are captured along with the general uncertainties of incident analysis below.

A review of the Ecological Incident Information System (EIIS, version 2.1), the „Aggregate Incident Reports' (v. 1.0) database, the Incident Database System (IDS), and the Avian Monitoring Information System (AIMS) for ecological incidents involving brodifacoum, was completed prior to the SAP meeting in the fall of 2011. A description of each database is found below, and the results of theses searches are tabulated in **Appendix D.**

4.4.1. Incident Databases Employed

Ecological incident reports entered into EFED's Ecological Incident Information System (EIIS) are generally from two main sources: pesticide registrants and state/local government offices. The majority of the reported incidents used for this analysis were provided by the states (predominantly New York and California); registrant submitted incidents make up a smaller number of reported incidents. Section 6(a)(2) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) requires that pesticide registrants report incidents of adverse effects that are linked to the pesticide products which they register; however, relatively few wildlife mortality incidents have been reported to the EPA by registrants of brodifacoum products used for commensal rodent control. This could be due to reporting requirements for registrant changing in the late 1990's that lowered the threshold for numbers of dead animals involved in an incident to report. Instead, most brodifacoum incidents that have been reported to the Agency have been submitted by state government agencies that are responsible for investigating such incidents.

Incidents recorded in EIIS were cross-referenced with those found in the Incident Data System (IDS). The IDS database, unlike EIIS (maintained by EFED), is maintained by the Information Technology and Resources Management Division (ITRMD) of OPP. IDS tracks incident reports submitted by registrants in compliance FIFRA section 6(a)(2) regulations as well as incident reports that are obtained from other sources, such as offices of state governments. In most cases, incidents within the EIIS corresponded with an incident report recorded in IDS.

The Avian Incident Monitoring System[22] (AIMS), an on-line database of pesticide-related avian incidents that is maintained by the American Bird Conservancy, was also consulted, but no unique brodifacoum incidents were identified in this database that were not in EIIS.

[21] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0718-0006
[22] http://www.abcbirds.org/abcprograms/policy/toxins/aims/aims

4.4.2. Uncertainties associated with ecological incidents

Interpretation of incident data is difficult and may be confounded by a number of factors. Because of the delayed toxicity of brodifacoum, the discovery of animals that are poisoned is affected, both spatially and temporally, from the exact site of brodifacoum use. Therefore, when a dead animal poisoned by a brodifacoum is discovered, there is often no suspicion at that time that an animal died as the result of exposure to the chemical. Typically, only when the mortality is reported to some authority, usually a state fish and wildlife office, and that office conducts an investigation to diagnoses the cause of death, is the incident linked to brodifacoum exposure.

Many steps must successfully occur for a pesticide-related wildlife kill to be reported to the EPA. First, the animal killed must be observed. Since brodifacoum incidents usually involve only one or a few animals per incident, they likely often go unnoticed. Carcasses of poisoned wildlife are often difficult to observe because the animals actively seek cover before dying, or may happen to die in an area where they are obscured by vegetation (Vyas, 1999). Furthermore, studies have shown that the majority of bird carcasses are removed by scavengers within one day (Balcomb, 1986; Wobeser and Wobeser, 1992), thus there often may be only a short window of opportunity for wildlife carcasses to be observed. Wildlife kills also must be reported to the appropriate wildlife agency or organization which is capable of diagnosing the cause. That agency or organization must have a program in place for investigating wildlife kills through conducting necropsy examinations and conducting residue analysis of tissue samples, and must have adequate funding available to pay for the analysis. The residue analysis must include an analysis for the chemical that caused the poisoning and the methodology must be adequate to detect the ingredient at the levels present in the tissue. Finally, the agency or organization must document the incident into a report and that report must be made available to the EPA. If any of these steps fail to take place, the incident will not be known to the EPA. Furthermore, the nature of brodifacoum incidents is that only one or a few dead animals are typically discovered per incident. Even if several non-target animals are poisoned by brodifacoum, the carcasses of the killed animals would likely be widely scattered. Mortality incidents involving one or a few animals are less likely to be observed, reported, and investigated than ones involving large numbers of animals. For these reasons, the Agency believes that the brodifacoum-related wildlife incidents reported here represent only a fraction of the incidents which are occurring.

Only states which have personnel and resources devoted to investigating and reporting on wildlife mortality incidents report such incidents to the EPA. Only two states, New York and California, have had programs that have systematically reported wildlife mortality incidents, and thus are responsible for the majority of the Agency's known brodifacoum incidents. Most of the incidents have been reported from only two states, New York and California, which have had effective and well-funded incident investigation and reporting programs. Reporting of wildlife incidents in many states have been inconsistent because of sporadic funding of wildlife programs. Many states have never reported any brodifacoum-related wildlife mortality incidents to the EPA.

Changes in the level of effort that states devote to monitoring and reporting wildlife incidents change overtime due to a changes of resources. During the late 1990's, many dead birds were collected and analyzed by some state and local health departments as part of surveillance for

West Nile virus, resulting in a temporary increase in incident reporting during those years. Reporting of brodifacoum-related incidents decreased after these West Nile virus surveillance programs were discontinued. In recent years, reductions of state budgets has impacted funding for state programs that are responsible for investigating wildlife mortality incidents, further reducing the incident reporting rates.

Reporting of brodifacoum-related wildlife incidents by pesticide registrants has also decreased. Changes made in 1998 to the FIFRA 6(a)(2) relaxed reporting requirements and resulted in reduced numbers of incident reports submitted by registrants. Registrants are now only required to submit individual reports on "major" wildlife incidents, whereas "minor" wildlife incidents may be reported only as aggregated counts without information on the individual events. Specifically, these "major," incidents are classified by 200 or more individuals in avian flocking species, or 50 or more avian songbird species, or 5 or more in a predatory species. "Major," mammalian incidents are classified as such as having 50 or more individuals in a relatively common or herding species or 5 or more in a predatory species. Since no information is generally provided on individual minor incidents, these incidents cannot be entered in the EIIS database and are not included in analyses based on EIIS data. The majority of brodifacoum-related incidents fall into the "minor" category of the 6(a)(2) rule because they involve mortality of only one or a few individual animals.

An important note, and one confirmed by the SAP, is that the presence of incidents demonstrates that one or more complete exposure pathways resulting in an effect (i.e. mortality) exists. The presence of fewer incidents in and of itself from one chemical to another does not necessarily suggest that one chemical is safer than another. Furthermore, incidents cannot be used to quantify risk, that is, if as chemical has more incidents than another, that chemical cannot be determined to be more risky. However, incident data can corroborate results from the deterministic risk assessment presented in this assessment. In addition, the incident data were used in this assessment to describe general land use patterns where effects have occurred and to describe whether mortality has been reported for different exposure types (e.g., primary exposure vs. secondary exposures).

An incident report within EIIS will have information about the legality of use (*e.g.*, registered use or a misuse), certainty (how certain a particular pesticide caused the incident), and use location associated with that incident. The legality index refers to the determination of the incident investigation as to whether the brodifacoum use linked to the incident was in compliance with the label. In all but 25 of the incidents evaluated for this report, the legality was "undetermined," generally because information was not available to linking the incident to a specific product and use. A few incidents were excluded from the analysis because they were associated with intentional misuse of brodifacoum, primarily because products labeled for commensal rodent controls were intentionally used to control pest species not on the label, such as squirrels.

4.4.3. Characterizing Incidents

A certainty index was assigned for each active ingredient linked to each incident. The certainty index indicates the likelihood that a particular ingredient was the cause of the adverse effects

observed in the incident. Certainty index values range from "unlikely" to "highly probable" "Unrelated" is also a certainty category used in EIIS but incidents with this certainty value were excluded from the analysis. In many cases, the certainty index value was determined by the wildlife pathologist who performed the necropsy and compiled the chemical residue analysis results (where applicable). In incidents where the certainty determination was not provided in the submitted report, staff of EFED assigned the certainty index based on tissue residue data and other diagnostic and circumstantial evidence provided in the incident report. However, whenever the submitted report included a certainty conclusion made by the wildlife pathologist who investigated the incident, this conclusion was never altered.

Reported incidents for brodifacoum were summarized as counts of reported incidents and compiled based on three variables: exposure type (primary or secondary), certainty level, and location (rural/field versus urban/suburban). The certainty levels indicate the likelihood that brodifacoum caused the effects observed in the animal. These levels were assigned to the incidents by the EPA when the incident records were entered into EIIS. For this analysis, incidents were further categorized by exposure type and location using the methods described in the next section. The purpose of the exposure type categorization was to evaluate how many of the incidents were likely related to primary exposure, *i.e.* animals directly consuming the brodifacoum bait, versus secondary exposure, *i.e.* animals consuming other animals that ingested the bait and had detectable levels of brodifacoum residues in their bodies. The purpose of the location categorization was to evaluate the occurrence of incidents in urban/suburban areas, which are thought to be predominantly related to residential and commercial uses, versus incidents that occurred in rural/field areas. The analyses performed in this section focuses on incidents that have been reported in the United States alone.

4.4.4. Characterizing Incidents as Primary and Secondary Exposure

An attempt was also made to characterize the exposure type of each incident as either "primary" or "secondary." Primary exposure refers to incidents where the animal was exposed to brodifacoum through direct consumption of bait, whereas secondary exposure refers to incidents where animals prey or scavenge on other animals which consumed brodifacoum bait. This designation was based primarily on the diet of the species affected. For example, raptors such as owls, hawks, and eagles were assigned an exposure code of "S" (secondary) due to their carnivorous feeding habits and the likelihood that they preyed or scavenged upon a brodifacoum-exposed animal. In contrast, strict herbivores such as squirrels and deer were assigned "P" (primary) because they likely fed on the bait directly. For omnivorous species such as crows, raccoons, and opossums, for which the exposure could have been either primary or secondary, the findings of the necropsy analysis information on the gastrointestinal (GI) tract contents were consulted when available. When the GI tract contents contained granules or material resembling bait, probable primary exposure was assigned. When the necropsy analysis noted bone fragments or tissues of another organism in the GI tract, probable secondary exposure was assigned. Finally, when the incident involved an omnivorous species and the necropsy report provided no useful information on the contents of the GI tract, unknown exposure was assigned. For simplicity, *Probable Primary* and *Probable Secondary* incidents were combined with *Primary* and *Secondary* incidents, respectively, in counts shown in the summary tables and charts (**Tables 4-7 and 4-8**.)

4.4.5. Characterizing the Location of Incidents

One question that was investigated through analysis of incident data is whether use of brodifacoum baits by homeowners and businesses to control commensal rodents in urban and suburban areas pose a hazard to non-target wildlife. This question was investigated by considering the locations of the reported incidents relative to urban, suburban, and rural areas. When possible, the locations of incidents were categorized as being "urban/suburban" or "rural" based on the location where the affected animals were found. This categorization was often based on information provided in the incident report on the land use type of the site of the incident and is recorded in the *Habitat* field of EIIS. In some instances, this field was entered as "not reported" (N/R) due to lack of information. In other cases, the location category was often determined from information given in the wildlife pathologist report on the location where the carcass was picked up. In some reports, the actual address of the site of the incident was provided. In those instances, the address was located using mapping software to ascertain its proximity to developed areas. A few incidents, including ones that occurred from use in zoos or from use in island rat eradication programs, were not considered representative of either typical urban or rural areas and thus were pooled with the "not reported" incidents.

Counts of reported wildlife mortality incidents occurring in the United States, which are attributed to exposure to brodifacoum are provided below (**Table 4-7**). Incident counts are based on three factors, (1) whether the exposure was believed to be primary or secondary (or unknown), (2) whether the incident occurred in a rural or urban/suburban location (or unknown), and (3) the certainty level assigned indicating the likelihood that the given active ingredient was the cause of the incident. Because some incidents involve the death of multiple animals, **Table 4-8** provides a summary of the number of mortalities observed in incidents attributed to brodifacoum. A summary of each of these incidents included in these counts are provided in **Appendix D**.

Table 4-7. Summary of Wildlife Incidents Linked to Brodifacoum Exposure.

Exposure	Location	Possible	Probable	Highly Probable	Total
Primary	Rural	1	0	3	4
	Urban/Suburban	1	8	25	34
	Unknown	0	5	1	6
	Total	2	13	29	44
Secondary	Rural	5	9	36	50
	Urban/Suburban	7	29	61	97
	Unknown	5	12	22	39
	Total	17	50	119	186
Unknown	Rural	4	2	2	8
	Urban/Suburban	1	5	13	19
	Unknown	3	1	1	5
	Island (rat eradication)	0	0	2	2

Table 4-7. Summary of Wildlife Incidents Linked to Brodifacoum Exposure.

Exposure	Location	Possible	Probable	Highly Probable	Total
	Other (Zoo)	0	2	1	3
	Total	8	10	19	37
Grand Total		27	73	167	**267**

An important consideration when examining the incident data is that one reported wildlife mortality incident does not necessarily correspond with a single dead animal. Several of the brodifacoum incidents involved multiple animals of the same species and sometimes multiple animals of different species. The counts of individuals affected are tabulated below in **Table 4-8.**

Table 4-8 Summary of Number of Mortalities (Total Number of Individuals Affected) in Wildlife Incidents Linked to Brodifacoum Exposure

Exposure	Location	Possible	Probable	Highly Probable	Total
Primary	Rural	0	0	10	10
	Urban/Suburban	0	10	40	50
	Unknown	1	12	1	14
	Total	1	22	51	74
Secondary	Rural	4	14	49	67
	Urban/Suburban	6	24	55	85
	Unknown	4	12	32	48
	Other (Golf Course, Military base)	0	1	1	2
	Total	14	51	137	202
Unknown	Rural	4	29	6	39
	Urban/Suburban	1	5	10	16
	Unknown	4	1	3	8
	Other (Zoo)	0	28	5	33
	Total	9	63	24	96
Grand Total		24	136	212	**372**

Primary Exposure Incidents

Many wildlife mortality incidents have been attributed to primary poisoning by brodifacoum, and the majority of the primary incidents have been linked to rodenticide poisoning with high certainty. Of the 35 incidents which were attributed to primary poisoning, all but one has a certainty index rating of "probable" or "highly probable." Most of these incidents have involved deer, squirrels, chipmunks, and passerine birds, all of which are believed to have been poisoned by directly consuming brodifacoum bait. Of the 35 primary-exposure incidents, 25 (71%) were identified as occurring in urban or suburban/residential areas. This indicates that use of brodifacoum as a

rodenticide represents a complete exposure pathway for non-target wildlife via primary exposure that can result in mortality for birds and mammals.

Stone et al. (1999) reported on six primary poisoning incidents of white-tailed deer which occurred on Fire Island, a barrier island on the south shore of Long Island, NY. Four of the incidents were associated with brodifacoum and two were associated with diphacinone. The incidents were believed to have resulted from outdoor residential use of rodenticides by homeowners on the island. They concluded that the risk of deer ingesting rodenticide bait is high in suburban residential areas like Fire Island where favorable habitat and restriction of hunting creates high deer density, and thus the population food limited. A similar situation occurred in the winter of 2008 on Big Pine Key in southern Florida, where the death of three key deer (*Odocoileus virginianus clavium*) was linked to exposure to anticoagulant bait placed by homeowners in the area (EIIS Incident I020713-002). Surveys of wildlife mortality following the use of brodifacoum by the USFWS for rat eradication on islands also has documented mortality of birds of species which would likely have been exposed by primary exposure (*e.g.* emperor goose, gray-crowned rosy finch, and rock ptarmigan), although the majority of mortality was to species which could have been exposed by secondary exposure (Ornithological Council, 2010).

Secondary Exposure Incidents

Analysis of incident reports attributed to brodifacoum exposure show 186 incidents associated with secondary exposure. The majority of these incidents (164 out of 186, 88%) had high certainty for being caused by brodifacoum, with a certainty index value of "probable" or "highly probable." This is because most of the incidents were identified by the presence of brodifacoum residues in the liver of the poisoned species, often along with supporting evidence of anticoagulation poisoning from the necropsy examination. Species that were most often killed in the available reports include a wide variety of raptors, including many species of hawks, eagles, and owls, as well a variety of predatory and scavenger mammals, including foxes, coyotes, bobcats, and mountain lions. Brodifacoum has no labeled field uses and is currently only labeled for use to control commensal rodents; therefore, these incidents show that use of brodifacoum for control of commensal rodents can result in secondary poisoning of raptors and canine predators which commonly feed on rodents.

Incidents of wildlife mortality from secondary exposure to brodifacoum have been reported throughout the United States. The largest numbers of reported incidents have been from New York and California, which is thought to be due to the presence of a more comprehensive or systematic programs for investigating and reporting pesticide-related wildlife incidents in those states than in other states. States other than New York and California that have reported secondary exposure incidents for rodenticides included in the rodenticide NOIC include Florida, Georgia, Virginia, Massachusetts, Wisconsin, and Kansas. Additionally, incidents of widespread wildlife mortality attributed to secondary exposure to rodenticides have been documented in numerous other countries, including Canada (Albert et al., 2009), France (Berny et al., 1997), Britain (Shore et al, 1999), and New Zealand (Eason et al., 2001, Dowding et al., 2006).

A spatial analysis of brodifacoum incidents reported in California (all of which were attributed to secondary exposure) also showed a similar pattern, with numerous incidents reported in or near

the metropolitan areas of Los Angeles, San Francisco, and Sacramento (**Figure 4-1**). Most of the reported secondary poisoning incidents were located in counties with dense human population, and the majority occurred near major metropolitan areas such as Los Angeles, Santa Barbara, San Francisco, and Sacramento. Other incidents with exact location information are scattered throughout the state but generally occur in areas that have moderate to high population densities as indicated by the legend on the California map.

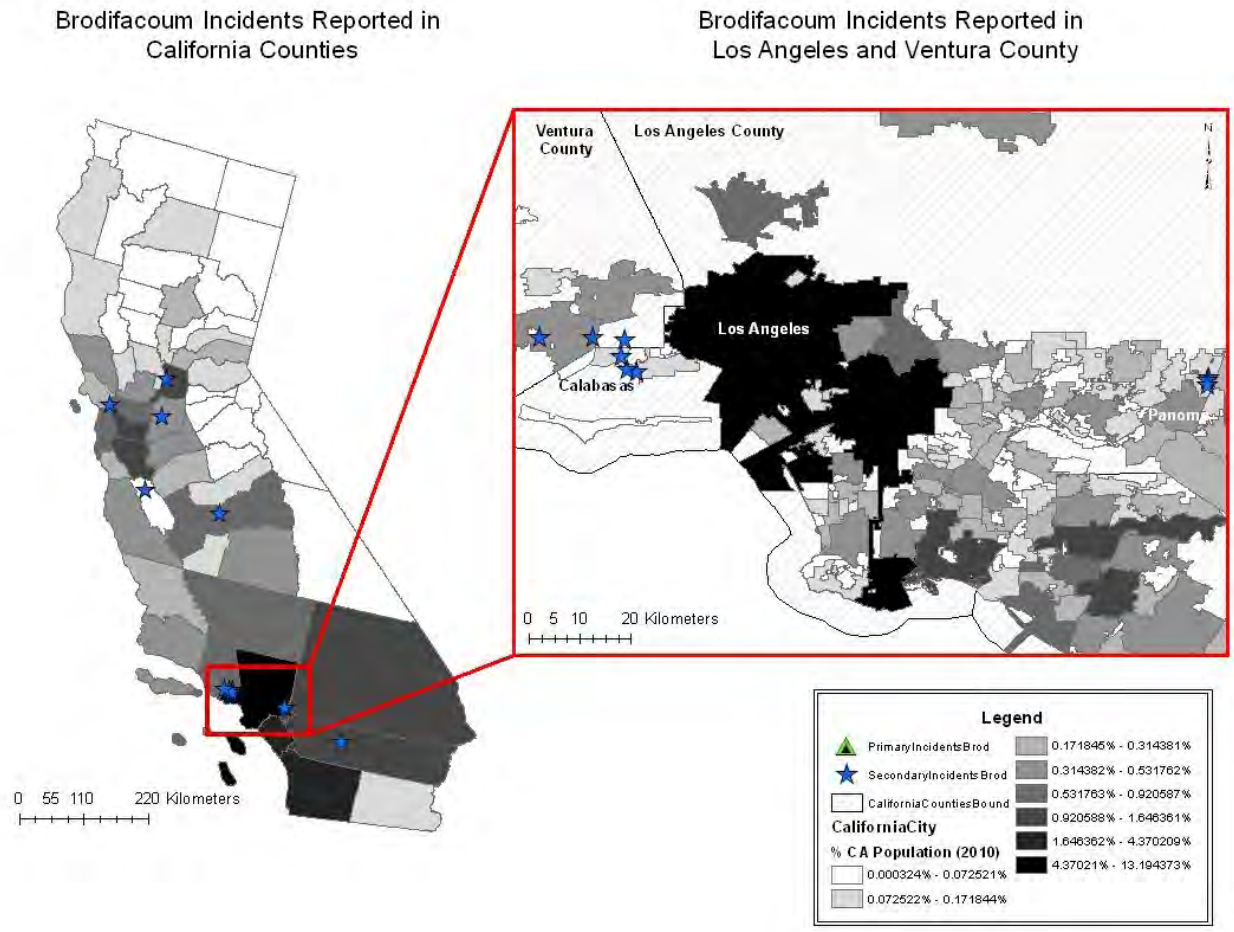

Figure 4-1. Distribution of wildlife mortality incidents attributed to brodifacoum reported in California.

Other researchers who have studied wildlife mortality incidents caused by anticoagulant rodenticides have also reported a greater number of incidents in highly populated areas than in rural or agricultural areas. Stone et al. (2003) found that 39% of positive cases of rodenticide mortality of raptors in the state of New York between 1998 and 2001 occurred in the New York City/Long Island region, which agrees with our spatial analysis of brodifacoum incidents in New York State. The authors of this paper stated that "urban and suburban origins were more common than rural origins," although noted that the difference could be at least in part due to greater probability of discovery and reporting of incidents in heavily populated areas. Murray (2011) reports on cases of anticoagulant poisoning of wildlife investigated by a wildlife clinic in central Massachusetts between 2006 and 2010. Of the nine raptors they positively identified as being killed by brodifacoum intoxication, six were found in urban areas, two from suburban

towns, and one from a farm. A study of anticoagulant rodenticide exposure in owls from Western Canada from 1998 through 2003 found that the majority of owls (42%) with positive detections of rodenticides came from the Upper Fraser Valley, and area characterized with relatively high population as well as intensive agriculture. The highest brodifacoum liver residue was observed in a barred owl (*Strix varia*) from an urban area in West Vancouver, and the highest bromadialone liver residue was observed in a barred owl from Surrey, and suburb of Vancouver. Finally, Lima and Salmon (2010) studied the distribution of detections of anticoagulant rodenticides in raptor carcasses collected in San Diego County and the largely agricultural counties of Fresno, Kern, and Madera. A spatial analysis of the location of raptor incidents found an association of carcasses with positive detections of SGAR with locations in urban areas with higher population density, a pattern similar to the one observed with wildlife mortality incidents in this current paper.

The most likely cause of secondary poisoning of wildlife is from predatory and scavenger animals consuming rats and mice that have been contaminated by consumption of bait containing anticoagulant rodenticides. In several of these incidents, remains of a dead rat or mouse was found either in the gastrointestinal tract of the poisoned animal, or near the site where the carcass was found. Most of the animals which have been poisoned in these incidents are species of owls, hawks, foxes, bobcat, or coyote (*Canis latrans*), all of which feed extensively on small mammals. Poisoning of two mountain lions (*Felis concolor*) in Simi Hills area near Los Angeles was suspected of being caused by tertiary poisoning when the lions consumed a coyote which had in turn consumed rodents poisoned by brodifacoum and bromodialone (Riley et al., 2007). In investigating the mortality of New Zealand dotterels (*Charadrius obscures*) following an application of brodifacoum for in a rat eradication program in New Zealand, Dowding et al. (2006) found that sandhoppers (*Talorchestia* spp.), a terrestrial crustacean commonly found on beaches, accumulated brodifacoum and served as a potential route of secondary exposure to the dotterels and other birds which feed on them. Also, some of the mortality of captive birds at the Philadelphia Zoo which followed use of a rodenticide bait stations containing brodifacoum was suspected of being caused by the birds consuming insects which had consumed bait from the stations (EIIS incidents I011274-001 and I011274-001).

Of particular relevance to this assessment is a study conducted by McMillin et al (2008). In this study the California Department of Fish and Game's Pesticide Investigations Unit (in conjunction with the Endangered Species Recovery Program's Urban Kit Fox Project) monitored San Joaquin Kit Foxes monitored from a Bakersfield, CA population. This study corresponds with the EIIS incident number I016100-001. Necropsies and liver tissue samples were collected from kit fox carcasses. A non-urban population of kit foxes from Lokern Natural Area (a 40,000 acre habitat 30 miles west of Bakersfield) was used as a control. Between 1999 and 2007, tissue samples from various animals were analyzed for residues of anticoagulant rodenticides. The fox carcasses were part of an ongoing monitoring effort dating back to 1977 from which 10-20 carcasses are collected from both the Bakersfield and Lokern area per year. The compounds identified included brodifacoum and chlorophacinone. Out of the 30 San Joaquin Kit Foxes analyzed from the Bakersfield population, 27 contained at least one anticoagulant and the most commonly detected from that set was brodifacoum (26 out of 30 or 87%). Chlorophacinone residues were detected in one fox (3%). All control foxes from the Lokern population had no

anticoagulant residues detected. The authors report that results from this study confirm that San Joaquin Kit Foxes are exposed to anticoagulants in urban environments.

Unknown Exposure Incidents

An additional 37 incidents could not be identified as being caused by primary or secondary poisoning. Most of these incidents were of omnivorous species which potentially could have consumed either the bait directly or a living or dead animal which had fed on the bait. The most common species in this group are the American crow (*Corvus brachyrhynchos*), the red fox (*Vulpes vulpes*), the gray fox (*Urocyon cinereoargenteus*), and the raccoon (*Procyon lotor*). These incidents were also associated with residential and commercial uses of bait, with 19 of the 39 incidents (49%) occurring in areas identified as urban or suburban, whereas only 10 out of 39 (26%) occurred in areas identified as rural. The location could not be characterized in the remaining 10 incidents.

In conclusion, available incident data show that brodifacoum has been associated with a number of incidents of secondary poisoning of wildlife throughout the United States, which suggests that commensal use of brodifacoum represents a complete exposure pathway for non-target predators and scavengers. Finally, primary and secondary exposure incidents were reported in both urban and suburban areas.

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

The Agency uses the probit dose response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (USEPA, 2004). As part of the risk characterization, an interpretation of acute RQs for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (*i.e.*, mortality or immobilization) should exposure at the EEC actually occur for a species with sensitivity to brodifacoum on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency uses the slope of the dose response relationship available from the toxicity study used to establish the acute toxicity measures of effect for each taxonomic group that is relevant to this assessment. The individual effects probability associated with the acute RQ is based on the mean estimate of the slope and an assumption of a probit dose response relationship. In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects probability are also provided to account for variance in the slope, if available. The upper and lower bounds of the effects probability are based on available information on the 95% confidence interval of the slope. A statement regarding the confidence in the estimated event probabilities is also included. Studies with good probit fit characteristics (*i.e.*, statistically appropriate for the data set) are associated with a high degree of confidence. Conversely, a low degree of confidence is associated with data from studies that do not statistically support a probit dose response relationship. In addition, confidence in the data set may be reduced by high variance in the slope (i.e., large 95% confidence intervals), despite good probit fit characteristics. In the event that dose response information is not available to estimate a slope, a default slope assumption of 4.5 (lower and upper bounds of 2 to 9) (Urban and Cook, 1986) is used.

Individual effect probabilities are calculated based on an Excel spreadsheet tool IEC v1.1 (Individual Effect Chance Model Version 1.1, June 22, 2004) developed by the U.S. EPA, OPP, Environmental Fate and Effects Division. The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the acute RQ is entered as the desired threshold.

5. Risk Characterization

Risk characterization is the integration of the exposure and effects characterizations. Risk characterization is used to determine the potential for direct and/or indirect effects to the AW, SMHM, and SJKF or for modification to the AW designated critical habitat from the use of brodifacoum in California. 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 modification of their designated critical habitat (*i.e.*, "no effect," "likely to adversely affect," or "may affect, but not likely to adversely affect"). In the risk estimation section, risk quotients are calculated using standard EFED procedures and models. In the risk description section, additional analyses may be conducted to help characterize the potential for risk.

5.1. Risk Estimation

Risk is estimated by calculating the ratio of exposure to toxicity. This ratio is the risk quotient (RQ), which is then compared to pre-established acute and chronic levels of concern (LOCs) for each category evaluated **(Appendix C**). For acute exposures to the listed birds (and thus, reptiles and terrestrial-phase amphibians) and listed mammals, the LOC is 0.1. The avian and mammalian non-listed species LOC is 0.5.

5.1.1. Exposures in the Terrestrial Habitat

5.1.1.a. Direct Effects to the SMHM (via primary exposure) and to the AW and SJKF (via secondary exposure)

As previously discussed in **Section 2**, potential direct effects to terrestrial species are based on bait applications of brodifacoum for use in and around homes and residential buildings, industrial, commercial and public buildings, food processing facilities, transport vehicles (ships, trains, aircraft) and their related ports, in and around agricultural buildings, alleys and sewers.

Potential risks to birds, mammals, reptiles, and terrestrial-phase amphibians were evaluated for both primary and secondary exposure. Primary exposure was based on the animal directly consuming the brodifacoum bait (which was assumed for the SMHM) and has indirect ramifications for the AW and SJKF as through reduction in prey. This section focuses on direct effects to the SMHM through primary exposure (direct consumption of brodifacoum bait) and to the AW and SJKF through secondary exposure, that is, consuming a bird, mammal, or reptile that has directly ingested brodifacoum bait. Although not confirmed by research, the probability of the AW and SJKF, which typically eat live prey, consuming brodifacoum bait pellets is

believed to be low; therefore, this route of exposure was not estimated for the AW and SJKF. As the exposure information from the literature and the ecological incidents in this assessment have shown, brodifacoum maintains a high level of lethality in a primary consumer's tissues that are available for secondary consumers like the AW and SJKF.

Direct effects to the SMHM (through Primary Exposure)

As discussed in **Section 3.3.1**, the SMHM is likely to be exposed to brodifacoum residues from primary exposure that occurs from direct ingestion of brodifacoum bait. Bait with one concentration of brodifacoum was modeled, 0.005%.

Acute dose-based risk quotients were calculated by dividing the expected dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for Richardson's ground squirrel, 0.13 mg-a.i./kg-bw (**Table 4-7**). Results of these calculations are presented in **Table 5-1**.
These RQs represent risk of direct effects to the SMHM mediated through effects on small mammals.

Table 5-1. Dose-Based Acute RQs for Effects to the SMHM from Consumption of Brodifacoum Bait

Mammal (bodyweight)	Bait Type	%AI	FI[1] (g/d)	Dose (mg/kg-bw)	Acute RQ[2]
SMHM (10 g)	Rodent Control	0.005	2.28	11.4	**87.7**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the FI and the Richardson's ground squirrel oral LD_{50} of 0.13 mg/kg-bw.

Since the acute RQs for the SMHM exceeded the LOC (RQ of **87.69**) for listed and non-listed species, use of brodifacoum has the potential to cause direct effects to the SMHM.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (a default slope of 4.5 was used (as the study did not provide one), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a SMHM consuming brodifacoum bait. The individual probability of death is 100% (1 in 1) for SMHM that ingested brodifacoum bait.

Dietary-based RQs for the SMHM (presented in **Table 5-2**) which consume brodifacoum bait were also calculated by simply dividing the concentration of brodifacoum in the bait by the subacute dietary LC_{50} value for the albino rat (0.53 mg a.i./kg-diet). The brodifacoum concentrations in the bait, when expressed as parts-per-million (mg-a.i./kg), is 50 for rodenticide bait. Therefore, the dietary RQs for direct effects resulting from toxicity to mammals is **94.3** for rodenticide bait.

Table 5-2. Dietary-based Acute RQs for the SMHM from Consumption of Brodifacoum Bait

Size (bodyweight)	%AI	Diet-based Acute RQ[1,2]
SMHM (10 g)	0.005	**94.3**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Based on the FI and the Richardson's ground squirrel oral LD_{50} of 0.13 mg/kg-bw.
[2] Based on the %AI of the bait and the albino rat dietary LC_{50} of 0.53 mg/kg-diet.

Because the acute risk quotient for mammals exceed the Agency's listed and nonlisted species LOCs (dose-based acute RQs of **87.7** and diet-based acute RQs were **94.3**), use of brodifacoum has the potential to cause direct effects to the SMHM. Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose and dietary-based RQs for primary exposure to the SMHM would be **43.9 and 47.2**, respectively (current RQs divided by 2, that is, half the percent a.i.) and still in exceedance of the listed and non-listed species LOCs.

There were no chronic mammalian risk quotients that could be calculated because toxicity data on the chronic effects of brodifacoum to mammals are not available.

Direct effects to the AW and SJKF (through Secondary Exposure Consuming Mammals)

As discussed in **Section 3.3.2**, the AW and SJKF are likely to be exposed to brodifacoum residues from secondary exposure that occurs from consumption of prey that has consumed brodifacoum bait. The AW and SJKF are capable of consuming all of the target small mammals species specified on the brodifacoum bait product labels, including rats and mice. Assumed body weights of these prey species were 485 g for the Norway rat and 23 g for the house mouse for the AW.

The amount of active ingredient the prey was assumed to ingest was also the dose, in mg, which the AW was assumed to ingest. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg a.i./kg bw. Finally, the acute secondary exposure risk quotients for the AW were calculated by dividing the predicted dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the most sensitive bird species, 0.26 mg-a.i./kg-bw, which is a surrogate value to represent the snake. Results of these calculations are presented in **Table 5-3.**

Table 5-3. Dose-based RQs for Acute Effects to the AW from Consumption of Mammals which Ingested Brodifacoum Bait

Bait Type	Prey Species	Assumed weight of AW	%AI in Bait	Prey FI[1] (mg/d)	Dose (mg a.i./kg BW)	Acute RQ[2]
Rodent control	Norway rat (485 g)	322 g	0.005	20.3	3.15	**12.1**
	House mouse (23 g)	18.6 g	0.005	3.64	9.78	**37.6**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the dose in the ingested prey and the avian acute oral LD_{50} of 0.26 mg/kg-bw; Richardson's ground squirrel oral LD_{50} of 0.13 mg/kg-bw.

Because the acute RQs for secondary exposure exceed 0.1 (RQs ranged from **12.1 – 37.6**), the LOC for acute effects to listed species, use of brodifacoum has the potential to directly affect the AW that feeds upon small mammals which ingested brodifacoum bait, by way of secondary exposure.

For mammals consuming other mammals that have ingested brodifacoum bait (*i.e.*, the SJKF consuming rodents or other small mammals), a different method of estimating exposure was employed than for the AW. As an equation for estimating the size of a mammal based on its prey size does not exist as it does for snakes, T-REX was used to estimate the ingestion rate for a given size mammal to consume to achieve its nutritional needs as discussed in **Section 3.3.2**.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the AW consuming mammals would range from **6.1 to 18.8**, depending on the size of the prey item (current RQs divided by 2, that is, half the percent a.i.) and still exceed of the listed and non-listed species LOCs.

When the dose based EEC (as derived in **Section 3.3.2**) is divided by the adjusted LD_{50} of 0.34 mg a.i/kg for the 244-g mammal, the resulting RQ is **4.41** (**Table 5-4**).

Table 5-4. Dose-based RQs for Acute Effects to the SJKF from Consumption of Mammals which Ingested Brodifacoum Bait

Bait Type	Prey Species	Assumed weight of SJKF	%AI in Bait	Dose received by prey FI[1] (mg a.i./d)	Dose-based EEC for SJKF (mg a.i./kg BW)	Adjusted LD_{50} (mg a.i./kg BW)	Acute RQ[2]
Rodent control	Small mammal (244 g)	2300 g	0.005	1.72	1.5	0.34	**4.41**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] As estimated by the product of the ingestion rate of a 244 g small mammal and the mg a.i. of brodifacoum in the bait (50 mg a.i.)

[2] Based on the dose-based EEC in the ingested prey and the adjusted LD_{50} of a 2300-g mammal of 0.34 mg/kg-bw

Since the acute RQ for secondary exposure exceeds 0.1, the LOC for acute effects to listed species, use of brodifacoum has the potential to directly affect the SJKF that feeds upon small mammals which ingested brodifacoum bait, by way of secondary exposure.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (a default slope of 4.5 was used as the original study report did not provide one), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a SJKF consuming a small mammal. The individual probability of death is 100% (1 in 1) for a SJKF consuming a small mammal that ingested brodifacoum bait.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the SJKF consuming mammals would be **2.2** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs.

Direct effects to the AW and SJKF (through Secondary Exposure Consuming Birds)

The AW and SJKF are likely to be exposed to brodifacoum residues from secondary exposure that occurs from consumption of prey that has consumed brodifacoum bait. The AW and SJKF are capable of consuming birds as prey that may have directly ingested brodifacoum bait. Therefore, risk based on secondary exposure was conducted for a snake and mammal which feeds on birds, as discussed in **Section 3.3.2**.

To assess the maximum exposure that an AW could receive through secondary exposure, 100% of the active ingredient which was ingested by the bird prey was assumed to be present in the animal when it was consumed by the snake. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg a.i./kg bw. Finally, the acute secondary exposure risk quotients were calculated by dividing the predicted dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the most sensitive bird species, 0.26 mg-a.i./kg-bw, which is used as a surrogate for snake. Results of these calculations are presented in **Table 5-5.**

Table 5-5. RQs for Acute Effects to the AW from Consumption of Birds which Ingested Brodifacoum Bait

Bait Type	Prey Species	Assumed weight of AW	%AI in Bait	Prey FI[1] (mg/d)	Dose (mg a.i./kg BW)	Acute RQ[2]
Rodent control	Small bird (20 g)	16.2	0.0050	4.55	14.04	**54.0**
	Medium Bird (100 g)	74.1	0.0050	13.00	8.77	**33.7**
	Large Bird (1000 g)	631	0.0050	58.1	4.60	**17.7**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the dose in the ingested prey and the avian acute oral LD_{50} of 0.26 mg/kg-bw

Because the acute RQs for secondary exposure exceed 0.1 (RQs ranged from **17.7 – 54.0**), the LOC for acute effects to listed species, use of brodifacoum has the potential to directly affect the AW that feed upon birds which ingested brodifacoum bait by way of secondary exposure.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the AW consuming birds would range from **8.9 – 27.0** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to birds (a slope of 3.0 was used per the study report), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for an AW consuming a contaminated bird. The individual probability of death is 100% (1 in 1) for an AW consuming either a small, medium, or large bird that ingested brodifacoum bait.

For mammals consuming birds that have ingested brodifacoum bait (*i.e.*, the SJKF consuming birds), a different method of estimating exposure was employed than for the AW. As an equation for estimating the size of a mammal based on its prey size does not exist as it does for snakes, T-REX was used to estimate the ingestion rate for a given size bird to consume to achieve its nutritional needs as discussed in **Section 3.3.2**.

When the dose-based EEC (as derived in **Section 3.3.2**) is divided by the adjusted LD_{50} of 0.20 mg a.i/kg for the 244-g bird, the resulting RQ is **12.6** (**Table 5-6**). This RQ exceeds the acute endangered species and acute non-listed species LOCs and therefore there is the potential for indirect effects to the SJKF that have consumed mammals which have ingested brodifacoum bait.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the SJKF consuming birds would be

6.3 (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs.

Table 5-6. RQs for Acute Effects to the SJKF from Consumption of Birds which Ingested Brodifacoum Bait

Bait Type	Prey Species	Assumed weight of SJKF	%AI in Bait	Dose received by prey [1] (mg a.i./d)	Dose-based EEC for SJKF (mg a.i./kg BW)	Adjusted LD_{50}	Acute RQ[2]
Rodent control	Bird (244-g)	2300 g	0.005	5.8	2.52	0.20	**12.6**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] As estimated by the product of the ingestion rate of a 244 g bird and the mg a.i. of brodifacoum in the bait (50 mg a.i.)
[2] Based on the dose-based EEC in the ingested prey and the adjusted LD_{50} of a 244-g bird of 0.20 mg/kg-bw

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (Richardson's ground squirrel) (a default slope of 4.5 was used per the study report), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a SJKFconsuming a contaminated bird. The individual probability of death is 100% (1 in 1) for a SJKF consuming either a small, medium, or large bird that ingested brodifacoum bait.

Direct effects to the AW (through Secondary Exposure Consuming Reptiles)

The AW is likely to be exposed to brodifacoum residues from secondary exposure that occurs from consumption of prey that has consumed brodifacoum bait. The AW is capable of consuming other reptiles such as lizards (their chief preference of food) as prey that may have directly ingested brodifacoum bait. Therefore, risk based on secondary exposure was conducted for a snake which feeds on lizards. The body weight of the snake was set at the weight of the minimum sized animal which would be able to consume prey of the assumed size, as described in **Section 3.3.2.**

To assess the maximum exposure that an AW could receive through secondary exposure, 100% of the active ingredient which was ingested by the reptile prey was assumed to be present in the animal when it was consumed by the snake. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg a.i./kg bw. Finally, the acute secondary exposure risk quotients were calculated by dividing the predicted dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the most sensitive bird species, 0.26 mg-a.i./kg-bw, used as a surrogate to the whipsnake. Results of these calculations are presented in **Table 5-7.**

Table 5-7. RQs for Acute Effects to the AW from Consumption of Reptiles which Ingested Brodifacoum Bait

Bait Type	Prey Species	Assumed weight of AW	%AI in Bait	Prey FI[1] (mg/d)	Dose (mg a.i./kg BW)	Acute RQ[2]
Rodent control	Small reptile (2 g)	1.91	0.0050	0.02	0.52	**2.0**
	Medium reptile (20 g)	16.2	0.0050	0.13	0.40	**1.5**
	Large reptile (800 g)	513	0.0050	2.28	0.22	**0.85**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the dose in the ingested prey and the avian acute oral LD_{50} of 0.26 mg/kg-bw

Because the acute RQs for secondary exposure exceed 0.1 (RQs ranged from **0.85 – 2.0**), the LOC for acute effects to listed species, use of brodifacoum has the potential to directly affect the AW that feed upon reptiles which ingested brodifacoum bait by way of secondary exposure.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the AW consuming reptiles would range from **0.43 to 1** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed species LOCs and exceed the non-listed species LOCs for the small and medium reptile prey items.

5.1.1.b. Indirect Effects to the AW, and SJKF (via direct effects to prey items leading to prey reduction) and to the SMHM (through reduction of rearing sites)

Reptiles

Direct acute effects from primary exposure to prey items for the AW and SJKF (mammals, birds, and reptiles) ingesting brodifacoum bait were evaluated by assuming an individual directly consumes a bait product containing brodifacoum at its daily ingestion rate. As all brodifacoum products are the same percent a.i., 0.005%, only one concentration of brodifacoum was assessed. The average daily food intake rate was estimated using the allometric equation for insectivorous reptiles (Nagy, 1987 as cited in USEPA, 1993) as discussed in **Section 3.3.1**.

Acute risk quotients were calculated by dividing the expected dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the northern bobwhite, 0.26 mg-a.i./kg-bw (surrogate for reptiles). RQs for acute toxicity to reptiles are given in **Table 5-8**. These RQs represent risk of direct effects to the reptiles from direct consumption of brodifacoum bait. They are also applicable to indirect effects to this species mediated through adverse effects to reptiles and terrestrial-phase amphibians which serve as prey for the AW. The Agency's LOC is exceeded

for the three size classes of reptiles (0.01) from direct consumption of brodifacoum bait with RQs ranging from **0.54** for the largest size reptile to **2.1** for the smallest size reptile.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for primary exposure to reptilian prey items consuming brodifacoum bait would range from **0.27 – 1.1** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed species LOCs and the non-listed species LOCs for small and medium sized reptiles.

Table 5-8. Acute RQs for to Reptiles that Consume Brodifacoum Bait

Size (bodyweight)	%AI	FI[1] (g/d)	Dose (mg ai/kg-BW)	Acute Dose-Based RQ[2]
Small (2 g)	0.005	0.022	0.55	**2.1**
Medium (20 g)	0.005	0.13	0.32	**1.2**
Large (800 g)	0.005	2.3	0.14	**0.54**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate based on an allometric equation for insectivorous reptiles.
[2] Based on the FI and the northern bobwhite oral LD_{50} of 0.26 mg/kg-bw

Birds

Indirect risk posed to the AW and SJKF mediated by toxic effects to birds was assessed using an approach similar to that used for reptiles, except the allometric equation for food ingestion rate (FI) was for birds rather than for reptiles. Risk was again assessed for bait with a brodifacoum concentration of 0.005%. The average daily food intake rate was estimated using the following allometric equation for birds (Nagy, 1987 as cited in USEPA, 1993) as discussed in **Section 3.3.1.**

Acute RQs were calculated by dividing the expected dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for the northern bobwhite, 0.26 mg-a.i./kg-bw (**Table 5-8**). Because the AW preys upon birds, it may be indirectly affected by adverse effects on bird populations. Dietary-based RQs for birds which consume brodifacoum bait were also calculated by dividing the concentration of brodifacoum in the bait by the subacute dietary LC_{50} value for the mallard duck (1.33 mg a.i./kg-diet). The brodifacoum concentrations in the bait, when expressed as parts-per-million (mg-a.i./kg), is 50 for rodenticide bait. Therefore, the dietary RQ for indirect effects resulting from toxicity to birds is **37.6** for rodenticide bait. Acute dose-based RQs ranged from **11.2 – 43.9** for birds that consume brodifacoum bait. All estimated dose and dietary-based RQs for birds consuming brodifacoum bait exceed the LOC.

Table 5-9. Acute RQs for Birds that Consume Brodifacoum Bait

Size (bodyweight)	%AI	FI[1] (g/d)	Dose (mg/kg-a.i.)	Dose-based Acute RQ[2]	Diet-based Acute RQ[3]
Small (20 g)	0.005	4.56	11.4	**43.9**	**37.6**
Medium (100 g)	0.005	13.0	6.5	**25.0**	
Large (1000 g)	0.005	58.2	2.91	**11.2**	

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the FI and the northern bobwhite oral LD_{50} of 0.26 mg/kg-bw.
[3] Based on the %AI of the bait and the mallard duck dietary LC_{50} of 1.33 mg/kg-diet.

There were no chronic avian risk quotients that could be calculated because toxicity data on the chronic effects of brodifacoum to birds are not available.

Because the acute risk quotient for reptiles exceed the Agency's listed and nonlisted species LOCs (dose-based acute RQs ranged from **11.2 - 43.9** and diet-based acute RQs were **37.6**), use of brodifacoum has the potential to cause indirect effects to the AW. Additionally, since the acute RQs for birds exceeded the non-endangered acute risk LOC of 0.5, the use of brodifacoum also has the potential to cause indirect effects to the AW through a reduction of prey available to the AW

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for primary exposure to avian prey items consuming brodifacoum bait would range from **5.6 – 22.0** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs. The resulting dietary based-RQ would be 18.8 and still exceed the listed and non-listed species LOCs.

Mammals

Risk quotients were calculated to assess risk to small and medium sized mammals which directly consume brodifacoum bait and which may serve as prey for the AW and SJKF. These also apply to effects to small mammals that may provide rearing sites for the SMHM. Bait with one concentration of brodifacoum was modeled, 0.005%. The small mammals were assumed to consume their average daily food intake in the form of the bait as discussed in **Section 3.3.1**.

Acute dose-based risk quotients were calculated by dividing the expected dose of brodifacoum (mg-a.i./kg-bw) by the acute oral LD_{50} value for Richardson's ground squirrel, 0.13 mg-a.i./kg-bw (**Table 4-7**). RQs for acute effects to mammals are presented in **Table 5-10**. These RQs represent risk of indirect effects to the AW and SJKF mediated through effects on small mammals.

Table 5-10. Dose-Based RQs for Acute Effects to Mammals from Consumption of Brodifacoum Bait

Mammal (bodyweight)	Bait Type	%AI	FI[1] (g/d)	Dose (mg/kg-bw)	Acute RQ[2]
House mouse (23g)	Rodent control	0.005	3.64	7.91	**60.9**
Norway rat (485 g)	Rodent Control	0.005	20.3	2.09	**16.1**

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the FI and the rat acute oral LD_{50} of 0.13 mg/kg-bw

Since the acute RQs for a 23-g mammal and a 485 g mammal exceeded the LOCs (RQs ranged from **16.18 – 60.9**) for listed and non-listed species, use of brodifacoum has the potential to cause indirect effects to the AW and SJKF mediated through effects on small mammals which serve as prey for the AW and SJKF. Additionally, direct effects to these small mammals indirectly affect the SMHM by reducing the number of rearing sites.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for primary exposure to mammalian prey item consuming brodifacoum bait would range from **8.1 – 30.1** (current RQs divided by 2, that is, half the percent a.i.) depending on the size of the mammal, and still exceed the listed and non-listed species LOCs.

Dose –based and dietary-based RQs for small, medium, and large mammals (presented in **Table 5-11**) which consume brodifacoum bait were also calculated by simply dividing the concentration of brodifacoum in the bait by the subacute dietary LC_{50} value for the albino rat (0.53 mg a.i./kg-diet). The brodifacoum concentrations in the bait, when expressed as parts-per-million (mg-a.i./kg), is 50 for rodenticide bait. Dose-based RQs ranged from **50.0 – 87.7** and the dietary RQ for direct effects resulting from toxicity to mammals is **94.3** for rodenticide bait. Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dietary-based RQs for primary exposure to mammalian prey item consuming brodifacoum bait would be **47.2** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs.

Table 5-11. Dietary-Based RQs for Acute Effects to Mammals from Consumption of Brodifacoum Bait

Size (bodyweight)	%AI	FI[1] (g/d)	Dose (mg/kg-a.i.)	Dose-based Acute RQ[2]	Diet-based Acute RQ[3]
Small (20 g)	0.005	4.56	11.4	**87.7**	**94.3**
Medium (100 g)	0.005	13.0	6.5	**50.0**	

LOC exceedances (acute RQ > 0.1) are bolded.
[1] Daily food ingestion rate.
[2] Based on the FI and the Richardson's ground squirrel oral LD_{50} of 0.13 mg/kg-bw.
[3] Based on the %AI of the bait and the albino rat dietary LC_{50} of 0.53 mg/kg-diet.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (a default slope of 4.5 was used as the study did not provide one), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a AW consuming a contaminated small mammal. The individual probability of death is 100% (1 in 1) for an AW consuming a small mammal that ingested brodifacoum bait. Similarly, the probability of chance of death from a small, medium, or large mammal consuming brodifacoum bait would be 1 in 1 (100%) using a default slope of 4.5.

5.1.2. Primary Constituent Elements of Designated Critical Habitat

For brodifacoum 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 final No Effect/May Affect determination is made after the spatial analysis is completed at the end of the risk description, **Section 5.2.2**. In **Section 5.2.2**, a discussion of any potential overlap between areas where potential usage may result in LAA effects and areas where species are expected to occur (including any designated critical habitat) is presented. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a No Effect determination is made.

If the RQs presented in the Risk Estimation (**Section 5.1**) show no direct or indirect effects for the assessed species, and no modification to PCEs of the designated critical habitat, a preliminary "no effect" determination is made, based on brodifacoum'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 brodifacoum. For this assessment of the use of vertebrate control bait products containing brodifacoum, a preliminary May Affect determination was made for the AW, SMHM, and SJKF. A preliminary May Affect determination was also made for adverse effects on the PCE's of the critical habitat of the AW. A summary of the risk estimation results are provided in **Table 5-7** for direct and indirect effects to the AW and in **Table 5-8** for the PCEs of their designated critical habitat.

Table 5-12. Risk Estimation Summary for Brodifacoum - Direct and Indirect Effects

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
Birds, Reptiles, and Terrestrial-Phase Amphibians	Non-listed Species: Yes	Risk of acute toxic effects to SMHM and AW prey (birds that feed on any brodifacoum bait and to reptiles and terrestrial-phase amphibians which feed on bait used for rodent control).	Indirect Effects: SMHM and AW
	Listed Species: Yes	Risk of acute secondary poisoning to snakes feeding on prey which ingested brodifacoum bait.	Direct Effects: AW
Mammals	Non-listed Species: Yes	Risk of acute effects to small mammals that feed on brodifacoum bait. Risk of acute toxic effects to mammals that serve as prey that feed on brodifacoum bait.	Direct Effects: SMHM Indirect Effects: AW, SJKF
	Listed Species: Yes	Risk of acute effects to small mammals that feed on brodifacoum bait.	Direct Effects: SMHM, SJKF

Table 5-13. Risk Estimation Summary for Brodifacoum – 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
Birds, Reptiles, and Terrestrial-Phase Amphibians	Non-listed Species: Yes	Risk of acute toxic effects to birds, reptiles, and terrestrial-phase amphibians that feed on brodifacoum bait that may be consumed by the AW.	AW
Mammals	Non-listed Species: Yes	Risk of acute effects to small mammals that feed on brodifacoum bait that serve as prey for the AW. Risk of acute effects to small mammals that feed on brodifacoum bait that create burrows for the AW.	AW

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.

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 brodifacoum. Finally, in **Section 5.2.2**, 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. Alameda Whipsnake

5.2.1.a. Direct Effects

The primary risk of direct effect of brodifacoum bait on the AW is believed to be secondary poisoning. Secondary poisoning may occur if a whipsnake consumes small mammals, birds, or reptiles that feed directly on the bait. The AW diet includes small mammals, birds, and reptiles, and it may consume any of the target species that brodifacoum bait products are meant to control (rats and mice). Whether a whipsnake would scavenge upon a dead mammal that was killed by brodifacoum bait is unknown, but since rats and mice poisoned by brodifacoum may not die for several days, considerable opportunity would exist for the snake to prey on a poisoned small mammal before it dies. Furthermore, small mammals partially incapacitated by brodifacoum exposure would likely be attractive prey to the snakes. Sublethal effects of brodifacoum include lethargy and tremors. These sublethal symptoms likely would make poisoned rodents easier to catch.

Extensive use of brodifacoum bait products is believed to be possible in the region where the AW occurs. The counties where the AW occurs (Contra Costa, Alameda, San Joaquin and Santa Clara Counties) include many highly developed and densely populated areas (**see Section 2.4.3**). Placement of brodifacoum rodenticide bait around residential homes, farm buildings, commercial buildings, and recreation buildings in these counties would provide widespread opportunities for

the snake to encounter prey poisoned by brodifacoum bait. The snakes may occur in close proximity to these buildings, for example by living in the crawlspace underneath a home, or in or under a utility shed or agricultural building. Since rodenticide bait would most likely be used in areas where high rodent populations exist, the dense abundance of rodents in these areas may attract the snake.

The restriction of the placement of the rodenticide bait to within 50 ft of exterior walls of buildings is not expected to protect the AW exposure to brodifacoum. There is no reason to believe that this snake would not venture near buildings, especially when one considers the term "buildings" includes buildings of all types, not just homes (*e.g.*, besides residential, includes commercial and industrial buildings/ structures, as well as transportation ports and terminals, and agricultural buildings). Furthermore, the acute rat toxicity studies showed that small mammals which feed on the brodifacoum bait may not die for several days. Poisoned small mammals may travel considerable distance away from the buildings and bait stations during that time. Therefore, the AW may be exposed through secondary exposure even if they do not forage near buildings.

Risk quotients for secondary poisoning show that the amount of active ingredient that a rat and mouse ingests would pose a risk of acute toxicity to a whipsnake that feeds on it (acute RQs: **12.1 – 37.6**). An assessment was also conducted to predict the length of time that toxicity in a prey animal would remain at levels that would yield a RQ above the LOC of 0.1, and thus may pose a risk of secondary poisoning to the AW. Since laboratory studies show that mammals that die from brodifacoum poisoning usually die within 7-10 days, prey which ingest a lethal dose would not be expected to remain alive for this long. Still, risk of secondary hazard would likely be high while the prey is intoxicated and immobilized by brodifacoum poisoning, but remains alive. Small mammals exposed to brodifacoum may be immobilized during this time, showing symptoms of brodifacoum toxicity such as lethargy and tremors. This could make them attractive prey which a snake could easily catch. Once the prey animal dies, it is not expected to pose a significant risk of secondary poisoning to the AW. Whipsnakes hunt by sight and are attracted to prey by movement, and thus would be unlikely to consume a dead carcass.

Although the RQs for secondary exposure were based on a single feeding of a single rodent, bird, or reptile, it is worth noting that the AW could feed upon multiple contaminated rodents, birds, or reptiles. While its feeding on multiple poisoned animals may be infrequent, the tendency of brodifacoum to persist in the liver and accumulate over time with repeated exposure is worth noting and could result in even higher RQs than those estimated previously.

The results of the risk assessment indicate that non-target reptiles like the AW would be susceptible to secondary poisoning from brodifacoum, and this risk has been confirmed by documented incidents. As discussed in **Section 4.4**, dozens of wildlife mortality incidents have been documented in which primary or secondary exposure to brodifacoum was identified as the cause.

Risk quotients indicate that direct consumption of brodifacoum bait by the AW also would pose an acute risk to the AW. Acute RQs for a reptile that directly ingested the bait ranged from **0.54 -2.1.** This risk is much less certain than the secondary exposure risk, however, because it is

uncertain if the AW would feed directly on the baits. The pellets or blocks of rodenticide baits would not be attractive food to an AW. It seems unlikely that a snake would be attracted to this bait since it does not provide the movement, odor, or heat cues that snakes normally use to identify prey.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the AW consuming birds and mammals would range from **6.1 - 27** (current RQs divided by 2, that is, half the percent a.i.) depending on the size of the mammal or bird, and still exceed the listed and non-listed species LOCs. For the AW consuming reptiles that had previously ingested brodifacoum bait, the resulting RQs would range from **0.43 – 1**, and exceed the listed and non-listed species LOC but only the non-listed species LOCs for small and medium sized prey items.

In conclusion, the weight of evidence justifies the conclusion that the labeled uses of brodifacoum are *Likely to Adversely Affect* the survival of the AW. This conclusion is based primarily on risk from direct effects of the snake exposure to brodifacoum, in particular from secondary exposure that may occur from consumption of poisoned prey.

5.2.1.b. Indirect Effects

The risk assessment also identified the potential for brodifacoum use to cause indirect effects on the AW. These indirect effects would be mediated through direct toxic effects on birds, small mammals, terrestrial-phase amphibians, and other reptiles, causing reduction in their abundance. Reduced abundance of these species would indirectly affect the AW by reducing the availability of prey, thereby possibly jeopardizing the ability of the species to meet its energy demands for survival and reproduction. Furthermore, since the AW uses small mammal burrows for cover and foraging (USFWS, 2006), reduced small mammal abundance may affect the habitat of the AW by reducing the abundance of these burrows. These indirect effects, however, are expected to have less impact on the success of this species than the direct toxicity effects.

Brodifacoum has over 260 reported ecological incidents, many of which involve other small mammals like chipmunks and squirrels ingesting brodifacoum bait that results in mortality. Even for the target species, effects on abundance would likely be localized to areas around buildings where bait stations are placed for rodent control. This limited area of use would make widespread effects on small mammal populations unlikely. Lizards in particular are believed to be the most important prey item of whipsnakes (USFWS, 2005). Lizards generally feed upon insects and other terrestrial arthropods and would not likely consume rodent bait. Additionally, although the AW diet may include terrestrial invertebrates, as mentioned previously, these organisms are not likely to consume rodent bait.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (a default slope of 4.5 was used as the study did not provide one), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a AW consuming a contaminated small mammal. The individual probability of death is 100% (1 in 1) for an AW consuming a small mammal that ingested brodifacoum bait.

5.2.1.c. Modification of Designated Critical Habitat

Critical habitat has been defined for the AW. As discussed above, the potential for brodifacoum use to 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 within the critical habitat. Since the AW preys on small mammals (along with other types of terrestrial vertebrates and invertebrates), adverse effects on small mammal 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 is uncertain. In addition to prey effect, 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.

5.2.1.d. Spatial Extent of Potential Effects

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

To determine this area, the footprint of brodifacoum's use pattern is identified using corresponding land cover data (**see Section 2.7**). Brodifacoum is used in and around any type of building, including residential, commercial, industrial, and commercial structures, as well as transportation ports and terminals. For these uses, potential land cover classes include, developed high intensity, developed medium intensity, developed low intensity, and possibly developed open space. Because brodifacoum may be used in and around agricultural buildings, other potential land cover categories also include cultivated crops, orchards/ vineyards, pasture/ hay. Actual usage is expected to occur in a smaller area as the chemical is only expected to be used on a portion of the identified area.

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 brodifacoum is a vertebrate pest control agent that may be used in a wide variety of urban and non-urban areas, the spatial extent of brodifacoum cannot be limited to defined areas. The Agency assumes that brodifacoum potentially may be used in any area of the state, as any area could potentially be adjacent to some kind of urban or agricultural building where brodifacoum rodenticide bait may be placed. Brodifacoum 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 these

species occur, and all areas of the critical habitat of the AW, are assumed to lie within the potential use area of brodifacoum.

An alternative type of spatial analysis was conducted to characterize the potential use of brodifacoum bait products within the region where the assessed species may occur. Since outdoor use of brodifacoum bait for rodent control should be within 50 ft of the wall of a building, the extent of this use is expected to be highly correlated with human development. Therefore, spatial analyses were conducted in which the occurrence locations of the AW were overlaid with a representation of human development. The "Developed" land cover classes of the NLCD were used to represent the intensity of human development. These land cover classes were displayed with gray shading, with darker grays representing areas of more intense development. This layer was overlaid on segments and points that represent the location of the assessed species, and for the AW, the location of its critical habitat. The results of these spatial analyses are shown in **Figure 5-1**.

5.2.1.e. Effects Determinations for Alameda Whipsnake (AW)

The results of this risk assessment indicate that use of brodifacoum in baits for vertebrate pest control poses a high risk of acute toxicity to the AW resulting from secondary exposure. Secondary poisoning may occur when the AW preys upon small mammals, birds, reptiles or other vertebrate prey species which have ingested the brodifacoum bait. Further risk to this species would be posed by sublethal behavioral and neurological effects which may result from acute exposure to brodifacoum. Although less certain, some additional risk also may exist for direct effects from primary exposure to brodifacoum bait. Finally, indirect effects are also possible from use of this product reducing the abundance of vertebrate prey, and reducing the availability of small mammal burrows where the AW could inhabit.

Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determination 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 the AW's critical habitat.

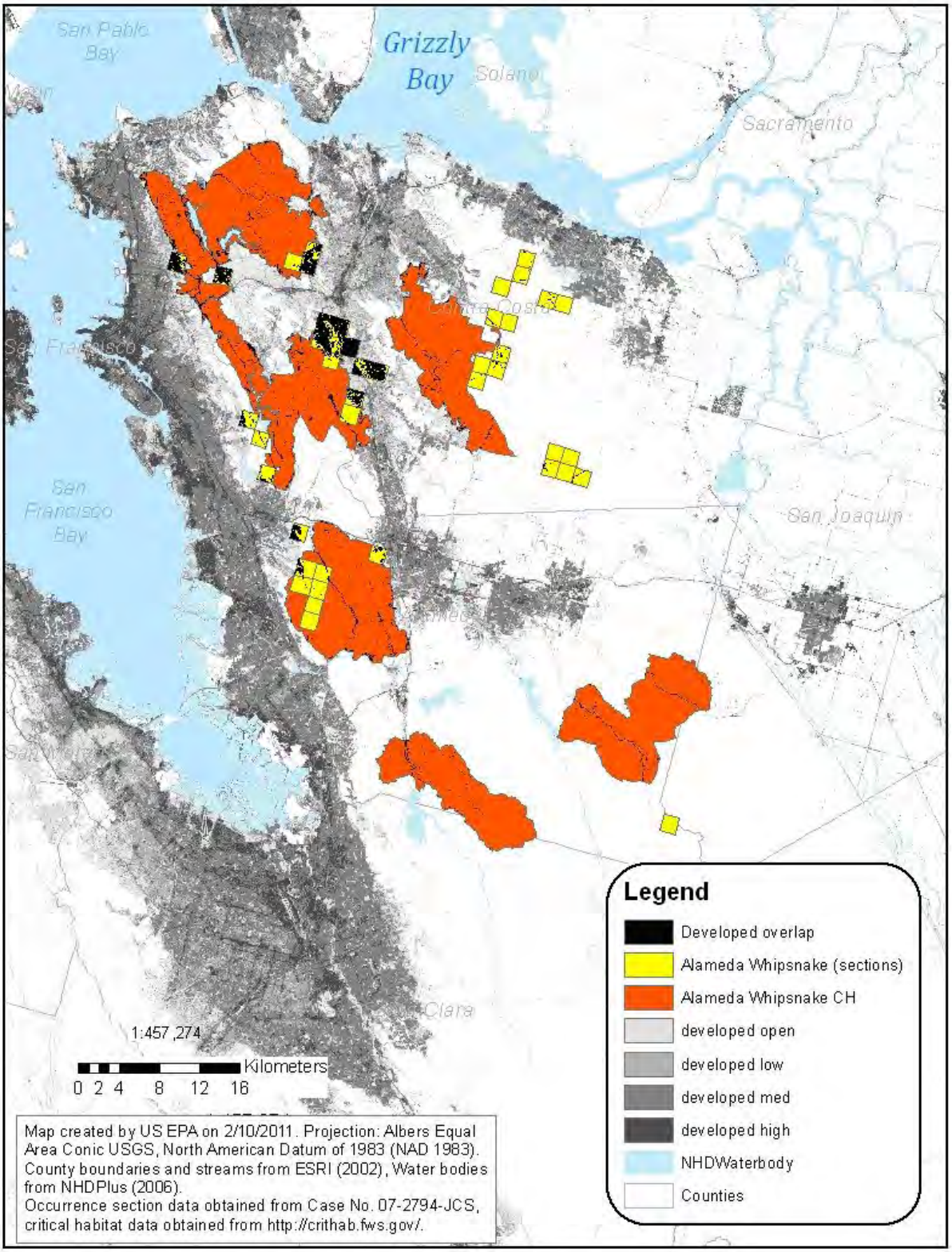

Figure 5-1. Map showing the occurrence of Alameda whipsnake, and its critical habitat, in relation to the intensity of human development.

Areas with higher human development are expected to represent areas where brodifacoum bait would be more intensively used and where species would be most vulnerable to exposure to brodifacoum. On the scale displayed, the maps have limited usefulness for identifying specific areas of vulnerability. However, the map shows that the AW occurs in a region of California where development is widespread, and a significant portion of range of both species occurs in areas with moderate to high development. As the species occurs in areas where brodifacoum bait may be intensively used, AW would be susceptible to exposure to brodifacoum.

5.2.2. Salt Marsh Harvest Mouse

5.2.2.a. Direct Effects

The primary risk of direct effects of brodifacoum bait on the SMHM is believed to be direct consumption of brodifacoum bait. The SMHM diet mainly includes the pickleweed plant but the small pellet like brodifacoum bait could be ingested.

Extensive use of brodifacoum bait products is believed to be possible in the region where the SMHM occurs. The counties where the SMHM occurs (Marin, Sonoma, Napa, Solano, Contra Costa, San Mateo, Alameda, and Santa Clara counties) include many highly developed and densely populated areas (see **Section 2.4.3**). Placement of brodifacoum rodenticide bait around residential homes, farm buildings, commercial buildings, and recreation buildings in these counties would provide widespread opportunities for the small mammals like the SMHM to encounter brodifacoum bait. Since rodenticide bait would most likely be used in areas where high rodent populations exist, this might further increase the direct impacts to the SMHM.

The restriction of the placement of the rodenticide bait to within 50 ft of exterior walls of buildings could reduce primary exposure of the SMHM to brodifacoum bait but to what extent is uncertain. Having an average weight of 8 – 14 g, the SMHM could easily still get into tamper resistant bait station and consume brodifacoum bait.

Since the dose-based acute RQs for the SMHM exceeded the LOC (**RQ of 87.7**) for listed and non-listed species, use of brodifacoum has the potential to cause direct effects to the SMHM. Dietary-based RQs for the SMHM also exceeded the LOC (**RQ of 94.33**) for listed and non-listed species.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose and dietary-based RQs for primary exposure to the SMHM would be **43.9 and 47.2**, respectively (current RQs divided by 2, that is, half the percent a.i.) and still in exceedance of the listed and non-listed species LOCs.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (a default slope of 4.5 was used as the study did not provide one), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a SMHM consuming bait. The individual probability of death is 100% (1 in 1) for a SMHM that ingested brodifacoum bait.

Furthermore there were dozens of primary exposure incident for brodifacoum that involved small non-target mammals, particularly rodents like squirrels. These reports suggest that one or more exposure pathways are complete when brodifacoum is used in areas inhabited by small mammals. Additionally, the previously discussed laboratory secondary toxicity studies as well as the terrestrial field monitoring studies that were conducted on farms cited numerous small mammals being observed consuming brodifacoum bait and ultimately suffering mortality.

5.2.2.b. Indirect Effects

Brodifacoum use may result in indirect effects to the SMHM due to a reduction in rearing sites.

Potential effects of brodifacoum to small mammals that provide rearing sites for the SMHM were evaluated (which would constitute indirect effects to the SMHM). For small mammals that consume bait directly, dose-based acute RQs exceeded Acute Endangered Species, Acute Restricted Use and Acute LOCs (**Table 5-1**). In addition, the probability of an individual mortality occurrence is 100% (1 in 1) for small mammals ingesting brodifacoum bait directly. Therefore, there is a high likelihood that the availability of rearing sites for SMHM use may decrease due to reductions in populations of small mammals.

5.2.2.c. Spatial Extent of Risks

Similar to the spatial analysis for the AW, all areas where the SMHM occurs are assumed to lie within the potential use area of brodifacoum. Based on CDPR Pesticide Usage Reporting data, brodifacoum has been used within the years 1999-2009 in all 8 of the California counties in which occurrences or occurrence sections were identified for the SMHM in Case No. 07-2794-JCS. See **Section 5.2.1.d** for an explanation of the spatial analysis that is represented in the land use cover maps. The map showing the co-occurrence of the SMHM with developed areas is presented below in **Figure 5-2**.

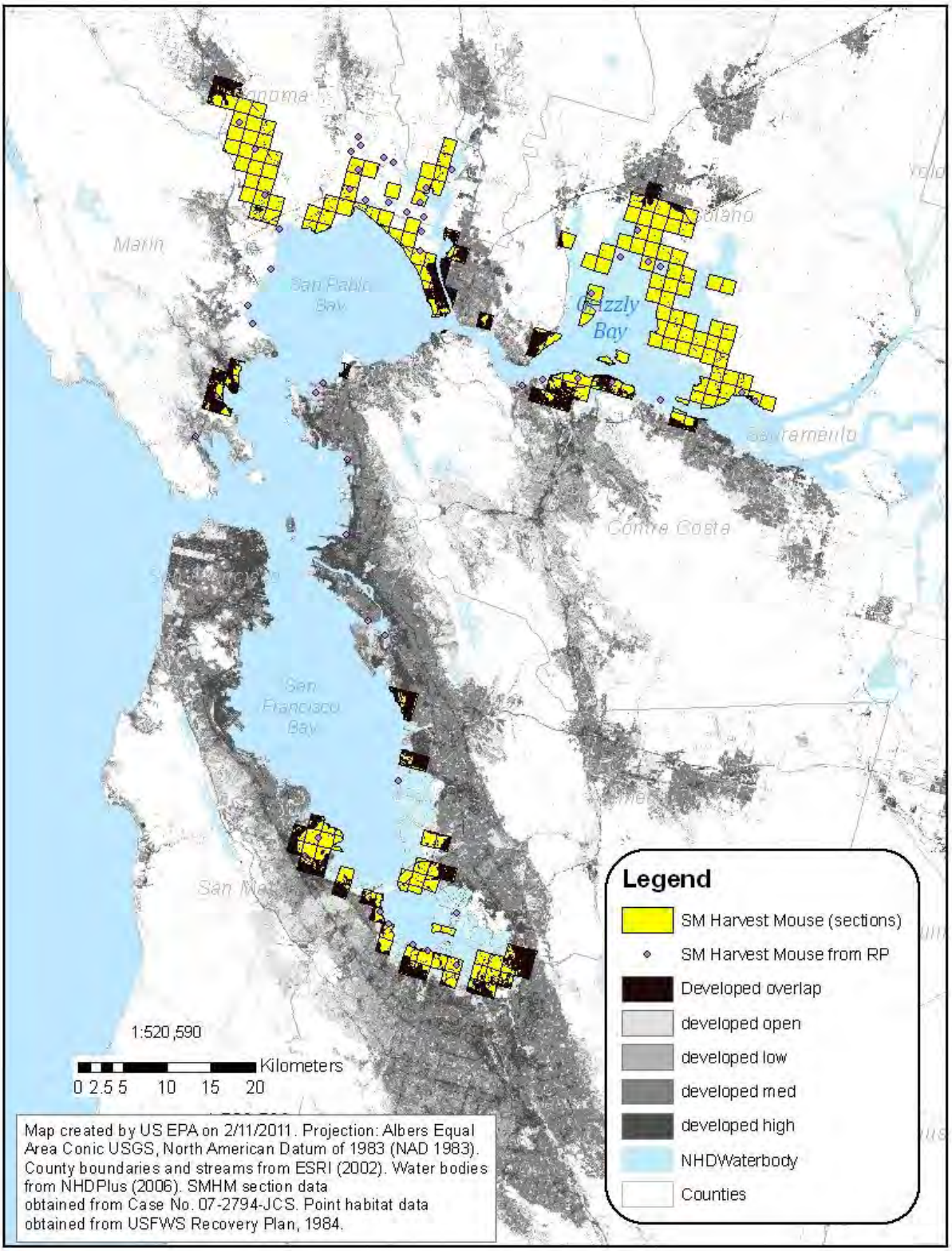

Figure 5-2. Map showing the occurrence of the salt marsh harvest mouse in relation to the intensity of human development.

5.2.2.d. Effects Determinations for Salt Marsh Harvest Mouse (SMHM)

The results of this risk assessment indicates that use of brodifacoum in baits for vertebrate pest control poses a high risk of acute toxicity to the SMHM resulting from primary exposure through direct consumption of brodifacoum bait. Further risk to this species would be posed by sublethal behavioral and neurological effects which may result from acute exposure to brodifacoum. Finally, indirect effects are also possible from use of this product reducing the abundance of rearing sites for the SMHM.

Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determination for the SMHM, based on the potential for direct and indirect effects

5.2.3. San Joaquin Kit Fox

5.2.3.a. Direct Effects

Direct effects to the SJKF are possible, based on the registered uses of brodifacoum. The dose-based acute RQs calculated in the risk estimation for secondary exposure of the SJKF to brodifacoum exceeded the acute listed species LOC, and acute non-listed species LOC (**Tables 5-3** and **5-5**). Therefore, there is potential for mortality to the SJKF through consumption of prey that ingested brodifacoum bait. Chronic studies for the toxicity of brodifacoum to mammals were not available but due to the high acute toxicity and effects of brodifacoum to mammals, chronic risk is also assumed.

Although this is a screening level assessment in which the product with the highest percent active ingredient is assessed, if the use involved a product containing 0.0025% brodifacoum, the resulting acute dose-based RQs for secondary exposure to the SJKF consuming mammals would be **2.2** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs. The resulting acute dose-based RQs for secondary exposure to the SJKF consuming birds would be **6.3** (current RQs divided by 2, that is, half the percent a.i.) and still exceed the listed and non-listed species LOCs.

For individual chance of effect calculations, dose-based acute RQs for secondary of the SJKF were used. The probability of an individual effect to the SJKF using the dose-based RQ was calculated using a default slope estimate of 4.5 because a probit slope for the dose-response could not be calculated for the associated acute oral study. The RQ for a SJKF ingesting a 244 g small mammal is **4.41** (**Table 5-5**). The estimated chance of an individual acute mortality of the SJKF ingesting a brodifacoum poisoned mammal is 1 in 1. These results indicate that the probability of an individual mortality occurrence is high and that brodifacoum has the potential to directly affect the SJKF via secondary exposure.

Furthermore, the laboratory secondary toxicity studies (particularly the one conducted with grey and red foxes, MRID 00128422) as well as the terrestrial field monitoring studies suggest that medium to large sized mammals like the SJKF are susceptible to secondary toxicity through the ingestion of brodifacoum poisoned prey. Additionally, there were 17 reported wildlife incident

with brodifacoum that involved either grey or red foxes suggesting that the one or more exposure pathways for canids like foxes are complete with brodifacoum in the wild.

Of particular relevance to this assessment is the previously discussed study conducted by McMillin et al (2008). Out of the 30 San Joaquin Kit Foxes analyzed from the Bakersfield population, 27 contained at least one anticoagulant and the most commonly detected from that set was brodifacoum (26 out of 30 or 87%). Chlorophacinone residues were detected in one fox (3%). All control foxes from the Lokern population had no anticoagulant residues detected. The authors report that results from this study confirm that San Joaquin Kit Foxes are exposed to anticoagulants in urban environments.

5.2.3.b. Indirect Effects

Indirect effects to the SJKF may occur through the potential for brodifacoum to adversely affect the abundance and quality of available mammalian, avian and reptilian prey items.

For non-listed mammalian prey consuming bait directly, acute dose-based RQs exceeded acute listed and non-listed species LOCs (RQs ranged from **4.98 – 18.84**) (**Table 5-9**). These RQs would range from **2.5 – 9.4** if the percent a.i. in the product was 0.0025% and still exceed the listed and non-listed species LOCs. Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to mammals (a default slope of 4.5 was used as one was not available from the study), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a mammal ingesting brodifacoum bait. The individual probability of death is 100% (1 in 1) for a Norway rat or house mouse that ingested brodifacoum bait.

For non-listed avian prey consuming bait directly, the acute RQs for primary exposure exceed 0.1 (RQs ranged from (**11.18 - 43.75**), the LOC for acute effects to listed species, use of brodifacoum has the potential to indirectly affect the SJKF by affecting the abundance of avian prey items. These RQs would range from **5.6 – 21.9** if the percent a.i. in the product was 0.0025% and still exceed the listed and non-listed species LOCs.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to birds (a slope of 3.0 was used per the study report), calculations were made to determine the probability that a particular individual would be killed by the dose predicted for a bird consuming brodifacoum bait. The individual probability of death is 100% (1 in 1) for small, medium, or large bird consuming brodifacoum bait.

For non-listed reptilian prey consuming bait directly, the acute RQs for primary exposure exceed 0.1 (RQs ranged from **0.54 – 2.11**), the LOC for acute effects to listed species, use of brodifacoum has the potential to indirectly affect the SJKF by affecting the abundance of reptilian prey items. These RQs would range from **0.27 – 1.06** if the percent a.i. in the product was 0.0025% and still exceed the listed species LOCs and the non-listed species LOCs for small and medium sized prey items.

Based on the RQs and the LD_{50} in the most sensitive acute oral toxicity study to birds (a slope of 3.0 was used per the study report), calculations were made to determine the probability that a

particular individual would be killed by the dose predicted for a reptile consuming a brodifacoum bait (using birds as surrogates). The individual probability of death is 100% (1 in 1) for a small, medium, or large reptile consuming brodifacoum bait.

5.2.3.c. Spatial Extent of Risks

Similar to the AW and SMHM, all areas where the SJKF occurs are assumed to lie within the potential use area of brodifacoum. Based on CDPR Pesticide Usage Reporting data, brodifacoum has been used within the years 1999-2009 in all 16 of the California counties in which occurrences or occurrence sections were identified for the SJKF in Case No. 07-2794-JCS. The map showing the co-occurrence of the SJKF with developed areas is presented below in **Figure 5-3**.

It is noted that the map depicted in **Figure 5-3** appears quite different from **Figures 5-1** and **Figures 5-2**, showing the overlap of the AW and SMHM, respectively. There are two points of explanation for this. The first reason is the overall scale of the map in **Figure 5-3** as compared to **Figures 5-1** and **5-2**. When one notices the zoom scale on **Figure 5-3**, it is noted that the zoomed out level is approximately 3 times that of **Figures 5-1** and **5-2**. This is primarily because the SJKF is much more widely distributed than the AW and the SMHM and so to account for all areas of occurrence, the map is further zoomed out. The second reason is that the grayscale used to show low to high areas of development as well as the black areas that are used to show overlap in **Figures 5-1** and **5-2** are not visible on the further zoomed out **Figure 5-3**. Attempts were made to include these areas; however, the areas of overlap and occurrence blended into one another and precluded the ability to tell a difference between these areas. The Agency plans to coordinate with the US FWS in its consultation to improve this map.

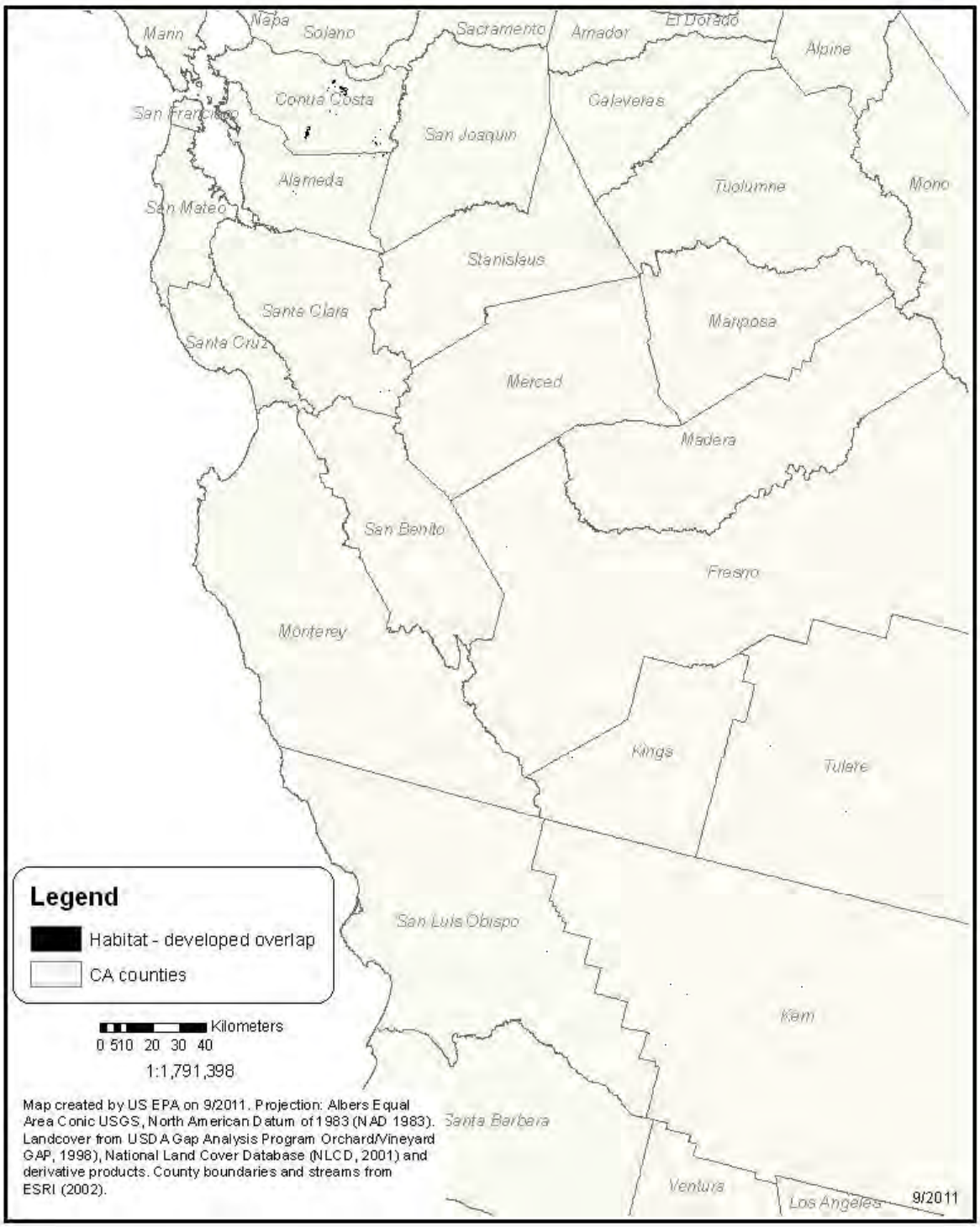

Figure 5-3. Map showing the occurrence of the San Joaquin Kit Fox in relation to the intensity of human development.

5.2.3.d. Effects Determination for San Joaquin Kit Fox (SJKF)

The results of this risk assessment indicates that use of brodifacoum in baits for vertebrate pest control poses a high risk of acute toxicity to the SJKF resulting from secondary exposure. Secondary poisoning may occur when the SJKF preys upon small mammals, birds, reptiles or other vertebrate prey species which have ingested brodifacoum bait. Further risk to this species would be posed by sublethal behavioral and neurological effects which may result from acute exposure to brodifacoum. Finally, indirect effects are also possible from use of this product reducing the abundance of vertebrate prey.

Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determination for the SJKF, based on the potential for direct and indirect effects.

5.2.4. Addressing the Risk Hypotheses

In order to conclude this risk assessment, it is necessary to address the risk hypotheses defined in **Section 2.9.1**. Based on the conclusions of this assessment, many of the risk hypotheses cannot be rejected, meaning that the stated hypotheses represent potential adverse effects that use of brodifacoum may cause. Specifically the risk hypotheses which cannot be rejected are listed below.

The labeled use of brodifacoum within the action area may:

- directly affect the AW and SJKF by causing mortality or by adversely affecting growth or fecundity via secondary exposure by consuming prey that have ingested brodifacoum bait;
- directly affect the SMHM by causing mortality or by adversely affecting growth or fecundity via primary poisoning by direct consumption of brodifacoum bait;
- indirectly affect the SMHM by reducing the number of small mammalian rearing sites by direct effects on mammals;
- indirectly affect the AW and/or modify the designated critical habitat of the AW by reducing or changing the composition of food supply; and
- indirectly affect the AW and/or modify its designated critical habitat of the AW by reducing or changing terrestrial habitat in their current range via reduction in availability of small burrowing mammals burrows used by the AW for cover.

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

- indirectly affect the AW and/or modify their designated critical habitat of the AW by reducing or changing the composition of the terrestrial plant community in the species' current range;

- indirectly affect the SMHM by reducing or changing the composition of the aquatic plant community in the species' current range, thus affecting primary productivity and/or cover;

Indirect effects mediated through effects on terrestrial and aquatic plant communities were judged to be discountable.

6. Uncertainties

6.1. Exposure Assessment Uncertainties

Uncertainty in the exposure assessment stems mainly from assumption made in the assessment related to the consumption of brodifacoum bait by various types of animals. Animals were assumed to consume an amount of bait equal to their predicted daily food ingestion rate. Ingestion of bait is most certain for omnivorous small mammals because the bait is designed to be attractive to rodents. However, small mammals could eat less bait than their average daily ingestion rate, either because they are also feeding on other food sources, or because they exhibit bait shyness. Alternatively, if other food is scarce and they find the bait to be very attractive, then they could exhibit gorging behavior, consuming bait in excess of their average daily intake rate. Furthermore, there could be multiple feedings of the bait. The consumption of brodifacoum bait by animals other than small mammals is less certain. No incidents or field studies have shown that species other than small mammals consume the bait. Animals which feed predominantly on live prey, including the AW and SJKF, may not consume the bait.

The food intake rate was estimated from the body weights of the animals using allometric equations. How well the generic allometric equations used predict the specific food intake rate of the assessed species introduces further uncertainty. For example, the relationship for the AW was based on an equation developed for insectivores, whereas the AW consumes a wide variety of vertebrate prey in addition to terrestrial invertebrates.

The assessment of secondary exposure to the AW and SJKF involves additional uncertainties. A conservative assumption was made that the entire amount of active ingredient consumed by the prey is present in the prey animal when it is consumed by the snake. In reality, the amount of active ingredient in the prey may decrease between the time the prey consumes the bait and the time the prey is consumed by the snake as the result of elimination and detoxification. However, studies discussed earlier in this assessment have shown brodifacoum to have a long half life in the liver tissue (307.4 days).

The dose of brodifacoum from secondary exposure is dependent on the size of the prey. The size of prey that the AW was predicted to be able to consume is uncertain. As described in **Section 3.3.2**, the body weight of the AW was estimated from an equation based on its length, and this body weight as then used in a second equation to predict the maximum size of the prey. Because the AW is a slender snake, these equations may overestimate both the body weight of this snake, and the maximum size prey which it may consume. Specifically, it is uncertain if an adult AW would be able to ingest a large Norway rat, even though these equations predict that it would.

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

6.2. Effects Assessment Uncertainties

6.2.1. Data Gaps and Uncertainties

The lack of research that directly measures the secondary poisoning hazard of brodifacoum in terrestrial animals brings uncertainty in the conclusions of the secondary poisoning assessment. A secondary poisoning study, in which animals are fed prey which have been allowed to feed on the bait, would reduce the uncertainties in the conclusion of the secondary poisoning risk of brodifacoum.

Finally, avian reproduction data have not been submitted for brodifacoum. This increases the uncertainty of the risk assessment for the AW because birds are used as surrogates for reptiles in toxicity testing. Without avian reproduction data, chronic risks to the AW could not be assessed. Additionally, there were no mammalian reproduction data available for the analysis of direct and indirect effects to the SMHM, and indirect effects to the AW and SJKF.

An additional level of uncertainty is the method of estimating exposure of doses of brodifacoum and the amount a prey item would carry over to an AW or a SJKF. The equations used were for insectivorous/herbivorous reptiles and mammals as equations for carnivorous reptiles were not available from the *Wildlife Exposure Handbook* were not available. However, given the acute toxicity of brodifacoum to birds and mammals, and the persistence it is expected to exhibit once consumed, the use of equations that would account for carnivorous mammals and reptiles would not be expected to change the LOC exceedances.

6.2.2. Use of Surrogate Species Effects Data

While the available toxicity data provides fairly certain information on the acute toxicity of brodifacoum to small mammals and birds (including the SMHM), extrapolation of these species to the AW (reptile) and SJKF (large mammal) is uncertain. Extrapolation to potential toxic effects to reptile and amphibian prey of the AW and SJKF is also uncertain.

6.2.3. Sublethal Effects

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

Brodifacoum is an anticoagulant pesticide. It has been shown to cause numerous adverse behavioral and neuromuscular effects at sublethal levels. The possible impact of these sublethal effects on the survival and reproduction of the assessed species was only qualitatively characterized. To the extent to which sublethal effects are not considered in the quantitative risk assessment, the potential direct and indirect effects of brodifacoum on listed species may be underestimated.

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 brodifacoum to the AW, SMHM, and SJKF, and to the designated critical habitat of the AW.

Based on the best available information, the Agency makes a ***May Affect*** and a ***Likely to Adversely Affect*** (**LAA**) determination for the use of brodifacoum relative to the AW, SMHM and SJKF. Additionally, the Agency has determined use of brodifacoum has the potential to cause modification of the designated critical habitat of the AW from the use of the chemical. Given the LAA determination for the AW, SMHM, and SJKF, and potential modification of designated critical habitat for the AW, a description of the baseline status and cumulative effects is provided in **Attachment III**.

A summary of the risk conclusions and effects determinations for the AW, SMHM and SJKF and the AW's critical habitat, given the uncertainties discussed in **Section 6** and **Attachment I**, is presented in **Table 7-1** and **Table 7-2**. Use specific effects determinations are provided in **Table 7-3.**

Table 7-1. Effects Determination Summary for Effects of Brodifacoum on the Alameda Whipsnake, Salt Marsh Harvest Mouse and San Joaquin Kit Fox

Species	Effects Determination	Basis for Determination
Alameda whipsnake (AW) (*Masticophis lateralis euryxanthus*)	*May Affect* and *Likely to Adversely Affect* (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of brodifacoum potentially will result in direct effects to the AW from acute toxicity through secondary exposure. Dietary exposure estimates and acute toxicity to reptiles (based on acute toxicity data for birds) result in acute RQs that exceed the LOC for secondary exposure. Secondary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Additionally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).
		Potential for Indirect Effects
		Terrestrial prey items Risk assessment indicates use of brodifacoum will likely reduce the abundance of terrestrial vertebrates which serve as prey for this species. This conclusion is based on acute RQs for birds, mammals, and reptiles

Species	Effects Determination	Basis for Determination
		which exceed the LOCs. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving small mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%). ***Habitat Modification*** Risk assessment indicates use of brodifacoum may modify the habitat of this species by reducing the availability of small mammal burrows. This conclusion is based on acute RQs for mammals that exceed the LOCs. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed.
Salt Marsh Harvest Mouse (SMHM) (*Reithyodontomys raviventris*)	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects**
		Risk assessment indicates that use of brodifacoum will result in direct effects to the SMHM from acute toxicity via primary exposure. Exposure estimates and acute toxicity to mammals result in acute RQs that exceed the LOCs for primary exposure to the SMHM. Primary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity, however since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving small mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).
		Potential for Indirect Effects
		Terrestrial Habitat Risk assessment indicates that the registered uses of brodifacoum will reduce SMHM rearing sites by adversely affecting small mammals. Estimated acute RQs for primary exposure to mammals exceeded acute LOCs for the small mammalian weight class considered.
San Joaquin Kit Fox (SJKF) (*Vulpes macrotis mutica)*	May Affect, Likely to Adversely Affect (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of brodifacoum potentially will result in direct effects to the SJKF from acute toxicity via secondary exposure. Secondary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).
		Potential for Indirect Effects
		Terrestrial prey items Risk assessment indicates use of brodifacoum will likely reduce the

Species	Effects Determination	Basis for Determination
		abundance of terrestrial vertebrates which serve as prey for this species. Dietary exposure estimates and acute toxicity to reptiles (based on acute toxicity data for birds), birds, and mammals result in acute RQs that exceed the LOC for secondary exposure. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed. Furthermore, incidents involving birds and mammals have been reported in association with the use of brodifacoum. Finally, the estimated individual chance of effect of mortality (IEC) was determined to be 1 in 1 (100%).

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

Designated Critical Habitat for:	Effects Determination	Basis for Determination
Alameda whipsnake (AW) (*Masticophis lateralis euryxanthus*)	Habitat Modification	Risk assessment indicates use of brodifacoum may 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.

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

Uses	Potential for Effects to Identified Taxa Found in the Terrestrial Environment[7]									
	SMHM and Small Mammals[1]		SJKF and Large Mammals[2]		AW and Reptiles[3]		Small Birds[4]		Terrestrial – phase Amphibians[5]	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
Rodent Control	Yes	Yes[6]	Yes	Yes[6]	Yes	Yes[6]	Yes	Yes[6]	Yes	Yes[6]

1 A yes in this column indicates a potential for direct effects to the SMHM and indirect effects to the AW and SJKF.
2 A yes in this column indicates a potential for direct and indirect effects to SJKF.
3 A yes in this column indicates the potential for direct (through secondary exposure) to the AW and indirect (through prey reduction) effects to the AW.
4 A yes in this column indicates a potential for direct effects to the AW, SMHM and SJKF.
5 A yes in this column indicates a potential for indirect effects to the AW.
6 Chronic toxicity data are not available to assess this species; however chronic risk is assumed based upon the high acute risks.
7 Terrestrial invertebrates and terrestrial plants, which have the potential to indirectly affect all three species were not assessed. In addition, aquatic plants, which have the potential to indirectly affect the SMHM, were also not assessed.

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 habitat modification effects determinations, it is important to note that pesticide exposures and predicted

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

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8. MRID List

Ecological Effects

71-1 Avian Single Dose Oral Toxicity

MRID	Citation Reference
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129705	ICI Americas, Inc. (1979) Talon Rodenticide Containing Brodifacoum: ?Fish and Wildlife Safety Summary|. (Unpublished study re- ceived Jul 19, 1979 under 10182-26; CDL:238840-A)
41563303	Ross, D.; Roberts, N.; Fairley, C. (1990) Brodifacoum: The Acute Oral Toxicity (LD50) OF Brodifacoum to Mallard Duck: Lab Project Number: ICI 308 WL/791275. Unpublished study prepared by Hunting don Research Centre. 24 p.
46351303	Roberts, N.; Fairley, C. (1985) The Acute Oral Toxicity of Brodifacoum to the Ring-Necked Pheasant: Final Report. Project Number: ISN/13BT/85982, AX3474. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 27 p.
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46351304	Ross, D.; Roberts, N.; Cameron, D. (1977) The Acute Oral Toxicity (LD50) of PP581 to the Japanese Quail: Final Report. Project Number: ICI/122WL/77599. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 14 p.

71-2 Avian Dietary Toxicity

MRID	Citation Reference
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97937 Fink, R. (1976) Final Report: Eight-day Dietary LC50--Bobwhite Quail: PP 581 Technical: Project No. 123-114. (Unpublished study received Jan 3, 1978 under 10182-EX-10; prepared by Wild- life International, Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:232750-D)

124475 Fink, R.; Beavers, J. (1978) Dietary LC50--Mallard Ducks: Technical Brodifacoum: Project No. 123-124. Final rept. (Unpublished study received Feb 27, 1979 under 10182-26; prepared by Wildlife International, Ltd., submitted by ICI Americas, Inc., Wilming- ton, DE; CDL:237703-F)

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80233 Ross, D.B.; Roberts, N.L.; Phillips, C.N.K. (1979) Assessment of the Palatability of Talon Pellets Containing 0.005% (50 ppm) Brodifacoum to the Bobwhite Quail: ICI 296 WL/79864; CTL/C/812. (Unpublished study received Jul 22, 1981 under 10182-38; pre- pared by Huntingdon Research Centre, England, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245704-C)

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71-3 Wild mammal toxicity

MRID	Citation Reference
2467	Pank, L.F.; Hirata, D.N. (1976) Primary and Secondary Toxicity of Anticoagulant Rodenticides: Job Completion Report: Work Unit DF-103.7. (Unpublished study received on unknown date under unknown admin. no.; prepared by U.S. Fish and Wildlife Service, Denver Wildlife Research Center, Wildlife Damage Research Station, submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL: 230307-B)
80248	Ringer, R.K.; Aulerich, R.J.; Padgett, G.; et al. (1979) Determina- tion of Oral LDI50^ of Brodifacoum for Mink. (Unpublished study received Jul 22, 1981 under 10182-38; prepared by Michigan State Univ., Dept. of Poultry Science, Fur Animal Project, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245704-S)
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80200	Morris, K.D.; Jaber, M.B. (1981) Laboratory Comparison of Brodi- facoum Tissue Residue in Voles Fed 10 0r 50 PPM Volid Pellets in a No-choice Feeding Situation for 3 Days: Report Series TMUE0006/B. (Unpublished study received Jul 22, 1981 under 10182-EX-21; prepared in cooperation with Virginia Tech and Analytical Biochemistry Laboratories, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245702-F)
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71-5 Simulated or Actual Field Testing

MRID	Citation Reference
139518	Kaukeinen, D.; Byers, R. (1981) Volak: Potential Hazard of the 50 ppm Black Pellet Broadcast at Three Rates As Indicated by Penned Ring-necked Pheasants: Report Series TMUD3451/B. (Un- published study received Apr 29, 1983 under 10182-58;

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40077205 Hegdal, P.; Blaskiewicz, R. (1984) Evaluation of the potential hazard to barn owls of Talon used to control rats and house mice. Environmental Toxicology Chemistry 3:167-179.

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ACC 244802 Kaukeinen, D.E.; Byers, R.; Merson, M.; et al. (1980) Volak^(TM)I: Efficacy to Meadow Voles and Wildlife Hazard from Broadcast Application of 50 ppm Pellets at 9.4 and 41 lb/A in a Dormant Apple Orchard (Virginia): Report Series TMUD3344/B. (Unpub- lished study received Apr 2, 1981 under 10182-EX-12; prepared in cooperation with Virginia Polytechnic Institute, Winchester Fruit Research Lab., submitted by ICI Americas, Inc., Wilming- ton, Del.; CDL:244802-B)

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72-1 Acute Toxicity to Freshwater Fish

MRID	Citation Reference
66943 or 124472	Hill, R.W. (1978) PP 581: Determination of the Acute Toxicity of PP 581 to Rainbow Trout (~Salmo gairdneri~): **BL/B/1877**. Includes undated method entitled: Analytical method for PP 581 in aqueous solution. (Unpublished study received Aug 15, 1978 under 10182- 26; prepared by Imperial Chemical Industries, Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:234655-K)
66946	Will, R.W.; Clyburn, M. (1978) PP 581: Talon--Feeding Trials with Rainbow Trout (~Salmo gairdneri~): **BL/B/1881**. (Unpublished study received Aug 15, 1978 under 10182-26; prepared by Imperial Chemical Industries, Ltd., submitted by ICI Americas, Inc., Wilmington, Del.; CDL:234655-N)
66947	Hill, R.W.; Clyburn, M.M. (1978) PP 581: Talon--Feeding Trials with Bluegill Sunfish (~Lepomis macrochirus~): **BL/B/1878**. (Unpub- lished study received Aug 15, 1978 under 10182-26; prepared by Imperial Chemical Industries, Ltd., submitted by ICI

Americas, Inc., Wilmington, Del.; CDL:234655-O)

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72-2 Acute Toxicity to Freshwater Invertebrates

MRID	Citation Reference
66948	Getty, C.; Wilkinson, W.; Sealey, C. (1978) Brodifacoum: Toxicity to First Instar~Daphnia magna~: Report Series RJ0007 B. (Un- published study received Aug 15, 1978 under 10182-26; prepared by Imperial Chemical Industries, Ltd., submitted by ICI Ameri- cas, Inc., Wilmington, Del.; CDL:234655-P)
128442	Getty, C.; Wilkinson, W.; Sealey, C. (1978) Brodifacoum: Toxicity of the Liquid Concentrate Pelleted Bait and Technical Material to First Instar Daphnia magna: Report Series RJ0046B. (Unpub- lished study received Mar 29, 1974 under 10182-26; prepared by Imperial Chemical Industries Ltd., Eng., submitted by ICI Ameri- cas, Inc., Wilmington, DE; CDL:237909-A)
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Non-Guideline Studies & Secondary Toxicity Studies

MRID	Citation Reference
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80239	Hegdal, P.L.; Blaskiewicz, R.W. (1981) Hazards to Barn Owls Associ- ated with the Use of Talon^(R)I (Brodifacoum Bait) for Control- ling Rats and House Mice. (Unpublished study received Jul 22, 1981 under 10182-38; prepared in cooperation with U.S. Fish and Wildlife Service, Wildlife Research Center, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245704-J)
80240	Morris, K.D.; Kaukeinen, D.E. (1980) Talon^(TM)I 15-day Choice Feeding of Blank Talon Pellets Containing Demeclocycline vs. EPA Meal Using Albino Norway Rats: Report Series TMUD3245/B. (Un- published study received Jul 22, 1981 under 10182-38; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245704-K)
80241	Morris, K.D.; Kaukeinen, D.E. (1980) Talon: Rodent Baiting Sites of the Barn Owl: Secondary Hazard Study: Report Series TMUD3335/B. (Unpublished study received Jul 22, 1981 under 10182-38; sub- mitted by ICI Americas, Inc., Wilmington, Del.; CDL:245704-L)
80242	Mendenhall, V.M.; Pank, L.F. (1979) Secondary Poisoning of Owls by Anticoagulant Rodenticides. (U.S. Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished study; CDL: 245704-M)
80243	Marsh, R.E.; Howard, W.E. (1978) Secondary Toxicity Hazards Tests of Brodifacoum to Raptors. Prelim. rept. (Unpublished study received Jul 22, 1981 under 10182-38; prepared in cooperation with Univ. of California--Davis, Dept. of Avian Science, Raptor Center, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245704-N)

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84347 Morris, K.D.; Kaukeinen, D.E. (1981) Volid: Effect of Candidate Avian Repellent Agents on Laboratory Acceptance of Blank Volid Pellets to Meadow Voles: Report Series TMUD3592/B. (Unpublished study received Sep 10, 1981 under 10182-58; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-H)

84348 Morris, K.D.; Kaukeinen, D.E. (1981) Volid: Effect of Candidate Avian Repellent Agents on Laboratory Group Acceptance of Blank Volid Pellets to Pigeons: Report Series TMUD3593/B. (Unpub- lished study received Sep 10, 1981 under 10182-58; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-I)

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84351 Morris, K.D.; Kaukeinen, D.E. (1980) Volak: Three-day Choice Feeding of 50 ppm Volak Pellets Containing 5% Graphite versus ?~Microtus~Challenge Diet Using Pine Voles: Report Series TMUD- 3107/B. (Unpublished study received Sep 10, 1981 under 10182- 58; submitted by ICI Americas, Inc., Wilmington, Del.; CDL: 245924-L)

84352 Morris, K.D.; Kaukeinen, D.E. (1981) Volid: Acceptance of 50 ppm Volid Pellets Containing 5% Graphite versus Blank, Undyed Volid Pellets Using Pigeons: Report Series TMUD3594/B. (Unpublished study received Sep 10, 1981 under 10182-58; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-M)

84353 Morris, K.D.; Kaukeinen, D.E. (1981) Volid: Acceptability of 50 ppm Volid Pellets Containing 5% Graphite versus 50 ppm Volid Pellets Containing 50 ppm Rhodamine B Using Ring-necked Pheas- ants: Report Series TMUD3595/B. (Unpublished study received Sep 10, 1981 under 10182-58; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-N)

84354 Morris, K.D.; Kaukeinen, D.E. (1981) Volid: Acceptability of 50 ppm Volid Pellets Containing 5% Graphite versus Blank, Un- dyed Volid Pellets Using Pigeons: Report Series TMUD3659/B. (Unpublished study received Sep 10, 1981 under 10182-58; sub- mitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-O)

84355	Morris, K.D.; Kaukeinen, D.E. (1981) Volid^(TM)I: Acceptability of 10 ppm Volid Pellets Containing 5% Graphite vs 50 ppm Volid Pellets Containing 50 ppm Rodamine B Using Ring-necked Pheas- ants: Report Series TMUD3625/B. (Unpublished study received Sep 10, 1981 under 10182-58; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-P)
84356	Kaukeinen, D.E.; Byers, R.; Merson, M.; et al. (1981) Volid^(TM)I: Efficacy to Meadow Voles and Wildlife Hazard from Broadcast Application of 10 ppm Pellets at 20.4 lb/A (22.9 kg/ha) in a Dormant Apple Orchard: Report Series TMUD3683/B. (Unpublished study received Sep 10, 1981 under 10182-58; prepared in coopera- tion with Virginia Polytechnic Institute, Winchester Fruit Re- search Laboratory, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-Q)
84357	Merson, M.H.; Byers, R.E. (1981) A Study of Nontarget Species Hazard of Brodifacoum Use as an Orchard Rodenticide. (Unpub- lished study received Sep 10, 1981 under 10182-58; prepared by Virginia Polytechnic Institute and State Univ., Winchester Fruit Research Laboratory, submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245924-R)
85726	Kaukeinen, D.E.; Ussary, J.P.; Koubek, K.G.; et al. (1981) Brodi- facoum Residues in Meadow Voles and Other Wildlife from a 10 ppm Volid~(TM)~ Treated Orchard--Trial 24VA81-001: Report Series TMU0660/B. (Unpublished study received Jul 22, 1981 under 10182-EX-21; submitted by ICI Americas, Inc., Wilmington, Del.; CDL:245702-D)
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MRID	Citation Reference
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