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REFINED EFFECTS DETERMINATION FOR CALIFORNIA RED-LEGGED FROG POTENTIALLY EXPOSED TO DIMETHOATE

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EXECUTIVE SUMMARY

The California red-legged frog (*Rana draytonii*; formerly known as the subspecies *Rana aurora* draytonii) is endemic to California and Baja, Mexico. The species has been extirpated from 70% of its former range. Critical habitat has been designated for 27 counties and dimethoate is known to be used in 23 of these counties (FWS, 2010). The Endangered Species Act (ESA) is the primary Federal law that provides protection for the California red-legged frog (CRLF) given its listing as a threatened species in 1996.

The US Environmental Protection Agency (EPA) must determine whether 66 pesticides currently authorized for use in California may adversely affect the CRLF. The draft effects determination released by EPA for dimethoate use concluded that dimethoate was "likely to adversely affect" the CRLF (EPA, 2008a). Dimethoate is a contact and systemic insecticide mainly used to control a variety of insect pests on a number of fruit, vegetable, grain, and field crops, as well as ornamentals and non-cropland areas adjacent to agricultural fields. The purpose of this report is to build on EPA's screening-level effects determination and develop a refined effects determination for the CRLF for direct and indirect effects associated with exposure to dimethoate. This effects determination focuses on dimethoate-containing products registered for use in California.

Because EPA used conservative effects metrics and exposure estimates to derive their effects determination, use pattern scenarios that were identified as not of concern by EPA were not considered in this refined effects determination. This effects determination focused on: 1) direct acute and chronic effects to the terrestrial-phase CRLF, 2) chronic effects to aquatic invertebrate prey of the CRLF, 3) effects to aquatic vascular plants that provide habitat for the CRLF, 4) acute and chronic effects to terrestrial-phase amphibian prey, i.e., the Pacific tree frog, and 5) effects to riparian and terrestrial plants that provide habitat for the CRLF. As part of this refined effects determination a conclusion of "no effect", "may affect, but not likely to adversely affect", or "may affect, but likely to adversely affect" was assigned to each of the use patterns and receptor group of interest.

This effects determination for dimethoate follows the guidance in the generic problem formulation for CRLF developed by Intrinsik (formerly, Cantox Environmental, Inc.) on behalf of CropLife America (Cantox Environmental, 2007). This effects determination also follows EPA's Guidelines for Ecological Risk Assessment (EPA, 1998).

Dimethoate formulations can be applied by ground sprayers, chemigation and aircraft. Based on the environmental fate and physical-chemical properties of dimethoate, the most likely routes of transport of dimethoate to habitat used by aquatic and terrestrial life stages of the CRLF are surface runoff, spray drift and deposition.

A tiered approach was used to assess the effects of dimethoate to CRLFs, their prey and their habitat. The approach is conceptually similar to the tiered approach that EPA uses for ecological risk assessment (EPA, 1998), in that increasingly refined analyses are only conducted for use patterns for which concern was not eliminated in a previous tier. Thus, only those use patterns for which a presumed risk remains proceed to the next tier. Aquatic-phase CRLF were not considered in this assessment because the EPA estimated negligible risk to this life stage (EPA, 2008a). Thus, aquatic exposure was considered only for effects to habitat and prey of the CRLF.

We began by conducting a screening-level effects determination for aquatic and terrestrial exposures to determine which use patterns, if any, posed risks to CRLFs, their prey and their habitat. The use patterns of potential concern were then assessed using refined methods to determine probabilities of effects of varying magnitude to CRLFs. The screening-level and refined effects determinations were each conducted in three phases: exposure assessment, effects assessment, and risk characterization.

Aquatic Exposure

Concentrations of dimethoate in the surface water of a standard-sized pond were estimated using EPA's PRZM/EXAMS model. The maximum allowable application rate and frequency, and minimum repeat application interval for dimethoate products in California were used in the aquatic exposure model for each use pattern. Best available physical and chemical properties and environmental fate studies were used as input parameters in each model run.

The PRZM scenarios used in EPA's effects determination (EPA, 2008a) were used in this effects determination. The scenarios included EPA's standard scenarios (STD), plus two scenarios developed for the cumulative organophosphate (OP) assessment and those specifically developed for the CRLF effects determination.

Dimethoate may be applied between emergence and harvest of a crop. Because rainfall patterns and other climatic variables vary temporally, off-field transport of dimethoate via runoff will also vary temporally. As a result, choice of application date can affect the estimated concentrations of dimethoate in the standard pond. Thus, each scenario was simulated for a range of application dates based on historical use data as identified using the California Pesticide Use Database for most of the simulated crops. The PRZM/EXAMS simulations were performed by Tammara Estes and John Hanzas of Stone Environmental, Inc. For crops that were not listed in the California Pesticide Use Database, date ranges were set to start at the emergence date and end at harvest date for the standard scenario selected to represent the crop.

Terrestrial Exposure

For direct effects to terrestrial-phase CRLFs and indirect effects to their amphibian prey, the Pacific tree frog, a total daily intake (*TDI*) model was used to estimate acute and chronic dietary exposure to dimethoate.

The maximum application rates were used in TerrPlant (version 1.2.2) and compared to the NOEL (An EC25 is usually required by TerrPlant for non-listed species. However, no effects were observed at highest tested application rate) for 10 monocot and dicot crops. The purpose of this portion of the assessment was to estimate risk to the structure of the plant community in terrestrial environments, including breeding and non-breeding habitats of the CRLF.

Measures of Effects for Aquatic and Terrestrial Biota

An evaluation of the available ecotoxicity data was conducted to ensure that the best data available were used in the effects determination. Aquatic and avian toxicity studies were screened with criteria designed to ensure that only high quality data were used in the effects determination. Based on the criteria, studies were classified as acceptable, supplemental, or unacceptable. Each study rating was based on an evaluation of study design and execution, adherence to toxicity testing protocols, statistical analyses, and other key aspects of the study. All other studies used as measures of effect (e.g., terrestrial plant toxicity studies) for the screening-level effects determination were also evaluated for quality.

Risk Characterization

Risk characterization integrates the exposure and effects assessments to estimate the risk associated with each receptor and use pattern combination (e.g., risk to an aquatic invertebrate community following applications to wheat via groundspray). Table 1 presents a summary of the assessment endpoints, measures of exposure and measures of ecological effects considered in this effects determination. In the screening-level effects determination, risks were determined using risk quotients (RQs) that were calculated by dividing estimated concentrations or doses by the corresponding acute and chronic effects metrics (e.g., LC50, NOEL). If a RQ was below the Agency's level of concern (LOC), the use pattern was eliminated from further consideration. Use patterns with a RQ>LOC proceeded to the more refined probabilistic risk assessment. In this effects determination, cottonwood grown for pulp, cropland areas adjacent to vineyards and Christmas tree nurseries use patterns were considered in the refined effects determination. Table 2 presents the assessment endpoints and measures of exposure and effect that were used in the refined effects determination.

Table 1 Summary of assessment endpoints and measures of exposure and effect for the screening-level effects determination			
Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Aquatic Invertebrate Prey			
Productivity of invertebrates associated with nearshore habitats of aquatic-phase CRLFs.	Chronic	Estimated 1-in-10 year annual peak 21 d average concentrations of dimethoate based on the 30-year simulation in standard-sized ponds located adjacent to treated agricultural fields.	NOEL of 0.04 mg/L for *Daphnia magna* (Wüthrich, 1990 [MRID 42864701]).
Aquatic Habitat			
Structure of the plant community in aquatic environments, including breeding and non-breeding habitats that potentially contain early stages of the CRLF.	Acute/Chronic	Estimated 1-in-10 year annual peak concentrations of dimethoate based on the 30-year simulation in standard-sized ponds located adjacent to treated agricultural fields.	7 d EC50 of >45.1 mg/L (frond number, biomass and growth) for duckweed (*Lemna gibba*) (Porch et al., 2009 [MRID 47709703]).
Terrestrial Life-stage of CRLF			
Survival, reproduction and growth of the CRLF.	Acute	Total daily intake (*TDI*) model for CRLFs exposed to dimethoate in diet.	LD50 for northern bobwhite (*Colinus virginianus*) of 14.6 mg/kg bw (Zok, 2001c [MRID 47769705]).
	Chronic	Total daily intake (*TDI*) model for CRLFs exposed to dimethoate in diet.	NOEL for northern bobwhite (*Colinus virginianus*) of 1.09 mg/kg bw/d (10.1 mg/kg diet) (Gallagher et al., 1996a [MRID 44049001]).
Terrestrial Amphibian Prey			
Productivity of amphibians associated with CRLF habitat.	Acute	Total daily intake (*TDI*) model for Pacific tree frogs exposed to dimethoate in diet.	LD50 for northern bobwhite (*Colinus virginianus*) of 14.6 mg/kg bw (Zok, 2001c [MRID 47769705]).
	Chronic	Total daily intake (*TDI*) model for Pacific tree frogs exposed to dimethoate in diet.	NOEL for northern bobwhite (*Colinus virginianus*) of 1.09 mg/kg bw/d (10.1 mg/kg diet)(Gallagher et al., 1996a [MRID 44049001]).
Terrestrial Habitat			

Table 1 Summary of assessment endpoints and measures of exposure and effect for the screening-level effects determination			
Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Structure of the plant community in terrestrial environments, including breeding and non-breeding habitats that potentially contain the CRLF.	Acute/Chronic	Estimated EEC in dry areas and semi-aquatic areas using application rate and application method in TerrPlant	21 d NOEL of >1.5 lb a.i./Acre (seedling emergence, growth) for 10 different crops (monocots and dicots) (Porch et al., 2011b [MRID 48572801; 48628101). 21 d NOEL of >1.5 lb a.i./Acre (vegetative vigor, growth) for 10 different crops (monocots and dicots) (Porch et al., 2011a [MRID 48572802]).

Table 2 Summary of assessment endpoints and measures of exposure and effect for the refined effects determination			
Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Aquatic Invertebrate Prey			
Productivity of invertebrates associated with nearshore habitats of aquatic-phase CRLFs.	Chronic	Distribution of estimated annual peak 21 d average concentrations of dimethoate in standard-sized ponds located adjacent to treated agricultural fields from 30-year simulation.	Species sensitivity distribution (SSD) for aquatic invertebrates
Terrestrial Amphibian Prey			
Productivity of amphibians associated with adult CRLF habitat.	Chronic	Probabilistic total daily intake (*TDI*) model for Pacific tree frogs exposed to dimethoate in diet.	Dose-response curve for most sensitive bird species (Gallagher et al., 1996a [MRID 44049001]).
Terrestrial Life-stage of CRLF			
Survival, reproduction and growth of the CRLF.	Acute	Probabilistic total daily intake (*TDI*) model for CRLF exposed to dimethoate in diet.	Dose-response curve for most sensitive bird species (Zok, 2001c; [MRID 47769705]).
Survival, reproduction and growth of the CRLF.	Chronic	Probabilistic total daily intake (*TDI*) model for CRLF exposed to dimethoate in diet.	Dose-response curve for most sensitive bird species (Gallagher et al., 1996a [MRID 44049001]).

The approach used in the refined effects determination was similar to that used in the screening-level effects determination except that distributions were used in the exposure and effects assessments, instead of conservative point estimates.

For aquatic invertebrate prey, the exposure distribution for cottonwood for pulp was integrated with the chronic species sensitivity distribution for aquatic invertebrates to derive a risk curve that indicates the cumulative probabilities of effects of differing magnitude. The risk curve was then used to categorize risk for this use pattern as *de minimis*, low, intermediate, or high. This exercise was conducted for both aerial and chemigation applications of dimethoate to cottonwood grown for pulp.

For effects to terrestrial-phase CRLF and their amphibian prey (Pacific tree frog), simulations were run to generate *TDI* exposure distributions for exposure scenarios of concern. Applications to broccoli, cottonwood grown for pulp, non-cropland areas adjacent to vineyards, Christmas tree nurseries and wheat were considered in the refined terrestrial assessment for terrestrial-phase CRLF and their amphibian prey. The exposure distributions were integrated with dose-response curves corresponding to the most sensitive avian dietary studies for acute and chronic exposures.

Other lines of evidence considered in the refined effects determination included: 1) Information from mesocosm and field studies, 2) Information available from monitoring data, and 3) Information available from incident reports.

Results and Discussion

Aquatic Assessment

The results of the screening-level assessment suggest that there is negligible risk of indirect effects to aquatic-phase CRLF via reduction in aquatic habitat (i.e., vascular plants). All RQs for vascular plants were <0.0015, which is well below the level of concern (LOC=1).

Based on the results of the screening-level assessment, indirect effects to CRLF via reduction in aquatic invertebrate prey due to chronic exposure poses neglible risk for all but one crop. With the exception of cottonwood grown for pulp, all RQs were below the LOC of 1. The RQs for cottonwood grown for pulp were 1.28 and 1.35 for chemigation and aerial applications, respectively.

The refined quantitative risk characterization indicates that dimethoate applied to cottonwood grown for pulp poses intermediate risk of chronic effects to aquatic invertebrates. However, there are a number of mitigating factors that must be considered:

- The preferred breeding and summer habitat of the CRLF includes still or slow-moving permanent streams with deep water (>0.7 meters) and dense riparian vegetation. Stone Environmental, Inc. conducted a spatial analysis of CRLF habitat types. The hydrography analyzed included: static ponds, flowing ponds, perennial and intermittent streams, and canals. CRLF core areas and critical habitat, as designated by FWS, are two habitat location sources that focus on preservation and conservation of the species. This analysis showed that lakes and ponds (perennial, intermittent, swamps/marshes) make up only 0.16 to 0.74 % of the total area of land within critical habitat and core areas, respectively (Stone Environmental, 2012). The analysis showed that the majority of waterbodies comprising CRLF aquatic critical habitat have in- and out-flows that would result in much lower concentrations of dimethoate due to dilution than would the stagnant standard pond modeled in PRZM/EXAMS. Following are two examples of how waterbodies having in-flow and out-flow reduce pesticide concentrations. Using the AgDrift Stream Assessment Tool, Rick Reiss of Exponent, Inc. demonstrated that even in slow-moving streams (0.07 ft/sec) dimethoate concentrations decline rapidly from initial peak concentrations of 50 µg/L to less than 1 µg/L in five hours (Bogen and Reiss, 2011; presentation to EPA and NMFS on October 23, 2009). Stone Environmental, Inc. derived more realistic EECs for malathion in water bodies inhabited by the CRLF (i.e. realistic in-flow and out-flow, volume, and location characteristics) using SWAT (Soil and Water Assessment Tool) modeling. Peak EECs were 5 to 12 times greater for the PRZM/EXAMS simulations (lettuce and strawberry, respectively) than they were for the most vulnerable water body in the SWAT simulation of the Watsonville watershed in California. For the 21-day duration, the EECs based on PRZM/EXAMS were 20 to 50 times greater (lettuce and strawberry, respectively) than the SWAT simulation predictions. This comparison shows that the interpretation of risk is significantly reduced when EECs are based on modeling actual aquatic ecosystems (rather than hypothetical ones in the case of PRZM/EXAMS), and when using a model that appropriately accounts for all hydrologic processes, such as SWAT (Intrinsik, In Prep(b); Stone Environmental, 2012).

- There is no documentation indicating that cottonwood is grown commercially for pulp use in California.

- CRLF habitats likely receive much less runoff and drift of dimethoate because of the presence of riparian vegetation adjacent to their preferred water bodies. Even bare tree barrier can reduce drift by up to 20%. Increasing leaf density (optical porosity) can reduce drift up to >90%, depending on barrier characteristics (e.g., height and width) and the location of measurement (Felsot et al., 2011). PRZM/EXAMS assumes that the standard pond is adjacent to the treated field and that there is no vegetation to intercept runoff or spray drift. These factors again support the idea that actual dimethoate concentrations in CRLF habitat are likely considerably lower than predicted for the standard pond.

- PRZM/EXAMS is a highly conservative modeling approach that is appropriate for screening-level ERAs, but it should not be used to guide decision-making. For example, all runoff from the 10 hectare field is assumed to drain into the standard pond, a highly unrealistic assumption. Many farms would have runoff draining in several directions. The wind is assumed to be blowing in the direction of the standard pond, which will not occur for most applications of pesticides. To derive valid probabilistic exposure estimates (e.g., a 90th percentile), all key input variables must be modelled as distributions that reflect the range of plausible values for each variable. However, the only probabilistic variable in PRZM/EXAMS is the meteorology (most importantly, rainfall). Conservative and sometimes implausible assumptions are made for almost all other key variables. The compounding effect of these conservative assumptions is implausibly high exposure estimates. Because CRLFs are opportunistic and generalist feeders, it is unlikely that adverse effects to a small proportion of sensitive aquatic species would significantly reduce the overall availability of prey, particularly given that their preferred foraging habitats are not stagnant ponds adjacent to cottonwood stands. Moreover, in our refined assessment, all potential start dates for application were considered, which did not account for the fact that pesticides would typically not be applied on or in advance of forecasted precipitation events.

Conservative PRZM/EXAMS modeling suggests that sensitive aquatic invertebrate prey would be at risk in stagnant ponds located next to cottonwood plantations treated with dimethoate at the maximum application rate. However, based on factors described above, this situation is highly unlikely to ever occur in CRLF habitats in California.

The results of the Hessen et al. (1994) mesocosm study showed that few effects occurred to rotifers when exposed to dimethoate at the highest concentration tested (100 µg/L) in an aquatic mesocosm study. This concentration is well above the chronic effects metric for aquatic invertebrates (40 µg/L). The crustacean community studied in Hessen et al. (1994) was composed of the copepod *Acanthodiaptomus gracilis* and the cladocerans *Holopedium gibberum*, *Bosmina longispina*, *Daphnia longispina*, *Ceriodaphnia quadrangula* and *Sida crystallina*. Hessen et al. (1994) reported that the most pronounced effect was found in the 100 µg/L concentration treatment where all cladocera disappeared. *Daphnia longispina* increased in abundance at 1 µg/L and then disappeared in the 10 µg/L concentration treatment. This species was the most sensitive of the cladoceran species observed in the enclosure bags. However, the lack of replication and low numbers of organisms make it difficult to determine if the results observed in the 10 µg/L treatment are statistically meaningful. The results of the Baekken and Aanes (1994) mesocosm study showed that the average number of drifting macroinvertebrates was higher in the dimethoate-treated stream (1 µg/L) than in the reference stream. However, RIVM (2008) found no significant differences between the treated and reference streams.

The results of our analysis showed that dimethoate has been rarely detected in drinking water and surface waters of California. In addition, the new restrictions identified in EPA's Registration Eligibility Document are expected to reduce the magnitude and frequency of detections of dimethoate in drinking and surface water (EPA, 2008c).

Terrestrial Assessment

TerrPlant was used to estimate the potential for risk to the structure of the plant community in terrestrial environments, including breeding and non-breeding habitats that potentially contain the CRLF. None of the RQs exceeded the level of concern (LOC=1). Thus, it is unlikely that dimethoate poses a risk to the vegetative habitats used by the CRLF.

With respect to CRLF and their amphibian prey, except for the use patterns presented below (Table 3), all use patterns had RQs below the corresponding LOCs for amphibian terrestrial exposure.

Table 3 Summary of terrestrial amphibian exposure scenarios considered in the refined effects determination

Crop/Use	*Receptor*	*Exposure*	*Diet*[a]
Broccoli	Adult CRLF	Acute	Whole mouse
Christmas tree nurseries	Juvenile CRLF	Acute	Worst case
	Adult CRLF	Acute	Worst case, whole mouse
Cottonwood grown for pulp	Juvenile CRLF	Acute and chronic	Intermediate (acute only) and worst case
	Adult CRLF	Acute and chronic	Worst case, whole mouse
	Pacific tree frog	Chronic	NA[b]
Non-cropland areas adjacent to vineyards	Juvenile CRLF	Acute and chronic	Intermediate and worst case
	Adult CRLF	Acute and chronic	Worst case, whole mouse
	Pacific tree frog	Chronic	NA[b]
Wheat	Adult CRLF	Acute	Whole mouse

[a] Worst-case diet was 100% terrestrial arthropods by field metabolic rate. Intermediate diet for juvenile CRLF consisted of 50% aquatic invertebrates and 50% terrestrial arthropods by wet weight based on field metabolic rate.

[b] The diet of 81% terrestrial arthropods and 19% aquatic invertebrates was assumed for all Pacific tree frog scenarios.

The refined effects determination resulted in estimates of *de minimis* risk of direct effects to CRLF due to acute dietary exposure following applications to broccoli, Christmas tree nurseries, cottonwood plantations, non-cropland areas adjacent to vineyards and wheat.

The estimated risk associated with chronic dietary exposure is low for both juvenile and adult CRLF consuming a worst-case diet following applications to cottonwood plantations or non-cropland adjacent to vineyards. Juvenile CRLF consuming an intermediate-case diet following applications to non-cropland adjacent to vineyards were also estimated to be at low risk of chronic effects from dietary exposure (See Table 4).

With respect to indirect effects to adult CRLF via reductions in amphibian prey, the results of the refined effects determination indicated that dimethoate applied via aerial or chemigation applications to cottonwood or to non-cropland areas adjacent to vineyards poses low risk of chronic effects from dietary exposure (See Table 4).

We assumed that CRLFs hunt for prey on treated fields receiving maximum label application rates, and that the frogs consume terrestrial arthropod prey immediately after application to fields. These assumptions do not agree with the literature suggesting that most frogs remain in close proximity to a water body most of the time, and that they forage opportunistically on mobile prey. Also, the feed item with the highest residues, terrestrial arthropods, is the target of the insecticide. This leads to two important points: (1) due to the efficacy of the product at label application rates, most terrestrial arthropods that are on a field at the time of dimethoate application will not be able to travel to the preferred riparian habitat of CRLF, and (2) immobilized terrestrial arthropods are not desirable prey for the CRLF because their predatory instincts are triggered by movement. Thus, the assumption that CRLFs are consuming terrestrial arthropods and other prey on treated fields immediately after application is highly conservative.

Table 4 Summary of quantitative refined risk characterization for terrestrial-phase CRLF

Crop/Use	*Application Method*	*Scenario (lb. a.i./A)/ No. Applications per Year/ Retreatment Interval (d)*	*Receptor*	*Diet Case*[a]	*Exposure Duration*	*Risk Category*
Broccoli	Aerial/groundspray	0.5/3/7	Adult	Whole mouse	Acute	*De minimis*
Christmas trees	Airblast/groundspray	1/3/14	Juvenile CRLF	Worst	Acute	*De minimis*
			Adult CRLF	Worst	Acute	*De minimis*
			Adult CRLF	Whole mouse	Acute	*De minimis*
Cottonwood grown for pulp	Aerial/ chemigation	2/3/10	Juvenile CRLF	Worst	Acute	*De minimis*
			Juvenile CRLF	Worst	Chronic	Low
			Adult CRLF	Worst	Acute	*De minimis*
			Adult CRLF	Worst	Chronic	Low
			Juvenile CRLF	Intermediate	Acute	*De minimis*
			Adult CRLF	Whole mouse	Acute	*De minimis*
			Pacific tree frog	NA	Chronic	Low
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Worst	Acute	*De minimis*
			Juvenile CRLF	Worst	Chronic	Low
			Juvenile CRLF	Intermediate	Acute	*De minimis*
			Juvenile CRLF	Intermediate	Chronic	Low
			Adult CRLF	Worst	Acute	*De minimis*
			Adult CRLF	Worst	Chronic	Low
			Adult CRLF	Whole mouse	Acute	*De minimis*
			Pacific tree frog	NA	Chronic	Low
Wheat (2)	Aerial/groundspray	0.67/2/7	Adult CRLF	Whole mouse	Acute	*De minimis*

[a] Worst-case diet was 100% terrestrial arthropods by field metabolic rate. Intermediate diet for juvenile CRLF consisted of 50% aquatic invertebrates and 50% terrestrial arthropods by wet weight based on field metabolic rate.

Based on the California Pesticide Use Reporting (PUR) database, cottonwood and non-cropland adjacent to vineyards (Table 4) represented a very small proportion of the total dimethoate used in California between 2000 and 2009 and the total area treated in these years. In fact, we could find no evidence to suggest that cottonwood grown for pulp was treated with dimethoate in California during those years. There is no record of uncultivated agricultural areas, which would include non-cropland adjacent to vineyards, being treated with dimethoate from 2006-2009. Incidents resulting from the legal, registered uses of dimethoate are infrequent. Moreover, the latest registered use incident occurred in 1993 and changes in labeling, application rates and best management practices since then suggest that future incidents will be even less likely.

Conclusions

The weight-of-evidence indicates that CRLF are unlikely to be at risk as a result of dimethoate application via direct effects associated with the consumption of prey items containing dimethoate residues or indirect effects via reduction of prey or habitat components (vascular plants and invertebrates, terrestrial amphibian prey). EPA (2008a) previously concluded that risk of direct effects of dimethoate to aquatic-phase CRLFs is negligible. Our analyses also show that risk of direct effects is negligible for terrestrial-phase CRLF, and risk of indirect effects via reductions in prey and habitat is negligible for both aquatic- and terrestrial-phase CRLF. Thus, the overall conclusion of this effects determination is that dimethoate use in California may affect, but is not likely to adversely affect CRLFs.

REFINED EFFECTS DETERMINATION FOR CALIFORNIA RED-LEGGED FROG POTENTIALLY EXPOSED TO DIMETHOATE

1.0 INTRODUCTION

The California red-legged frog (CRLF; *Rana draytonii*, formerly known as the subspecies *Rana aurora draytonii*) is endemic to the State of California and Baja California in Mexico (FWS, 2002a). The species has been extirpated from 70% of its former range and populations remain in approximately 256 streams and drainages in 27 counties in California (FWS, 2002a; 2010). Given the reduction in CRLF numbers, the species was listed as threatened under the US Endangered Species Act (ESA) in 1996.

The US Environmental Protection Agency (EPA) is in the process of assessing whether or not 66 pesticides, currently authorized for use in California, can adversely affect the CRLF. Dimethoate (O,O-dimethyl S-[N-(methylcarbamoyl)methyl] phosphorodithioate; CAS Registry Number is 60-51-5), a systemic organophosphate insecticide, is one of the pesticides under investigation. Dimethoate is mainly used to control a variety of insect pests on a number of fruit, vegetable, grain, and field crops, as well as ornamentals and non-cropland areas adjacent to agricultural fields.

The EPA issued the following documents with regard to dimethoate and ecological risk:

- Risks of dimethoate use to the federally-listed California red-legged frog (*Rana aurora* draytonii) (EPA, 2008a); and
- Registration review – preliminary problem formulation for ecological risk, environmental fate, and endangered species assessments for dimethoate (EPA, 2008b).

Based on the effects determination for dimethoate, EPA concluded that .... "a refinement of all 'may affect' determinations resulted in a 'likely to adversely affect' determination based on direct effects to the terrestrial-phase CRLF, indirect effects to the CRLF based on effects to its prey and for indirect effects to the CRLF based on effects to its habitat."

Cheminova retained Intrinsik Environmental Sciences, Inc. (hereafter Intrinsik) and Stone Environmental, Inc. (hereafter Stone Environmental) to review and comment on EPA's dimethoate CRLF effects determination (Intrinsik, 2012). Intrinsik was also retained to comment on EPA's preliminary problem formulation (Intrinsik, In Prep(a)). Some of the major concerns raised in our comments included the use of incorrect use pattern information, failure to use registrant Good Laboratory Practice (GLP) studies when available, inappropriate derivation of effects metrics, improper derivation of the action area, and inappropriate assessment of indirect effects. As a result of the comments raised by Intrinsik, Cheminova has undertaken this refined effects determination, the purpose of which is to assess direct and indirect effects to the CRLF from potential exposure to dimethoate.

As part of this refined effects determination a conclusion of "no effect", "may affect, but not likely to adversely affect", or "may affect, likely to adversely affect" was reached for the assessment endpoints based on weight-of-evidence. The purpose of this refined effects determination is to assess:

1) direct acute and chronic effects to the terrestrial-phase CRLF;
2) chronic effects to aquatic invertebrate prey;
3) effects to aquatic vascular plants that provide habitat for the CRLF;
4) acute and chronic effects to terrestrial-phase amphibian prey; and
5) effects to riparian and terrestrial plants that provide habitat for the CRLF.

Cheminova's refined effects determination for dimethoate follows guidance in the generic problem formulation for CRLF developed by Intrinsik (formerly, Cantox Environmental, Inc.) on behalf of CropLife America (Cantox Environmental, 2007). This refined effects determination also follows procedures outlined in EPA's Guidelines for Ecological Risk Assessment (EPA, 1998). This report is organized in five major sections: problem formulation (Section 2.0), aquatic-phase CRLF effects determination (Section 3.0), terrestrial-phase CRLF effects determination (Section 4.0), and final conclusion (Section 5.0).

2.0 PROBLEM FORMULATION

2.1 California Red-legged Frog (*Rana draytonii*)

2.1.1 Species Listing Status

The US Fish and Wildlife Service (FWS) listed the CRLF as a threatened species on June 24, 1996. The FWS has given the CRLF a recovery priority number of 6C (FWS, 2002a). This code identifies the species as having a high degree of threat and a low potential for recovery. Threats to the CRLF include, but are not limited to trematode and chytrid fungal disease, direct and indirect impacts from some human recreational activities, flood control maintenance activities, water diversions, unmanaged overgrazing activities, competition and predation by non-native species (e.g., warm water fish, bullfrog), habitat removal and alteration by urbanization, and exposure to pesticides and fertilizers (FWS, 2010).

2.1.2 Description and Taxonomy

The CRLF is endemic to California and Baja California, Mexico. It is one of two species of the red-legged frog. The other is the northern red-legged frog (*Rana aurora*) found from Vancouver Island, British Columbia to northern California (FWS, 2002a). The CRLF is the largest native frog in the western US (Wright and Wright, 1949).

2.1.3 Distribution

The historical distribution of the CRLF is believed to have included 46 counties in California from the Point Reyes National Seashore, Marin County, California, and inland from Redding and Shasta County, California, south to northwestern Baja California, Mexico (FWS, 2002a, 2006; 2010). The current distribution of the CRLF includes from Riverside County to Mendocino County along the Coast Range; from Calaveras County to Butte County in the Sierra Nevada; and in Baja California (shown in shaded areas of Figure 2-1; FWS, 1996, 2002b, 2006; 2010). These areas are further described below.

The FWS recovery plan summarizes the status of the CRLF in different portions of its current range (FWS, 2002a).

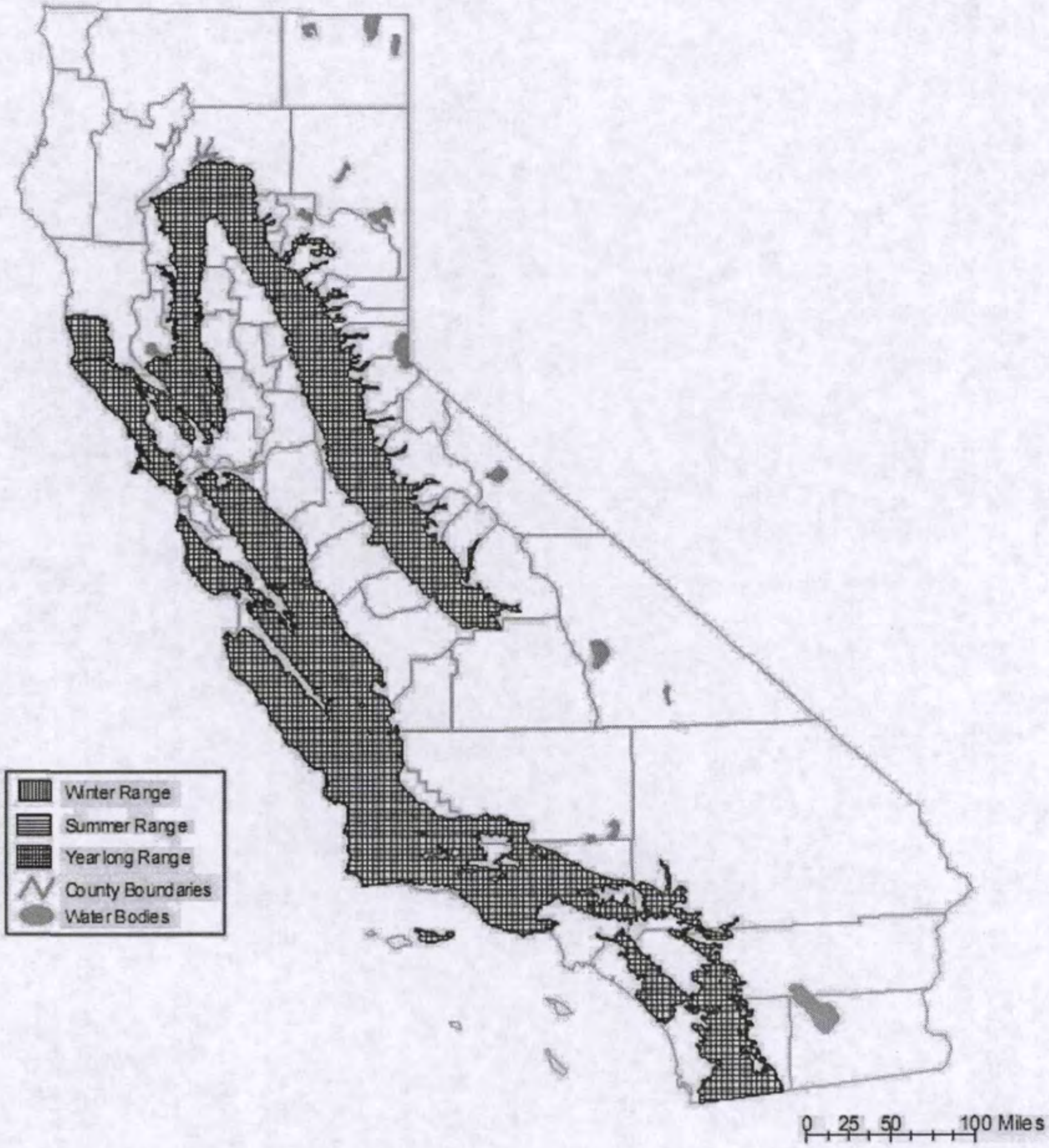

Figure 2-1 Current distribution of the CRLF (CWHR Program, 2008)

Sierra Nevada Foothills and Central Valley

Most of this region has not been surveyed, thus the true status of the CRLF is unknown. CRLFs have been observed in a few drainages in the foothills of the Sierra Nevada. In Butte County, CRLF populations have been documented in French and Indian Creeks. These populations are on private lands near the Plumas National Forest (FWS, 2002a). In 2000, another population of CRLFs was discovered in this county on the Feather River Ranger District of the Plumas National Forest (FWS, 2002a). Populations of CRLFs have also been reported in El Dorado County (1997 and 1998), and in 2001 a single CRLF was observed in Placer County on US Forest Service land near the confluence of the Rubican River and middle fork of the American River (FWS, 2002a).

North Coast Range Foothills and Western Sacramento River Valley

CRLFs have historically been observed in the tributaries of several counties in this recovery unit, including Glenn Colusa, and Lake Counties (FWS, 2002a). More recently, sightings have been reported in upper and lower Napa and Lake Counties (FWS, 2002a).

North Coast and North San Francisco Bay

Populations of CRLFs occur around Point Reyes in Marin County, including locations in Point Reyes National Seashore and the Golden Gate National Recreation Area (FWS, 2002a). CRLFs have also been observed on Mount Tamalpais and the Tiburon Peninsula in Marin County. A large breeding population of CRLFs occurs in Ledson Marsh in Annadel State Park, Sonoma County. Three occurrences have been reported in Solano County near Suisun Marsh (FWS, 2002a). Based on new genetic information on the northern coastal species, additional observations have also been made in Mendocino County (FWS, 2010).

South and East San Francisco Bay

The most recent recorded sighting of CRLFs in San Francisco County occurred in 2005, in Golden Gate Park. These populations face severe barriers that are expected to inhibit dispersal between populations (FWS, 2002a). Populations are known to occur in the canals near the San Francisco International Airport in San Mateo County. CRLF reproduction has been confirmed in some of the populations (FWS, 2002a).

Contra Costa and Alameda Counties contain most of the known CRLF populations in the San Francisco Bay area. Healthy populations of CRLFs occur in the eastern portions of Contra Costa and Alameda Counties (FWS, 2002a). Many of the ponds and creeks found in the Simas Valley in Contra Costa County support populations of CRLF (FWS, 2002a). Recent CRLF sightings have been made in ponds and seeps in the foothills of Mount Diablo, Contra Costa

County. Populations have also been observed in Corral Hollow Creek in San Joaquin County and near the San Joaquin/Alameda County border (FWS, 2002a).

Central Coast

The Central Coast region spans San Francisco to Santa Barbara County and has the greatest number of drainages currently populated by CRLFs (FWS, 2002a). Most of the coastal drainages of San Mateo and Santa Cruz Counties support populations of CRLF. CRLFs are found throughout Monterey County in nearly every coastal drainage system. In San Luis Obispo County, CRLFs are found in suitable water bodies on the coastal plain and western slopes of the Santa Lucia Range (FWS, 2002a).

Diablo Range and Salinas Valley

The CRLF was once abundant in the inner Coast ranges between the Salinas River system and the San Joaquin Valley (FWS, 2002a). It currently occupies ≤10% of its historic range in these localities. Several populations of CRLF occur on the eastern side of the Diablo range in creeks in Fresno and Merced Counties (FWS, 2002a). In Monterey County, CRLFs occur in the Elkhorn Slough watershed (FWS, 2002a).

Northern Transverse Ranges and Tehachapi Mountains

This region is comprised of all of Santa Barbara and parts of Ventura, Los Angeles and Kern Counties. CRLFs occur on the Santa Maria River, Santa Barbara County, up and downstream of the Twitchell Reservoir (FWS, 2002a). Locations to the south (San Antonio Creek, Terrace, and Lagoon) are considered among the most productive CRLF locations in Santa Barbara County (FWS, 2002a). Most of these locations are found on Vandenberg Air Force Base. The habitat in this area has been relatively undisturbed and there are few occurrences of exotic species (e.g., bullfrogs). The largest populations in the northern Transverse Range are located on creeks that flow into the Cuyama and Sisquoc Rivers (FWS, 2002a). Poor habitat and introduction of aquatic predators have resulted in smaller populations of CRLFs in the Santa Ynez River Basin in Santa Barbara County. Recent surveys for CRLFs in the Tehachapi Mountains are not available (FWS, 2002a).

Southern Transverse and Peninsular Ranges

The CRLF is native to parts of Los Angeles, San Bernardino, Orange, Riverside, and San Diego counties (FWS, 2002a). In 1999, a population of 15 to 25 adults was reported in the Angeles National Forest, Los Angeles County. Non-native predators, disease and parasites threaten this population (FWS, 2002a). A breeding population of 20 to 25 adults, ten to 15 juveniles and several hundred tadpoles was recently discovered in East Las Virgenes Creek, Ventura County. South of the Tehachapi Mountains, CRLFs are currently known to occur in Amargosa Creek, Los Angeles County, and Cole Creek, Riverside County (FWS, 2002a). Bullfrog predation is believed to be the reason for the reduction in population size.

2.1.4 Habitat

CRLFs use a variety of aquatic, riparian, and upland habitats from sea level to an elevation of 1,500 meters (FWS, 2002b). Dispersal and habitat use depends on climate, habitat suitability, and life stage (FWS, 2002a). Preferred breeding and summer habitat includes still or slow-moving permanent streams with deep water (>0.7 meters) and dense riparian vegetation (FWS, 1996, 2002a). Alternative habitats include marshes, ponds, damp woods and meadows. Stone Environmental conducted a spatial analysis of CRLF habitat types. The hydrography analyzed included: static ponds, flowing ponds, perennial and intermittent streams, and canals. CRLF core areas and critical habitat, as designated by FWS, are two habitat location sources that focus on preservation and conservation of the species. This analysis showed that lakes and ponds (perennial, intermittent, swamps/marshes) make up only 0.16 to 0.74 % of the total area of land within critical habitat and core areas, respectively (Stone Environmental, 2012). CRLFs will breed in artificial impoundments such as stock ponds (FWS, 2002b). The CRLF is active year-round in coastal areas (Bulger et al., 2003). Upland summer habitats include small mammal burrows and moist leaf litter (Jennings and Hayes, 1994), the underside of boulders, rocks, and debris, various agricultural features (FWS, 2002a) and cracks in the bottom of dried ponds (FWS, 2002a).

Research has focused on CRLF in aquatic habitats and little is known about their terrestrial movements. Tatarian (2008) reported that average total terrestrial movements ranged from 1 to 71 m during a two year-long study period. Time spent away from source pools ranged from 1 to 28 d. A field study by Bulger et al. (2003) reported that over 75% of the individuals monitored traveled short distances to upland areas following rain events, but returned to aquatic habitat after a short period (Bulger et al., 2003). Ninety percent of these individuals remained within 60 meters of water at all times (Bulger et al., 2003). The authors referred to these individuals as non-migrating frogs. Non-migrating frogs were almost always within five meters of their summer aquatic habitat, but would move as far as 130 meters upland during rain events for a median period of approximately four to six days (Bulger et al., 2003). The higher levels of rain that occur in November and early December increased the median distance of CRLF from water (15 to 25 meters) and median time in upland habitats (20 to 30 days). CRLF make little use of upland habitats as winter passes and the breeding season approaches (mid December) (Bulger et al., 2003). From February to May, 90% of the non-migrating frogs remained within six meters of water (Bulger et al., 2003).

The remainder of the adult population (<25%) made additional overland trips between different aquatic sites and were referred to as migrating frogs. Twenty-five migration events, ranging from 200 to 2,800 meters, were observed (Bulger et al., 2003). CRLF traveled shorter distances (<300 meters) in one to three days and took up to two months to complete longer journeys

(Bulger et al., 2003). These migrations occurred through coniferous forests and agricultural and range lands (Bulger et al., 2003). Rather than using corridors, CRLF followed straight-line migrations between habitats (Bulger et al., 2003). The authors estimated that 11 to 22% of the adult population made annual migrations from their breeding habitat.

2.1.5 Life History

The CRLF is the largest native frog in the western United States (Wright and Wright, 1949). Adult females are generally longer than males (F: 8.7 to 13.8 cm, M: 7.8 to 11.6 cm) (Hayes and Miyamoto, 1984). Larvae range in length from 1.4 to 8.0 cm (Storer, 1925).

The foraging behavior of the CRLF is highly variable and is defined by life stage and habitat (Hayes and Tennant, 1985; FWS, 2002a). The diet of larvae has not been well studied, but they are primarily algal grazers (FWS, 2002a). They also consume organic debris, plant tissue and minute organisms (NatureServe, 2006). Their anatomy enables them to filter and entrap suspended algae (Seale and Beckvar, 1980) and their mouthparts are designed for effective grazing of periphyton (Wassersug, 1984; Kupferberg et al., 1994; Kupferberg, 1997; Altig and McDiarmid, 1999). Some of the more common food items consumed by larvae include filamentous green algae (Dickman, 1968), filamentous blue-green algae (Pryor, 2003), epiphytic diatoms (Kupferberg, 1997) and detritus and various other algae (Jenssen, 1967). Larvae are also known to feed on algal species that are considered nuisance species or form blooms (Bold and Wynne, 1985).

Adult CRLFs consume a variety of invertebrate and vertebrate species found along the shoreline and on the water surface. They will also forage several meters into dense riparian vegetation along the shoreline (FWS, 2002a). A study examining the gut contents of 35 CRLFs reported prey from 42 taxa (Hayes and Tennant, 1985). The prey groups observed most often included carabid and tenebrionid beetles, water striders, lycosid spiders, and larval neuropterans (Hayes and Tennant, 1985). The most commonly observed prey species were larval alderflies (*Sialis cf. californica*), pillbugs (*Armadillidrium vulgare*), and water striders (*Gerris sp.*; Hayes and Tennant, 1985). These taxa represent a mix of terrestrial and aquatic prey. A preference for particular prey species was not observed in this study, and CRLFs appeared to select prey based on availability (Hayes and Tennant, 1985). The largest prey items consumed by large CRLFs (snout-vent length (SVL) >10 cm) were Pacific tree frogs (*Hyla regilla*; two individuals found in the gut of one of 35 CRLFs) and California mice (*Peromyscus californicus*; one individual found in the gut of one of 35 CRLFs). Juveniles (SVL ≤6.5 cm) feeding day and night were observed whereas adult and sub-adult frogs (SVL >6.5 cm) fed only at night.

Observations made during the study suggested that predatory instincts are triggered by movement (Hayes and Tennant, 1985). This led the authors to conclude that CRLFs are not good at identifying prey and tend to forage in an indiscriminant manner (Hayes and Tennant, 1985). The study authors did not observe CRLFs foraging underwater and the prey observed in gut analyses suggest that limited feeding occurs underwater. However, similar studies for ranid frogs have observed the consumption of fish, thus this forage item should not be disregarded (Hayes and Tennant, 1985).

The CRLF breeds from November to March, with most egg laying occurring in March (FWS, 2002a). Breeding typically occurs during or shortly after major rainfall events (Hayes and Miyamoto, 1984). Males arrive at breeding sites two to four weeks prior to females and call as individuals or groups of two to seven frogs (Storer, 1925; FWS, 2002a). Breeding usually occurs in still to slow-moving water greater than 0.7 meters in depth and near dense shrubby riparian vegetation (Hayes and Jennings, 1988). The eggs are laid on emergent vegetation such as bulrushes, cattails, roots, and twigs (Hayes and Miyamoto, 1984). The time to egg hatching depends on water temperature and generally takes six to 14 days (Jennings, 1988). Eggs take 20 to 22 days to develop to tadpoles and then 11 to 20 weeks to develop into terrestrial frogs (Bobzien et al., 2000; Storer, 1925; Wright and Wright, 1949). Males and females reach sexual maturity in two and three years, respectively, and adults can live up to ten years (FWS, 2002a).

2.2 Dimethoate Use Patterns

Dimethoate is classified as a general use contact and systemic insecticide and acarcide, and is applied using ground spraying (e.g., boom sprayers), aerial (e.g., aircraft) and chemigation application methods. It is formulated as an emulsifiable concentrate formulation, or sold as wettable powder end use products packaged in water-soluble bags. Dimethoate is one of very few systemic insecticides still available to U.S. agriculture. It is registered for use on a wide variety of agricultural sites such as: feed, food, forestry, and ornamental crops to control a wide range of insects and mites which includes aphids, beetles, citrus thrips, grasshoppers, fruit flies, fruit worms, leafhoppers, leaf miners, lygus bug, maggots, mealy bugs, midges, mites, moths, pear psylla, rootworms, tarnished plant bug, scale insects, spider mites, thrips, weevils, whiteflies. Dimethoate is important in Integrated Pest Management programs as it provides an option for rotation with insecticides from other chemical groups. It is highly effective against the Asian citrus psyllid, which transmits citrus greening disease and it is a critical component of some mandatory pest quarantine programs (cherry fruit fly). Finally, for some of the uses for which it is registered, there are few if any other effective registered alternatives.

2.2.1 Dimethoate Use in California

The California pesticide use database (CAPUR) is one of the most extensive pesticide use databases available (see http://www.cdpr.ca.gov/docs/pur/purmain.htm) (CA DPR, 2000, 2011; CaDFG, 2011; FWS, 2010.). Since 1995, all agricultural pesticide use in California has been reported monthly to the county agricultural commissioner who, in turn, reported the data to the California Department of Pesticide Regulation (CA DPR). These reports included the date and location (section, township, and range) where the pesticide was applied, the kind and amount of pesticides used, the crops to which the pesticide was applied, the type of commodity, identification numbers (IDs) for the site and the pesticide user ("operator"), and the number of planted and treated acres (CA DPR, 2000; 2011). Before buying or using pesticides, every operator is required to obtain a unique operator ID from the county where the pest control work will be performed. Growers obtain a site ID from the county agricultural commissioner for each location and crop or commodity where pest control work is anticipated. The information is then recorded on the restricted material permit or other approved form. California has a broad definition of "agricultural use". Thus, reporting requirements include pesticide applications to parks, golf courses, cemeteries, rangeland, pastures, and along roadside and railroad rights-of-way. In addition, post-harvest pesticide treatments of agricultural commodities must be reported, along with pesticide treatments in poultry and fish production, and some livestock applications. Exceptions to the full use reporting requirements are home and garden use and most industrial and institutional uses (CA DPR, 2011).

Data for dimethoate use were downloaded from the CAPUR database and imported into MS-Access 2003. Pesticide use data from 2000 to 2009 were then queried to determine the amount of dimethoate, as active ingredient and formulated product, used in all counties in California (Table 2-1).

The agricultural use pattern information for dimethoate is presented in Table 2-1. The dominant use for dimethoate is treatment of alfalfa (411,087 lb active ingredient). The next highest uses are application to wheat (326,601 lb active ingredient) and tomato (190,443 lb active ingredient).

Table 2-1 Crop-specific dimethoate use in California in 2000-2009

Crop	*Formulated Product Applied (lb)*	*Active Ingredient Applied (lb)*	*Acres Treated (A)*
Alfalfa (forage – fodder; alfalfa hay)	1,142,780	411,087	1,081,210
Beans (all or unspecified)[a]	300,815	117945	237,268
Broccoli	253,511	103,439	221,379
Brussels sprouts	29,331	12,741	14,132
Cantaloupe	18,420	6,524	15,523
Cauliflower	70,949	29,011	60,488
Celery, general	35,746	14,078	28,312
Cherry	4.54	1.98	7
Christmas tree nurseries	504	211	67.8
Citrus (all or unspecified)	434,838	180,922	119,976
Corn (field corn or popcorn)	262,844	103,549	210,338
Cotton, general	353,189	134,004	299,695
Endive (escarole)	487	177	745.48
Kale	1,133	418	1,735
Lettuce, head (all or unspecified)	154,778	55,498	236,211
Mustard, general	58.7	23.8	74.6

Table 2-1 Crop-specific dimethoate use in California in 2000-2009			
Crop	***Formulated Product Applied (lb)***	***Active Ingredient Applied (lb)***	***Acres Treated (A)***
Nursery grown cut flowers or greens	8,100	2,750	--[b]
Pastures (all or unspecified)	382	148	513.5
Pear	715	237	260
Peas, general	3,426	1,481	4,632
Pecan	1,041	435	898.4
Peppers (all)[c]	15,706	5,940	19,163
Potato (all)[d]	3,559	1,193	3,303
Safflower, general	86,642	34,656	61,189
Sorghum (forage - fodder)[e]	8,164	2,628	5,394
Soybeans (all)	109	47.4	96
Swiss chard (spinach beet)	156.6	62.9	249
Tomato	518,522	190,443	403,541
Turnip, general	292	91.1	386.3
Wheat (forage – fodder)[f]	89,990	326,601	94,016

[a] Beans including all and unspecific beans, dried beans, succulent other than Lima.
[b] Herbaceous ornamentals = N-GRWN cut FLWRS (Nursery grown cut flowers) or greens are typically associated with pots and other planters and thus no acreage is reported.
[c] Peppers including chilli type (flavoring and spice crop) and fruiting vegetables (bell, chilli, etc).
[d] Potato including white, Irish, red, russet.
[e] Sorghum including milo/general.
[f] Wheat including forage and fodder and general.

2.2.2 Dimethoate Use and CRLF Habitat by County

Counties containing CRLF critical habitat and/or CRLF observations (1919 to 2011) are reported in Table 2-2.

Table 2-2 Dimethoate use (2000 to 2009) and presence of CRLF critical habitat and CRLF observations (1919 - 2011) by California County					
County Name	***CRLF Critical Habitat Present?[a]***	***CRLF Observations[b]***	***Formulated Product Applied (lb)***	***Active Ingredient Applied (lb)***	***Acres Treated***
Alameda	Yes	Yes	812	352	914
Butte	Yes	Yes	3,039	1,061	2,324
Colusa	No	No	28,677	11,828	25,958
Contra Costa	Yes	Yes	19,209	8,019	17,583
Del Norte	No	No	1,271	553	1,119
Fresno	No	Yes	663,941	247,054	534,086
Glenn	No	No	14,533	5,220	11,757
Imperial	No	No	878,453	295,489	770,289
Kern	Yes	No	304,208	116,239	152,914
Kings	Yes	No	329,308	123,443	249,336
Lake	No	No	253	100	88
Lassen	No	No	22,024	9,170	28,583
Los Angeles	Yes	Yes	7,130	3,041	88,419
Madera	No	No	32,553	13,282	34,890
Marin	Yes	Yes	50	22	70,600
Merced	Yes	Yes	211,235	87,044	218,470

Table 2-2	Dimethoate use (2000 to 2009) and presence of CRLF critical habitat and CRLF observations (1919 - 2011) by California County				
County Name	***CRLF Critical Habitat Present?***[a]	***CRLF Observations***[b]	***Formulated Product Applied (lb)***	***Active Ingredient Applied (lb)***	***Acres Treated***
Modoc	No	No	32,307	13,991	38,609
Mono	No	No	1,700	740	1,569
Monterey	Yes	Yes	376,561	153,808	2,240,506
Orange	No	No	2,569	1,058	915
Placer	Yes	Yes	9	4	3
Riverside	Yes[c]	Yes	109,839	47,623	119,398
Sacramento	No	No	13,568	5,470	13,179
San Benito	Yes	Yes	16,467	6,878	145,818
San Bernardino	No	Yes	6,339	2,606	8,276
San Diego	No	Yes	888	301	1,478,552
San Joaquin	Yes	Yes	133,940	52,828	113,151
San Luis Obispo	Yes	Yes	16,618	6,851	57,255
San Mateo	Yes	Yes	2,571	1,113	766,560
Santa Barbara	Yes	Yes	56,005	23,084	85,071
Santa Clara	Yes	Yes	6,210	2,516	226,858
Santa Cruz	Yes	Yes	6,322	2,613	230,379
Siskiyou	No	No	4,365	1,885	4,950
Solano	Yes	Yes	19,342	7,859	15,196
Stanislaus	Yes	Yes	141,498	54,129	119,578
Sutter	No	No	22,313	8,342	19,800
Tehama	No	Yes	651	236	661
Tulare	No	No	259,151	106,903	110,688
Ventura	Yes	Yes	14,139	5,107	11,316
Yolo	No	No	35,804	14,444	33,074
Yuba	Yes	Yes	453	138	365

Sources: CA DPR, 2011; CaDFG, 2011; FWS, 2010.

[a] Indicates presence of CRLF Critical Habitat as defined by US Fish and Wildlife Service, March 2010 (FWS, 2010). Counties in which there is critical habitat as designated by FWS, 2010, but for which no dimethoate use for currently labelled crops is reported includes: Calaveras, El Dorado, Mendocino, Napa, Nevada, and Sonoma.

[b] Indicates observations of CRLFs from April 1919 to 2011 (CaDFG, 2011).

[c] Riverside county is removed from the counties with critical habitat present due to an exclusion for a military base located in Riverside county.

2.2.3 Application Rates and Timing

Historic Changes

At the start of the dimethoate registration standard review in 1982, there were more crops, slightly higher application rates for some crops, and few (if any) restrictions on the number of applications allowed per year or the intervals between repeated applications (EPA, 1983). Over the years, some of the application rates have been reduced and some crops were removed from registered use. For example, in 2002, all non-agricultural use of dimethoate, including all residential uses were cancelled. EPA's 2008 IRED required further limitations on the use of dimethoate products on numerous food uses (n=36) and non-food uses (e.g., alfalfa for seed, grass for seed, non-crop land areas adjacent to vineyards etc) (EPA, 2008c) (Table 2-3). These requirements addressed the fact that many labels did not specify the maximum number of applications allowed per year or minimum retreatment intervals. Approximately 241 registered uses were approved in 1983. Currently, dimethoate has about 60 registered uses.

Table 2-3	**Use pattern changes for dimethoate products as a result of the revised final IRED**			
Crop	***Maximum Single Application Rate (lb a.i./A)***		***Maximum No. of Applications per Year***	***Maximum Seasonal Amount (lb a.i./A)***
Alfalfa	Old	0.5	1/cutting - EPA assumes up to 9 cuttings per year	4.5
	New	0.5	1/cutting - limited by registrants to 3 per year (reduced by 66%)	1.5 (reduced by 66%)
Apples	Old	0.5	3	1.5
	New	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)
Broccoli	Old	0.5	6	3.0
	New	0.5	3 (reduced by 50%)	1.5 (reduced by 50%)
Cabbage	Old	0.5	3	1.5
	New	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)
Cauliflower	Old	0.5	6	3.0
	New	0.5	3 (reduced by 50%)	1.5 (reduced by 50%)
Celery	Old	0.5	6	3.0
	New	0.5	3 (reduced by 50%)	1.5 (reduced by 50%)
Cherry	Old	2.0	1	2.0
	New	1.33 (reduced by 33%)	1	1.33 (reduced by 33%)
Citrus	Old	2.0	2	4.0
	New	1.0 (reduced by 50%)	2	2.0 (reduced by 50%)
Collards	Old	0.25	4	1.0
	New	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)
Corn, field	Old	0.5	3	1.5
	New	0.5	1 (reduced by 66%)	0.5 (reduced by 66%)
Grapes	Old	2.0	1	2.0
	New	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)
Lettuce, head	Old	0.25	3	0.75
	New	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)
Pear	Old	0.5	3	1.5
	New	1.0	1 (reduced by 66%)	1.0 (reduced by 33%)
Pecan	Old	0.67	Not stated	Not stated
	New	0.33	1	0.33
Sorghum	Old	0.5	3	1.5
	New	0.5	2 (reduced by 33%)	1.0 (reduced by 33%)
Spinach	Old	0.25	2	0.5
	New	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)	Use cancelled (reduced by 100%)
Wheat	Old	0.67	2	1.34
	New	0.5 (reduced by 25%)	2	1.0 (reduced by 25%)

In the RED, EPA stated that, "The primary ecological risks of concern are to birds and mammals on a chronic basis. The Agency is attempting to reduce those risks by reducing application rates and numbers of applications, and increasing application intervals." In addition, the Agency stipulated that best management practices (BMPs) be added to labels, with the purpose of reducing the amount of dimethoate that enters surface water bodies through spray drift (EPA, 2006b). These BMPs include requiring medium or coarser sprays for aerial applications and prohibiting aerial sprays in winds greater than 10 miles per hour. To further reduce the amount of dimethoate entering surface water bodies as runoff, the Agency recommends use of vegetative filter strips, if practical. These changes included some reductions of application rates, limiting the number of applications per year, and increasing some retreatment intervals. Label changes were required in response to the IRED and took effect in 2006-2008.

Current Label Application in California

There are currently 11 dimethoate-containing products that are registered for use in California. These products are listed in Table 2-4 along with the percent active ingredient in each product.

Table 2-4 Dimethoate-containing end-use products registered in California (April 2, 2012)

EPA Registration No.	*Registration Name*	*% Active Ingredient*
34704-489	Dimethoate 2.67 EC	30.5
19713-232	Drexel Dimethoate 2.67	30.5
10163-56	Gowan Dimethoate E267	30.5
66330-223	Dimethoate 4E	43.5
34704-207	Cheminova Dimethoate 4E	43.5
19713-231-9779	Dimate 4E Insecticide	43.5
19713-231	Drexel Dimethoate 4EC	43.5
9779-273	Agrisolutions Dimate 4E	44.74
66330-245	Dimethoate 267	30.5
67760-44	Dimethoate 4E	44.74
SLN CA-970003 (Parent 34704-207)	Dimethoate 400	43.5

The maximum allowable application rates for dimethoate products in California, as specified on the labels, are provided in Table 2-5. This table also provides the maximum number of applications per season, maximum seasonal application rate and retreatment interval for each crop. With the exception of cottonwood grown for pulp, where the maximum single application is 2 lb a.i./A, the maximum single application rates for dimethoate range from 0.16 to 1.33 lb a.i./A. The minimum repeat application interval is typically 3 to 14 days depending on the crop, but can be as much as 30 days for alfalfa (forage and hay) and 90 days for grass grown for seeds.

Table 2-5	Dimethoate use patterns by crop				
Crop	***Application Method***	***Maximum Single Application Rate (lb a.i./A)***	***Maximum Number of Applications per Season***	***Maximum Seasonal Application Rate (lb a.i./A)***	***Minimum Retreatment Interval (d)***
Alfalfa (forage and hay, sainfois)	Groundspray/aerial	0.5	3 (1/cutting)	1.5	30
Alfalfa (seed)	Groundspray/aerial	0.5	1	0.5	NA
Asparagus	Groundspray/aerial	0.5	2	1	14
Beans (garbanzo beans and lupine)	Groundspray/aerial	0.5	2	1	14
Broccoli	Groundspray/aerial	0.5	3	1.5	7
Brussels sprouts	Groundspray/aerial	0.5	3	1.5	7
Cauliflower	Groundspray/aerial	0.5	3	1.5	7
Celery	Groundspray/aerial	0.5	3	1.5	7
Cherries	Airblast/aerial	1.33	1	1.33	NA
Christmas tree nurseries	Groundspray/airblast	1	3	3	14
Citrus	Airblast	1	1	0	
Conifer seed orchards	Groundspray/airblast	1	1	1	NA
Cotton	Groundspray/aerial	0.5	2	1	14
Cottonwood grown for pulp	Chemigation and aerial	2	3	6	10[a]
Endive (escarole)	Groundspray/aerial	0.25	3	0. 75	7
Field corn	Groundspray/aerial	0.5	1	0.5	NA
Grass grown for seed	Groundspray/aerial	0.5	2	1	90
Herbaceous ornamentals	Groundspray	0.25	1	0.25	NA
Honeydew	Groundspray/aerial	0.5	2	1	7
Kale	Groundspray/aerial	0.25	2	0.5	15
Leaf lettuce	Groundspray/aerial	0.25	3	0. 75	7
Lentils	Groundspray/aerial	0.5	2	1	7
Melon	Groundspray/aerial	0.5	2	1	7
Mustard greens	Groundspray/aerial	0.25	2	0.5	9
Non-cropland areas adjacent to vineyards	Groundspray	2	2	4	14[a]
Pears	Airblast/aerial	1	1	1	NA
Peas (Not for Use on Field Peas)	Groundspray/aerial	0.16	1	0.16	NA

Table 2-5	Dimethoate use patterns by crop				
Crop	***Application Method***	***Maximum Single Application Rate (lb a.i./A)***	***Maximum Number of Applications per Season***	***Maximum Seasonal Application Rate (lb a.i./A)***	***Minimum Retreatment Interval (d)***
Peas (Succulent) (CA only)	Groundspray/aerial	0.16	4	0.5	14[a]
Pecans	Groundspray/aerial	0.33	1	0.33	NA
Peppers	Groundspray/aerial	0.33	5	1.65	7
Popcorn	Groundspray/aerial	0.5	1	0.5	NA
Potatoes	Groundspray/aerial	0.5	2	1	7
Safflower	Groundspray/aerial	0.5	2 (1/cutting)	1	14[b]
Sorghum	Groundspray/aerial	0.5	2	1	7
Soybean	Groundspray/aerial	0.5	2	1	7
Swiss chard	Groundspray/aerial	0.25	3	0. 75	7
Tomatoes	Groundspray/aerial	0.5	2	1	6
Turnips	Groundspray/aerial	0.25	7	1.75	3
Wheat (1)[c]	Groundspray/aerial	0.67	1	0.67	NA
Wheat (2)[c]		0.67	2	1.34	7
Wheat (triticle) (3)		0.5	1	0.5	NA
Wheat (4)		0.5	2	1	7
Wheat (5)[c]		0.33	2	0.66	7
Woody Ornamentals	Groundspray	1	3	3	14

NA Not applicable because only one application is allowed per season.

[a] Minimum re-treatment interval not available in the Revised Interim Registration Eligibility Decisions Document for Dimethoate (EPA, 2008c).

[b] Minimum re-treatment interval not available in the Revised Interim Registration Eligibility Decisions Document for Dimethoate (EPA, 2008c). The minimum retreatment interval of 14 d is recommended on the Dimethoate 4E label (EPA Registration No. 67760-44).

[c] These use patterns have maximum single or seasonal application rates that exceed or is below the approved rates in the Revised Interim Registration Eligibility Decisions Document for Dimethoate (EPA, 2008c).

2.3 Physical and Chemical Properties

Technical dimethoate is a white crystalline solid that has a mercaptic odor and a melting point of 50 to 51.5°C (Figure 2-2). Dimethoate has a vapor pressure of 1.8×10^{-6} mmHg at 20ºC and a Henry's Law Constant of 7.8×10^{-11} atm-m^3/mol at 25°C indicating that dimethoate is unlikely to volatilize from dry soil and water, respectively. Dimethoate has a solubility in water of 39,800 mg/L at 25 °C. The K_{ow} for dimethoate is 5.06 suggesting a very low potential for bioaccumulation (Table 2-6). The values of K_d range from 0.06 to 0.74 depending on soil type.

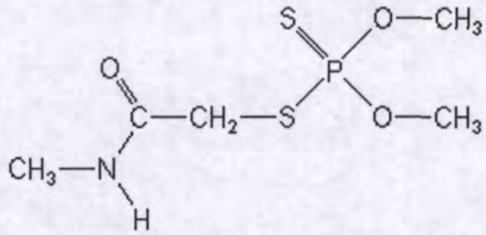

Figure 2-2 Chemical structure of dimethoate

The physical and chemical properties of dimethoate relevant to the environmental fate and behavior of the chemical are summarized in Table 2-6.

Table 2-6 Physical and chemical properties of dimethoate

Chemical Property	***Value***	***Reference [MRID]***
Molecular weight (g/mol)	229.5	Friis, 1992 [42730901; 42730902]
Vapor pressure (mm Hg; at 20°C)	1.8×10^{-6}	Teeter, 1988 [42261203]
Water solubility (mg/L; at 25°C)	39,800	Mangels, 1994 [43461402]
Henry's Law constant (atm-m^3/mol; at 25°C)	7.8×10^{-11}	Calculated using EPA guidance
Octanol-water partition coefficient (K_{ow})	5.06	Mangels, 1987 [43274001]
Soil-water partition coefficient (K_d - L/kg-soil) (% organic carbon)	Sand: 0.06 (0.9% OC) Sandy Loam: 0.30 (1.5% OC); Silt Loam: 0.57 (3.5% OC) Clay Loam: 0.74 (7.4% OC) Sandy/loamy Sand: 0.25 (0.48% OC) Sandy Loam: 0.33 (2.05% OC) Silt Loam: 0.42 (1.42% OC) Loam/silt Loam: 0.42 (1.4% OC) Sand: 0.34 (1.5% OC) Loam: 0.37 (1.9% OC)	Hawkins et al., 1986c [00164959]; Schanné 1992 [47477301]

2.4 Environmental Fate and Transport

In this section, we provide a discussion of the transport and fate of dimethoate in the environment after application in California as it relates to the CRLF. Once applied (i.e., ground sprayers, chemigation and aircraft) dimethoate may be transported by spray drift and run off from fields into streams, ponds and lakes that are habitat for the CRLF and their prey. As a result, CRLF can be exposed to dimethoate in different environmental compartments. The following is a description of the fate and behavior of dimethoate in these media.

2.4.1 Fate and Behavior in Water

2.4.1.1 Hydrolysis

A hydrolysis study was conducted at 25°C in sterile buffered solutions at pHs 5, 7 and 9 (Hawkins et al., 1986a [MRID 00159761]). The study indicated that hydrolysis of dimethoate was pH dependent, with relatively slow degradation at pHs 5 and 7 (1st order half-lives of 156 days and 68 days, respectively), but much faster degradation at pH 9 (1st order half-life of 4.4 days). At day 30, O-desmethyl dimethoate was detected in maximum amounts of 12%, 22% and 62.2% of applied parent at pHs 5, 7 and 9, respectively. Dimethoate represented 87.8%, 74.4% and 1.1% of solution radioactivity after 30 days at pHs 5, 7, and 9, respectively. O-desmethyl dimethoate was the only major degradate observed at pHs 5 and 7. At pH 9, O,O-dimethyl thiophosphoric acid was also formed with a maximum amount of 36% of applied parent at day 30. Thus, under environmental conditions, dimethoate would only be expected to hydrolyse rapidly when surface water pH is relatively high. However, under such conditions, there could be relatively high levels of formation of both O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid. These breakdown products are not toxic to aquatic species (Hertl, 2001a,b,c; 2002a,b) and thus are not considered further in this effects determination (see Section 2.6).

2.4.1.2 Photolytic Degradation

Hawkins et al. (1986b [MRID 00159762]) showed that dimethoate photodegrades very slowly in water at pH 5. After 15 d, Hawkins et al. (1986b) estimated a half-life for dimethoate of greater than 175 d.

2.4.1.3 Microbial Degradation

The degradation of dimethoate in water/sediment systems was investigated by Völkl (1993 [MRID 47784101]). Dimethoate was rapidly dissipated from the water phase by degradation to CO_2 and adsorption to the sediment. Adsorption of dimethoate to sediment and further metabolism in the sediment led to the formation of non-extractable residues. Dimethoate had an estimated DT_{50} in the water phase of 14.8 days (Rhine water with loamy sand sediment) and 12.5 days (pond water with sandy clay sediment). The DT_{50} values for the entire systems were 13.2 days (pond) and 17.2 days (Rhine river). The only major degradation product detected in the water phase (up to 13.3% and 17.6% at days 7 and 30, respectively) was O-desmethyl dimethoate. However, the estimated DT_{50} value of this metabolite was less than 30 days indicating a transient compound. An aerobic aquatic metabolism half-life of 10.1 days (Reiss, 2009a) was estimated based on EPA (2002a) guidance using soil half-lives from Hawkins et al. (1988 [MRID 42843201]) and Burden (1991 [MRID 46719202]).

2.4.2 Fate and Behavior in Soil

2.4.2.1 Photolytic Degradation

Dimethoate was not significantly degraded by photolytic processes at the soil surface (Skinner and Shepler, 1994 [MRID 43276401]). Dimethoate degraded faster in dark control samples (DT_{50} = 7.9 days) than in light-exposed samples (DT_{50} = 10.5 days) indicating that photolytic degradation is not an important removal process for dimethoate from soil.

2.4.2.2 Microbial Degradation

The aerobic degradation of dimethoate was investigated in three soils including clay loam, silty loam and sandy loam (Burden, 1991). The amount of dimethoate in the soil extracts decreased in clay loam, silty loam and sandy loam to 4, 2 and 10% of applied dimethoate, respectively, after 12 days of aerobic incubation. Assuming first-order degradation kinetics, DT_{50} values were 2.4, 2.0 and 4.1 days, respectively. Hawkins et al. (1988) found similar results in an aerobic metabolism study of dimethoate in sandy loam soil. The DT_{50} was estimated to be 2.4 days. The amount of dimethoate decreased from 96.2% immediately after application to 7% after seven days, and 0.2% after 181 d. Twelve degradation products were detected in the soil extracts, including O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid, none of which exceeded 2% of parent.

A DT_{50} of 22 days was estimated under anaerobic conditions in sandy loam soil (Hawkins et al., 1990) [MRID 42884402]. Carbon dioxide accounted for 41% of applied radioactivity at the end of the anaerobic incubation. O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid were mainly observed in the aqueous phase and had maximum values of 9.7% (7.2% water extract; 2.5% soil) and 4.5% (3.4% water extract; 1.1% soil) of applied radioactivity after 14 days of anaerobic incubation. These amounts are not considered to be relevant under realistic outdoor conditions. Anaerobic conditions are unlikely to occur in the soil for long periods after application of dimethoate. Therefore, O-desmethyl dimethoate and O,O-dimethyl thiophosphoric are not expected to be formed in significant amounts.

2.4.2.3 Field Dissipation

A soil dissipation study with beans, grapes and bare ground plots in Fresno County, California was conducted to investigate the degradation and leaching behavior of dimethoate under field conditions (Becker, 1991 [MRID 42884403]). The soil type at the test sites was sandy loam soil. Dimethoate was applied at rates of approximately 3 x 0.56 kg a.i./ha (0.5 lb/A) to beans (7 days interval) and of 2 x 2.8 kg a.i./ha (2.5 lb/A) to grapes and bare ground (14-day interval). The DT_{50} for dimethoate was estimated to be 9.8, 6 and 7.8 days for beans, grapes and bare ground, respectively, assuming first-order degradation kinetics. Dimethoate residues were mostly confined to the uppermost soil layers (0 to 15 cm).

Jacobson and Williams (1994a,b [MRID 43388001, 43388002]) conducted soil dissipation studies with grain sorghum in Burleson County, Texas and bare ground in Seneca County, New York, to investigate the degradation and leaching behavior of dimethoate under field conditions. The soil type was silty clay loam in Texas and loamy fine sand in New York. Application rates were 1 x 1.68 kg a.i./ha (1.5 lb/A) (sorghum) and 1 x 4.48 kg a.i./ha (4 lb/A) (bare ground). In Texas, the dimethoate concentration in the upper 15 cm of soil ranged from 0.48 mg/kg immediately after application to 0.088 mg/kg at 28 d. After 28 d, no residues of dimethoate were found at or above the 0.01 mg/kg limit of quantitation (LOQ) in any samples analysed in the 0 to 15 cm soil layer or below. The DT_{50} for dimethoate was determined to be 8.8 days assuming pseudo first-order degradation kinetics. In New York, dimethoate was found in the upper 15 cm soil layer at a maximum concentration of 1.38 mg/kg immediately after application. After 28 d, the dimethoate concentration in soil samples was below the LOQ (0.01 mg/kg) except for one replicate where the dimethoate concentration was 0.025 mg/kg. Ten days after application, dimethoate was detected in the 15.2 to 30.5 cm soil layer at a concentration of 0.011 mg/kg. However, residues of dimethoate were not found below 30.5 cm soil depth. The DT_{50} of dimethoate was 4.6 days using non-linear regression analysis and assuming first-order kinetics.

The longer half-lives of dimethoate in the field compared to those observed in the laboratory studies (2.0 to 4.1 days) can be explained by the higher application rates used in the field dissipation studies. Exaggerated application rates often lead to slower decay (EU Joint Submission Group, 2002). Furthermore, the organic matter content of the soils used in the field dissipation studies was rather low (OM: 0.3 to 1.9 %). Low organic content is generally associated with low microbial activity which is likely responsible for the longer half-lives of dimethoate observed in the field studies.

2.4.3 *Fate and Behavior in Air*

Dimethoate has a modest tendency to volatilize from soil and plant surfaces (<15% of applied radioactivity after 24 h) (Kubiak, 1992). Three 24 h experiments were carried out, one with sandy soil and two with bush beans (Canadian Wonder, older than three weeks). In the experiment investigating the volatilization of dimethoate from the soil surface, volatiles absorbed in the PU-foam accounted for 1.3% of the applied radioactivity after 24 h. The amount of $^{14}CO_2$ was found to be 7.9% of applied radioactivity. 83.2 % of the initial measured dose was found in the soil with non-extractable residues accounting for 7.8% of this activity. The experiments involving the volatilization of dimethoate from the surface of bush beans showed that after 24 h, 13.1-13.8% of the applied radioactivity had volatilized. 82.2-94.3% of the initial activity was present in or on plants, of which 9.3-11.7 % was not extractable. These results indicate that dimethoate is not particularly volatile either from soil or plant surfaces.

2.4.4 *Fate and Behavior in Plants*

Willis and McDowell (1987) conducted a literature review of foliar dissipation half-lives for many pesticides including dimethoate. Using the results of this study, the Environmental Fate and Effects Division of the Office of Pesticide Products in the United States calculated a foliar dissipation half-life value of 2.88 days (EPA, 2005a). This value is the 90^{th} percentile of 24 values reported in Willis and McDowell (1987). Cheminova verified the calculation and is in agreement with this value (Reiss, 2009a). However, the results of numerous monitoring studies in Europe and United States conducted on behalf of Cheminova are available (Corden, 2000, 2001, 2005; Goodband, 2003; Knäbe, 2004a; Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001a-l, 2002a-f, 2003 a,b) and are specific to dimethoate. These studies are more recent and represent current dimethoate product formulations. These studies were used by Cheminova to estimate an average foliar DT_{50} of 3.05 days.

2.4.5 *Summary of Fate and Behavior in the Environment*

Hydrolysis of dimethoate is slow except at high pH (Hawkins et al., 1986a). However, biodegradation will also contribute significantly to the dissipation of dimethoate in surface waters with adequate microbiological activity somewhat offsetting large decreases in abiotic hydrolysis rates with decreasing pH. In addition, dimethoate photodegrades slowly, having an estimated half-life of 175 days (Hawkins et al., 1986b). The degradation of dimethoate in water/sediment systems was investigated by Völkl (1993). The aerobic aquatic DT_{50} values for the entire systems were 13.2 days (pond) and 17.2 days (Rhine river). In soil, photolytic degradation is not a major removal process for dimethoate (Skinner and Shepler, 1994). DT_{50} values for aerobic microbial degradation in a variety of soils ranged from 2.0 to 4.1 days (Burden, 1991); Hawkins et al., 1988). Under anaerobic conditions, dimethoate was estimated to have a DT_{50} of 22 days in sandy loam soil (Hawkins et al., 1990). Leaching of dimethoate in soil is considered to be negligible. The average foliar DT_{50} of 3.05 days was predicted from a number of recent field studies as described in the previous section. Dimethoate is not volatile and therefore long-range transport is not an important route of transport in the environment. A summary of the fate properties of dimethoate is presented in Table 2-7.

Table 2-7 Summary of fate characteristics of dimethoate

Chemical Property	*Value*	*Reference [MRID]*
Hydrolysis half-lives (d) (23-25°C)	pH 5: 156 pH 7: 68 pH 9: 4.4	Hawkins et al., 1986a [00159761]
Aqueous photolysis half-life (d)	>175	Hawkins et al., 1986b [00159762]
Aerobic aquatic DT_{50} (d)	17.2 (Rhine River) 13.2 (pond)	Völkl 1993 [47784101]
Soil photolysis half-life (days; assuming 12 h Light/d)	No significant degradation	Skinner and Shepler, 1994 [43276401]
Aerobic soil metabolism half-life (d)	2.4; 2.0, 2.4 and 4.1	Hawkins et al., 1988 [42843201]; Burden, 1991 [46719202]
Anaerobic soil metabolism half-life (d)	22 d	Hawkins, 1990 [42884402]
Field dissipation DT_{50} (d)	CA loamy sand: 7.8 CA sandy loam: 9.8 CA sandy loam: 6 TX silt loam: 8.8 Chenango gravelly silt loam: 4.6	Becker, 1991 [42884403]. Jacobson and Williams, 1994a,b [43388001, 43388002]
Average foliar dissipation DT_{50} (d)	3.05	Corden, 2000; 2001; 2005; Goodband, 2003; Knäbe, 2004a; Pollman, 2006; Wilson, 2001a-l; 2002a-f; 2003 a,b

2.5 Mode of Action

Dimethoate is a contact and systemic phosphorodithioate organophosphate insecticide. Organophosphates elicit an effect by binding to, and phosphorylation of, acetylcholinesterase (AChE) in the central (brain) and peripheral nervous systems. The inhibition of AChE results in a temporary effect, but overexposure can lead to the build-up of the neurotransmitter acetylcholine (ACh) at cholinergic nerve endings, which may cause continual nerve stimulation leading to very specific clinical signs of toxicity and possible death (Risher et al., 1987; WHO, 1991).

2.6 Toxicity of Dimethoate

The following section provides an overview of the toxicity of technical dimethoate to species that were considered to be at risk in EPA's effects determination (EPA, 2008a) and subsequently assessed in this refined effects determination.

Information about the toxic effects of dimethoate to animals can be found in various sources of literature, namely GLP studies, peer-reviewed journals, grey literature and review articles and handbooks. Studies conducted under GLP use widely accepted protocols and guidelines (e.g., OECD, EPA) based on current and well-tested analytical methods that have been through rigorous scientific review. These studies are considered to be the "best available data" because the source, purity and impurities used in each study are known. Studies in the peer-reviewed scientific literature seldom follow GLP, and may or may not follow an acceptable guideline. Graduate studies and studies conducted in research centers and contract laboratories are examples of grey literature studies. Such studies may not follow an acceptable guideline or follow GLP. Review articles and handbooks usually provide a compilation of results from previous studies. Most often insufficient experimental details are available in these sources to verify the quality of the original studies. Original sources are sometimes not provided.

Regulatory authorities such as EPA and the California Department of Pesticide Regulation often rely on "best professional judgment" in evaluating ecotoxicological studies. In some cases, little evaluation is done at all. This is particularly true for peer-reviewed journal articles. A scientific evaluation of the quality of these studies is often lacking and authorities simply use the most sensitive endpoint to drive their ecological risk assessments. Simply providing a judgment on quality without a supporting rationale lacks transparency, objectivity and is not scientifically defensible. Reliance on best professional judgment, in the absence of rigorous criteria, can also lead to different reviewers arriving at different conclusions.

In this ERA, available toxicity studies from all sources were evaluated for quality and acceptability using the criteria presented in Appendix A. Each study was classified as: Acceptable, Supplemental or Unacceptable. Those studies scored as Acceptable or, in their absence, those scored as Supplemental were used in the determination of effects metrics. The study evaluations are presented in Appendix B, C and D. A summary of the results from Acceptable and Supplemental studies considered in this ERA is provided below.

2.6.1 Aquatic Invertebrates

Invertebrate toxicity studies were used to assess the potential for indirect effects to terrestrial-phase CRLFs via reduction of food supply. In EPA's CRLF effects determination (pp. 101), the Agency stated for acute effects that "...the majority of uses of dimethoate result in <0.01% chance of effects to an individual aquatic invertebrate ... the impact of these effects on the CRLF is insignificant for all uses". The Agency also stated (pp. 103), "Based on chronic LOC exceedances for aquatic invertebrates, all uses of dimethoate, except herbaceous ornamentals, are likely to indirectly affect the CRLF via adverse effects to aquatic invertebrates". Therefore, the focus of this effects determination is on chronic effects to aquatic invertebrates.

A review of the available acceptable and supplemental toxicity data for aquatic invertebrates indicated that *Daphnia magna* is the most sensitive aquatic invertebrate species for chronic exposure. No-observable-effects-concentrations (NOELs) for *Daphnia magna* determined from acceptable and supplemental studies range from 0.04 to 0.1 mg/L (Table 2-8).

EPA derived an estimated NOEL of 0.0005 mg/L for stonefly by applying an acute-to-chronic ratio (ACR) of 83 (derived from a 48 h acute study and a 21-day chronic study for *Daphnia magna*) to a 96 h LC50 for stonefly. This ACR is inappropriate for several reasons. The two species used to derive the ACR (daphnids and stoneflies) are not closely related, and there are significant differences in the lifecycles of these species. EPA did not provide references for the studies that were used to derive the daphnid-based ACR. It is unlikely that the acute and chronic studies were done in the same laboratory, or at the same time, which is generally recognized as best practice to calculate an ACR. Most importantly, a GLP chronic effects study conducted on *Daphnia magna* is available (Wüthrich, 1990 [MRID 42864701]) which obviates the need to estimate a chronic toxicity value for this species. Thus, EPA should not have relied on an estimated value in deriving the chronic effects metric for aquatic invertebrates (EPA, 2008a). The chronic GLP study with *Daphnia magna* (Wüthrich, 1990) submitted by Cheminova reported a 21 day NOEL of 0.04 mg/L. This value is also in general agreement with a *Daphnia magna* study from the ECOTOX database. Beusen and Neven (1989) reported a 23-day NOEL of 0.080 mg/L.

Acute toxicity endpoints for aquatic invertebrates are presented in Table 2-9.

Table 2-8 Chronic toxicity data for freshwater invertebrates exposed to dimethoate

Common Name	*Scientific Name*	*Exposure Duration*	*Purity (%)*	*Endpoint*	*Effect Concentration (mg/L)*[a]	*Reference [MRID]*	*Study Rating*
Midge	*Chironomus riparius*	28 d	99.1	NOEL (emergence)	0.1	Heintze, 2002 [48298309]	Acceptable
				EC50 (emergence)	0.162		
Water flea	*Daphnia magna*	21 d	99	NOEL (growth/reproduction)	0.04	Wüthrich, 1990 [42864701]	Acceptable
Water flea	*Daphnia magna*	23 d	99	EC50 (immobilization)	0.11	Beusen and Neven, 1989	Supplemental
				EC50 (immobilization)	0.19		
				LC50	0.23		
				LC50	0.11		
				MATC (reproduction)	0.085		
				MATC (reproduction)	0.13		
				NOEL (immobilization)	0.08		
				NOEL (immobilization)	0.1		
Brown hydra	*Hydra oligactis*	21 d	—	NOEL (growth)	100	Slooff and Canton, 1983	Unacceptable
Copepod	*Arctodiaptomus salinus*	96 h	—	NOEL (hatching rate)	2	Parra et al., 2005	Unacceptable
					20		
Great pond snail	*Lymnaea stagnalis*	40 d	—	NOEL (reproduction)	10	Slooff and Canton, 1983	Unacceptable
			—	NOEL (survival)	32		
		7 d	—	NOEL (hatchability)	32		
Mosquito	*Culex pipiens*	25 d	—	NOEL (survival/development)	0.32	Slooff and Canton, 1983	Unacceptable
Snail	*Lymnaea acuminata*	96 h	—	LOEL (number of eggs and number of hatched eggs)	1	Tripathi and Singh, 2003	Unacceptable
		7 d	—	LOEL (survivability of hatchlings)	1		
Water flea	*Daphnia magna*	20 d	98	NOEL (survival)	0.032	Canton et al., 1980	Unacceptable
				NOEL (reproduction)	0.1		
				LC25	0.145		
				LC50	0.31		
Water flea	*Daphnia magna*	16 d	—	NOEL (growth)	0.029	Deneer et al., 1988	Unacceptable
Water flea	*Daphnia magna*	16 d	—	EC50 (reproduction)	0.31	Hermens et al., 1984	Unacceptable
Water flea	*Daphnia magna*	21 d	—	NOEL (survival)	0.032	Slooff and Canton, 1983	Unacceptable
				NOEL (reproduction)	0.1		

[a] Effect concentration as mg test substance/L .

Table 2-9 Acute toxicity data for freshwater and marine invertebrates exposed to dimethoate

Common Name	*Scientific Name*	*Exposure Duration*	*Purity (%)*	*Endpoint*	*Effect Concentration (mg/L)*[a]	*Reference [MRID]*	*Study Rating*
Freshwater Invertebrates							
Water flea	*Daphnia magna*	48 h	37.7	EC50 (immobilization)	8.9[b] (3.4)	Hamitou, 2009a	Acceptable
Water flea	*Daphnia magna*	48 h	99.1	EC50 (immobilization)	2	Hertl, 2002c	Acceptable
Water flea	*Daphnia magna*	96 h	99	EC50 (survival)	0.465	Wüthrich, 1990 [42864701]	Acceptable
Midge	*Chironomus tentans*	48 h	99.5	EC50 (immobilization)	0.249	Anderson and Zhu, 2004	Supplemental
Water flea	*Daphnia magna*	48 h	99.8	EC50 (immobilization)	1.1	Andersen et al., 2006	Supplemental
Water flea	*Daphnia magna*	48 h	99	EC50 (immobilization)	1.5	Beusen and Neven, 1989	Supplemental
				LC50	1.7		
				EC50 (immobilization)	1.8		
				LC50	2		
Water flea	*Daphnia magna*	48 h	>95	LC50	3.12 (20°C)	Song et al., 1997	Supplemental
					3.32 (27°C)		
Yellow fever mosquito	*Aedes aegypti*	48 h	>95	LC50	5.04 (27°C)	Song et al., 1997	Supplemental
					6.41 (20°C)		
Amphipod	*Echinogammarus tibaldii*	96 h	99	LC50	4.1	Pantani et al., 1997	Unacceptable
Amphipod	*Gammarus italicus*	96 h	99	LC50	3.8	Pantani et al., 1997	Unacceptable
Amphipod	*Gammarus pulex*	96 h	—	LC50	0.0022	Aboul-Ela and Khalil, 1987	Unacceptable
Caddisfly	*Hydropsyche siltalai*	96 h	200 g/L	LC50	0.023[b,c]	Baekken and Aanes, 1991	Unacceptable
Copepod	*Arctodiaptomus salinus*	24 h	—	LC50	16	Parra et al., 2005	Unacceptable
		48 h	—		9.56		
		72 h	—		4.88		
		96 h	—		3.16		
Copepod	*Cyclops strenuus*	96 h	—	LC50	0.002	Aboul-Ela and Khalil, 1987	Unacceptable

Table 2-9 Acute toxicity data for freshwater and marine invertebrates exposed to dimethoate

Common Name	Scientific Name	Exposure Duration	Purity (%)	Endpoint	Effect Concentration (mg/L)[a]	Reference [MRID]	Study Rating
Crayfish	*Procambarus clarki*	72 h	—	LC50	>20	Muncy and Oliver, 1963	Unacceptable
Isopod	*Asellus aquaticus*	48 h	—	LC50	2.96	Thybaud et al., 1987	Unacceptable
Mayfly	*Baetis rhodani*	96 h	200 g/L	LC50	0.007[b,c]	Baekken and Aanes, 1991	Unacceptable
Mayfly	*Heptagenia sulphurea*	96 h	200 g/L	LC50	0.081[b,c]	Baekken and Aanes, 1991	Unacceptable
Prawn	*Macrobrachium lamerrii*	24 h	30	LC50	4.28[b] (1.28)	Mary et al., 1986	Unacceptable
		48 h			3.46[b] (1.04)		
		72 h			2.63[b] (0.789)		
Scud	*Gammarus lacustris*	96 h	200 g/L	LC50	0.18[b,c]	Baekken and Aanes, 1991	Unacceptable
Scud	*Gammarus lacustris*	24 h	97.4	LC50	0.9	Sanders, 1969 [96 h LC50 also in Johnson and Finley 1980 [40094602]	Unacceptable
Scud	*Gammarus lacustris*	48 h	97.4	LC50	0.4	Sanders, 1969 [96 h LC50 also in Johnson and Finley, 1980 [40094602]	Unacceptable
		96 h			0.2		
Snail	*Biomphalaria alexandrina*	96 h	—	LC50	0.0031	Aboul-Ela and Khalil, 1987	Unacceptable
Snail	*Biomphalaria alexandrina*	24 h	40	LC50	23[b] (9.2)	Oteifa et al., 1975	Unacceptable
Snail	*Bulinus truncatus*	96 h	—	LC50	0.0029	Aboul-Ela and Khalil, 1987	Unacceptable
Snail	*Bulinus truncatus*	24 h	40	LC50	18.9[b] (7.56)	Oteifa et al., 1975	Unacceptable
Snail	*Indoplanorbis exustus*	96 h	—	LC50 (18°C)	10.0	Srivastava and Singh, 2001	Unacceptable
					11.6		
					11.7		
					13.1		
				LC50 (28°C)	9.41		
					12.0		
					14.3		
					16.2		
Snail	*Lymnaea*	24 h	30	LC50	0.0359[b] (0.012)	Chaudhari et al., 1988	Unacceptable

Table 2-9 Acute toxicity data for freshwater and marine invertebrates exposed to dimethoate

Common Name	Scientific Name	Exposure Duration	Purity (%)	Endpoint	Effect Concentration (mg/L)[a]	Reference [MRID]	Study Rating
	acuminata	48 h			0.0245[b] (0.0074)		
Snail	Lymnaea acuminata	96 h	—	LC50 (18°C)	11.2	Srivastava and Singh, 2001	Unacceptable
					11.8		
					12.7		
					14.3		
				LC50 (28°C)	10.8		
					15.3		
					18.1		
					19.7		
Snail	Thiara lineata	24 h	30	LC50	0.0359[b] (0.012)	Chaudhari et al., 1988	Unacceptable
		48 h			0.0245[b] (0.0074)		
Snail	Thiara scabra	24 h	30	LC50	0.0444[b] (0.0133)	Chaudhari et al., 1988	Unacceptable
		48 h			0.0358[b] (0.011)		
Snail	Viviparus bengalensis	12 h	30EC	LC50	(29.3)	Gupta, 1984	Unacceptable
		24 h			(20.2)		
		48 h			(11.1)		
		72 h			(6.88)		
		96 h			(5.36)		
Stonefly	Pteronarcys californica	96 h	—	LC50	0.043	Johnson and Finley, 1980 [40094602]; Sanders and Cope, 1968; Mayer and Ellersieck, 1986 [40098001]	Unacceptable
Stonefly	Pteronarcys californica	24 h	97.4	LC50	0.51	Sanders and Cope, 1968 96 h LC50 also in Johnson and Finley, 1980 [40094602] and Mayer and Ellersieck, 1986 [40098001]	Unacceptable
		48 h			0.14		Unacceptable
		96 h			0.043		Unacceptable
Water flea	Ceriodaphnia quadrangula	1 h	40	EC20 (survival)	4[b] (1.6)	Mansour and Hassan, 1993	Unacceptable
				EC90 (survival)	7.8[b] (3.12)		
Water flea	Daphnia longispina	96 h	—	LC50	0.0026	Aboul-Ela and Khalil, 1987	Unacceptable
Water flea	Daphnia magna	48 h	98	EC50 (immobilization)	2.9	Canton et al., 1980	Unacceptable
				LC50	6.4		

Table 2-9 Acute toxicity data for freshwater and marine invertebrates exposed to dimethoate

Common Name	Scientific Name	Exposure Duration	Purity (%)	Endpoint	Effect Concentration (mg/L)[a]	Reference [MRID]	Study Rating
Water flea	*Daphnia magna*	26 h	—	LC50	2.5	Frear and Boyd, 1967	Unacceptable
Water flea	*Daphnia magna*	48 h	—	LC50	6.4	Hermens et al., 1984	Unacceptable
Marine invertebrates							
Eastern oyster	*Crassostrea virginica*	96 h	99.1	EC50 (shell deposition)	113	Graves and Swigert, 1993b [42760002]	Acceptable
Mysid	*Mysidopsis bahia*	48 h	99.1	LC50	22	Graves and Swigert, 1993a [42760003]	Acceptable
		96 h			15		
Black saltmarsh mosquito	*Aedes taeniorhynchus*	48 h	>95	LC50	0.031 (27°C)	Song et al., 1997; Song and Brown 1998	Supplemental
Brine shrimp	*Artemia salina*	48 h	>95	LC50	15.7 (27°C)	Song et al., 1997; Song and Brown, 1998	Supplemental
		72 h			10.1		
Brine shrimp	*Artemia salina*	24 h	>95	LC50	303	Guzzella et al., 1997	Supplemental
Mollusc	*Venus gallina*	96 h	93-99	LC50	>32	Serrano et al., 1995	Supplemental
Mollusc	*Mytilus galloprovincialis*	96 h	93-99	LC50	>56	Serrano et al., 1995	Supplemental
Rotifer	*Brachionus plicatilis*	24 h	>95	LC50	244	Guzzella et al., 1997	Supplemental
Brown shrimp	*Penaeus aztecus*	48 h	99.3	EC50	>1	Mayer, 1987 [40228401]	Unacceptable
Mysid	*Neomysis integer*	96 h	—	LC50	0.543	Roast et al., 1999	Unacceptable
Penaeid prawn	*Metapenaeus monoceros*	96 h	30	LC50	2.08[b] (0.62)	Reddy and Rao, 1992	Unacceptable
					2.31[b] (0.69)		
					2.47[b] (0.74)		
					2.86[b] (0.86)		

[a] Effect concentration as mg test substance/L. Reported in brackets as mg a.i./L for studies conducted using formulated products. Values in mg a.i./L were calculated by dividing the reported endpoint (LC/EC50) in mg test substance/L by the percent active ingredient of the formulation tested.

[b] Test conducted using a formulation.

[c] Effect concentration in mg a.i./L could not be calculated because purity of formulation was not provided.

2.6.2 *Vascular Aquatic Plants*

Porch et al. (2009 [MRID 47709703]) conducted a seven-day static renewal toxicity test on duckweed (*Lemna gibba*) exposed to dimethoate. Duckweed were exposed to one of five concentrations of dimethoate formulation (Dimethoate 400) and dimethoate technical and evaluated for effects on frond number, biomass and growth rate. The results for the technical product indicated EC50 values for all three endpoints that were >41.5 mg a.i./L, the highest concentration included in the test. The same results were observed with the formulation product (Dimethoate 400).

2.6.3 *Birds*

Toxicological information for the terrestrial stage of amphibians is not normally generated for pesticide registration packages. As a result, birds are typically used as a surrogate for the terrestrial-stage of amphibians (EPA, 2004a).

The LD50 for acute oral exposure to birds ranges from 5 to 63.5 mg a.i./kg bw (Zok, 2001a [MRID 47769701], 2001b [MRID 47769702]; Schafer, 1972 [MRID 0020560]; Hudson et al., 1984 [MRID 00160000]; See Table 2-10).

The LD50 of 5.4 mg a.i./kg bw reported by Schafer (1972) for red-winged blackbird (*Agelaius phoeniceus*) was used by the EPA in their effects determination for direct effects to terrestrial-phase CRLF and their amphibian prey (EPA, 2008a). However, the Schafer (1972) study used to derive the LD50 value of 5.4 mg/kg bw for the red-winged blackbird has several limitations including: (1) use of only 2 birds in some dose groups and 4 in others (2) unreported environmental conditions, (3) no analytical confirmation of doses, and (4) the source and purity of the test substance was not reported. Thus, this study was not considered in this effects determination.

Considering acute avian oral gavage studies classified as acceptable studies, bobwhite quail is the most sensitive tested species. Zok (2001a) conducted a GLP study on northern bobwhite quail exposed to dimethoate. Six-month old male and female northern bobwhite quail (*Colinus virginianus*) were exposed to a single dose of 0, 5, 10, 20, 40, 80 or 160 mg a.i./kg bw. After a 14-day observation period, the combined male and female LD50 and NOEL were estimated to be 10.5 mg/kg bw and 5 mg/kg bw, respectively (Zok, 2001a).

Dietary LC50s for dimethoate range from 154 to 1,066 mg/kg diet (Hill et al., 1975 [MRID 0022923]; Zok 2001c [MRID 47769705]; Hubbard et al., 2009c [MRID 47744401], 2010; See Table 2-11). Bobwhite quail (*Colinus virginianus*) were the most sensitive species based on the study by Zok (2011c). Zok (2001c) is a GLP study classified as an acceptable study by Cheminova. Ten-day old chicks were fed a diet of 0, 36, 75, 150, 300 or 600 mg dimethoate/kg diet for 5 consecutive days followed by a three-day post exposure period. The LC50 was 154 mg/kg diet and the NOEL was 36 mg/kg diet (Zok, 2001c).

Table 2-10 Acute oral gavage toxicity data for birds exposed to dimethoate

Common Name	*Scientific Name*	*Purity (%)*	*Endpoint*	*Dose (mg/kg bw)*	*Reference [MRID]*	*Study Rating*
Northern bobwhite quail (females)	*Colinus virginianus*	99.1	LD50	10.2	Zok, 2001a [47769701]	Acceptable
Northern bobwhite quail	*Colinus virginianus*	99.1	NOEL	5	Zok, 2001a [47769701]	Acceptable
Northern bobwhite quail	*Colinus virginianus*	99.1	LD50	10.5	Zok, 2001a [47769701]	Acceptable
Northern bobwhite quail (male)	*Colinus virginianus*	99.1	LD50	10.8	Zok, 2001a [47769701]	Acceptable
Ring-necked pheasant	*Phasianus colchicus*	99.1	LD50	14.1	Zok, 2001b [47769702]	Acceptable
Ring-necked pheasant (male)	*Phasianus colchicus*	99.1	LD50	5	Zok, 2001b [47769702]	Acceptable
Ring-necked pheasant (female)	*Phasianus colchicus*	99.1	LD50	10	Zok, 2001b [47769702]	Acceptable
Leghorn hen (female)	*Gallus domesticus*	96.42	LD50	55	Redgrave et al., 1991	Acceptable
Domestic chicken	NR	98.1	LD50	50	Levinskas, 1965	Unacceptable
European starling	*Sturnus vulgaris*	NR	LD50	32	Schafer, 1972 [0020560] (Schafer, E.W. Jr. 1982. Letter with attached bird toxicity test results. USFWS, Denver WRC, Denver, Co.)	Unacceptable
House sparrow	NR	NR	LD50	18.75	Bakre and Rajasekaran, 1989	Unacceptable
Mallard duck (males)	*Anas platyrhynchos*	97	LD50	41.7	Hudson et al., 1984 [00160000]	Unacceptable
Mallard duck (females)	*Anas platyrhynchos*	99.8	LD50	63.5	Hudson et al., 1984 [00160000]	Unacceptable
Red-winged blackbird (males)	*Agelaius phoeniceus*	NR	LD50	5.4	Schafer, 1972 [0020560] (Schafer, E.W. Jr. 1982. Letter with attached bird toxicity test results. USFWS, Denver WRC, Denver, Co.)	Unacceptable
Red-winged blackbird	*Agelaius phoeniceus*	NR	LD50	8.8	Schafer, 1972 [0020560] (Schafer, E.W. Jr. 1982. Letter with attached bird toxicity test results. USFWS, Denver WRC, Denver, Co.)	Unacceptable
Red-winged blackbird	*Agelaius phoeniceus*	NR (formulation)	LD50	9.9	Brunet et al., 1997	Unacceptable

Table 2-10 Acute oral gavage toxicity data for birds exposed to dimethoate

Common Name	*Scientific Name*	*Purity (%)*	*Endpoint*	*Dose (mg/kg bw)*	*Reference [MRID]*	*Study Rating*
Red-winged blackbird	*Agelaius phoeniceus*	NR	LD50	17.8	Schafer, 1972 [0020560] (Schafer, E.W. Jr. 1982. Letter with attached bird toxicity test results. USFWS, Denver WRC, Denver, Co.)	Unacceptable
Ring-necked pheasant (females)	*Phasianus colchicus*	97	LD50	20	Hudson et al., 1984 [00160000]	Unacceptable

Table 2-11 Acute and subacute dietary toxicity data for birds exposed to dimethoate

Common Name	*Scientific Name*	*Purity (%)*	*Endpoint*	*Exposure Duration*	*Effect*	*Dietary Concentration (mg/kg diet)*	*Reference [MRID]*	*Study Rating*
Mallard duck	*Anas platyrhynchos*	99.1	NOEL	5 d	Body weight	94 (42 mg/kg bw/d)	Hubbard et al., 2009c [47744401]	Acceptable
Mallard duck	*Anas platyrhynchos*	99.1	LC50	5 d	Survival	1066	Hubbard et al., 2009c [47744401]	Acceptable
Northern bobwhite quail	*Colinus virginianus*	98	LOEL	1 h	Body weight	100	Hubbard et al., 2010	Acceptable
Northern bobwhite quail	*Colinus virginianus*	98	LC50	1 h	Survival	365	Hubbard et al., 2010	Acceptable
Northern bobwhite quail	*Colinus virginianus*	98	LOEL	1 h	Survival	306	Hubbard et al., 2010	Acceptable
Northern bobwhite quail	*Colinus virginianus*	98	NOEL	1 h	Survival	175	Hubbard et al., 2010	Acceptable
Northern bobwhite quail	*Colinus virginianus*	99.1	LC50	5 d	Survival	154 (14.64 mg/kg bw/d)	Zok, 2001c [47769705]	Acceptable
Northern bobwhite quail	*Colinus virginianus*	99.1	NOEL	5 d	Survival	36	Zok, 2001c [47769705]	Acceptable
Ring-necked Pheasant	*Phasianus colchicus*	99.1	LC50	5 d	Survival	396	Zok, 2001d	Acceptable
Japanese quail	*Cotumix cotumix*	99	LC50	5 d	Survival	346	Hill et al., 1975 [00022923]	Unacceptable
Mallard duck	*Anas platyrhynchos*	99	NOEL	5 d	Body weight	94	Hill et al., 1975 [0022923]	Unacceptable
Mallard duck	*Anas platyrhynchos*	99	LC50	5 d	Survival	1011	Hill et al., 1975 [0022923]	Unacceptable

Table 2-11 Acute and subacute dietary toxicity data for birds exposed to dimethoate

Common Name	*Scientific Name*	*Purity (%)*	*Endpoint*	*Exposure Duration*	*Effect*	*Dietary Concentration (mg/kg diet)*	*Reference [MRID]*	*Study Rating*
Mallard duck	*Anas platyrhynchos*	99	NOEL	5 d	Survival	375	Hill et al., 1975 [0022923]	Unacceptable
Ring-necked Pheasant	*Phasianus colchicus*	99	LC50	5 d	Survival	332	Hill et al., 1975 [0022923]	Unacceptable

Table 2-12 Chronic toxicity data for birds exposed to dimethoate

Common Name	*Scientific Name*	*Purity (%)*	*Exposure Duration (weeks)*	*Endpoint*	*Effect*	*Dietary Concentration (mg/kg diet)*	*Reference [MRID]*	*Study Rating*
Northern bobwhite quail	*Colinus virginianus*	99.1	22	LOEL	Reduction in adult body weight and feed consumption, egg production and hatchling survivorship	35.4	Gallagher et al., 1996a [44049001]	Acceptable
Northern bobwhite quail	*Colinus virginianus*	99.1	22	NOEL	Reduction in adult body weight and feed consumption, egg production and hatchling survivorship	10.1 (1.092 mg/kg bw/d) [a]	Gallagher et al., 1996a [44049001]	Acceptable
Mallard duck	*Anas platyrhynchos*	99.1	22	LOEL	Reduction in adult body weight and feed consumption, egg production and embryo viability	152	Gallagher et al., 1996b	Acceptable
Mallard duck	*Anas platyrhynchos*	99.1	22	NOEL	Reduction in adult body weight and feed consumption, egg production and embryo viability	35.4	Gallagher et al., 1996b	Acceptable
Japanese quail	*Coturnix coturnix*	99.1	6	LOEL	Adult body weight gain (growth)	35	Solecki et al., 2001	Acceptable
Japanese quail	*Coturnix coturnix*	99.1	6	NOEL	Adult body weight gain (growth)	10	Solecki et al., 2001	Acceptable
Japanese quail	*Coturnix coturnix*	99.1	6	LOEL	Reproductive success	70	Solecki et al., 2001	Acceptable

Table 2-12 Chronic toxicity data for birds exposed to dimethoate

Common Name	*Scientific Name*	*Purity (%)*	*Exposure Duration (weeks)*	*Endpoint*	*Effect*	*Dietary Concentration (mg/kg diet)*	*Reference [MRID]*	*Study Rating*
Japanese quail	*Cotumix cotumix*	99.1	6	NOEL	Reproductive success	35	Solecki et al., 2001	Acceptable

Based on the results of chronic avian toxicity studies summarized in Table 2-12, northern bobwhite quail was selected as the most sensitive bird species tested. In one-generation reproduction studies, northern bobwhite quail had a NOEL of 10.1 mg/kg diet (Gallagher et al., 1996a [MRID 44049001]) and the mallard duck had a NOEL of 35.4 mg/kg diet (Gallagher et al., 1996b [MRID 43967101]). In their effects determination, EPA used the NOEL of 4.0 mg/kg diet based on reduced body weights of 14-day-old northern bobwhite (Gallagher et al., 1996a). However, Gallagher et al. (1996a) calculated a NOEL of 10.1 mg/kg diet for the same endpoint in the same study. In the study, 19-week old northern bobwhites were fed nominal dietary concentrations of 0, 4, 10.1 or 35.4 mg/kg diet for 22 weeks. The study authors reported that there were no deaths, overt signs of toxicity, effects upon body weight, reduced feed consumption or reduced reproductive performance at the 4 and 10.1 mg/kg test concentrations. There were statistically significant reductions in the body weight of hens and reduction of feed consumption, egg production and hatchling survivorship at the 35.4 mg/kg dietary test concentration. In addition, Cheminova re-analyzed the data of Gallagher et al. (1996a) using the benchmark dose (BMD) methodology and available EPA BMD analysis software and found that there is no rationale supporting EPA's use of the NOEL of 4.0 mg/kg diet for birds (Crump et al., 1995; EPA, 2000). See Appendix E for a summary of this analysis.

2.6.4 *Terrestrial Plants*

Terrestrial plant toxicity data were used to evaluate the potential for dimethoate to affect upland and riparian/wetland vegetation. If such effects were to occur, they could impact habitat of the CRLF and their prey and affect water quality. Vegetative vigor and seed germination/seedling emergence were assessed for 10 different crop species (four monocots including onion, ryegrass, wheat and corn; six dicots including sugarbeet, soybean, lettuce, flax, tomato and radish) exposed to technical grade dimethoate (Porch et al., 2011a [MRID 48572802], 2011b [MRID 48572801;48628101]).

To determine the effect of foliar application of dimethoate on plant growth and survival, technical grade dimethoate was applied to plants at rates of 0.25, 0.5, 0.75, 1.0 and 1.5 lb a.i./A to four monocot and six dicot crop species (Porch et al., 2011a). Treatment group means were not statistically different ($p > 0.05$) from respective control means, with four exceptions. The 0.75 and 1.0 lb a.i./A treatment group dry weight means for *Beta vulgaris* (sugarbeet), the 0.5 lb a.i./A treatment group survival mean for *Lactuca sativa* (lettuce), and the 0.25 lb a.i./A treatment group survival mean for *Linum usitatissimum* (flax) were significantly different from respective control means. These effects were not dose-responsive, and therefore were not considered to be treatment related. There were no adverse effects of foliar application of dimethoate technical product at rates up to 1.5 lb a.i./A on the height, survival, and dry weights of the ten species tested. The NOEL and EC25 were 1.5 and >1.5 lb a.i./A, respectively.

To determine the effect of pre-emergent application of dimethoate on seedling emergence and survival, technical grade dimethoate was applied at rates of 0.25, 0.5, 0.75, 1.0 and 1.5 lb a.i./A to the four monocot and six dicot crop species (Porch et al., 2011b). There were no significant differences on seedling emergence (21 days), height and dry weight, with three exceptions. The mean emergence of 0.5 lb a.i./A treatment group for *Allium cepa* (onion; $p > 0.05$), the 0.75 lb a.i./A treatment group for *Beta vulgaris* (sugarbeet; $p > 0.05$) and the 0.25 lb a.i./A mean dry weight treatment group for *Linum usitatissimum* (flax; $p > 0.01$) were significantly different from respective control means. However, these effects were not dose-responsive and therefore were not considered to be treatment related. Therefore, the NOEL and EC25 for technical dimethoate were 1.5 and >1.5 lb a.i./A respectively.

Overall, application of technical dimethoate at rates up to 1.5 lb a.i./A resulted in no adverse effects on seedling emergence, survival, height and dry weight of the ten plant species tested. The NOEL and EC25 for technical dimethoate is 1.5 lb a.i./A and >1.5 lb a.i./A, respectively.

2.7 Routes of Exposure

Based on the environmental fate, physical and chemical properties of dimethoate, and the registered applications in California (e.g., groundspray, chemigation and aerial), the most likely routes of transport of dimethoate to the habitat of CRLF and their prey are spray drift and deposition, and subsequent run-off from fields into soils or aquatic systems. In keeping with the approaches used in past EPA assessments of dimethoate, the effects determination for CRLF focused on the transport routes of runoff and spray drift (EPA, 2008a).

2.7.1 Aquatic Exposure

Dimethoate applied to a field can be transported to CRLF aquatic habitat by several exposure pathways; principally runoff and spray drift from the area of application.

CRLF gills and/or integument may come into contact with dimethoate in the water column. The most important routes of exposure for the aquatic life stage of the CRLF (i.e., larvae and tadpoles) to dimethoate is via direct exposure in surface water. CRLF may also be exposed to dimethoate via ingestion of aquatic prey items (e.g., algae, aquatic invertebrates and fish) that have been exposed to dimethoate in the water column.

Indirect effects to CRLF could potentially occur as a result of effects to aquatic habitat components and prey populations. Algae, aquatic vascular plants, aquatic invertebrates and fish may come in direct contact with dimethoate in the water column. Aquatic animals that are CRLF prey may also consume dimethoate residues on their feed items.

2.7.2 *Terrestrial Exposure*

Dimethoate applied to a field could potentially come in direct contact with CRLF, their habitat and/or their terrestrial prey.

Potential routes of exposure for terrestrial-phase CRLF and their terrestrial prey (e.g., tree frogs, small mammals and terrestrial arthropods) include direct contact with dimethoate via runoff, spray drift and deposition, and ingestion of contaminated prey, water and incidental soil.

Terrestrial plants that are an important element of CRLF habitat may come in direct contact with dimethoate via field runoff, spray drift and deposition.

2.8 Protection Goals

Protection goals are defined by scientific knowledge and societal values, describe the overall aim of a risk-based decision-making, and are used as the basis for defining assessment endpoints. In turn, assessment endpoints are ecological characteristics that are deemed important to evaluate and protect (e.g., survival of CRLF). They guide the assessment by providing a basis for assessing potential risks to receptors. Factors considered in selecting assessment endpoints include mode of action, potential exposure pathways, and sensitivity of ecological receptors. Assessment endpoints can be general (e.g., maintenance of insect populations) or specific (e.g., survival of Pacific tree frogs) but must be relevant to the ecosystem they represent and susceptible to the stressors of concern (EPA, 1998; Suter et al., 1993).

Section 7(a)(2) of The Endangered Species Act, Counterpart Regulations and various lawsuit settlements and implementing regulations, consistently indicate that the protection goal with respect to listed species potentially exposed to pesticides is no jeopardy of the continued existence of listed species and or destruction or adverse modification of their habitat. Therefore, the protection goal for the CRLF is to ensure that exposure to dimethoate is not likely to jeopardize the continued existence of the CRLF species, result in the destruction or adverse modification of the habitat of this species, or cause indirect effects to prey upon which the CRLF depends.

For direct effects to the CRLF, the assessment endpoint is the survival, growth and reproduction of this species. Protection at the organism level will ensure the continued existence of CRLF populations.

The following assessment endpoints were chosen to address indirect effects of dimethoate to CRLF:

- *Productivity of algae and prey communities* (aquatic and terrestrial invertebrates, fish and small terrestrial vertebrates) associated with CRLF habitat. This assessment endpoint is at the community level of organization because CRLF is a generalist feeder. Section 2.1.5 describes the diet of CRLFs. Based on this information, adverse effects to only a few, sensitive individual algal or prey species are unlikely to impact the overall availability of food for CRLFs; and,

- *Structure of aquatic and terrestrial plant communities* associated with CRLF habitat. CRLF habitat is described in Section 2.1.4. The assessment endpoint for habitat is at the community level of organization because it is unlikely that adverse effects to one or a few sensitive plant species would adversely affect the overall habitat of the CRLF.

In addition to the need to have a general assessment endpoint for indirect effects to CRLF habitat, there is a need to have assessment endpoints for CRLF critical habitat, as defined by the Fish and Wildlife Service (FWS, 2010). Critical habitat is defined in Section 3.0 of the Endangered Species Act as: (i) the specific areas within the geographic area occupied by the species ... on which are found those physical and biological features essential to the conservation of the species and that may require special management considerations or protection, and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential in the conservation of the species. In determining which areas to designate as critical habitat, FWS considers those physical and biological features (primary constituent elements or PCEs) that are essential to the conservation of the CRLF. The FWS final rule on critical habitat for the CRLF took effect on May 15, 2006. Approximately 450,228 acres of critical habitat have been designated for the CRLF (Figure 2-3) (FWS, 2010). Critical habitat is either occupied by the CRLF, is within the historic range of the CRLF, and/or contains sufficient PCEs to support at least one life history function of the CRLF. Four PCEs have been identified that represent the life history functions of the CRLF: aquatic breeding habitat, aquatic non-breeding habitat, upland habitat, and dispersal habitat.

Because of the special concern associated with protection of critical habitats of the CRLF, the following assessment endpoints were developed for each of the primary constituent elements of CRLF critical habitats:

- Structure of the plant community that constitutes aquatic breeding habitat of the CRLF;
- Structure of the plant community that constitutes aquatic non-breeding habitat of the CRLF;
- Structure of the plant community that constitutes upland habitat of the CRLF; and,
- Structure of the plant community that constitutes dispersal habitat of the CRLF.

The PCE assessment endpoints for habitat are at the community level of organization because it is unlikely that adverse effects to one or a few sensitive plant species would lead to adverse effects to the habitat of the CRLF.

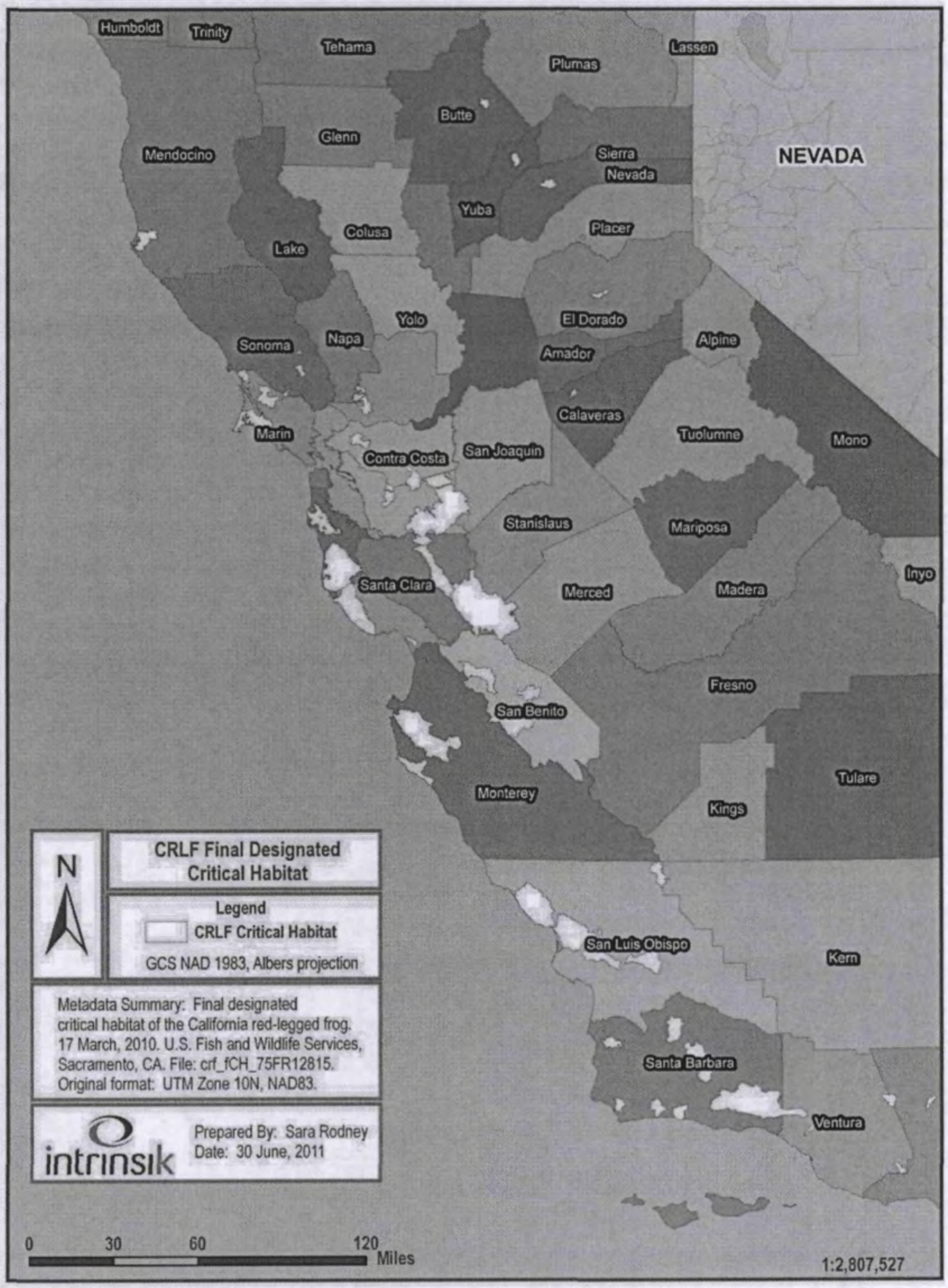

Figure 2-3 Critical habitat of the CRLF in California

2.9 Risk Hypotheses and Conceptual Model

All chemicals have the potential to cause toxicological effects. The likelihood of adverse ecological effects depends on the receptors being exposed, the route and duration of exposure, and the inherent toxicity of the chemical. If all three components (i.e., a receptor, a route of exposure and any level of toxicity) are present, the possibility of a toxicological risk exists. Risk hypotheses are specific assumptions about potential adverse effects and are based on what is known about the chemical, receptors and environment. Risk hypotheses are derived using professional judgment and information available on the sources of exposure, characteristics of the stressor (e.g., chemistry, fate and transport), the ecosystems at risk, and anticipated effects to ecological receptors. A conceptual model provides a written and visual description of the possible exposure routes between ecological receptors and a stressor. The model includes risk hypotheses for how a stressor might come in contact with, and affect, receptors.

2.9.1 Exclusions from Effects Determination

Based in part on the results of EPA's assessment, and the information presented in Sections 2.0 to 2.9, some factors believed not to contribute significantly to risk to CRLF have been removed from consideration in this assessment. These exclusions are presented below.

2.9.1.1 Species

To evaluate the potential risk to CRLF from the use of dimethoate products, the EPA effects determination (EPA, 2008a) calculated risk quotients (RQs) by determining the ratio of the estimated environmental concentrations (EECs) to a sensitive toxicity endpoint value (e.g., LC50, NOEL). The RQs were then compared to the Agency's levels of concern (LOCs) to determine whether dimethoate had the potential to cause adverse effects to CRLFs, their prey or their habitat.

The Agency chose a conservative approach by using the most sensitive toxicity endpoint values for birds, mammals, fish, invertebrates, and plants, the maximum labeled application rates (which are identical or higher than those of current Cheminova labels) and upper bound estimates of concentrations on prey items or in the environment.

Based on the results of EPA's effects determination (EPA, 2008a), the following receptors and endpoints were deemed not at risk from exposure to dimethoate and were not considered in this effects determination:

- Direct effects to aquatic-phase CRLF for all use patterns
- Indirect effects to CRLF via effects to algae for all use patterns
- Indirect effects to CRLF via acute and chronic effects to fish for all use patterns

Using the listed species LOC of 0.05 for aquatic animals, the EPA found potential acute risk to aquatic invertebrate prey. However, using the dose-response data for sensitive aquatic invertebrates, EPA reported insignificant risk to aquatic invertebrates exposed to conservative peak EEC estimates (see EPA, 2008a). Further, no RQs for aquatic invertebrates exceed the more appropriate non-listed aquatic animal LOC of 0.5. We agree with EPA in that risk of indirect effects to CRLF via reduction of aquatic invertebrate prey due to acute exposure is negligible. Therefore, this indirect effect was not considered in this risk assessment.

EPA (2008a) concluded that acute effects to small mammal prey for citrus and non-cropland areas adjacent to vineyards, and chronic effects to small mammal prey for all crops were "likely to adversely affect" the CRLF. However, this conclusion is inconsistent with data supporting our understanding of the life history of both small mammals and CRLF. CRLFs are opportunistic feeders. Although the California mouse (*Peromyscus californicus*) has been observed to be part of the terrestrial-phase CRLF diet (Hayes and Tennant, 1985), the available data suggest that mice make up only a small portion of the overall adult CRLF diet (only 1 in 35 CRLF had mouse (*P. californicus*) remains in its digestive system; Hayes and Tennant, 1985).

Further, mice are typically prolific breeders. Female California mice reach sexual maturity 11 weeks after birth (McCabe and Blanchard, 1950) (http://www.sibr.com/mammals/M116.html). The California mouse can have three to four litters per year, with litter sizes ranging from one to four pups. A typical litter size is two pups (Drickamer and Vestal, 1973; Rood, 1966; McCabe and Blanchard, 1950). Because the California mouse reproduces at a high rate, as do many other potential small mammal prey species, it is unlikely that potential effects of pesticides on mice will translate into significant reduced prey abundance for CRLFs. Thus, indirect effects to the CRLF via direct effects to small mammals will not be investigated in this effects determination.

Mouse consumption is expected to be infrequent. However, to assess possible direct effects to CRLF consuming mice potentially containing dimethoate residues, California mouse will be considered as a potential residue-carrying prey item in the assessment of direct effects to adult CRLF.

The potential exposure of insects to dimethoate is limited to those individuals that occur on treated fields or are exposed via spray drift. Because dimethoate is a potent insecticide, there is a limit to how high the residue load of an insect can be before the insect can no longer move from the treated field to the habitat of the CRLF. If an insect received a lethal or near lethal dose of dimethoate, it would become immobilized and incapable of moving off-site. EPA (2008a) calculated risk quotients for small and large terrestrial invertebrates by comparing environmental exposure concentrations (EECs) calculated by T-REX to the LD50 value of 0.39 µg a.i./g for bees. For all uses, RQ values exceeded the acute risk LOC for both small and large terrestrial insects. This result implies that the estimated body burdens on terrestrial insects in recently treated fields would likely render them immobile and thus unavailable for consumption by CRLFs located in their preferred aquatic and riparian habitats. Ninety percent of the terrestrial CRLFs that Bulger et al. (2003) monitored stayed within 60 m of water at all times and were almost always within 5 m of their summer aquatic habitat. The furthest upland movement that frogs made occurred during rain events when they travelled up to 130 m upland for approximately four to six days (Bulger et al., 2003).

When exposed to dimethoate under field conditions, acute toxic effects (e.g., mortality, reduced weight) occurred in honey bees (Schmitzer, 2005 [MRID 48101302]). However, at the end of the observation period 29 days following dimethoate application, the colonies were in good condition and developed normally. All treated colonies survived the trial with no observed treatment-related effects on the brood. This study showed that under realistic conditions, a terrestrial arthropod population recovered relatively quickly from dimethoate exposure-related effects. Further, effects to insects on treated fields are not expected to impact prey abundance to a degree that would adversely affect the CRLF. Effects to terrestrial invertebrate prey in riparian areas is expected to be limited given that dimethoate is not applied to riparian habitat, and pesticide drift has been shown to decrease exponentially with distance away from treatment (Wolf and Caldwell, 2001). Indirect effects to CRLFs via reduction in abundance of terrestrial arthropods were, therefore, not considered in this effects determination. It is possible, however, that CRLF could consume contaminated insects (Gathmann and Tscharntke, 2002; Osborne et al., 1999). For this reason, terrestrial invertebrates were considered as a potential residue-carrying food item of terrestrial CRLFs in the exposure modeling (Section 4.1.2).

EPA calculated risk quotients for small and large terrestrial invertebrates by comparing EECs estimated by T-REX to the LD50 value of 0.39 μg a.i./g of bee (EPA, 2008a). For all uses, RQ values exceeded the acute risk LOC of 0.05 used by EPA (2008a) for both small and large terrestrial insects. This implies that estimated body burdens on terrestrial insects could render them immobile and unavailable for consumption by CRLFs located well away from agricultural fields. Indirect effects to CRLFs via reduction in abundance of terrestrial insects were not considered in this effects determination because effects to insects on treated fields are unlikely to affect prey availability in riverine or wetland habitats.

2.9.1.2 Metabolites

Available data suggest that most dimethoate metabolites are practically non-toxic (See Appendix F). Laboratory studies and monitoring data suggest that the one metabolite that is comparably toxic for many receptors, the oxon, omethoate, is not produced in significant amounts in the aquatic environment. Omethoate can be produced in relatively small quantities on terrestrial feed items (e.g., plants and insects), with peak concentrations observed in the days following application (Corden, 2000, 2001, 2005; Goodband, 2003; Knäbe, 2004a; Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001 a-l; 2002a-f, 2003a,b.). However, acceptable toxicity studies indicate that omethoate has similar toxicity as dimethoate to birds (surrogate taxon for terrestrial-phase CRLF; see Appendix F). Thus, the metabolites of dimethoate are not being assessed because they are not expected to contribute significantly to the overall risk to CRLF associated with recommended label uses of dimethoate.

2.9.1.3 Formulations

Registrant GLP toxicity studies were conducted for aquatic organisms (fish and invertebrates) using technical dimethoate and a formulated product. A comparison of the effect concentrations from these studies shows that technical dimethoate is more toxic to aquatic organisms than is the dimethoate formulation (Table 2-13). As a result, this ERA focussed on the active ingredient only and effects metrics considered in this effects determination are from studies conducted using technical dimethoate.

Table 2-13 Comparison of toxicity of technical dimethoate and formulated product to aquatic biota						
Product Tested	***Purity***	***Species***	***Duration***	***Reported Endpoint***	***Endpoint Value Corrected for a.i.***	***Reference [MRID]***
Aquatic Invertebrates						
Formulation[a]	37.7% w/w	Water flea (*Daphnia magna*)	48-h	EC50 (immobilization) = 8.9 mg/L	3.4 mg a.i./L	Hamitou, 2009a
Technical	99%	Water flea (*Daphnia magna*)	96-h	EC50 (immobilization) = 0.465 mg a.i./L	—	Wüthrich, 1990 [42864701]
Fish						
Formulation[a]	37.7% w/w	Bluegill (*Lepomis macrochirus*)	96-h	LC50 >100 mg/L	>37.7 mg a.i/L	Hamitou, 2009b
Formulation[a]	38.9% g/L	Bluegill (*Lepomis macrochirus*)	96-h	LC50 = 44 mg/L	17.1 mg a.i./L	Caley et al., 1992a
Formulation[a]	400 g/L	Rainbow trout (*Oncorhynchus mykiss*)	96-h	LC50 = 61.3 mg/L	23.8 mg a.i./L	Caley et al., 1992b
Technical	98.1%	Rainbow trout (*Oncorhynchus mykiss*)	96-h	LC50 = 24 mg a.i./L	—	Brougher et al., 2012
Aquatic plants						
Formulation[a]	41.5%	Duckweed (*Lemna gibba*)	7-d	EC50 (Growth Rate) = >100 mg/L	>41.5 mg a.i./L	Porch et al., 2009 [47709703]
Technical	99.1%	Duckweed (*Lemna gibba*)	7-d	EC50 (Growth Rate) = >41.5 mg a.i./L	—	Porch et al., 2009 [47709703]

[a] Endpoint values for formulated products are reported as mg test item/L

2.9.1.4 Routes of Exposure

The water balance of frogs is complex, in part because they can absorb water through their skin as well as drink water and extract water from their food (Duellman and Trueb, 1986; Minnich, 1982). The USDA (2007) stated that frogs may absorb the water that they need through their skin. The relative contributions of the different routes of water intake depend on the species, habitat, temperature and body surface area. As a result of this complexity, allometric equations relating body weight and intake rates for drinking water are not available for amphibians (EPA, 1993). Thus, the drinking water route of exposure was not assessed in the screening-level effects determination conducted by EPA (2008a) nor will it be in this refined effects determination.

CRLFs could be exposed to dimethoate through the incidental ingestion of sediment, soil and sand while foraging in water or consuming prey. The incidental ingestion of a considerable amount of sand was observed by a CRLF that consumed a mouse (Hayes and Tennant, 1985). Thus, incidental soil and sediment ingestion is a potential route of exposure to CRLFs. However, soil and sediment ingestion are not considered important routes of exposure because the rates of ingestion are far lower than the food ingestion rate (EPA, 2004a). EPA (2004a) showed that ingestion of soil at an incidental rate of up to 15% of the diet would not increase dietary exposure significantly. According to EPA (2004a), inclusion of soil in the diet for the majority of food items would effectively reduce total exposure because pesticide concentrations are lower in soil than they are in dietary items.

Inhalation and dermal contact are unlikely to be important routes of exposure for terrestrial CRLFs unless they are foraging on a field during or soon after dimethoate has been applied. Given that their preferred breeding and summer habitats are still or slow-moving permanent streams with deep water, dense riparian vegetation, marshes, ponds, damp woods and meadows (FWS, 1996, 2002a; Stone Environmental, 2012), it is unlikely that CRLFs will forage on-site when pesticides are applied. Thus, on-site exposure of CRLFs to dimethoate (direct exposure) via inhalation and dermal contact will not be considered in this effects determination.

2.9.2 Risk Hypotheses for this Effects Determination

Based on the habitat and ecology of the CRLF and the results of EPA's effects determination (EPA, 2008a), the risk hypotheses tested in this refined effects determination are presented below.

Aquatic Exposure

Potential Indirect Effects to CRLF

- Dimethoate in surface water due to spray drift and/or runoff might adversely affect aquatic vascular plants, potentially leading to significant structural modification of the aquatic plant community and CRLF habitat.
- Dimethoate in surface water due to spray drift and/or runoff might come in direct contact with aquatic invertebrate prey of terrestrial-phase CRLF. Exposure to dimethoate in the water column could have chronic effects on the survival, growth and reproduction of aquatic invertebrates. Significant reductions in aquatic prey could adversely affect CRLF via reduction in available prey.

Terrestrial Exposure

Potential Direct Effects to CRLF

- CRLF may be acutely and/or chronically exposed to dimethoate via ingestion of residue-carrying prey (i.e. invertebrates, fish, tree frogs and mammals). Potential dietary exposure could lead to reduced survival, growth or reproduction of CRLFs.

Potential Indirect Effects to CRLF

- Terrestrial-phase amphibian prey of CRLF (e.g., Pacific tree frog) may be acutely and/or chronically exposed to dimethoate via ingestion of residue-carrying prey (i.e. invertebrates). Potential dietary exposure could lead to reduced survival, growth or reproduction of CRLF amphibian prey. Significant reductions in amphibian prey could adversely affect CRLF via reduction in available prey.
- Terrestrial plants may be exposed to dimethoate in spray drift and/or runoff. Exposure to dimethoate could have effects on the survival, growth and reproduction of terrestrial plants. Significant modifications to the plant community structure could adversely affect CRLF via reduction in suitable habitat.

2.9.3 Conceptual Model

A conceptual model provides a written and visual description of the possible exposure routes between ecological receptors and a stressor. The conceptual model is derived using professional judgment and information available on the sources of exposure, characteristics of the stressor (e.g., chemistry, fate and transport), the ecosystems at risk, and anticipated potential effects to ecological receptors. For this assessment, the stressor is the release of dimethoate to the environment. The conceptual model for evaluating risks to CRLF from the use of dimethoate is shown in Figure 2-4. Only those pathways assessed in the refined effects determination are illustrated. The anticipated sequence of events following dimethoate application is shown in the conceptual model and forms the basis for the risk hypotheses presented above.

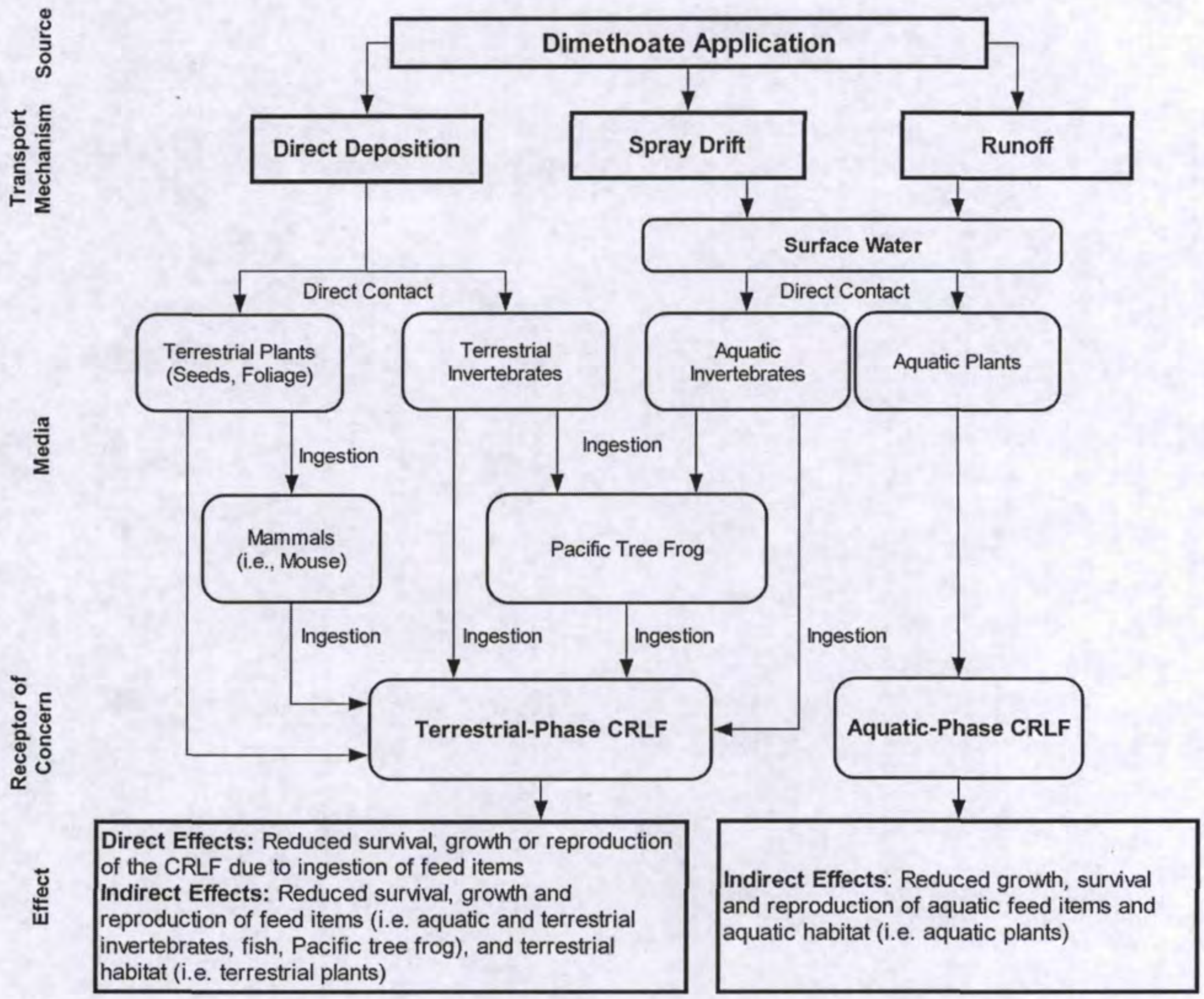

Figure 2-4 Conceptual model for the application of dimethoate in California, leading to exposure to CRLFs, their prey and/or their habitat

2.10 Analysis Plan

The Analysis Plan outlines the rationale and approach for the complete effects determination.

A tiered approach will be used to assess the effects to CRLF, their prey and habitat. The approach is conceptually similar to the tiered approach that EPA uses for ecological risk assessment (EPA 1998), in that increasingly refined analyses are only conducted for exposure scenarios where concern was not eliminated in a previous tier (See Figure 2-5 and Figure 2-6 below).

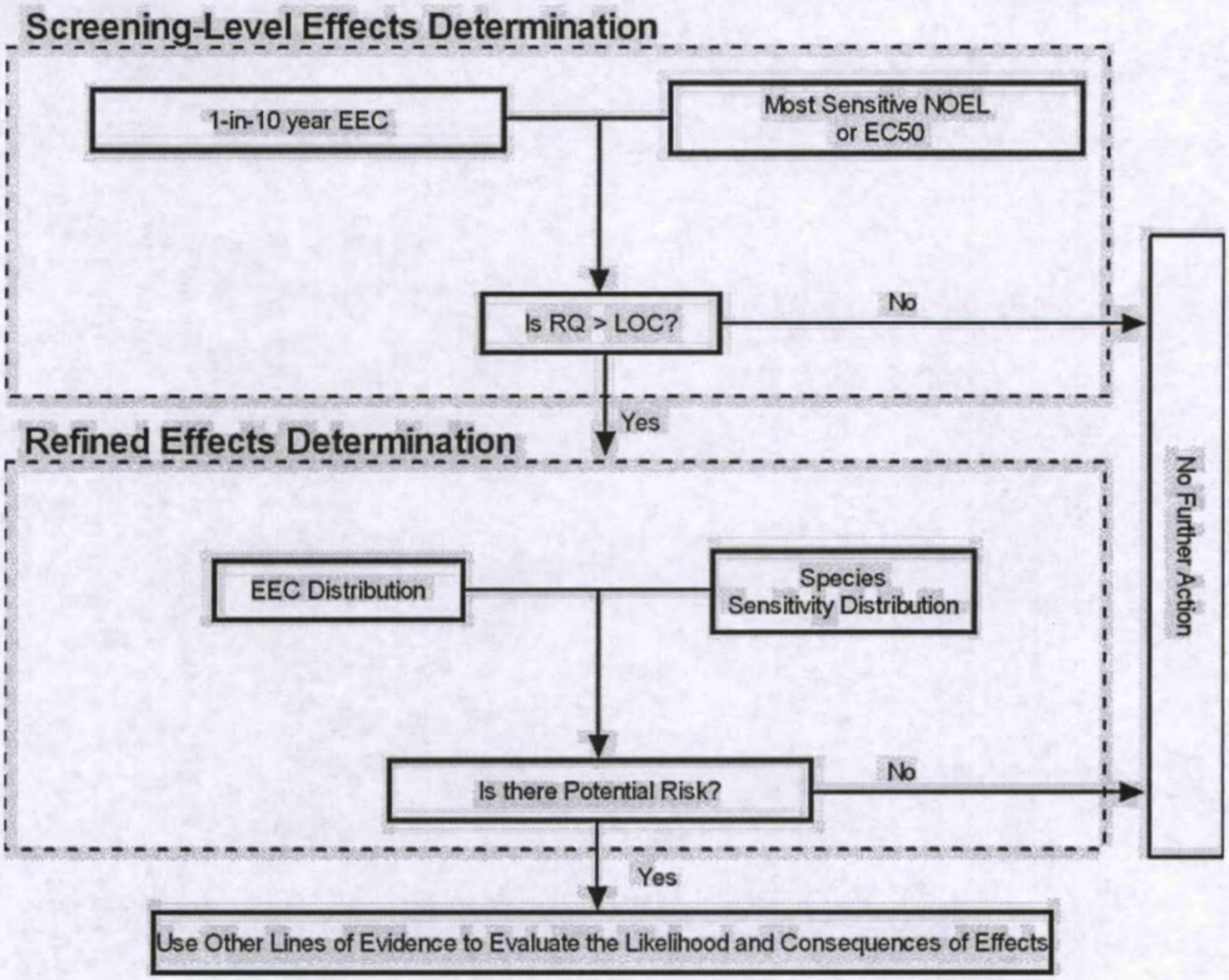

Figure 2-5 **Tiered approach for assessing effects to aquatic invertebrates and aquatic plants exposed to dimethoate**

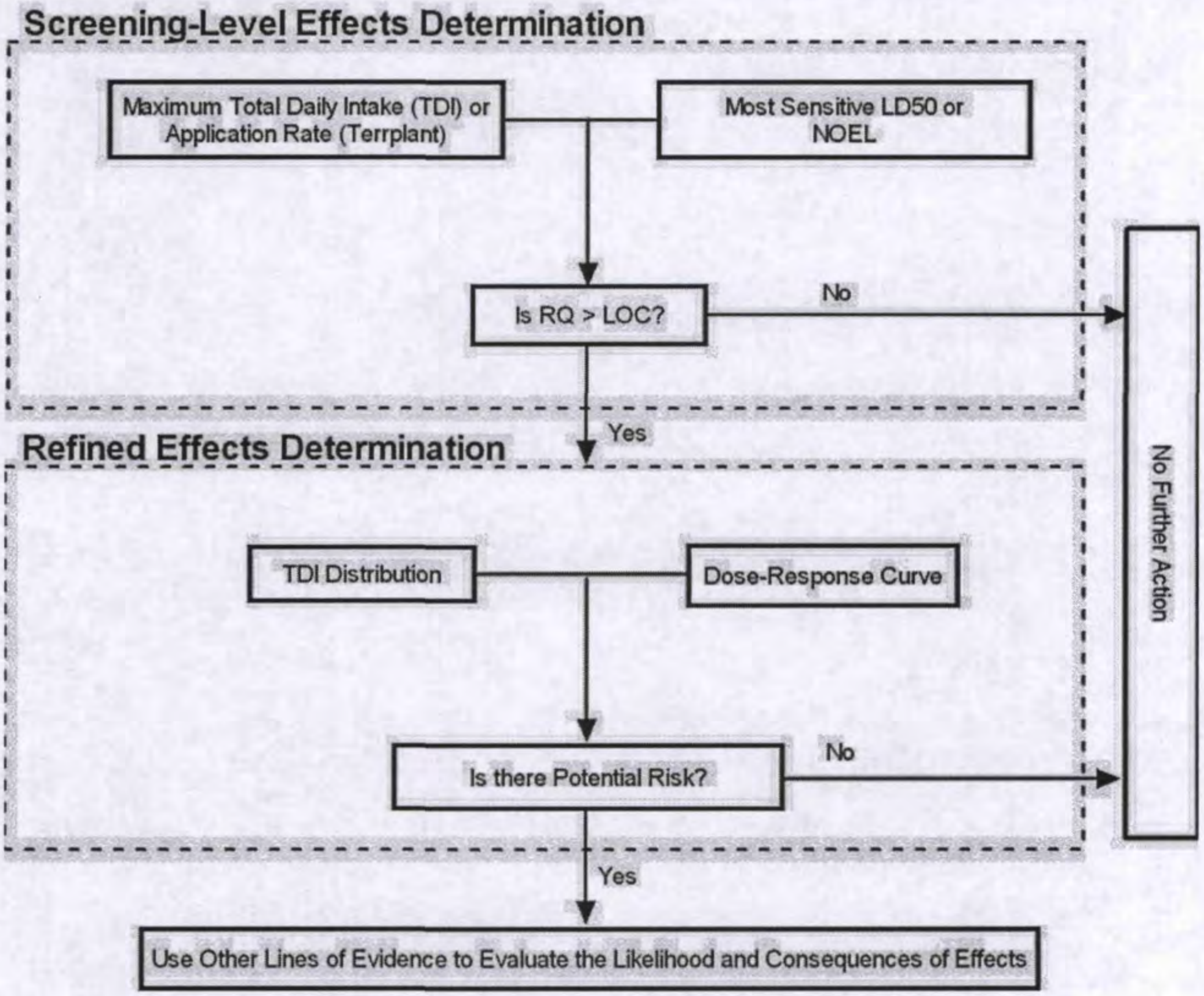

Figure 2-6 Tiered approach for assessing effects to the terrestrial-phase CRLF, its terrestrial prey and habitat

Measures of exposure and effect are the metrics used to quantify potential risks to a receptor (i.e., taxon of concern). EPA (1998) groups measures into one of three categories: (1) Measures of effect are measurable changes in an attribute of the receptor, or a surrogate, in response to the stressor; (2) Measures of exposure account for the presence and movement of the stressor in the environment and co-occurrence with the assessment endpoint; (3) Measures of ecosystem and receptor characteristics consider the influence that the environment, and organism behavior and life history will have on exposure and response to the stressor (EPA, 1998). Measures of exposure are weighed against measures of effect in the process of risk characterization for each receptor and exposure scenario permutation. The measures of exposure and effects that will be considered in the effects determination, at both the screening and refined tiers are presented below. Measures of ecosystem and receptor characteristics (e.g., home range, avoidance, etc.) are also used as part of a weight-of-evidence to support overall assessment focus and conclusions.

2.10.1 Screening-Level Aquatic Measures of Effect and Exposure

The aquatic assessment will focus on indirect effects on the CRLF via reduction in aquatic invertebrate prey and aquatic habitat. The following indirect effects will be considered at the screening-level of the aquatic assessment:

- Chronic effects to the survival, growth, and reproduction of aquatic invertebrates (prey); and,
- Effects to the structure of the aquatic vascular plant community that provides habitat for aquatic-phase CRLFs for all crops.

The most sensitive and relevant measures of effect will be selected for each taxon at the screening-level (Table 2-14).

An evaluation of available data was conducted to ensure that the best data available were used in this effects determination. Toxicity study reports were screened using criteria designed to ensure that only high quality data were used. Report screening criteria for aquatic and avian toxicity studies distinguished these studies as acceptable (i.e., best available data), supplemental, or unacceptable. Each study rating was based on an evaluation of study design and execution, adherence to toxicity testing protocols, statistical analyses, and other key aspects of the study (Appendix A). The results of the data screening criteria process for these studies are available in Appendix B and C. All other studies used as endpoints (e.g., terrestrial plants) for the screening ERA were also evaluated for quality. Table 3-1 lists the effects metrics used in the screening-level effects determination.

A combination of the EPA simulation models Pesticide Root Zone Model (PRZM 3.12.2) (executable date May 12, 2005) and Exposure Analysis Modeling System (EXAMS 2.98.04) (executable date April 25, 2005) will be run using the EPA/OPP/EFED shell PE Version 5 (November 15, 2006) to estimate surface water concentrations for dimethoate.

PRZM predicts pesticide transport and transformation in the soil profile and is capable of simulating pesticide runoff, erosion, plant uptake, leaching, transformation, foliar washoff, and volatilization. Daily edge-of-field loadings of pesticides dissolved in runoff waters and sorbed to sediment are discharged into a standard water body ("standard pond") simulated by the EXAMS model. Input data are required for soil characteristics, hydrology, pesticide chemistry, meteorology, use pattern, and the crop of interest. For each scenario, PRZM uses 30 years (1961-90) of site-specific climate data to generate exposure results.

EXAMS II takes the runoff loadings generated by PRZM and estimates the concentration in the pond on a day-to-day basis. The simulated results from EXAMS will be used to determine a distribution of annual peak concentrations for varying exposure durations (e.g., 24, 96 h; 21, 60 d; one year) based on the 30-year simulation.

The exposure scenarios evaluated in this effects determination will be based on those modeled in EPA's effects determination (EPA, 2008a), but updated using current application rates and re-application intervals, and a few additional crops identified on the labels (Table 2-5). The PRZM scenarios that were used in EPA's effects determination (EPA, 2008a) will also be used in this effects determination including the standard scenarios (STD), two scenarios developed for the cumulative organophosphate (OP) assessment and those specifically developed for the CRLF effects determination.

The methods for establishing measures of exposure and effect for the aquatic screening-level assessment of CRLF aquatic invertebrate prey and vascular plant habitat elements are summarized in Table 2-14 below.

Table 2-14 Summary of assessment endpoints and measures of exposure and effect for the screening-level aquatic effects determination

Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Aquatic Invertebrate Prey			
Productivity of invertebrates associated with nearshore habitats of CRLFs	Chronic	Estimated 1-in-10 year annual peak 21 d average concentrations of dimethoate based on the 30-year simulation in standard-sized ponds located adjacent to treated agricultural fields	Lowest relevant chronic NOEL for either survival, growth or reproduction of an aquatic invertebrate species
Aquatic Habitat			
Structure of the plant community in aquatic environments, including breeding and non-breeding habitats that potentially contain early stages of the CRLF	Acute/chronic	Estimated 1–in-10 year annual peak concentrations of dimethoate based on the 30-year simulation in standard-sized ponds located adjacent to treated agricultural fields	Lowest relevant effects metric for an aquatic vascular plant

2.10.2 Refined Aquatic Measures of Exposure and Effect

Most probabilistic risk assessments estimate the probability that exposure exceeds a specified no-observed-effects or lowest-observed-effects concentration or dose. An alternative approach is to estimate the probabilities of effects of varying magnitude. Because CRLFs are generalist feeders, this effects determination was not restricted to the most sensitive prey species. As long as overall productivity of prey species is protected, indirect effects to CRLFs are not expected. To determine overall effects on prey productivity, the preferred measure of effect is at the community level of organization. A species sensitivity distribution (SSD) was used as an effects metric for community structure. A SSD is a statistical distribution that captures the variation in toxicological sensitivity among a given set of species to a contaminant. The SSD is expressed as a cumulative distribution function (CDF) and is comprised of effect concentrations or doses (e.g., 48 h EC50) on the x-axis and cumulative probability (p) on the y-axis (Posthuma et al., 2002). The number of data points used to construct the SSD depends on the number of species tested for the endpoint of interest. Generally, at least eight species are recommended to derive an SSD using regression analysis (Stephan, 2002) (Table 2-15).

SSD Master v2.0 will be used to fit five sigmoid-shaped models to the acute toxicity values for aquatic invertebrates species including the logistic, probit, Weibull, Gompertz and Fisher-Tippett models (Rodney et al., 2008). SSD Master v2.0 was designed to facilitate the derivation and selection of appropriate SSD models for use in benchmark setting and risk assessment. The application is fully automated and Excel-based. SSD Master v2.0 uses the standard Excel Solver add-in to fit the five cumulative distribution functions (CDF) models. Solver proceeds through different combinations of model parameter values until the sum of square error term cannot be further minimized. The application automatically generates residual plots and goodness-of-fit, p-p and q-q plots, as well as plots of the SSDs and associated approximate confidence intervals.

Probabilistic methods allow for a complete characterization of risk given all of the available data. The benefit of using probabilistic methods is that they fully characterize risk, rather than providing a best estimate or a conservatively biased estimate of risk. Estimating a mean risk would miss the potential for relatively rare, but serious, extreme events (e.g., mass mortality of CRLF or their prey). By including the entire distribution of risk, all events are considered and all of the data and information collected to characterize an exposure scenario are included.

Concentrations of dimethoate in aquatic media will be estimated using PRZM/EXAMS. The simulated results from PRZM/EXAMS will be used to derive distributions of dimethoate concentrations for varying exposure durations based on the 30-year simulation. Distributions will be derived using peak average concentration per year in standard-sized ponds located adjacent to a treated agricultural field for each of the 30-year in the simulation (i.e., 30 data points). Though a distribution is derived, the exposure model output is still quite conservative. The standard pond in the PRZM/EXAMS model is located adjacent to the edge of the field, has no in-flow other than runoff from the adjoining treated fields, and has no out-flow. Most aquatic systems frequented by CRLFs would not be adjacent to treated fields and would likely have in-flows and out-flows that would dilute dimethoate concentrations. A discussion of the conservativeness of PRZM/EXAMS is provided in Section 3.4.3.

Table 2-15 Summary of assessment endpoints and measures of exposure and effect for the refined aquatic effects determination

Assessment Endpoint	*Exposure Duration*	*Measures of Exposure*	*Measures of Ecological Effect*
Aquatic Invertebrate Prey			
Productivity of invertebrates associated with nearshore habitats of aquatic-phase CRLFs	Chronic	Distribution of estimated annual peak 21 d average concentrations of dimethoate on the day of the year with the highest average EECs in standard-sized ponds located adjacent to treated agricultural fields from 30-year simulation	Species sensitivity distribution (SSD) for aquatic invertebrates
Aquatic Habitat			
Structure of the plant community in aquatic environments, including breeding and non-breeding habitats that potentially contain early stages of the CRLF	Acute/chronic	Distribution of estimated annual peak 21 d average concentrations of dimethoate on the day of the year with the highest average EECs in standard-sized ponds located adjacent to treated agricultural fields from 30-year simulation	Concentration-response curve[a]

[a] Ideally, a SSD would be used to assess effects to the vascular plant community. Since there is only one relevant toxicity study available, which was conducted on only one species of plant, there is insufficient data for a vascular plant SSD.

2.10.3 Screening-Level Terrestrial Measures of Effect and Exposure

The terrestrial assessment considered both direct and indirect effects to the terrestrial-phase CRLF via direct ingestion and reduction in terrestrial prey and habitat. The following effects were considered at the screening-level of the terrestrial assessment:

Direct Effects

- Acute and chronic effects to the survival, growth, and reproduction of terrestrial-phase CRLFs for all crops.

Indirect Effects

- Acute and chronic effects to the survival, growth, and reproduction of terrestrial amphibian prey of CRLFs; and,

- Indirect effects to the structure of the terrestrial plant community that provides habitat for terrestrial-phase CRLFs.

The screening-level effects determination for terrestrial-phase CRLFs, their prey and their habitat used the most sensitive and relevant measures of effect for each assessment endpoint. Similar to the assessment of aquatic-phase CRLFs, an evaluation of available data was conducted to ensure that the best available data were used in this effects determination. Data screening criteria distinguished studies as acceptable, supplemental, or unacceptable. The results of the data screening criteria process for these studies are available in Appendix D. All other studies used as endpoints (e.g., terrestrial plants) for the screening ERA were also evaluated for quality. Table 2-16 lists the effects metrics used in the screening-level effects determination.

A total daily intake (*TDI*) model was used to estimate acute and chronic dietary exposure to dimethoate for representative amphibian prey of CRLF (e.g., Pacific tree frog).

For indirect effects to the CRLF via reduction in habitat, the maximum application rates were used in TerrPlant (version 1.2.2) to estimate EECs for all crops (Table 2-5). These measures of exposure were then compared to the NOEL (An EC25 is usually required by TerrPlant for non-listed species. However, no effects were observed at the highest tested application rate) for four monocot and six dicot crops to estimate risk to the structure of the plant community in terrestrial environments, including breeding and non-breeding habitats that potentially contain the CRLF.

A summary of the assessment endpoints and measures of exposure and effect selected to characterize potential CRLF risks associated with exposure to dimethoate is provided in Table 2-16 for the screening-level effects determination conducted herein.

Table 2-16 Summary of assessment endpoints and measures of exposure and effect for the screening-level terrestrial effects determination

Assessment Endpoint	*Exposure Duration*	*Measures of Exposure*	*Measures of Ecological Effect*
Terrestrial Life-stage of CRLF			
Survival, reproduction and growth of the CRLF	Acute	Total daily intake (*TDI*) of CRLFs exposed to dimethoate in diet	Lowest relevant acute LD50 for a bird species
	Chronic	Total daily intake (*TDI*) of CRLFs exposed to dimethoate in diet	Lowest relevant chronic NOEL for either survival, growth or reproduction of a bird species
Terrestrial Vertebrate Prey			
Productivity of vertebrates associated with nearshore habitats of adult CRLFs	Acute	Total daily intake (*TDI*) of Pacific tree frogs exposed to dimethoate in diet	Lowest relevant acute LD50 for a bird species
	Chronic	Total daily intake (*TDI*) of Pacific tree frogs exposed to dimethoate in diet	Lowest relevant chronic NOEL for either survival, growth or reproduction of a bird species

Table 2-16	Summary of assessment endpoints and measures of exposure and effect for the screening-level terrestrial effects determination		
Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Terrestrial Habitat			
Structure of the plant community in terrestrial environments, including breeding and non-breeding habitats that potentially contain the CRLF	Acute/Chronic	Estimated EEC in dry areas and semi-aquatic areas using application rate and application method in TerrPlant	Lowest relevant NOELfrom a seedling emergence study Lowest relevant NOEL from a vegetative vigour study

2.10.4 Refined Terrestrial Measures of Effects and Exposure

As in the screening-level effects determination, total daily intake (*TDI*) models were used to estimate exposure for terrestrial-phase amphibians. However, in contrast to the screening-level assessment, distributions were used for input parameters rather than point estimates. The result was a distribution of *TDI*s for each exposure scenario considered. These exposure distributions were integrated with the results of the refined effects assessment to quantify risk to terrestrial-phase amphibians.

The objective of the refined terrestrial effects determination was to estimate the probabilities of effects of varying magnitude. For acute and chronic exposures, a dose-response curve was fit to the data from the avian dietary study demonstrating the highest degree of sensitivity to dimethoate (Table 2-17).

Table 2-17	Summary of assessment endpoints and measures of exposure and effect for the refined terrestrial effects determination		
Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Terrestrial Life-stage of CRLF			
Survival, reproduction and growth of the CRLF	Acute	Probabilistic total daily intake (*TDI*) for CRLF exposed to dimethoate in diet	Acute dose-response curve for most sensitive bird species
Survival, reproduction and growth of the CRLF	Chronic	Probabilistic total daily intake (*TDI*) for CRLF exposed to dimethoate in diet	Chronic dose-response curve for most sensitive bird species
Terrestrial Vertebrate Prey			

Table 2-17 Summary of assessment endpoints and measures of exposure and effect for the refined terrestrial effects determination			
Assessment Endpoint	***Exposure Duration***	***Measures of Exposure***	***Measures of Ecological Effect***
Productivity of vertebrates associated with nearshore habitats of adult CRLFs	Acute	Probabilistic total daily intake (*TDI*) for Pacific tree frog exposed to dimethoate in diet	Acute dose-response curve for most sensitive bird species
Productivity of vertebrates associated with nearshore habitats of adult CRLFs	Chronic	Probabilistic total daily intake (*TDI*) for Pacific tree frog exposed to dimethoate in diet	Chronic dose-response curve for most sensitive bird species

2.10.5 Risk Characterization

Risk characterization integrates the exposure and effects assessments to estimate the potential risk for each use pattern for both direct and indirect effects on the CRLF. A tiered approach will be taken for both the aquatic and terrestrial assessments (Figure 2-5 and Figure 2-6).

2.10.5.1 Screening-level Risk Characterization

In the screening-level effects determination, risks were determined using RQs that were calculated by dividing estimated exposure concentrations, rates or daily doses by acute and chronic effects metrics (e.g., LD50, NOEL). If RQs were below EPA's LOCs for a specific category, the exposure scenarios were eliminated from further consideration. The LOCs used in this screening-level effects determination are outlined in Table 2-18 . Exposure scenarios with a RQ>LOC proceeded to the more refined effects determination (see Figure 2-5 and Figure 2-6).

When assessing indirect effects to listed species, the EPA uses listed species LOCs for non-listed species (e.g., prey) when non-listed species are the receptors of concern for indirect effects to listed species (e.g., a listed species LOC of 0.05 for aquatic animals was used to assess acute effects to aquatic invertebrates for assessment of indirect effects to CRLF via reductions in aquatic invertebrate prey; EPA, 2004a, 2008a). This is an overly conservative approach, particularly when the listed species is not an obligate species requiring specific taxa for diet or habitat. Thus, in our screening-level risk assessment, non-listed species LOCs were applied when assessing the risk of indirect effects to CRLF via effects to prey or habitat (see Table 2-18).

Table 2-18 Level of concern (LOC) for the aquatic and terrestrial screening-level effects determinations		
Species	***Exposure***	***LOC***
Aquatic invertebrates	Chronic	1
Aquatic vascular plant (habitat)	Acute/chronic	1
Terrestrial plant	Acute /chronic	1
Terrestrial-phase CRLF	Acute (listed species)	0.1
	Chronic (listed species)	1
Pacific tree frog	Acute	0.5
	Chronic	1

2.10.5.2 Refined Risk Characterization

For both aquatic and terrestrial exposure scenarios screening through to the refined assessment, risk curves will be used to quantify risk.

Each exposure distribution will be integrated with an effects distribution (e.g., species sensitivity distribution or exposure-response curve) to derive a risk curve that indicates the probability of exceeding effects of varying magnitude. The risk curve will then be used to categorize risk as *de minimis*, low, intermediate, or high for each use pattern.

The Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM, 1999) referred to risk curves as "joint probability curves" while others use the term used herein, i.e., "risk curves" (e.g., EPA, 2004b; Giddings et al., 2005). This approach has been used in ecological risk assessments performed for EPA at the Calcasieu Estuary, Louisiana, the Housatonic River, Massachusetts (EPA, 2002b; EPA, 2004b) and by others in ecological risk assessments of pesticides (Giesy et al., 1999; Giddings et al., 2005; Moore et al., 2006a,b; Moore et al., 2010a,b).

The risk categories of *de minimis*, low, intermediate and high are intended to be qualitative descriptors of the risks to CRLFs, their prey and their habitat exposed to dimethoate.

In this assessment, the probability of an exposure concentration exceeding a level of effect is quantified as the area under a risk curve (AUC). The AUC will be used to categorize risk.

For each exposure scenario, risk is categorized as follows:

- If the AUC is less than the AUC associated with a risk product (risk product = exceedence probability x magnitude of effect) of 0.25%, then the risk is categorized as *de minimis*;
- If the AUC is equal to or greater than the AUC associated with a risk product of 0.25% but less than 2%, then the risk is categorized as low;

- If the AUC is equal to or greater than the AUC of 2% but less than 10%, then the risk is categorized as intermediate; and
- If the AUC is equal to or greater than the AUC associated with a risk product of 10%, then the risk is categorized as high.

The risk category boundaries, as described above are shown in Figure 2-7 and Table 2-19. The risk categories are based on several considerations including:

- An effect level of 10% is unlikely to be ecologically significant to a local population. Such an effect generally cannot be reliably confirmed by field studies (Moore, 1998; Suter et al., 2000). Thus, when concentrations of a pesticide are less than the 10^{th} percentile on the low-effects SSD or 10^{th} percentile on a single species dose response curve, it is likely that the community or species are being protected;
- Controlled exposure–response experiments with microcosms and mesocosms have demonstrated that, at some level of exposure, temporary changes occur in the abundance of a few, sensitive species. At a higher level of exposure, more severe and longer lasting effects occur that may have pronounced ramifications for community structure and function. The transition from minor to major effects usually occurs at concentrations greater than the 10th percentile of single-species low-toxic-effect values (Giddings et al., 1996, 1997; Solomon et al., 1996; Versteeg et al., 1999);
- Suter et al. (2000) concluded, based on an analysis of EPA regulatory practice, that decreases in an ecological assessment endpoint of <20% are generally acceptable. For example, the approximate detection limit of field measurement techniques used in regulating contaminants based on bioassessment of aquatic ecosystems is 20%. The community metrics for an exposed benthic invertebrate community must be reduced by >20% compared with pristine reference sites to be considered even slightly impaired in the EPA rapid bioassessment procedure (Plafkin et al., 1989).

CRLFs are opportunistic predators and thus effects limited to sensitive populations of prey species are unlikely to lead to adverse effects to CRLFs via reduction in food availability. The high reproductive potential of most aquatic invertebrate species allows them to recover in a relatively short time after experiencing low-to-moderate adverse effects (van den Brink et al., 1996; Sherratt et al., 1999; Suter et al., 2000; Barnthouse, 2004). Liess and Schulz (1999), however, showed that recovery can take a very long time (months to years) for aquatic invertebrates when local populations are extirpated.

Aquatic ecosystems exhibit "functional redundancy" in the temperate zone (Baskin, 1994; Moore, 1998). This means that multiple species are generally present to perform each critical function. Agricultural ecosystems are, to some degree, already affected because of changes brought by the presence of humans, crop fields, livestock, infrastructure, and so on. It is a generally accepted notion among ecologists that systems in relatively unstable environments (the case for most agro-ecosystems) are more likely to recover from new disturbances (e.g., a pesticide application), especially those that mimic historical disturbance events (e.g., previous pesticide applications; Denslow, 1985; Rapport et al., 1985; Moore, 1998).

Table 2-19 Refined risk categories and AUC risk boundaries

Boundary	***AUC Boundary Points (%)***
De minimis-Low	1.75
Low-Intermediate	9.82
Intermediate-High	33.03

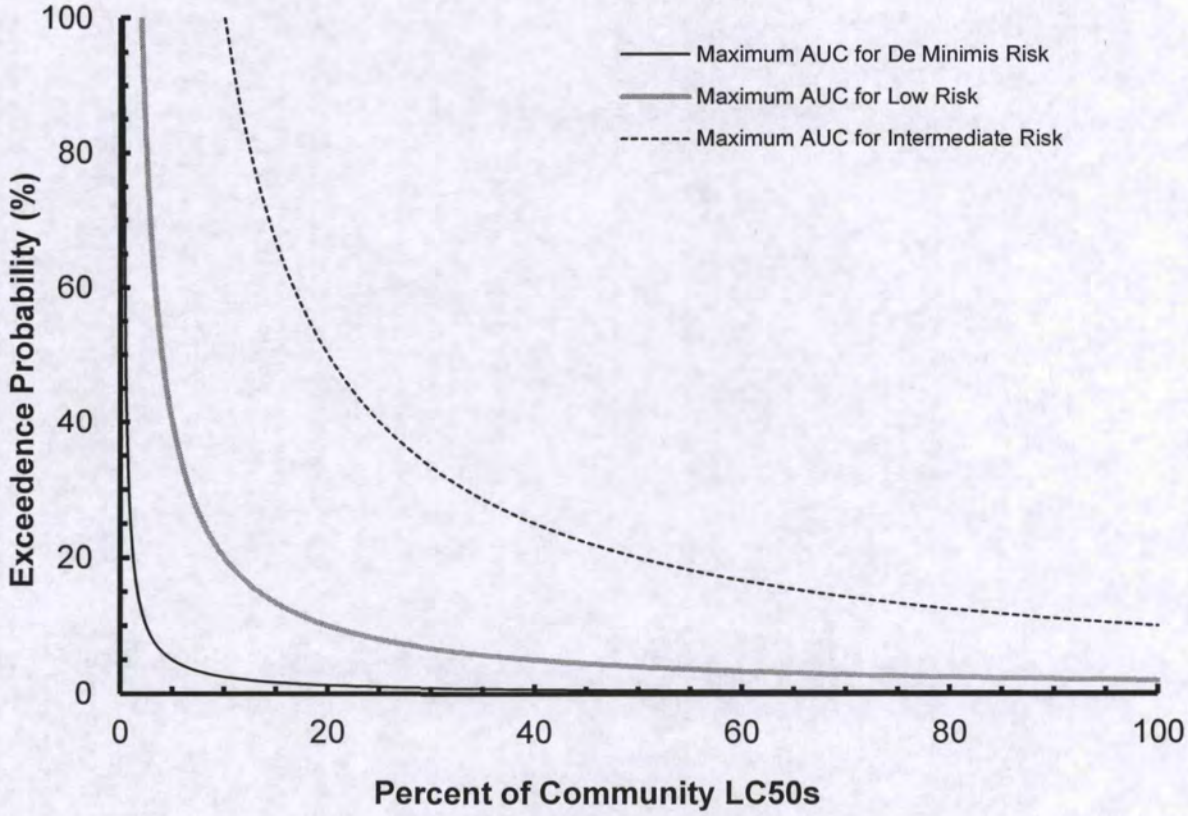

Figure 2-7 Risk curves defining the AUC boundaries for risk categorization.

2.10.6 Other Lines of Evidence

In addition to the results of the screening and refined assessments, other lines of evidence will be considered in the conclusive risk characterization. Other information sources include:

- Mesocosm and field studies;
- Monitoring data; and,
- Incident reports.

2.10.7 Uncertainties, Strengths and Limitations of the Assessment

Uncertainties in the problem formulation and assessments of exposure and effects can influence the characterization of risks. The sources of uncertainty in the effects determination were identified, and their magnitude and the direction of their influence discussed when possible. A discussion of the strengths and limitations of the effects determination was also prepared (Sections 3.4 and 4.4).

2.10.8 Overall Characterization of Risk to CRLF

The effects determination concluded with either "no effect", "may affect, but notlikely to adversely affect" or "may affect, but likely to adversely affect" for each assessment endpoint (i.e., direct and indirect effects). In general, the exposure scenario(s) assigned the risk category of greatest concern ("no effect" < "may affect, but not likely to adversely affect" < "may affect, but likely to adversely affect") for a particular assessment endpoint drove the overall risk conclusion for dimethoate. The following information provides additional details on how the risk conclusions will be formulated.

A determination of "no effect" implies that all exposure scenarios for an assessment endpoint were screened out prior to the refined CRLF effects determination for all exposure scenarios. Otherwise, the risk conclusion for the assessment endpoint was "may affect, but not likely to adversely affect" or "may effect, but likely to adversely affect", depending on the results of the refined quantitative risk characterization, uncertainty and other lines of evidence. All lines of evidence will be reviewed and evaluated in depth in the risk characterization and an overall weight-of-evidence conclusion derived.

3.0 AQUATIC EFFECTS DETERMINATION

Dimethoate exposures in the aquatic environment potentially resulting in indirect effects to CRLF are considered in this aquatic effects determination. Section 3.1 describes the screening-level assessment while Section 3.2 describes the refined assessment. Section 3.3 describes the other lines of evidence for the aquatic effects determination.

3.1 Aquatic Screening-Level Effects Determination

This screening-level effects determination used a conservative approach to determine if there is significant risk to CRLF aquatic prey or habitat. The phases of each section of the effects determination include: effects assessment, exposure assessment and risk characterization. Each of these phases are described below.

3.1.1 Aquatic Screening-Level Effects Assessment

The screening-level effects determination used the most sensitive and relevant measures of effect for the assessment endpoints under consideration. An evaluation of all available toxicity data was conducted to ensure that the best available data were used in the effects determination. The criteria used to evaluate the aquatic invertebrate and vascular plant studies and the evaluations of these studies are presented in Appendix A, B and C.

There was only one aquatic vascular plant toxicity study available, which is summarized below.

A summary of key effects data is presented in Section 2.6. The measures of ecological effect selected for the aquatic screening-level effects determination are presented in Table 3-1.

Table 3-1 Measures of ecological effects selected for the aquatic screening-level effects determination for dimethoate

Species	*Exposure Duration*	*Endpoint*	*Concentration*	*Reference [MRID]*
Aquatic Life Stage – Indirect Effects				
Water flea (*Daphnia magna*)	Chronic	NOEL	0.04 mg/L	Wüthrich, 1990 [42864701]
Duckweed (*Lemna gibba*)	Acute/chronic	7 d EC50 (Growth)	>45.1 mg/L	Porch et al., 2009 [47709703]

3.1.2 Aquatic Screening-Level Exposure Assessment

The Pesticide Root Zone Model (PRZM3.12.2, executable date: May 12, 2005) and Exposure Analysis Modeling System (EXAMS2.98.04, executable date: April 25, 2005) were used by Stone Environmental to estimate concentrations (EECs) of dimethoate in an edge of field standard pond. These models simulate the application of dimethoate exposure scenarios based on use patterns found on the labels (Table 2-5). Worst-case scenarios (i.e., maximum application rates, maximum frequency, application method most likely to facilitate off-site transport, maximum spray drift) were investigated for dimethoate.

The PRZM is a one-dimensional, flow and transport model that can be used to simulate chemical movement in unsaturated soil systems within and immediately below the plant root zone (EPA, 2003a). It has two major components - hydrology (and hydraulics) and chemical transport. The hydrologic component simulates the surface and subsurface flow of water. The surface runoff simulation is based on a modified algorithm of the Soil Conservation Service (SCS) curve number technique. The subsurface water movement through the soil compartments (or layers) is simulated by the storage routing technique (also known as the "tipping-bucket method") that uses generalized soil parameters such as field capacity, wilting point, saturation water content, and bulk density. The chemical transport component can simulate the movement of pesticides applied on soil or on plant foliage. Biodegradation can also be considered in the root zone. Dissolved, sorbed, and vapor-phase concentrations in the soil are estimated by simultaneously considering the processes of pesticide uptake by plants, surface runoff, erosion, decay, volatilization, foliar wash-off, advection, dispersion, and retardation. The model has a daily time-step and the outputs can be summarized for a variety of durations. Runoff, sediment load, dissolved and sorbed chemical loads can be written to sequential files (PRZM-EXAMS transfer files) during program execution, which can be imported into a surface water simulation using EXAMS.

The EXAMS is an interactive computer program that evaluates the behavior of chemicals in aquatic environments based on general laboratory descriptions of the chemical (EPA, 2003a). The model estimates the exposure, fate, and persistence of a compound after its release into the aquatic system. The EXAMS uses physically-based relationships to define these three processes. The program consists of a set of unit process models that are founded on the law of conservation of mass. The EXAMS treats ionization and partitioning of the compound with sediments and biota discretely for each model segment, thus including the effects of spatial variability of system inputs. The model uses user-defined kinetic rate constants to compute transformation kinetics for processes such as photolysis, hydrolysis, biolysis, and oxidation reactions. The outputs from the model include peak EECs (maximum instantaneous), 96-hour, 21-day, 60-day, and 90-day averages, along with mean annual EECs in the system compartments such as water column, sediment, and pore water.

3.1.2.1 Exposure Scenarios

For each exposure scenario, PRZM used 30 years of site-specific climate data to generate exposure concentrations. The PRZM results were used as inputs into EXAMS to estimate concentrations of dimethoate in surface waters of a standard pond. A standard surface water exposure assessment scenario consists of a hypothetical treated field of 10 ha draining into a 1 ha pond that is 2 m deep. PRZM/EXAMS estimates exposure for a static water body, and thus produces more conservative estimates than would be the case for water bodies with in-flows and out-flows.

Dimethoate may be applied over a period of time between emergence and harvest of a crop. Because rainfall patterns and other climatic variables vary temporally, off-field transport of dimethoate via runoff will also vary temporally. As a result, choice of application date can affect the estimated concentrations of dimethoate in the standard pond. Thus, each scenario was simulated for a range of application dates based on historical use data using the California Pesticide Use Database for most of the simulated crops. The PRZM/EXAMS simulations were performed by Tammara Estes and John Hanzas of Stone Environmental, Inc. For crops that were not listed in the California Pesticide Use Database, date ranges were set to start at the emergence date and end at harvest date for the standard scenario selected to represent the crop. Table 3-2 presents the application dates that were modeled in PRZM/EXAMS. These dates represent the overlap between dates of application of dimethoate reported in the CAPUR (California Pesticide Use Reporting) database and those provided as emergence and harvest dates in PRZM.

Table 3-3 shows the PRZM scenario, the category (STD, OP or CRLF), the county for which these scenarios were developed, application rates, number of applications and re-application intervals that were modeled for this effects determination. In keeping with the conservative nature of the screening-level effects determination, the worst-case scenarios (i.e., maximum application rates, maximum frequency, application method most likely to facilitate off-site transport, maximum spray drift) were investigated. When a specific crop scenario did not exist in PRZM, a surrogate scenario was assigned.

Each exposure scenario was simulated for a range of application dates. Dimethoate may be applied over a period of time between emergence and harvest of a crop. For each starting application date within a range of application dates for a particular exposure scenario, EXAMS determined a distribution of one-day peak and 21-day average concentrations based on the 30-year simulation (i.e., 30 data points). The peak and 21-day concentrations were calculated for each starting application date. For example, if an exposure scenario had a starting application date range of sixty days, sixty peak one-day maxima and 21-day average maximum concentrations were estimated. Of these, the highest peak and 21-day average represented worst-case EECs for that year. This was done for each of thirty years, resulting in 30 maximum peak and 21-day average values. The 90th percentile of these values was used for screening. Use of 90th percentiles of maximum estimated EECs provides extremely conservative risk estimates because it does not account for the fact that farmers are expected to avoid applications before forecasted rain events, as labels advise.

Table 3-2 Range of application dates for dimethoate applied to crops in California

Crop	*PRZM Scenario*	*State*	*EPA Application Date*	*Application Date Range (CAPUR)*	*PRZM Emergence to Harvest Range*	*Overlap Between the CAPUR and PRZM Dates*
Alfalfa (forage and hay)	Alfalfa	CA	January 2	January 1 – December 31	January 16 – December 31	January 16 – November 1
Alfalfa (seed)	Alfalfa	CA	January 2	January 1 – December 31	January 16 – December 31	January 16 – December 31
Asparagus	Alfalfa	CA	None	January 15 – June 30[a]	January 16 – December 31	January 16 – June 30
Asparagus	Asparagus	MI	None	January 15 – June 30[a]	January 16 – December 31	January 16 – June 30
Beans, celery, lentils, peas, peppers	Row Crop	CA	March 1	January 1 – October 31	January 1 – April 8	January 1 – April 8
Broccoli, cauliflower, kale, mustard greens	Cole	CA	February 1	January 1 – December 31	January 1 – March 1	January 1 – March 1
Brussel sprouts	Lettuce	CA	August 12	June 1 – November 30	February 16 – May 12	February 16 – May 12
Christmas tree nurseries	Christmas Tree	OR	None	January 1 – December 31[a]	January 1 – December 31	January 1 – November 19
Cherries	Fruit	CA	None	March 1 – June 30[a]	January 1 – August 1	March 1 – June 30
Cherries	Cherries	MI	None	March 1 – June 30[a]	May 1 – July 21	May 1 – June 30
Citrus	Citrus	CA	May 15	March 1 – November 30	January 1 – December 31	March 1 – December 1
Conifer seed orchards	Forestry	CA	January 15	Not in CAPUR Database	January 1 – December 31	January 1 – December 3
Cottonwood grown for pulp	Forestry	CA	January 15	Not in CAPUR Database	January 1 – December 31	January 1 – December 11
Cotton	Cotton	CA	August 15	April 1 – October 31	May 1 – November 11; May 5 – November 11	May 1 – October 31
Endive, lettuce, swiss chard	Lettuce	CA	October 15	January 1 – December 31	February 16 – May 12	February 16 – May 12
Field corn, popcorn, soybeans	Corn	CA	July 15	May 1 – September 30	April 1 – September 8	May 1 – September 8
Grass for seed	Turf		January 15	Not in CAPUR Database	January 1 – December 31	January 1 – October 2
Melon, honeydew	Melon	CA	July 1	March 1 – September 30	May 16 – August 2	May 16 – August 2
Non-cropland areas adjacent to vineyards	Wine Grapes	CA	July 15	March 1 – September 30	March 1 – August 1	March 1 – August 1
Non-cropland areas adjacent to vineyards	Grapes	CA	July 15	March 1 – September 30	February 1 – August 31	March 1 – August 31
Ornamentals	Nursery	CA	August 15	January 1 – December 31	March 1 – November 1	March 1 – November 1
Pears	Fruit	CA	June 15	May 1 – June 30	January 16 – August 1	May 1 – June 30
Pecans	Almonds	CA	June 15	June 1 – September 30	January 16 – September 13	June 1 – September 13
Potato	Potato	CA	May 25	December – August 31	February 16 – June 15	February 16 – June 15

Table 3-2 Range of application dates for dimethoate applied to crops in California

Crop	PRZM Scenario	State	EPA Application Date	Application Date Range (CAPUR)	PRZM Emergence to Harvest Range	Overlap Between the CAPUR and PRZM Dates
Safflower, sorghum, wheat	Wheat	CA	March 15	January 1 – August 31	January 1 – June 15	January 1 – June 15
Tomato	Tomato	CA	July 15	March 1 – October 31	March 1 – September 1	March 1 – September 1
Turnips	Potato	CA	May 15	December 1 – March 31	February 16 – June 15	February 16 – June 15

[a] Application date range from USDA crop profiles.

Table 3-3 Use patterns for PRZM/EXAMS modeling for application of dimethoate to crops

Crop	PRZM Scenario	Category	County	Application Method	Maximum Single Application Rate (lb a.i./A)	Maximum Number of Applications per Season	Maximum Seasonal Application Rate (lb a.i./A)	Minimum Retreatment Interval (d)
Alfalfa (forage and hay)	Alfalfa	OP	San Joaquin and Stanislaus	Groundspray/aerial	0.5	3 (1/cutting)	1.5	30
Alfalfa (seed)	Alfalfa	OP	San Joaquin and Stanislaus	Groundspray/aerial	0.5	1	0.5	NA
Asparagus	Alfalfa	OP	San Joaquin and Stanislaus	Groundspray/aerial	0.5	2	1	14
Asparagus	Asparagus	STD	Oceana	Groundspray/aerial	0.5	2	1	14
Beans	Row crop	CRLF	Santa Maria	Groundspray/aerial	0.5	2	1	14
Broccoli, cauliflower	Cole	CRLF	Santa Maria Valley	Groundspray/aerial	0.5	3	1.5	7
Brussel sprouts	Lettuce	STD	Monterey	Groundspray/aerial	0.5	3	1.5	7
Celery	Row crop	CRLF	Santa Maria	Groundspray/aerial	0.5	3	1.5	7
Cherries	Fruit	STD	Central Valley	Airblast/aerial	1.33	1	1.33	NA
Cherries	Cherries	STD	Leelanau	Airblast/aerial	1.33	1	1.33	NA
Christmas tree nurseries	Christmas tree	OR	Benton	Groundspray/airblast	1	3	3	14
Citrus	Citrus	STD	Central Valley	Airblast	1	1	1	NA
Conifer seed orchards	Forestry	CRLF	Shasta	Groundspray/airblast	1	1	1	NA

Table 3-3 Use patterns for PRZM/EXAMS modeling for application of dimethoate to crops

Crop	*PRZM Scenario*	*Category*	*County*	*Application Method*	*Maximum Single Application Rate (lb a.i./A)*	*Maximum Number of Applications per Season*	*Maximum Seasonal Application Rate (lb a.i./A)*	*Minimum Retreatment Interval (d)*
Cotton	Cotton with irrigation	STD	Fresno	Groundspray/aerial	0.5	2	1	14
Cotton	Cotton without irrigation	STD	Fresno	Groundspray/aerial	0.5	2	1	14
Cottonwood for pulp	Forestry	CRLF	Shasta	Chemigation/aerial	2	3	6	10
Endive	Lettuce	STD	Monterey	Groundspray/aerial	0.25	3	0.75	7
Field corn, popcorn	Corn	OP	San Joaquin and Stanislaus	Groundspray/aerial	0.5	1	0.5	NA
Grass grown for seed	Turf	CRLF	San Francisco Bay Area	Groundspray/aerial	0.5	2	1	90
Kale	Cole	CRLF	Santa Maria Valley	Groundspray/aerial	0.25	2	0.5	15
Lentils	Row crop	CRLF	Santa Maria	Groundspray/aerial	0.5	2	1	7
Leaf lettuce, swiss chard	Lettuce	STD	Monterey	Groundspray/aerial	0.25	3	0.75	7
Melon, honeydew	Melon	CRLF	Kern, Kings, Madera and Merced	Groundspray/aerial	0.5	2	1	7
Mustard greens	Cole	CRLF	Santa Maria Valley	Groundspray/aerial	0.25	2	0.5	9
Non-cropland areas adjacent to vineyards	Wine grapes	CRLF	Sonoma	Groundspray	2	2	4	14
Non-cropland areas adjacent to vineyards	Grapes	STD	Central Valley	Groundspray	2	2	4	14

Table 3-3 Use patterns for PRZM/EXAMS modeling for application of dimethoate to crops

Crop	PRZM Scenario	Category	County	Application Method	Maximum Single Application Rate (lb a.i./A)	Maximum Number of Applications per Season	Maximum Seasonal Application Rate (lb a.i./A)	Minimum Retreatment Interval (d)
Ornamentals (herbaceous)	Nursery	STD	San Diego	Groundspray	0.25	1	0.25	NA
Ornamentals (woody)	Nursery	STD	San Diego	Groundspray	1	3	3	14
Pears	Fruit	STD	Central Valley	Airblast/aerial	1	1	1	NA
Peas (succulent)	Row crop	CRLF	Santa Maria	Groundspray/aerial	0.16	4	0.5	14
Peas (not for use on field peas)	Row crop	CRLF	Santa Maria	Groundspray/aerial	0.16	1	0.16	NA
Pecans	Almonds	STD	San Joaquin	Groundspray/aerial	0.33	1	0.33	NA
Peppers	Row crop	CRLF	Santa Maria	Groundspray/aerial	0.33	5	1.65	7
Potatoes	Potato	CRLF	Lewkalb in Kern	Groundspray/aerial	0.5	2	1	7
Safflower	Wheat	CRLF	Central Valley, Kings	Groundspray/aerial	0.5	2 (1/cutting)	1	14
Sorghum	Wheat	CRLF	Central Valley, Kings	Groundspray/aerial	0.5	2	1	7
Soybean	Corn	OP	San Joaquin and Stanislaus	Groundspray/aerial	0.5	2	1	7
Tomatoes	Tomato	STD	San Joaquin	Groundspray/aerial	0.5	2	1	6
Turnips	Potato	CRLF	Lewkalb in Kern	Groundspray/aerial	0.25	7	1.75	3
Wheat (1)	Wheat	CRLF	Central Valley, Kings	Groundspray/aerial	0.67	1	0.67	NA
Wheat (2)					0.67	2	1.34	7
Wheat (3)					0.5	1	0.5	NA
Wheat (4)					0.5	2	1	7
Wheat (5)					0.33	2	0.66	7

NA = Not applicable because number of applications per season is one

The PRZM3.12.2/EXAMS2.98.04 analyses were run using the EFED OPP/EFED shell PE5 (November 15, 2006). Table 3-4 presents the PE5 script scenarios used for the modeling. The standard scenarios simulated by PRZM3.12.2 scripts load into the PE5 shell. The multiple application date scenarios were run using the multi-application date option in the PE5 shell. For most of the exposure scenarios, the date range was selected to cover the entire range of dates recorded in the California Pesticide Use Report (CA PUR) database for 2003- 2007. This database is maintained by the California Department of Pesticide Regulation (CDPR) and can be accessed at http://calpip.cdpr.ca.gov/main.cfm. For those crop scenarios with no information in the CA PUR database, the date range selected covered the time from the emergence date to the harvest date as listed in the EFED standard scenario description. For multiple applications, some date ranges were shortened to allow for the last annual application to occur on December 31. This was done because PE5 does not allow annual application patterns to cross calendar years. The only modification made to these scripts was for the CACottonC script. This script was developed for a previous version of the PRZM model and was missing Card 9E which is required for PRZM3.12.2. This card lists the runoff curve number of antecedent moisture condition II for each USLE (Universal Soil Loss Equation) date. To make this script run, the Card 9E was added to the script. The soil surface condition after harvest for this script was set to residue with a runoff curve of 87 during non-cropping periods of time. During cropping (i.e., emergence to harvest), the runoff curve number was set to 86 for the scenario. The same pattern was followed for the addition of runoff curve numbers associated with the USLE dates. For USLE dates during cropping and non-cropping periods, the USLE runoff curve number was set to 86 and 87, respectively. This is the same approach used in the standard scenario development process.

Dimethoate application was modeled for aerial application to foliage with an interception based on crop canopy as a straight-line function of crop development. The chemical reaching the soil surface was assumed to be incorporated to a depth of 4 cm (CAM = 2).

Table 3-4 PE5 scenarios used to model concentrations of dimethoate in surface water

Crop	*Scenario*	*State*	*PE5 Scenario Script File*
Alfalfa (forage and hay)	Alfalfa	CA	CAalfala_WirrigOP
Alfalfa (seed)	Alfalfa	CA	CAalfala_WirrigOP
Asparagus	Alfalfa	CA	CAalfala_WirrigOP
Asparagus	Asparagus	MI	MIasparagusSTD
Beans, celery, lentils, peas, peppers	Row crop	CA	CArowcropRLF_V2
Broccoli, cauliflower, kale, mustard greens	Cole	CA	CAcolecropRLF_V2
Brussel sprouts	Lettuce	CA	CAlettuceSTD
Christmas tree nurseries	Christmas tree	OR	ORXmastreeSTD
Cherries	Fruit	CA	CAfruit_WirrigSTD
Cherries	Cherries	MI	MICherriesSTD
Citrus	Citrus	CA	CAcitrus_WirrigSTD
Conifer seed orchards	Forestry	CA	CAforestry_RLF
Cottonwood grown for pulp	Forestry	CA	CAforestry_RLF

Table 3-4 PE5 scenarios used to model concentrations of dimethoate in surface water			
Crop	***Scenario***	***State***	***PE5 Scenario Script File***
Cotton	Cotton	CA	CAcotton_WirrigSTD and CAcottonC
Endive, lettuce, swiss chard	Lettuce	CA	CAlettuceSTD
Field corn, popcorn, soybeans	Corn	CA	CAcornOP
Grass for seed	Turf	CA	CAturfRLF
Melon, honeydew	Melon	CA	CAmelonsRLF_V2
Non-cropland areas adjacent to vineyards	Wine grapes	CA	CAwinegrapesRLF_V2
Non-cropland areas adjacent to vineyards	Grapes	CA	CAgrapes_WirrigSTD
Ornamentals	Nursery	CA	CAnurserySTD_V2
Pears	Fruit	CA	CAfruit_WirrigSTD
Pecans	Almonds	CA	CAalmond_WirrigSTD
Potato	Potato	CA	CApotatoRLF_V2
Safflower, sorghum, wheat	Wheat	CA	CAwheatRLF_V2
Tomato	Tomato	CA	CAtomato_WirrigSTD
Turnips	Potato	CA	CApotatoRLF_V2

3.1.2.2 Input Parameters for PRZM and EXAMS

The input parameters for the PRZM/EXAMS model runs are presented in Table 3-5. The chemical and physical input values for dimethoate were estimated using the guidelines provided by the EPA in the document, “Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides, Version 2.1” (October 22, 2009) in conjunction with laboratory data obtained from Cheminova, Inc., USA.

Table 3-5 Input parameters used in PRZM and EXAMS to estimate concentrations of dimethoate in a standard pond at field's edge	
Parameter	***Input Value***
Application type	Groundspray , Airblast, Aerial, Chemigation
Runoff flow	None
Incorporation depth	CAM 2
Spray drift fraction	0.01 (ground) 0.03 (airblast and chemigation) 0.05 (aerial)
Application efficiency	0.99 (ground, airblast and chemigation) 0.95 (aerial)
Molecular weight	229.2 g/mol
Vapor pressure	1.8×10^{-6} mmHg @ 20°C
Henry's Law constant	7.8×10^{-11} atm m^3 mol^{-1} @ 25°C
K_{OC}	22.3 ml/g[a]
Aqueous solubility	39,800 mg/L @ 25°C
Aqueous photolysis half-life	350 d[b]
Aerobic aquatic biolysis half-life	31.1 d[c]
Benthic half-life	66 d[d]
Soil half-life	3.5 d[e]
Foliar dissipation half-life	2.88 d[e]
Hydrolysis half-life at pH 7	68 d[f]

[a] As calculated below.

[b] The aqueous photolysis half-life for dimethoate is > 175 d. This value was multiplied by 2 as per EPA (2008a).

[c] Calculation conducted according to EPA guidance (http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm). The average total system half-lives (DT_{50} – Table 2-6) is 15.2 d (standard deviation = 2.83; n = 2). The t90 is 21.36 d, or equivalently 0.032450711 d^{-1}. The hydrolysis half-life at pH 7 is 68 d or equivalently, 0.010193341 d^{-1}. Subtracting 0.032450711 d^{-1} minus 0.010193341 d^{-1} gives 0.02225737 d^{-1} or equivalently a biolysis half-life value of 31.1 d.

[d] The anaerobic soil metabolism half-life is 22 d. This value was multiplied by 3 as per EPA guidance (http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm).

[e] Reiss (2009a) calculated 90[th] percentile of estimated t-distribution. Intrinsik confirmed this half-life.

[f] Hawkins et al. (1986a [MRID 00159761]) (Latest guidance uses only pH 7 in PE5).

Dimethoate was simulated as a non-volatile chemical. The foliar extraction coefficient for pesticide wash off per centimeter of rainfall was set to 0.5. There was no simulation of volatilization from the foliage or plant uptake of dimethoate. However, dimethoate decay on the plant surface was simulated.

A notable difference between the EPA OPP/EFED CRLF exposure modeling and this modeling exercise was the use of K_{OC} instead of K_d to simulate sorption. Per EPA OPP/EFED guidance, "Binding is correlated with organic carbon content if the coefficient of variation (i.e., mean divided by the standard deviation) for K_{OC} values is less than that for K_d values. Use of the mean K_d may not be appropriate for certain chemicals with binding not correlated with organic carbon content, such as those that are ionic at environmental pH values. In these cases, the model user should document the rationale for the selected model input values. Additional guidance may be sought at the EFED WQTT." For dimethoate, sorption is correlated with percent organic carbon content. However, EFED used the K_d instead of the K_{OC} in their modeling. This inaccurately limited the modeled portion of dimethoate that sorbed to soils with high organic matter. The coefficient of variation was calculated for both the K_d and K_{OC} based on the laboratory adsorption/desorption studies and found that the K_{OC} had the lower coefficient of variation (Table 3-6). Therefore, the average K_{OC} of 22.3 was used for this exposure modeling exercise.

Table 3-6 Coefficient of variation for K_d and K_{OC} values for dimethoate

Soil Type	***K_d (L/kg)***	***% OC***	***K_{OC}***	***Reference [MRID]***
Sand	0.06	0.9	6.67	Hawkins, 1986c [00164959]
Sandy silt loam	0.3	1.5	20	
Clay loam	0.57	3.5	16.3	
Sandy loam	0.74	7.4	10	
Sandy/loam sand	0.25	0.48	51.9	Schanné, 1992 [47477301]
Sandy loam	0.33	2.05	16.3	
Silt loam	0.42	1.42	29.6	
Loam/silt loam	0.42	1.4	30.2	
Sand	0.34	1.5	22.5	
Loam	0.37	1.9	19.5	
Summary Statistics				
Mean	0.44	-	22.3	-
Standard deviation	0.21	-	16.2	-
Coefficient of Variation	2.05	-	1.49	-

3.1.2.3 Aquatic Exposure PRZM/EXAMS Results

It is highly unlikely that CRLFs would reside in a stagnant pond receiving surface runoff from an immediately adjacent 10 ha treated field. The preferred breeding and summer habitat of the CRLF includes still or slow-moving permanent streams with deep water (>0.7 meters) and dense riparian vegetation (FWS, 1996, 2002a). PRZM/EXAMS estimates exposure for a static water body, and thus produces more conservative estimates than would be the case for water bodies with in-flows and out-flows. Following are two examples of how waterbodies having in-flows and out-flows reduce pesticide concentrations. Using the AgDrift Stream Assessment Tool, Rick Reiss of Exponent, Inc. demonstrated that even in slow-moving streams (0.07 ft/sec) dimethoate concentrations decline rapidly from initial peak concentrations of 50 µg/L to less than 1 µg/L in five hours (Bogen and Reiss, 2011; presentation to EPA and NMFS on October 23, 2009). Stone Environmental derived EECs for malathion in more realistic water bodies inhabited by the CRLF (i.e. realistic in-flow and out-flow, volume, and location characteristics) using SWAT (Soil and Water Assessment Tool) modeling. Peak EECs were 5 to 12 times greater for the PRZM/EXAMS simulations (lettuce and strawberry, respectively) than they were for the most vulnerable water body in the SWAT simulation of the Watsonville watershed in California. For the 21-day duration, the EECs based on PRZM/EXAMS were 20 to 50 times greater (lettuce and strawberry, respectively) than the SWAT simulation predictions. This comparison shows that the interpretation of risk is significantly reduced when EECs are based on modeling actual aquatic ecosystems (rather than hypothetical ones in the case of PRZM/EXAMS), and when using a model that appropriately accounts for all hydrologic processes, such as SWAT (Intrinsik, In Prep(b); Stone Environmental, 2012). Because the standard pond in the EXAMS has no in-flows or out-flows, concentrations of dimethoate decline much more slowly from peak concentrations. Thus, use of PRZM/EXAMS to estimate EECs for dimethoate, as done here, is a highly conservative approach and will lead to overestimation of exposure and risk of dimethoate to CRLF and their prey. Additional discussion on the conservativeness of PRZM/EXAMS is presented in Section 3.4.3.

The 90[th] percentile of maximum peak, 96-hour and 21-day average concentrations estimated for each of 30 years, as described above, of dimethoate across a range of application dates are summarized in Table 3-7.

Table 3-7 Maximum 90[th] percentile dimethoate concentrations across a range of application dates

Crop	*PRZM Scenario Modeled*	*Application Method*	*Application Rate (lb a.i./A)/ Number of Applications/ Re-application Interval (d)*	*Peak (mg/L)*	*96-hour Mean (mg/L)*	*21-d Mean (mg/L)*
Alfalfa (forage and hay)	Alfalfa	Aerial	0.5/3/30	0.0098	0.0095	0.0081
		Groundspray	0.5/3/30	0.0085	0.0082	0.0070
Alfalfa (seed)	Alfalfa	Aerial	0.5/1/NA	0.0076	0.0074	0.0064
		Groundspray	0.5/1/NA	0.0068	0.0066	0.0057
Asparagus	Alfalfa	Aerial	0.5/2/14	0.0095	0.0092	0.0079
		Groundspray	0.5/2/14	0.0079	0.0077	0.0066
Asparagus	Asparagus	Aerial	0.5/2/14	0.0047	0.0045	0.0041
		Groundspray	0.5/2/14	0.0037	0.0035	0.0030
Beans	Row crop	Aerial	0.5/2/14	0.0072	0.0069	0.0060
		Groundspray	0.5/2/14	0.0055	0.0053	0.0046
Broccoli, cauliflower	Cole	Aerial	0.5/3/7	0.0245	0.0236	0.0205
		Groundspray	0.5/3/7	0.0224	0.0216	0.0188
Brussel sprouts	Lettuce	Aerial	0.5/3/7	0.0183	0.0176	0.0149
		Groundspray	0.5/3/7	0.0160	0.0154	0.0130
Celery	Row crop	Aerial	0.5/3/7	0.0115	0.0112	0.0096
		Groundspray	0.5/3/7	0.0100	0.0097	0.0086
Cherries	Fruit	Aerial	1.33/1/NA	0.0069	0.0066	0.0056
		Airblast	1.33/1/NA	0.0056	0.0054	0.0045
Cherries	Cherries	Aerial	1.33/1/NA	0.0139	0.0133	0.0109
		Airblast	1.33/1/NA	0.0129	0.0123	0.0101
Christmas tree nurseries	Christmas tree	Airblast	1/3/14	0.0177	0.0171	0.0151
		Groundspray	1/3/14	0.0151	0.0146	0.0129
Citrus	Citrus	Airblast	0.5/2/30	0.0018	0.0017	0.0014
Conifer seed orchards	Forestry	Airblast	1/1/NA	0.0164	0.0160	0.0140
		Groundspray	1/1/NA	0.0154	0.0150	0.0131
Cotton	Cotton with irrigation	Aerial	0.5/2/14	0.0049	0.0047	0.0041
		Groundspray	0.5/2/14	0.0030	0.0029	0.0025
Cotton	Cotton without irrigation	Aerial	0.5/2/14	0.0042	0.0041	0.0035
		Groundspray	0.5/2/14	0.0025	0.0024	0.0021
Cottonwood grown for pulp	Forestry	Aerial	2/3/10	0.0606	0.0587	0.0540
		Chemigation	2/3/10	0.0573	0.0554	0.0513
Endive	Lettuce	Aerial	0.25/3/7	0.0092	0.0088	0.0074
		Groundspray	0.25/3/7	0.0080	0.0077	0.0065
Field corn, popcorn	Corn	Aerial	0.5/1/NA	0.0014	0.0013	0.0011
		Groundspray	0.5/1/NA	0.0003	0.0003	0.0002

Table 3-7	Maximum 90th percentile dimethoate concentrations across a range of application dates					
Crop	***PRZM Scenario Modeled***	***Application Method***	***Application Rate (lb a.i./A)/ Number of Applications/ Re-application Interval (d)***	***Peak (mg/L)***	***96-hour Mean (mg/L)***	***21-d Mean (mg/L)***
Grass for seed	Turf	Aerial	0.5/2/90	0.0048	0.0043	0.0020
		Groundspray	0.5/2/90	0.0037	0.0036	0.0011
Kale	Cole	Aerial	0.25/2/15	0.0086	0.0083	0.0071
		Groundspray	0.25/2/15	0.0079	0.0076	0.0066
Lentils	Row crop	Aerial	0.5/2/7	0.0090	0.0088	0.0080
		Groundspray	0.5/2/7	0.0086	0.0084	0.0074
Lettuce, swiss chard	Lettuce	Aerial	0.25/3/7	0.0092	0.0088	0.0074
		Groundspray	0.25/3/7	0.0080	0.0077	0.0065
Melon, honeydew	Melon	Aerial	0.5/2/7	0.0026	0.0023	0.0019
		Groundspray	0.5/2/7	0.0007	0.0006	0.0005
Mustard greens	Cole	Aerial	0.25/2/9	0.0091	0.0089	0.0077
		Groundspray	0.25/2/9	0.0084	0.0082	0.0072
Non-cropland areas adjacent to vineyards	Wine grapes	Groundspray	2/2/14	0.0093	0.0900	0.0084
Non-cropland areas adjacent to vineyards	Grapes	Groundspray	2/2/14	0.0078	0.0075	0.0067
Ornamentals (herbaceous)	Nursery	Groundspray	0.25/1/NA	0.0015	0.0014	0.0012
Ornamentals (woody)	Nursery	Groundspray	1/3/14	0.0141	0.0137	0.0117
Pears	Fruit	Aerial	1/1/NA	0.0029	0.0027	0.0020
		Airblast	1/1/NA	0.0018	0.0016	0.0012
Peas (succulent)	Row crop	Aerial	0.16/4/14	0.0033	0.0032	0.0029
		Groundspray	0.16/4/14	0.0026	0.0025	0.0022
Peas (not for use on field peas)	Row crop	Aerial	0.16/1/NA	0.0014	0.0013	0.0012
		Groundspray	0.16/1/NA	0.0013	0.0012	0.0011
Pecans	Almonds	Aerial	0.33/1/NA	0.0012	0.0011	0.0009
		Groundspray	0.33/1/NA	0.0005	0.0005	0.0004
Peppers	Row crop	Aerial	0.33/5/7	0.0089	0.0086	0.0079
		Groundspray	0.33/5/7	0.0064	0.0062	0.0055
Potatoes	Potato	Aerial	0.5/2/7	0.0039	0.0037	0.0030
		Groundspray	0.5/2/7	0.0019	0.0018	0.0015
Safflower	Wheat	Aerial	0.5/2/14	0.0147	0.0142	0.0122
		Groundspray	0.5/2/14	0.0133	0.0129	0.0111
Sorghum	Wheat	Aerial	0.5/2/7	0.0141	0.0137	0.0119
		Groundspray	0.5/2/7	0.0125	0.0122	0.0106
Soybean	Corn	Aerial	0.5/2/7	0.0026	0.0025	0.0021
		Groundspray	0.5/2/7	0.0007	0.0007	0.0006
Tomatoes	Tomato	Aerial	0.5/2/6	0.0064	0.0061	0.0052
		Groundspray	0.5/2/6	0.0045	0.0043	0.0037
Turnips	Potato	Aerial	0.25/7/3	0.0054	0.0051	0.0044
		Groundspray	0.25/7/3	0.0024	0.0022	0.0020
Wheat(1)	Wheat	Aerial	0.67/1/NA	0.0156	0.0153	0.0133
		Groundspray	0.67/1/NA	0.0148	0.0144	0.0125

Table 3-7	Maximum 90th percentile dimethoate concentrations across a range of application dates					
Crop	*PRZM Scenario Modeled*	*Application Method*	*Application Rate (lb a.i./A)/ Number of Applications/ Re-application Interval (d)*	*Peak (mg/L)*	*96-hour Mean (mg/L)*	*21-d Mean (mg/L)*
Wheat(2)	Wheat	Aerial	0.67/2/7	0.0188	0.0184	0.0160
		Groundspray	0.67/2/7	0.0167	0.0163	0.0142
Wheat(3)	Wheat	Aerial	0.5/1/NA	0.0117	0.0114	0.0099
		Groundspray	0.5/1/NA	0.0110	0.0107	0.0093
Wheat(4)	Wheat	Aerial	0.5/2/7	0.0141	0.0137	0.0119
		Groundspray	0.5/2/7	0.0125	0.0122	0.0106
Wheat(5)	Wheat	Aerial	0.33/2/7	0.0093	0.0091	0.0079
		Groundspray	0.33/2/7	0.0082	0.0080	0.0070

3.1.3 Aquatic Screening-Level Risk Characterization

Risk characterization integrates the exposure and effects assessments to determine the potential risk for various exposure scenarios for both direct and indirect effects on the CRLF. The screening-level effects determination evaluated risks using RQs that were calculated by dividing EECs by acute and chronic effects metrics (e.g., LC50, LD50, NOEL). For plants, the RQs were compared to EPA's LOC for non-listed plants (>1 for aquatic and terrestrial plants). For acute effects, the RQs for direct effects to adult CRLF were compared to the Agency's LOC's for endangered species (>0.1 for birds). Chronic risks to aquatic prey were determined using the chronic LOC of >1.

3.1.3.1 Aquatic Invertebrate Prey

Based on the results of EPA's effects determination, acute effects to aquatic invertebrates for all crops were not of concern. The RQs for indirect effects to aquatic-phase CRLFs via chronic effects to their aquatic invertebrate prey are presented in Table 3-8. The RQs were obtained by dividing the 21-day average EECs by the effects metric of 0.04 mg/L as indicated in Table 2-14. The chronic aquatic animal LOC of 1 was exceeded for one exposure scenario, cottonwood grown for pulp. The RQs for this scenario were 1.35 and 1.28 for aerial and chemigation applications, respectively. RQs for all other scenarios ranged from 0.01 to 0.57. The cottonwood grown for pulp scenario proceeded to a refined effects determination. All other scenarios pose no risk to aquatic invertebrates and, therefore, no further assessment is required.

Table 3-8	**RQs for indirect chronic effects to CRLFs via adverse effects to aquatic invertebrates potentially exposed to dimethoate**			
Crop	***Scenario***	***Application Method***	***21-d Mean EEC (mg/L)***	***Chronic RQ (EEC/NOEL)***
Alfalfa (forage and hay)	Alfalfa	Aerial	0.0081	0.20
		Groundspray	0.0070	0.17
Alfalfa (seed)	Alfalfa	Aerial	0.0064	0.16
		Groundspray	0.0057	0.14
Asparagus	Alfalfa	Aerial	0.0080	0.20
		Groundspray	0.0065	0.16
Asparagus	Asparagus	Aerial	0.0049	0.12
		Groundspray	0.0033	0.08
Beans	Row crop	Aerial	0.0060	0.15
		Groundspray	0.0046	0.11
Broccoli, cauliflower	Cole	Aerial	0.0205	0.51
		Groundspray	0.0188	0.47
Brussel sprouts	Lettuce	Aerial	0.0149	0.37
		Groundspray	0.0130	0.33
Celery	Row crop	Aerial	0.0096	0.24
		Groundspray	0.0086	0.22
Cherries	Fruit	Aerial	0.0056	0.14
		Airblast	0.0045	0.11
Cherries	Cherries	Aerial	0.0109	0.27
		Airblast	0.0101	0.25
Christmas tree nurseries	Christmas tree	Aerial	0.0151	0.38
		Groundspray	0.0129	0.32
Citrus	Citrus	Airblast	0.0014	0.04
Conifer seed orchards	Forestry	Airblast	0.0226	0.57
		Groundspray	0.0210	0.52
Cotton	Cotton with irrigation	Aerial	0.0041	0.10
		Groundspray	0.0025	0.06
Cotton	Cotton without irrigation	Aerial	0.0035	0.09
		Groundspray	0.0021	0.05
Cottonwood grown for pulp	Forestry	Aerial	0.0540	**1.35**
		Chemigation	0.0513	**1.28**
Endive	Lettuce	Aerial	0.0074	0.19
		Groundspray	0.0065	0.16
Field corn, popcorn	Corn	Aerial	0.0011	0.03
		Groundspray	0.0002	0.01
Grass for seed	Turf	Aerial	0.0020	0.05
		Groundspray	0.0011	0.03
Kale	Cole	Aerial	0.0072	0.18
		Groundspray	0.0067	0.17
Lentils	Row crop	Aerial	0.0080	0.20
		Groundspray	0.0074	0.18
Lettuce, swiss chard	Lettuce	Aerial	0.0055	0.14
		Groundspray	0.0053	0.13
Melon, honeydew	Melon	Aerial	0.0019	0.05
		Groundspray	0.0005	0.01
Mustard greens	Cole	Aerial	0.0077	0.19
		Groundspray	0.0072	0.18
Non-cropland areas adjacent to vineyards	Wine grapes	Groundspray	0.0084	0.21

Table 3-8 RQs for indirect chronic effects to CRLFs via adverse effects to aquatic invertebrates potentially exposed to dimethoate				
Crop	***Scenario***	***Application Method***	***21-d Mean EEC (mg/L)***	***Chronic RQ (EEC/NOEL)***
Non-cropland areas adjacent to vineyards	Grapes	Groundspray	0.0067	0.17
Pears	Fruit	Aerial	0.0020	0.05
		Airblast	0.0012	0.03
Peas (succulent)	Row crop	Aerial	0.0029	0.07
		Groundspray	0.0022	0.05
Peas (not for use on field peas)	Row crop	Aerial	0.0012	0.03
		Groundspray	0.0011	0.03
Pecans	Almonds	Aerial	0.0009	0.02
		Groundspray	0.0004	0.01
Peppers	Row crop	Aerial	0.0079	0.20
		Groundspray	0.0055	0.14
Potato	Potato	Aerial	0.0030	0.08
		Groundspray	0.0015	0.04
Safflower	Wheat	Aerial	0.0122	0.31
		Groundspray	0.0111	0.28
Sorghum	Wheat	Aerial	0.0119	0.30
		Groundspray	0.0106	0.26
Soybean	Corn	Aerial	0.0021	0.05
		Groundspray	0.0006	0.01
Tomato	Tomato	Aerial	0.0052	0.13
		Groundspray	0.0037	0.09
Turnips	Potato	Aerial	0.0044	0.11
		Groundspray	0.0020	0.05
Wheat(1)	Wheat	Aerial	0.0133	0.33
		Groundspray	0.0125	0.31
Wheat(2)	Wheat	Aerial	0.0160	0.40
		Groundspray	0.0142	0.35
Wheat(3)	Wheat	Aerial	0.0099	0.25
		Groundspray	0.0093	0.23
Wheat(4)	Wheat	Aerial	0.0119	0.30
		Groundspray	0.0106	0.26
Wheat(5)	Wheat	Aerial	0.0079	0.20
		Groundspray	0.0070	0.17

3.1.3.2 Aquatic Plants

The RQs for indirect effects to aquatic-phase CRLFs via direct effects to aquatic vascular plants (habitat of CRLFs) are presented in Table 3-9. The RQs were obtained by dividing the peak EEC by the effects metric of >45.1 mg/L as indicated in Table 2-16. None of the scenarios exceeded the LOC of 1 for plant species. The RQs ranged from 0.0001 to 0.0014. Thus, aquatic vascular plants are not considered to be at risk from exposure to dimethoate and no further assessment is required.

Table 3-9 **RQs for indirect effects to CRLFs via effects to aquatic plants potentially exposed to dimethoate**				
Crop	***Scenario***	***Application Method***	***Peak EEC (mg/L)***	***RQ (EEC/EC50)***
Alfalfa (forage and hay)	Alfalfa	Aerial	0.0098	< 0.0002
		Groundspray	0.0085	< 0.0002
Alfalfa (seed)	Alfalfa	Aerial	0.0076	< 0.0002
		Groundspray	0.0068	< 0.0002
Asparagus	Alfalfa	Aerial	0.0095	< 0.0002
		Groundspray	0.0077	< 0.0002
Asparagus	Asparagus	Aerial	0.0059	< 0.0001
		Groundspray	0.0040	< 0.0001
Beans	Row crop	Aerial	0.0072	< 0.0002
		Groundspray	0.0055	< 0.0001
Broccoli, cauliflower	Cole	Aerial	0.0245	< 0.0005
		Groundspray	0.0224	< 0.0005
Brussel sprouts	Lettuce	Aerial	0.0183	< 0.0004
		Groundspray	0.0160	< 0.0004
Celery	Row crop	Aerial	0.0115	< 0.0003
		Groundspray	0.0100	< 0.0002
Cherries	Fruit	Aerial	0.0069	< 0.0002
		Airblast	0.0056	< 0.0001
Cherries	Cherries	Aerial	0.0139	< 0.0003
		Airblast	0.0129	< 0.0003
Christmas tree nurseries	Christmas tree	Aerial	0.0177	< 0.0004
		Groundspray	0.0151	< 0.0003
Citrus	Citrus	Airblast	0.0019	< 0.0001
Conifer seed orchards	Forestry	Airblast	0.0272	< 0.0006
		Groundspray	0.0252	< 0.0006
Cotton	Cotton with irrigation	Aerial	0.0049	< 0.0001
		Groundspray	0.0030	< 0.0001
Cotton	Cotton without irrigation	Aerial	0.0042	< 0.0001
		Groundspray	0.0025	< 0.0001
Cottonwood grown for pulp	Forestry	Aerial	0.0606	< 0.0013
		Chemigation	0.0573	< 0.0013
Endive	Lettuce	Aerial	0.0092	< 0.0002
		Groundspray	0.0080	< 0.0002
Field corn, popcorn	Corn	Aerial	0.0014	< 0.00003
		Groundspray	0.0003	< 0.000007
Grass for seed	Turf	Aerial	0.0048	< 0.0001
		Groundspray	0.0037	< 0.0001
Kale	Cole	Aerial	0.0084	< 0.0002
		Groundspray	0.0078	< 0.0002
Lentils	Row crop	Aerial	0.0090	< 0.0002
		Groundspray	0.0086	< 0.0002
Lettuce, swiss chard	Lettuce	Aerial	0.0066	< 0.0001
		Groundspray	0.0063	< 0.0001
Melon, honeydew	Melon	Aerial	0.0026	< 0.0001
		Groundspray	0.0007	< 0.00002
Mustard greens	Cole	Aerial	0.0091	< .0002
		Groundspray	0.0084	< 0.0002
Noncropland areas adjacent to vineyards	Wine grapes	Groundspray	0.0093	< 0.0002
Noncropland areas adjacent to vineyards	Grapes	Groundspray	0.0078	< 0.0002
Ornamentals(herbaceous)	Nursery	Groundspray	0.0015	< 0.00003

Table 3-9 RQs for indirect effects to CRLFs via effects to aquatic plants potentially exposed to dimethoate				
Crop	***Scenario***	***Application Method***	***Peak EEC (mg/L)***	***RQ (EEC/EC50)***
Ornamentals (woody)	Nursery	Groundspray	0.0141	< 0.0003
Pears	Fruit	Aerial	0.0029	< 0.0001
		Airblast	0.0018	< 0.00004
Peas (succulent)	Row crop	Aerial	0.0033	< 0.0001
		Groundspray	0.0026	< 0.0001
Peas (not for use on field peas)	Row crop	Aerial	0.0014	< 0.00003
		Groundspray	0.0013	< 0.00003
Pecans	Almonds	Aerial	0.0012	< 0.00003
		Groundspray	0.0005	< 0.00001
Peppers	Row crop	Aerial	0.0089	< 0.0002
		Groundspray	0.0064	< 0.0001
Potato	Potato	Aerial	0.0039	< 0.0001
		Groundspray	0.0019	< 0.00004
Safflower	Wheat	Aerial	0.0147	< 0.0003
		Groundspray	0.0133	< 0.0004
Sorghum	Wheat	Aerial	0.0141	< 0.0003
		Groundspray	0.0125	< 0.0003
Soybean	Corn	Aerial	0.0026	< 0.0001
		Groundspray	0.0007	< 0.00002
Tomato	Tomato	Aerial	0.0064	< 0.0001
		Groundspray	0.0045	< 0.0001
Turnips	Potato	Aerial	0.0054	< 0.0001
		Groundspray	0.0024	< 0.0001
Wheat(1)	Wheat	Aerial	0.0156	< 0.0003
		Groundspray	0.0148	< 0.0003
Wheat(2)	Wheat	Aerial	0.0188	< 0.0004
		Groundspray	0.0167	< 0.0004
Wheat(3)	Wheat	Aerial	0.0117	< 0.0003
		Groundspray	0.0110	< 0.0002
Wheat(4)	Wheat	Aerial	0.0141	< 0.0003
		Groundspray	0.0125	< 0.0003
Wheat(5)	Wheat	Aerial	0.0093	< 0.0002
		Groundspray	0.0082	< 0.0002

3.2 Refined Aquatic Effects Determination

The only aquatic exposure scenario that required additional refined analyses was application of dimethoate at 2 lbs/A (maximum of 3 treatments per season at minimum 10-day retreatment interval) to cottonwood (grown for pulp) for chronic effects to aquatic invertebrates.

For aquatic invertebrates, the refined risk analysis the cottonwood scenario involved integrating a species sensitivity distribution (SSD) for chronic effects of dimethoate to aquatic invertebrates with the 30-year distribution of annual peak 21-day average concentrations for aerial and chemigation applications. The exposure distributions were derived for the standard pond using PRZM/EXAMS. The result is a risk curve that shows the relationship between probability and magnitude of effect. Each risk curve is categorized *de minimis*, low, intermediate or high risk using the criteria described in Section 2.10.5.2.

3.2.1 *Refined Aquatic Effects Assessment*

For the refined effects determination, we derived an SSD for aquatic invertebrates exposed to dimethoate. An evaluation of available acute toxicity studies on aquatic invertebrates was conducted to ensure that the best available data were used to derive the acute SSD distribution for dimethoate. Insufficient chronic toxicity data were available for aquatic invertebrates, thus necessitating the use of an acute SSD. The acute SSD was converted to chronic SSD via use of an acute-to-chronic ratio (ACR). Toxicity studies were screened using criteria designed to ensure that only high quality data were used in deriving the SSD (Appendix A).

The number of acute toxicity studies available for freshwater invertebrates was limited. As a result, acute toxicity studies on saltwater invertebrates were included in the acute SSD dataset. In the case of dimethoate, there is no reason to believe that freshwater invertebrates are more sensitive than saltwater invertebrates. The sensitivity range of freshwater (LC/EC50 range from 0.249 to 6.41 mg/L) and saltwater (LC/EC50 range from 0.031 to 303 mg/L) aquatic invertebrate species exposed to dimethoate overlaps. These ranges are for supplementary and acceptable studies only. Therefore, it is reasonable to combine freshwater and saltwater aquatic invertebrate species to derive the acute SSD.

The acceptable and supplementary acute toxicity data used to derive the acute SSD are presented in Table 3-10. When multiple endpoint values were available for the same species, the average of these values was used to represent toxicity of that species in the SSD. This calculation was required for *Daphnia magna* and the yellow fever mosquito. The exposure period for all freshwater endpoints was 48 hours. The exposure period for saltwater species was generally 48 hours except for the mysid (*Mysidopsis bahia*) and Eastern oyster (Crassostrea monoceros), which had an exposure period of 96 hours, and the rotifer (*Brachionus plicatilis*), which had an exposure period of 24 hours. Toxicity data were available for three different exposure periods, 24, 48 and 72 hours, for brine shrimp (*Artemia salina*). The 48-hour toxicity value was selected for this species as this exposure duration is consistent with most of the data.

Table 3-10 Acute toxicity data used to develop the SSD for dimethoate.

Common Name	*Scientific Name*	*EC/LC_{50} Result (mg/L)*	*SSD Mean Acute EC/LC_{50} (mg/L)*	*Reference [MRID]*
Water flea	*Daphnia magna*	2	2.07	Hertl, 2002c
		1.1		Andersen et al., 2006
		3.32		Song et al., 1997
		3.12		
		1.7		Beusen and Neven, 1989
		2		
		1.5		
		1.8		
Midge	*Chironomus tentans*	0.249	0.249	Anderson and Zhu, 2004

Table 3-10 Acute toxicity data used to develop the SSD for dimethoate.

Common Name	Scientific Name	EC/LC$_{50}$ Result (mg/L)	SSD Mean Acute EC/LC$_{50}$ (mg/L)	Reference [MRID]
Yellow fever mosquito	*Aedes aegypti*	5.04	5.73	Song et al., 1987; Song and Brown 1998
		6.41		
Brine shrimp	*Artemia sp.*	15.73	15.73	
Black saltmarsh mosquito	*Aedes taeniorhynchus*	0.031	0.031	
Mysid	*Mysidopsis bahia*	22	22	Graves and Swigert, 1993a [42760003]
Eastern oyster	*Crassostrea virginica*	113	113	Graves and Swigert, 1993b [42760002]
Rotifer	*Brachionus plicatilis*	244	244	Guzzella et al., 1997

The acute SSD was generated using SSD Master v2.0 (Rodney et al., 2008), an Excel-based regression tool that fits five different cumulative distribution functions (normal, logistic, Gompertz, Weibull and Fisher-Tippett). The Gompertz model using log LC50 and EC50 values was the best fitting model according to the Anderson-Darling (AD) goodness-of-fit test statistic (AD statistic = 0.129, p>0.05) and various graphical plots of model residuals (e.g., p-p and q-q plots). The Gompertz model equation is shown below.

$$f(x) = 1 - e^{-e^{\frac{(x-\mu)}{s}}}$$

Equation 3-1

where *x* is concentration, and the functional response, *f(x)*, is the proportion of taxa affected. The parameters, μ and *s*, are the location and scale parameters of the model. The fitted model parameters were: μ=4.342 and *s*=1.124 for acute toxicity data reported in µg/L. The HC5 value is 10.12 µg/L (Lower confidence limit (LCL): 3.95 µg/L and upper confidence limit (UCL): 25.96 µg/L).

Insufficient chronic toxicity data were available to derive a species sensitivity distribution for the refined effects determination. As a result, acute toxicity data (Table 3-10) in combination with ACRs were used to derive the chronic effects metrics for the refined effects determination. Acute effects to freshwater aquatic invertebrates determined from acceptable and supplemental studies range from 0.249 to 6.41 mg/L (Anderson and Zhu, 2004; Song et al., 1997) while effects to saltwater species range from 0.031 to 303 mg/L (Song et al.,1997; Song and Brown, 1998; Guzzella et al., 1997).

For the refined chronic effects determination for aquatic invertebrates, the acute SSD was converted to a chronic SSD. The acute SSD, as shown in Figure 3-1, was divided by an acute-to-chronic ratio (ACR) to derive the corresponding chronic SSD. The ACR was calculated by dividing the acute 96-hour EC50 for *Daphnia magna* (0.465 mg/L) (Wüthrich, 1990 [MRID 42864701]) by the chronic NOEL (0.04 mg/L) for *Daphnia magna* (Wüthrich, 1990). The Wüthrich (1990) study is a GLP study and found to be an acceptable study. The resulting ACR is 11.6 for *Daphnia magna*. Further, it is recognized that the best practice for calculating an ACR is to use data from the same study, thus eliminating variability due to different procedures, environmental conditions, and sensitivity of the test populations.

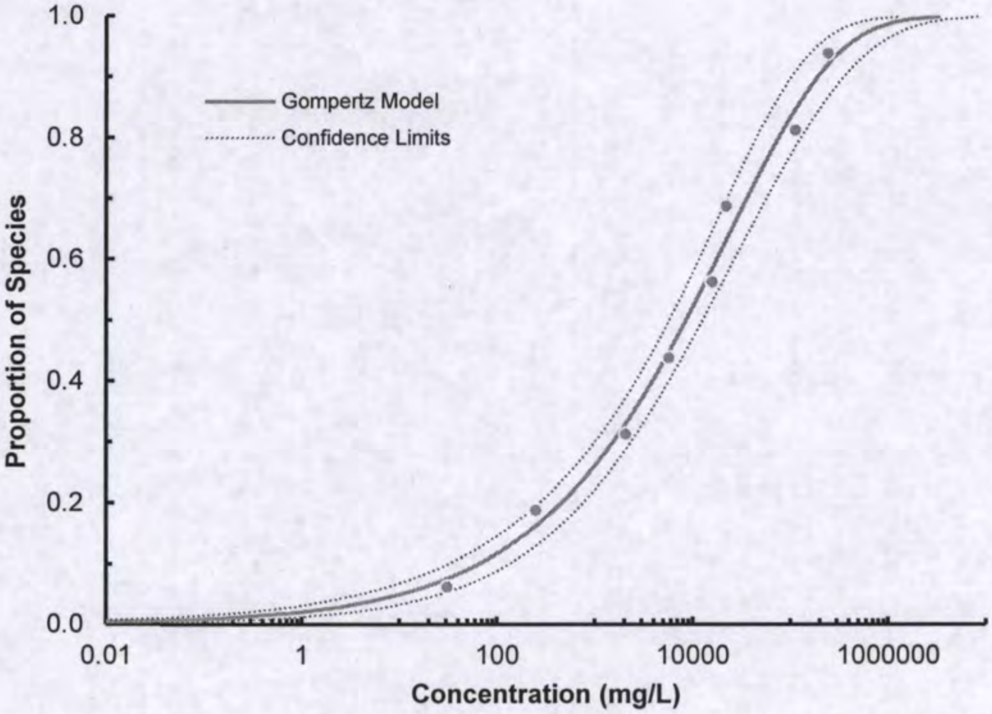

Figure 3-1 Acute SSD for aquatic invertebrate species exposed to dimethoate

3.2.2 Refined Aquatic Exposure Assessment

The PRZM/EXAMS analysis conducted for cottonwood grown for pulp with an application rate of 2 lb a.i./A, three times per year with a 10-day retreatment interval, was described in Section 3.1.2. Instead of relying on the 90th percentile of maximum annual EECs as was done in the screening-level assessment, we used a distribution of 21-day average concentrations in the refined effects determination. As in the screening assessment, 21-day average pond concentrations were simulated in PRZM/EXAMS for the 30 years considering application start dates from January 1st to December 11th of each year. For each date, a 30-year 21-day average concentration was calculated (you obtain an average 21-day average EEC per date). The date that had the highest average EEC was deemed the one that produced the worst-case EECs for the entire 30-year simulation. The 30-year EEC distribution from the worst-case application date was used to derive the exposure distribution for cottonwood grown for pulp

This is highly conservative because there is no adjustment to account for the fact that dimethoate applicators will avoid applying a pesticide before rain events, and it is likely that this EEC distribution is closely related to peak rainfall events occurring shortly after applications. Moreover, the approach is also highly conservative because the standard pond has no in-flows or out-flows (i.e., no dilution).

The distribution of 30 21-day average dimethoate concentrations associated with the three-week date range in which the highest standard pond EECs are expected are shown in Figure 3-2 for dimethoate applied via chemigation and aerially.

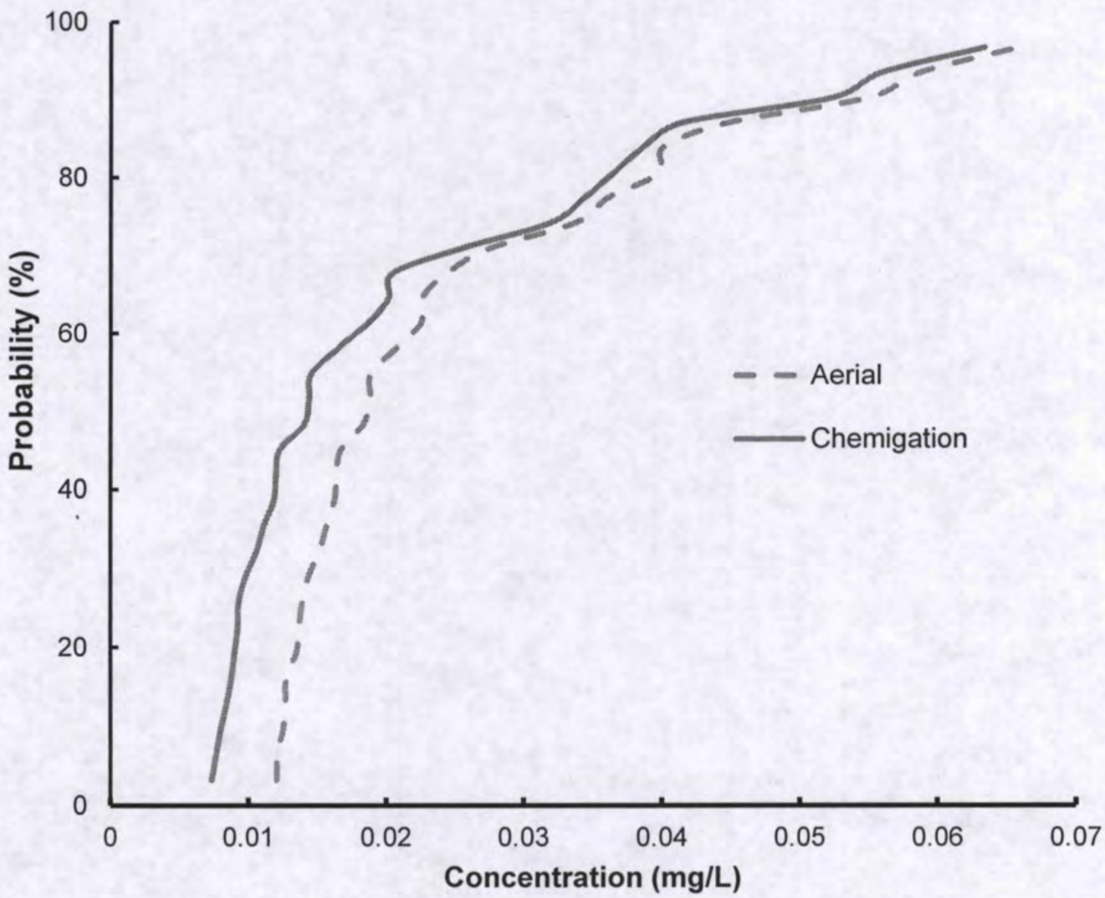

Figure 3-2 **Distributions of annual peak 21 d average dimethoate concentrations in the standard pond for application dates ranging from January 1 to December 11 following aerial and chemigation applications at a rate of 2 lb a.i./A to cottonwood grown for pulp.**

3.2.3 Refined Aquatic Risk Characterization

To derive each risk curve, the exposure distribution (e.g. Figure 3-2) was integrated with the chronic SSD that was itself derived by dividing the acute SSD (Figure 3-1) by the ACR of 11.6. The resulting risk curves are shown in Figure 3-4 for dimethoate applied via chemigation and Figure 3-5 for dimethoate applied aerially. Curves were analyzed and categorized based on the area under the risk curve (AUC) approach. The details of this approach are presented in Section 2.10.5.2.

The AUC estimates for chemigation and aerial applications to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a retreatment interval of 10 days) were 14.3 and 15.5%, respectively. Based on these highest potential exposure estimates, the risk category for invertebrates is intermediate for both application types. Specifically, the maximum risk product is associated with a 97% probability of exceeding the estimated NOELs of 11% and 13% of aquatic invertebrate species for chemigation and aerial application methods, respectively (Figure 3-3, Figure 3-4, and Figure 3-5). However, the probability of exceeding the estimated NOELs of more than 25% of aquatic invertebrates is negligible for both application methods.

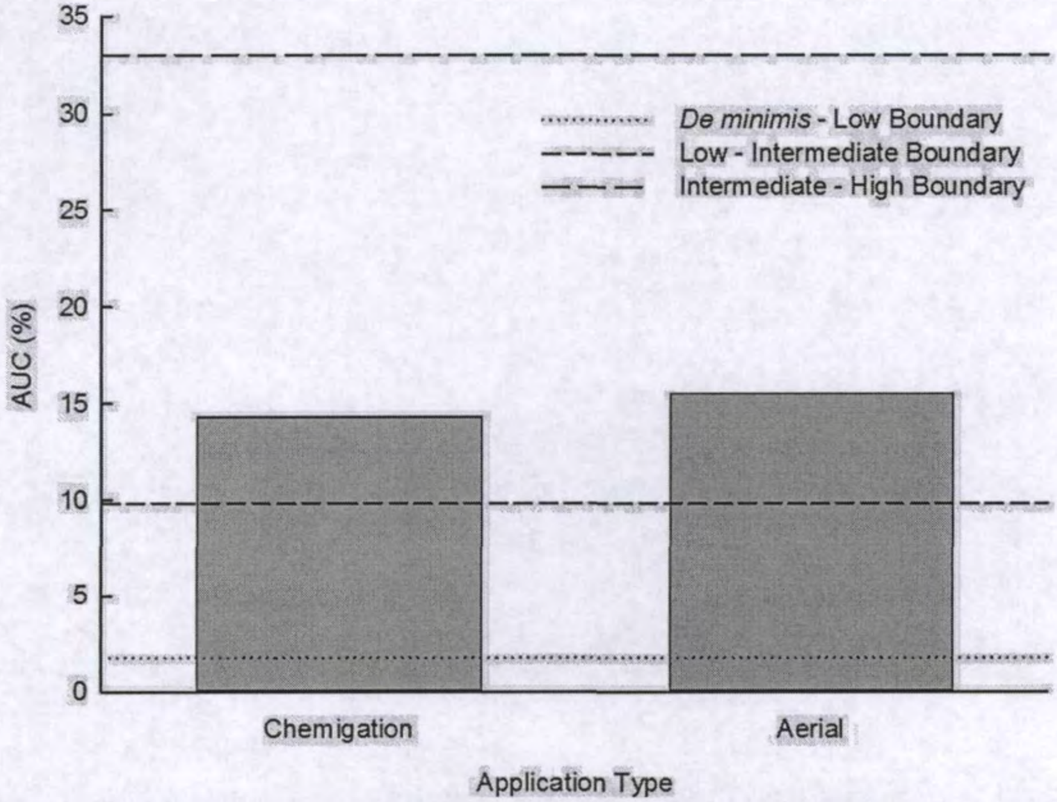

Figure 3-3 **Risk characterization demonstrating intermediate risk for aquatic invertebrate species exposed to dimethoate applied aerially and by chemigation to cottonwood grown for pulp.**

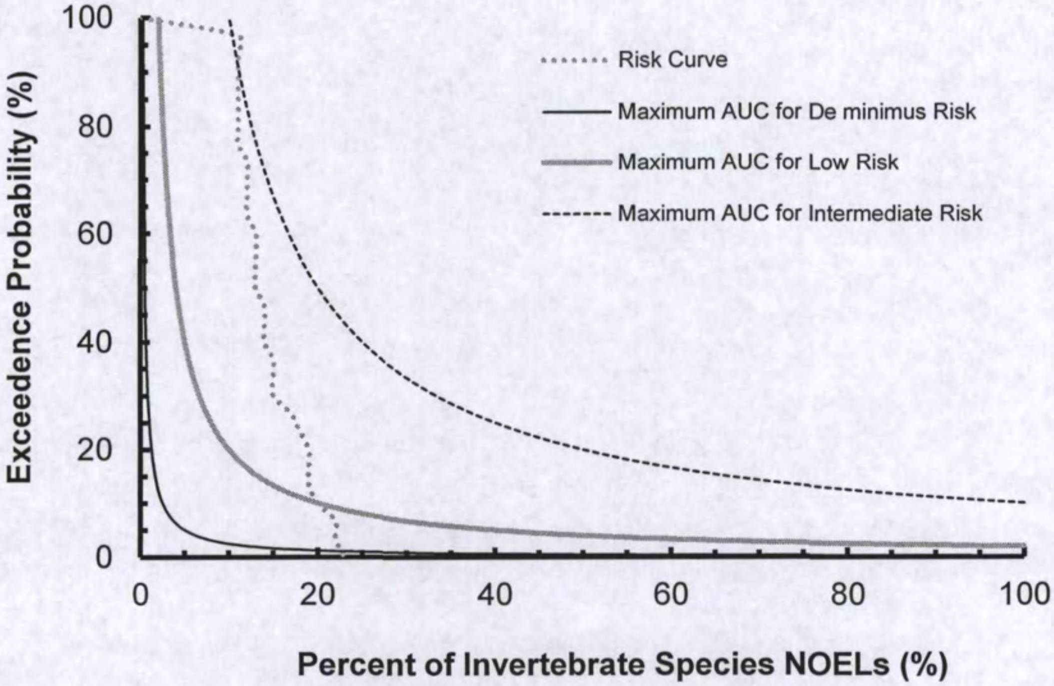

Figure 3-4 **Risk curve for aquatic invertebrate species exposed to dimethoate applied via chemigation to cottonwood grown for pulp showing intermediate risk.**

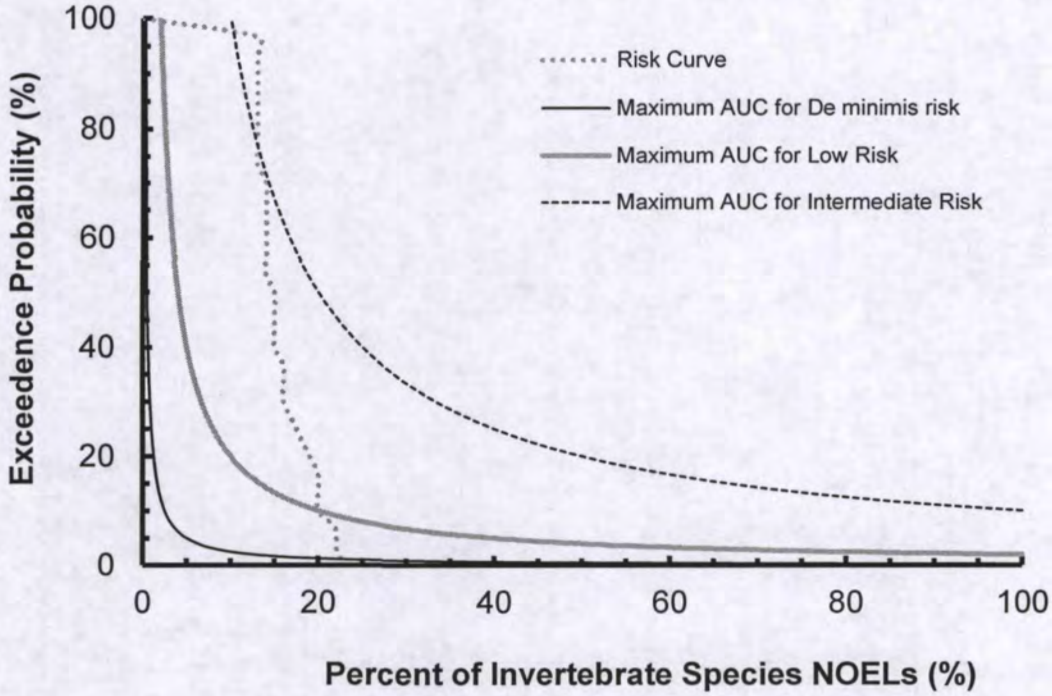

Figure 3-5 Risk curve for aquatic invertebrate species exposed to dimethoate applied aerially to cottonwood grown for pulp showing intermediate risk.

3.3 Other Lines of Evidence for the Aquatic Effects Determination

This section describes lines of evidence other than the quantitative modeling results. The other lines of evidence include mesocosm and field studies (Section 3.3.1), monitoring data for the aquatic assessment (Section 3.3.2) and incident reports (Section 3.3.3).

3.3.1 Mesocosm and Field Studies

3.3.1.1 Lake Enclosure Study

The effects of dimethoate were studied on lake zooplankton communities in 14 pelagic enclosure bags for 12 days in Lake Omdalsvann, Norway (Hessen et al., 1994). Lake water contained 7 µg of total phosphorus/L, 200 µg total nitrogen/L, 19 mg calcium/L and was slightly alkaline with a pH ranging from 7.5 to 8.3. Mesh bags containing zooplankton were added to the enclosures. The bags were sealed below but open to air at the surface and had a volume of 22 m^3. Zooplankton samples were taken with a hose that penetrated the whole depth of each bag.

Because of low concentrations of the crustacean zooplankton community, this community was assessed using cumulative samples. Rotifers were high in density throughout the experiment, allowing a day-to-day evaluation. The study was conducted using two control replicates and three dimethoate treatments with one replicate each (1, 10 and 100 µg/L). Concentrations were measured at the beginning and end of the test. Mean concentrations were 0.95, 11.5 and 103 µg/L. The method of chemical analysis was not reported.

Rotifer communities in the lake and the enclosure bags were almost exclusively composed of *Conochilus unicornis*, *Kelicottia longiseta*, *Polyarthra sp.* and *Asplanchna priodonta*. Hessen et al. (1994) reported that dimethoate had little effect on the rotifer community even at the highest concentration tested. *C. unicornis* declined in all bags, including the controls. This colony-building species had pronounced density variations in the samples as even small variations in number of colonies strongly affected the number of individuals. The two dominant species, *Polyarthra sp.* and *K. longiseta* had a more or less similar response to all treatments. *A. priodonta* was negatively affected by the 100 µg/L concentration treatment.

The crustacean community was composed of the copepod *Acanthodiaptomus gracilis* and the cladocerans *Holopedium gibberum*, *Bosmina longispina*, *Daphnia longispina*, *Ceriodaphnia quadrangula* and *Sida crystallina*. Hessen et al. (1994) reported that the most pronounced effect was found in the 100 µg/L concentration treatment where all cladocera disappeared. *Daphnia longispina* increased in abundance at 1 µg/L and then disappeared in the 10 µg/L concentration treatment. This species was the most sensitive of the cladoceran species observed in the enclosure bags.

3.3.1.2 Experimental Stream Study

Baekken and Aanes (1994) conducted spring (May/June) and autumn (August/September) indoor experimental stream studies at one nominal test concentration (1 µg/L) of dimethoate and in parallel reference streams. The tests were conducted under flow-through conditions. For each of the spring and autumn tests, a total of 30 trays were filled with a defined combination of sand, gravel, and pebbles and colonized by natural stream biota for five weeks. For each test, 10 randomly selected trays were placed in each indoor experimental steam. The remaining 10 trays represented the invertebrate communities at the start of the experiment. One part of the stream was channeled into a net and pumped back again, and the number of drifting individuals counted. The temperature of the water was 15°C. The water contained 4.5 µg of total phosphorus/L, 300 µg total nitrogen/L, 2.9 mg calcium/L and had a pH of 6.9.

The autumn study showed that, except for the last two weeks where almost no drift occurred, the average number of drifting animals was equal or higher in the treated stream than in the reference stream. The tendency for drifting differed among taxa. For example, almost 100% of chydorids were found in the drift fauna, whereas drifting beetle larvae were not observed. A total of 10.4% and 6.8% individuals of the benthic macroinvertebrate communities were caught in the drift nets of the treated and reference streams, respectively. The differences observed between treated and reference streams could not be tested for statistical significance because of the lack of replication in the study.

Similarly, the average daily drift rate was higher in the treated stream compared to the control stream in the spring study, though the difference was less pronounced. Drift rates varied from 24 to 68 individuals/d in the treated stream and from 13 to 82 individuals/d in the control stream.

The percentage of fauna that moved outside the trays, but were not found in the drift net, was 22% and 19% for the treated and reference streams, respectively, in the autumn study. In the spring study, 36% and 32% of the fauna were found outside the trays in the treated and reference streams, respectively. The differences in movement out of the trays between the treated and reference streams were minor in both the autumn and spring studies. The differences could not be tested for statistical significance because of the lack of replication in the studies.

Structural changes in the abundance of species were also measured by Baekken and Aanes (1994). In the autumn study, 9 out of 13 populations had a lower number of individuals in the dimethoate-treated stream than in the reference steam at the end of the experiment. For example, the beetle larvae and the caddisflies were reduced by 70% and 50%, respectively, in the dimethoate-treated stream relative to the reference stream. Conversely, oligochaetes were 70% more abundant in the dimethoate-treated stream than in the reference stream. In both streams, the total number of animals almost doubled during the experimental period. This was mostly caused by an increase of newly hatched stonefly species, with the exception of *Leuctra digitata* whose abundance was reduced by two thirds from start to end of the experiment. The abundance of mayflies was low both at the start and end of the experiment. The most common species was *Paraleptophlebia sp.*, which had an equal abundance in both streams.

In the spring study, the number of animals in the treated and reference streams was similar at the end of the study. However, there were differences in species composition. Oligochaetes, dipterans and chironomid pupae were more abundant in the dimethoate-treated stream, whereas mayflies, ostracods and copepods were more abundant in the reference stream. For mayflies and ostracods, the differences were reported to be significantly different. However, it is unknown how statistical significance was determined given that there was only 1 replicate for the dimethoate-treated stream. The authors did not describe the statistical method used. For the other taxa, only minor differences were found. Reductions in the total number of animals in both streams were reported, mainly due to reductions in young stonefly of the genus Leuctra and in chironomids. Mayflies, however, mainly *Baetis rhodani*, were significantly more reduced in the treated stream.

RIVM (Rijksinstituut voor Volksgezondheid en Milieu [Netherlands National Institute for Public Health and the Environment], 2008) conducted a "rough" statistical analysis (the methods were not described) and found no significant difference between control and treated communities for both the autumn and spring experiments. Also, replicated observations (pairing of autumn and spring data) gave no significant differences compared to the control streams for any of the taxa. Differences in abundance of individual taxa and whole community were found by RIVM (2008) to be minor between control and dimethoate-treated streams.

3.3.2 Monitoring Studies

Cheminova submitted to EPA a summary of drinking water and surface water monitoring data for dimethoate (Reiss, 2009b). This section summarizes those findings and updates them to account for new data and information from the monitoring programs previously reviewed, and adds information from one additional monitoring program. Data sources included the USDA Pesticide Data Program (PDP) (2001-2009), the US Geological Survey (USGS) National Water Quality Assessment (NAWQA) Program (2001-2011), California Department of Pesticide Regulation (DPR), and the California Environmental Data Exchange Network (CEDEN) (2001 – 2008). Results from each of these programs are discussed below.

During the period from 2001 to 2007, the PDP collected samples in 26 states at sites that use surface water as the primary source of drinking water and located in regions of heavy agricultural pesticide use. The PDP data showed that dimethoate was detected only once in 3,094 untreated and finished drinking water samples at a concentration of ~0.009 µg/L (DL= 0.0006-0.063 µg/L) (Reiss, 2009b).

In 2011, the PDP released their annual report for the 2009 calendar year (USDA, 2011). Monitoring data were contributed by 12 states (i.e., CA, CO, FL, MD, MI, MN, MO, NY, OH, TX, WA, and WI). Media sampled included finished and raw water for drinking and potable groundwater from domestic wells (agricultural/farm wells, school or childcare facility wells, and private domestic wells). A total of 278 potable groundwater samples were collected and analyzed for 19 pesticides. Dimethoate was not detected in any of the 278 groundwater samples. In 2009, the PDP analyzed 306 finished drinking water samples and 306 untreated (raw) drinking water samples. In the 306 finished drinking water samples, dimethoate was detected twice, once at the detection limit of 0.0075 µg/L and once at 0.068 µg/L. Dimethoate was not detected in untreated (raw) drinking waters.

The United States Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) database was accessed (June 28, 2011) to isolate surface water data nationally for dimethoate over the temporal range 2001 – 2011. The NAWQA data are accessible through the web interface at the USGS NAWQA data warehouse using the following link, http://infotrek.er.usgs.gov/traverse/f?p=NAWQA:HOME:0. Data from the surface water and bed sediments category were selected. The surface water and bed sediments category provides water quality results from NAWQA surface water sites (USGS, 2009). The raw NAWQA data were imported into MS-Access© 2007 to facilitate subsequent queries and organization. The

NAWQA program uses a result qualifier field code (i.e., '<', '--', 'E') to identify records that were less than ('<'), greater than ('--') or estimated to be greater than ('E') the detection limit. A total of 563 records were isolate for dimethoate.

The analytical detection limit (DL) is not specifically reported for each record. However, for those records with 'less than' qualifiers, the common DL is generally close to 0.006 µg/L with a range from 0.006 µg/L to 0.031 µg/L.

The NAWQA program identifies the dominant land use surrounding each of the NAWQA monitoring stations as urban, mixed, agricultural/crops, or no data. NAWQA defines the various land uses as follows (USGS, 2009): mixed land use may contain urban, forest, agriculture, or mining land use, but no one land use is considered dominant; agricultural land use is >50% agricultural and <5% urban; and urban is considered >25% urban and < 25% agricultural land. The NAWQA program data contained dimethoate detections in 102 of 6,068 samples (~1.7%) (0.0036–0.158 µg/L) in surface waters near agricultural areas. Table 3-11 summarizes the available data by land use for each year. This low level of detection of dimethoate supports the findings of the PDP.

Table 3-11 Summary of USGS NAWQA data from 2001 to mid 2011 (Updated and modified from Reiss (2009b))

Year	*Land Use*	*# Samples*	*# Detects*	*Detects (%)*	*Range of Detected Values (µg/L)*	*Range of LODs (µg/L)*
2001	Ag	5	1	20	0.0064	
	Mixed	4	0	0	-	
	Urban	7	0	0	-	
	Other	-	0	0	-	
	Total	**16**	**1**	**6.3**	**0.0064**	**0.0021-0.0061**
2002	Ag	32	0	0	-	
	Mixed	24	1	4.2	0.0036	
	Urban	50	1	2.0	0.0092	
	Other	79	2	2.6	0.0168-0.018	
	Total	**185**	**4**	**2.2**	**0.0036-0.018**	**0.0061**
2003	Ag	188	6	3.2	0.0055-0.158	
	Mixed	63	6	10	0.0064-0.0185	
	Urban	172	1	0.6	0.0048	
	Other	420	1	0.7	0.0094-0.045	
	Total	**843**	**14**	**1.9**	**0.0045-0.158**	**0.0061-0.015**
2004	Ag	130	3	2.3	0.0036-0.0973	
	Mixed	59	1	1.7	0.0093	
	Urban	51	0	0	-	
	Other	306	0	0	-	
	Total	**546**	**4**	**0.7**	**0.0036-0.0973**	**0.0061-0.0312**
2005	Ag	153	5	3.3	0.0187-0.117	
	Mixed	243	4	1.6	0.0064-0.026	
	Urban	160	1	0.6	0.009	
	Other	60	0	0	-	
	Total	**616**	**10**	**1.6**	**0.0064-0.117**	**0.0061-0.020**

Table 3-11 Summary of USGS NAWQA data from 2001 to mid 2011 (Updated and modified from Reiss (2009b))						
Year	***Land Use***	***# Samples***	***# Detects***	***Detects (%)***	***Range of Detected Values (µg/L)***	***Range of LODs (µg/L)***
2006	Ag	184	3	1.6	0.0187-0.0888	
	Mixed	281	4	1.4	0.0078-0.0432	
	Urban	178	1	0.6	0.0312	
	Other	31	0	0	-	
	Total	**674**	**8**	**1.2**	**0.0078-0.0888**	**0.0061-0.020**
2007	Ag	131	3	2.3	0.0119-0.0966	
	Mixed	362	9	2.5	0.0081-0.0399	
	Urban	225	0	0	-	
	Other	169	0	0	-	
	Total	**887**	**12**	**1.3**	**0.0081-0.0966**	**0.006-0.0076**
2008	Ag	230	3	1.3	0.0065-0.0105	
	Mixed	355	11	2.8	0.0065-0.0231	
	Urban	128	0	0	-	
	Other	253	1	0	0.0196	
	Total	**966**	**15**	**1.4**	**0.0065-0.0231**	**0.006-0.036**
2009	Ag	190	3	1.6	0.0172 – 0.128	
	Mixed	338	8	2.4	0.0083	
	Urban	171	0	0	-	
	Other	243	0	0	-	
	Total	**942**	**11**	**1.2**	**0.0083**	**0.006-0.010**
2010	Ag	131	8	6.1	0.0104-0.494	
	Mixed	371	15	4.0	0.0075-0.0695	
	Urban	156	0	0	-	
	Other	239	0	0	-	
	Total	**897**	**23**	**2.5**	**0.0075-0.494**	**0.006-0.0138**
2011	Ag	17	0	0	-	
	Mixed	125	1	0.01	-	
	Urban	58	0	0	-	
	Other	96	0	0	-	
	Total	**296**	**1**	**0.3**	**-**	**0.006-0.03**
OVERALL	Ag	1386	34	2.5	0.004 – 0.158	
	Mixed	2221	60	2.7	0.004 – 0.043	
	Urban	1356	5	0.37	0.004 – 0.031	
	Other	1896	3	0.16	0.009 – 0.045	
	Total	**6068**	**102**	**1.7**	**0.004 – 0.158**	**0.002 – 0.036**

The California Environmental Data Exchange Network (CEDEN) is a portal for monitoring data collected from a range of state organizations. Current participants in the CEDEN network include several of the state water boards, Surface Water Ambient Monitoring Program (SWAMP), Southern California Coastal Water Research Project (SCCWRP), San Francisco Estuary Institute (SFEI), Marine Pollution Studies Laboratory at Moss Landing Marine Laboratories (MPSL – MLML), Central Valley Regional Data Center (CV RDC), and the EPA. These partners contribute data from their own monitoring programs to CEDEN to facilitate its dissemination to the public, and other interested parties. Currently, CEDEN contains data from the 1999 EPA EMAP monitoring study for 80 stations in California estuaries, SWAMP stream pollution trends (SPoT) monitoring program data, SWAMP sportfish contamination data, and SWAMP historic bioaccumulation review. CEDEN data were accessed using the main data access page http://www.ceden.org/ceden_data.shtml. Using the advanced query tool, the parameter group selected was 'pesticides', the pesticide selected was 'dimethoate', and the matrix selected was 'samplewater'. The available date range was from September 18, 2001 to October 29, 2008. The query was also designed to include QA data. The total number of records was 30,418 (accessed June 28, 2011) with 2,583 of these records associated with dimethoate. The available data were collected as part of the Irrigated Lands Program, SWAMP Surface Ambient Water Monitoring Program, and Total Maximum Daily Load monitoring. They consisted of both grab samples (at different depths) and integrated monitoring samples (samples from fixed monitoring stations). A summary of the CEDEN data for dimethoate is provided in Table 3-12.

Table 3-12 Summary of CEDEN surface water monitoring data from 2011 to 2007

Year	# Records	# Detects	Detects (%)	Range of Detected Values (µg/L)	Range of LODs (µg/L)
2001	37	1	2.7	0.03 – 0.21	0.03
2002	272	10	3.7	0.06 – 0.18	0.03
2003	336	30	8.9	0.13 – 0.20	0.03
2004	296	50	16.9	0.04 – 1.2	0.03
2005	576	58	10.1	0.03 – 1.2	0.03
2006	485	54	11.1	0.03 – 11	0.03 – 4
2007	581	96	16.5	0.03 – 2.27	0.03 – 0.4
Totals	2583	299	11.6	0.03 – 11	0.03 – 4

The highest total dimethoate concentration detected was 11 µg/L in the Grant Line Canal in July, 2006. The Grant Line Canal is a large manmade surface water body that runs along a large agricultural area in California. The water sample was taken as part of the Irrigated Lands Regulatory Program by the San Joaquin Water Quality Coalition. The majority of the water samples analyzed were below the LOD for dimethoate with 12% (299/2583 x 100) having detected levels.

Lisker et al. (2011) reported on pesticide concentrations detected in California's surface water monitoring results from 1991 to 2010. The monitoring results were examined in the context of concerns over potential effects to Pacific salmonid populations in the state. Monitoring data were extracted from the California surface water database (SWD). The SWD contains monitoring data with a temporal range of 1990 to 2010 from numerous private and public agencies across California. In total, 330,000 monitoring results from rivers, creeks, streams, agricultural drains, and the San Francisco Bay delta region are found in the SWD. Of these 47,529 records were available for 21 organophosphate pesticides including dimethoate. California pesticide use data were also considered to provide some context to the monitoring results. Pesticide monitoring results were compared to maximum acceptable limits (MCL) for salmon habitats proposed by the National Marine Fisheries Service (NMFS). The proposed MCL for dimethoate is 60 µg/L (Lisker et al., 2011). The results indicated that dimethoate was infrequently detected (detection frequency: 421 / 5012 = 8.4%). Dimethoate concentrations never exceeded the MCL and ranged from 0.0193 to 11.3 μg/L.

Dimethoate concentrations measured in surface water from each of the programs mentioned above are low. The maximum concentration reported in the PDP data was 0.004 μg/L for dimethoate. From the NAWQA program the maximum detected concentration was 0.494 μg/L. The maximum dimethoate concentration from the CEDEN database and Lisker et al. (2011) was 11.6 μg/L. This concentration occurred July, 2006 in the Grant Line canal, which is a large surface water body adjacent to a large agricultural area in California. The maximum detected concentration from all of these monitoring datasets are below all acute and chronic effect metrics for aquatic invertebrates determined from acceptable and supplemental studies. The RQ generated using the selected acute effect metric (465 μg/L) is 0.03 (RQ = 11.6 / 465 = 0.03). The RQ is therefore below the LOC of 0.5 for non-listed and 0.05 for listed species. The peak instantaneous concentration of 11.6 μg/L was also well below the reported chronic NOEL of 40 μg/L for *D. magna* (Wüthrich, 1990)(RQ = 11.6 / 40 = 0.29). The RQ is therefore also below the level of concern (LOC) of 1. Using the peak monitoring concentration is highly conservative when comparing against a chronic effect metric because it does not account for dilution and degradation over the appropriate exposure duration.

3.3.3 Aquatic Incident Reports

A copy of the dimethoate incident reports in the Ecological Incident Information System (EIIS) was provided to Intrinsik Environmental Sciences by the USEPA (EPA, 2010a). There have been 26 incidences from 1972 to 2006 (Table 3-13). Only three incidences were reported after 2000. The EIIS report provides general information on the incident location, data, county and state, certainty, legality, formulation type, application method and total magnitude. Certainty is ranked on a scale from 0 to 4 where 0 is considered unrelated and 4 is considered highly probable. The legality code indicates whether the incident was due to a registered use, misuse (not applied as per label), accidental misuse (e.g., spill), intentional misuse (e.g., baiting) or unknown. In some incident reports, information is also available that describes the affected species, response observed (e.g., mortality, behavioural), and the identified route of exposure. Additional information on application rate and type, and local meteorological conditions was not provided.

There were five aquatic incidents reported. Two of the five aquatic incidents had no date recorded, however, the incident report number places the incident around 1972 (Table 3-13). Three of the 5 incidents, Riverside County, CA in approximately 1972 (two recordings for the same County)) and Haakon County, SD in 1991, were due to either an accident (i.e., a spill) or intentional misuse of dimethoate. These incidents are not considered further in this assessment. The 1988 Tazewell County, IL aquatic incident was associated with a registered aerial application on soybeans. The 1995 incident occurred at a tobacco site in Johnston County, NC and the cause of that incident is unknown. All 5 aquatic incidents involved additional pesticides along with dimethoate. Thus, it is not possible to determine if the fish were adversely affected by dimethoate or by one (or a combination) of the other pesticides. The two registered use aquatic incidents occurred in 1988 and 1995. Thus, these two incidents do not necessarily reflect current dimethoate labeled uses, formulations, application rates, and protections.

There have been no incident reports, aquatic (or terrestrial), since the mitigations imposed by EPA took place (see Section 2.2). The risk mitigation imposed in the recent IRED should continue to reduce the probability of the occurrence of ecological incidents.

There are two primary sources of incident reports. The first source is Section 6(a)(2) of FIFRA, under which pesticide registrants are required to report to EPA allegations or other information the registrant receives regarding adverse effects associated registered pesticides. Investigative reports voluntarily submitted to the EPA from state and other federal agencies that oversee agriculture, wildlife, natural resources, and environmental quality are the second major information source. Diagnostic reports are also obtained from the National Wildlife Health Institute (USGS), the Patuxent Wildlife Research Center (USGS), the Southwest Wildlife Cooperative Disease Study, and state wildlife forensic laboratories (EPA, 2010b). Information is also extracted from accounts of ecological incidents reported in newspapers and reliable internet sources (EPA, 2010b). One of the issues with the development of the EIIS based on these sources is the proper tracking and quality control of each incident. Within the EIIS, each incident is assigned a unique incident number. However, in the dimethoate EIIS reports there is a high probability that duplicate incidents exist. For example, the following incidents appear to be duplicates (see Table 3-13):

I005754-017 and B000-219-12: Identical date, location, crop, magnitude, and certainty code. Only the exposure route differs.

Table 3-13 Ecological Incident Information System (EIIS) summary for dimethoate (accessed April 28th, 2010)[a]

Incident #	*Date*	*General Description*	*County, State*	*Certainty Code[b]*	*Legality Code[c]*	*Other Pesticides Involved*	*Application Method*	*Organism Affected*	*Magnitude[d]*	*Exposure Route*
I005754-017[e]	--	Agricultural area	Riverside, CA	3	MA	Methyl parathion, parathion, diazinon, malathion, thiodan	Spill	Fish (Unknown)	13,000	Runoff
B000-219-12[e]	--	Lake	Riverside, CA	3	MA	Methyl parathion, parathion, diazinon, malathion, thiodan	--	Fish (Unknown)	13,000	Ingestion
I000403-001	8/11/1988	Soybean	Tazewell, IL	3	RU	Chlorpyrifos	Broadcast	Bass (*Micropterus spp.*)	54	Drift
								Bullhead (*Ameiurus sp.*)	2	
								Carp (*Cyprinus carpio*)	78	
								Channel Catfish (*Ictalurus punctatus*)	26	
								Drum (*Aplodinotus grunniens*)	26	
								Minnow (Cyprinidae)	8195	
								Shad (*Clupeidae*)	221	
								Sucker (*Catostomodidae*)	55	

Table 3-13 Ecological Incident Information System (EIIS) summary for dimethoate (accessed April 28th, 2010)[a]

Incident #	*Date*	*General Description*	*County, State*	*Certainty Code*[b]	*Legality Code*[c]	*Other Pesticides Involved*	*Application Method*	*Organism Affected*	*Magnitude*[d]	*Exposure Route*
								Sunfish (*Centrar-chidae*)	563	
								White Bass (*Morone chrysops*)	17	
								Total	9242	
I000804-014	6/24/1991	Loading area	Haakon, SD	3	MI	2,4-D	--	Fish (Unknown)	Unknown	Ingestion
I003826-002	6/12/1995	Tobacco	Johnston, NC	2	UN	2,4-D, aldicarb, disulfoton	--	--	--	Runoff

[a] The formulation(s) were not reported for any of the incidents presented in this table
[b] Certainty Code: 0 = Unrelated, 1=Unlikely, 2=Possible, 3=Probable, 4=Highly Probable
[c] Legality Code: RU = Registered Use, M=Misuse, MA=Misuse (Accidental), MI=Misuse (Intentional), UN=Unknown.
[d] The magnitude of the incident in the number of organisms of the reported taxa affected
[e] An e-mail was sent to the EPA (Mastrota.Nicholas@epa.gov – May 5th, 2010) to enquire about the potential for duplicate records in the EIIS database for dimethoate. No response had been received as of June 28th, 2012.

3.4 Uncertainties in the Aquatic Effects Determination

The problem formulation and the aquatic effects determination for CRLFs contains several sources of uncertainty. Uncertainties in the problem formulation and assessment of exposure and effects can influence the characterization of risks. It is important to identify the sources of uncertainty in the assessment and specify the magnitude and direction of their influence. The following sources of uncertainty were identified.

3.4.1 Problem Formulation

The conceptual model was intended to define the linkages between the application of dimethoate and potential exposure pathways to CRLF prey and habitat. As such, the conceptual model provides the scientific basis for selecting assessment and measurement endpoints to support the risk determination process. Potential uncertainties arise from lack of knowledge regarding ecosystem functions, failure to adequately address spatial and temporal variability in the evaluations of sources, fate, and effects, omission of stressors, and overlooking secondary effects (EPA, 1998). The physical and chemical properties, modes of transport, exposure routes, and other characteristics of dimethoate have been extensively researched and documented. Thus, the relationships identified in the conceptual model carry a high level of confidence and are considered a low source of uncertainty in the effects determination.

3.4.2 Effects Assessment

There are uncertainties associated with the selection of acceptable studies of good quality to derive the measures of effects. The uncertainties were reduced by using data screening criteria to identify "best available data". In the end, GLP studies were selected to derive the effects metrics. Raw data are typically available in GLP studies to confirm the calculations and reported results. Also, the test material used in recent GLP studies is more representative of the dimethoate currently produced by Cheminova. As a result, the magnitude of the uncertainty stemming from data quality issues is considered low.

In both the screening-level and refined assessments, effects of technical grade dimethoate were considered. However, agricultural applications are made with dimethoate formulations. Available aquatic toxicity studies indicate that dimethoate formulations are less toxic to aquatic biota than the technical grade material (see Section 2.9.1.3). This result suggests that effect levels may be over estimated in the effects determination, likely leading to conservative risk estimates.

In the screening-level aquatic effects assessment the most sensitive relevant endpoints were selected for effects metrics. There is some uncertainty associated with these endpoints. It is unknown how protective these values are in consideration of all aquatic invertebrate and vascular plant species that comprise the aquatic prey and habitat of CRLF.

In the refined aquatic assessment a chronic species sensitivity distribution (SSD) was estimated by shifting an acute SSD that was derived using acute effects data for aquatic invertebrates with an acute-to-chronic ratio (ACR). There is some uncertainty in the acute SSD due to limited data, and the uncertainty associated with the available data. The ACR was derived using acute and chronic toxicity results from one acceptable study. The uncertainty in the estimated chronic SSD is considerable, and may have resulted in either over or under estimation of risk to aquatic invertebrates.

3.4.3 Exposure Assessment

EPA/EFED's standard Tier II modeling for pesticides in surface water involves using PRZM3.12 to estimate off-field loadings of runoff, eroded sediment and pesticide using a series of standard crop scenarios (Burns, 2000; Carsel et al., 1997). For ecological risk assessments and effects determinations, these off-field loadings are then input into the EPA surface water model, EXAMS2.98.04, using the EPA standard pond scenario. The standard pond assumes that a 10 hectare field loads directly into an adjacent one hectare pond that is 2 m deep.

There are many uncertainties associated with the Tier II modeling approach. For this Tier II modeling effort, the following sources of uncertainty are of particular note:

- EFED uses an expert judgment procedure for identifying the soil series and geographical conditions that represent 90th percentile worst-case scenarios in the Tier II exposure concentration estimation process. It is not possible to determine whether these scenarios actually represent a 90th percentile vulnerability. This expert judgment procedure is used in lieu of a quantitative process that would examine the entire set of available soil and geographical data and then rank vulnerability based upon predicted exposure.
- Many parameters in the Tier II standard scenarios are estimated individually without consideration of whether they coexist in reality. For example, some scenarios assume high curve numbers, high erosion parameters, steep slopes and fine soil textures, each independently selected to generate high runoff and erosion off-field loads. Each parameter was selected to individually represent a 90th percentile vulnerability for that parameter. Collectively, however, combining these parameter values creates a vulnerability scenario much higher than the 90th percentile.
- When a specific crop scenario was not available in PRZM3.12.2, a surrogate scenario was assigned. Surrogate crops may be inappropriate due to differences in geographical location, planting, emergence and maturity dates, irrigation practices, pesticide application timing, soil texture and other factors where the crop of interest is grown.
- The Tier II results represent a situation with a farm pond immediately adjacent to an agricultural field without any distance or buffer between the field and the water body. The

vast majority of CRLF habitat likely occurs some distance from treated agricultural fields. Further, vegetative buffers are recommended on dimethoate pesticide labels and will likely be present to intercept or partially intercept runoff from treated fields (EPA, 2003b).

- Antecedent Moisture Curve Numbers and erosion parameters are set extremely high for many of the standard scenarios. This leads to the question of whether the generated runoff and eroded sediment quantities are within realistic bounds (Suárez, 2005).
- A model sensitivity analysis performed in 2002 revealed that EXAMS2.98.04 is extremely insensitive to assignment of Koc values and, as a result, adsorption of pesticide residues by sediment in the EPA/EFED standard farm pond tends to be under-estimated by EXAMS2.98.04 (Estes and Hendley, 2002).
- The current PRZM3.12.2 crop standard scenarios do not include plant uptake as a potential source of pesticide removal from the treated field (EPA, 2003b).
- For foliar applications, the current EPA/EFED PRZM3.12.2 crop standard scenarios set foliar wash off from plant leaves to 50%, which for many products, is quite high (EPA, 2003b).
- The current EPA/EFED PRZM3.12.2 crop scenarios ignore the likelihood that farmers are unlikely to apply pesticide during rainy conditions. Rainy conditions increase the quantity of off-field pesticide residues in runoff because the other loss functions (e.g., degradation in soil, infiltration into soil, volitilization, etc.) have not yet had a chance to take place before the pesticide runs off (EPA, 2003b).
- The EPA standard farm pond scenario assumes that pesticide from an application to a 10 hectare field drains (from runoff and erosion) into a 1 hectare farm pond, with spray drift from 1 hectare of the field also falling into the pond. No in-flow or out-flow of the EPA pond is assumed over the course of the 30-year model simulation. As a result, the standard pond scenario is irrelevant to nearly all water bodies with aquatic biota in agricultural areas of California. Fully functional aquatic biota communities generally reside in flowing water bodies or ponds and lakes with in and out flows where any pulse of malathion from an application would quickly disperse.

For acute exposure, the screening-level effects determination derived RQs using the peak instantaneous 1-in-10 year EEC. Using peak concentrations was a conservative approach given that the effects data used in the assessment came from a seven-day EC50 for duckweed (*Lemna gibba*) (EPA, 2002c).

The exposure assessment assumed that dimethoate were used at the maximum application rates and applied using methods that would result in the highest EECs. In practice, lower application rates are more commonly used. Thus, the assumptions that were made in the PRZM/EXAMS modelling biased the effects determination in a conservative direction (EPA, 2002c).

The use of highly conservative tools such as PRZM/EXAMS *are not useful in a refined risk assessment.* PRZM/EXAMS should not be used to guide decision-making. Although Cheminova does not support the use of PRZM/EXAMS in a refined ERA because the model and the corresponding EPA pond scenario are hyperconservative, the model was used in this refined effects determination because other lines of evidence strongly indicate that cottonwood grown for pulp are not at risk.

Other reasons why the EPA/EFED standard farm pond scenario is conservative and results in unrealistic estimates of dimethoate exposure include:

- Stagnant farm wetlands or ponds are likely to have a far less diverse biota than other more common aquatic water bodies, such as natural ponds, lakes, and streams, due to little or no exchange of mass with other water bodies. Species that are entirely aquatic (e.g., fish, clams, mussels, non-emergent insects) would not be present in a stagnant farm wetland. For refined aquatic assessments, a set of modeling scenarios that includes lakes and streams should be developed by the EPA/EFED. Such scenarios would produce more representative estimates of the concentrations of pesticides in water bodies that support functional aquatic communities.

- All runoff from the 10 hectare field is assumed to drain into the standard farm wetland, a highly unrealistic assumption. Many farms would have runoff draining in several different directions.

- The wind is assumed to be blowing in the direction of the farm wetland at the time of application, which is unlikely to occur for most actual applications of dimethoate.

In addition to the above concerns regarding EPA/EFED's standard pond scenario, the output from PRZM3.12.2/EXAMS2.98.04 modelingis designed to be highly conservative. For example, EPA reports that their PRZM/EXAMS EECs are 1-in-10 year estimates, i.e., "90th percentiles" (e.g., page 47 in EPA, 2008a). This designation is very misleading for the reasons described below:

- Before estimating a "90^{th} percentile", the PRZM3.12.2/EXAMS2.98.04 combined output is processed by first determining the highest daily pesticide concentration (or longer-term concentrations for non-acute exposures) for each year in a 30 year simulation period. The model then calculates the 90^{th} percentile from these 30 maximum annual values. For a 30-year period, EPA's "90^{th} percentile" is actually a concentration that would only be exceeded on three days in 30 years (or a 1-in-10 year event). On a daily basis, this estimate would actually be a 99.97^{th} percentile. In other words, the concentration estimated by EPA would be less for 99.97 percent of days in the farm wetland, assuming all of the other components of the modeling were accurate and unbiased (which they are not).

- To derive valid probabilistic exposure estimates (e.g., a 90th percentile), all key input variables must be modelled as distributions that reflect the range of plausible values for each variable. However, the only probabilistic variable in PRZM3.12.2/EXAMS2.98.04 is the meteorology (most importantly, rainfall). Conservative and sometimes implausible assumptions are made for almost all other key variables. The compounding effect of these multiple, conservative assumptions is an implausibly high exposure estimate.
- EPA has acknowledged that PRZM3.12.2/EXAMS2.98.04 is highly conservative and does not produce realistic estimates of environmental concentrations. For example, Dr. Norman Birchfield, a Senior Biologist and acting Risk Assessment Process Leader at the Environmental Fate and Effects Division (EFED) at EPA (at the time), stated in his expert declaration in a court case that EFED's models predict environmental concentrations that "are higher than most, if not all, analogous concentrations in the environment resulting from labeled uses" (Birchfield, 2003).
- Fully functional aquatic biota communities generally reside in flowing water bodies or ponds and lakes with in- and out-flows where any pulse of dimethoate from an application would quickly disperse. Concentrations of dimethoate in flowing water bodies as well as ponds and lakes with in-flows and out-flows are likely to be substantially lower than those estimated by PRZM/EXAMS for stagnant farm wetlands. Immediately upon entering the water body, dimethoate will begin to disperse from the turbulence of the river flow or within pond and lake flows. Following are two examples of how waterbodies having in-flow and out-flow reduce pesticide concentrations. Using the AgDrift Stream Assessment Tool, Rick Reiss of Exponent, Inc. demonstrated that even in slow-moving streams (0.07 ft/sec) dimethoate concentrations decline rapidly from initial peak concentrations of 50 µg/L to less than 1 µg/L in five hours (Bogen and Reiss, 2011; presentation to EPA and NMFS on October 23, 2009). Stone Environmental derived EECs for malathion in more realistic water bodies inhabited by the CRLF (i.e. realistic in-flow and out-flow, volume, and location characteristics) using SWAT (Soil and Water Assessment Tool) modeling. Peak EECs were 5 to 12 times greater for the PRZM3.12/EXAMS2.98.04 simulations (lettuce and strawberry, respectively) than they were for the most vulnerable water body in the SWAT simulation of the Watsonville watershed in California. For the 21-day duration, the EECs based on PRZM3.12/EXAMS2.98.04 were 20 to 50 times greater (lettuce and strawberry, respectively) than the SWAT simulation predictions. This comparison shows that the interpretation of risk is significantly reduced when EECs are based on modeling actual aquatic ecosystems (rather than hypothetical ones in the case of PRZM/EXAMS), and when using a model that appropriately accounts for all hydrologic processes, such as SWAT (Intrinsik, In Prep(b); Stone Environmental, 2012).

Although the probabilistic risk assessment indicates that dimethoate applied to cottonwood grown for pulp poses an intermediate risk for chronic effects to sensitive aquatic invertebrate species, there are a number of mitigating factors that need to be considered:

- As with EPA's approach, the California Forestry PRZM scenario was used to estimate EECs for the application of dimethoate to cottonwood grown for pulp. This is a highly conservative scenario as this PRZM scenario uses a 40% slope, a slope that is much higher than most agricultural scenarios. While native cottonwood can grow and is harvested at slopes of 40% or more, cottonwood plantations are typically found on soils with a slope of less than 10%. For example, hybrid cottonwood grown for pulp, also called hybrid poplar, is typically grown at slopes of less than 8% (Segal Ranch, 2012). A regional analysis of the extent of suitable planting for hybrid poplars was conducted using spatial analysis and mapping in a geographic information system (GIS) (NRCS, 2012). The authors determined that based on the STATSGO soil data, drainage, soil slopes and soil pH in areas with hybrid poplar plantations, a slope of 6% was a reasonable estimate of preferred slope for the poplar. The Canadian AgroForestry Development Centre describes hybrid poplar production as requiring level or gradually sloped soils (AAFC, 2012). AAFC (2012) also indicates that hybrid poplar production requires a high degree of management, thereby precluding large soil slopes that would hinder management. Considering the above, hybrid poplar plantations should be modeled as an agricultural scenario, such as the PRZM Christmas tree scenario (4% slope), rather than a forestry setting. The use of the PRZM Forestry scenario is exceptionally conservative and produced overestimates of EECs for the cottonwood grown for pulp use pattern.

- The preferred breeding and summer habitat of the CRLF includes still or slow-moving permanent streams with deep water (>0.7 meters) and dense riparian vegetation (FWS, 1996, 2002a). Alternative habitats include marshes, ponds, damp woods and meadows. CRLFs will breed in artificial impoundments such as stock ponds (FWS, 2002b). Stone Environmental conducted a spatial analysis of CRLF habitat types. The hydrography analyzed included: static ponds, flowing ponds, perennial and intermittent streams, and canals. CRLF core areas and critical habitat, as designated by FWS, are two habitat location sources that focus on preservation and conservation of the species. This analysis showed that lakes and ponds (perennial, intermittent, swamps/marshes) make up only 0.16 to 0.74 % of the total area of land within critical habitat and core areas, respectively (Stone Environmental, 2012). The majority of CRLF potential habitats have in-flows and out-flows that would result in much lower concentrations of dimethoate due to dilution than would the stagnant standard pond modeled in PRZM/EXAMS (See Section 3.4). Further, it seems unlikely that monocultures of cottonwood would meet the habitat requirements of the CRLF.

- CRLF habitats likely receive much less runoff and drift of dimethoate because of the presence of dense riparian vegetation adjacent to their preferred water bodies. PRZM/EXAMS assumes that the standard pond is adjacent to the treated field and that there is no vegetation to intercept runoff or spray drift. These factors again argue for lower dimethoate concentrations in CRLF habitats than predicted for the standard pond.
- Because CRLFs are opportunistic and generalist feeders, it is unlikely that adverse effects to a small proportion of sensitive aquatic species would significantly reduce the overall availability of prey, particularly given that their preferred foraging habitats are not stagnant ponds adjacent to cottonwood stands.
- There is no documentation indicating that cottonwood is grown commercially for pulp use in California. Information available in the Ca PUR database does not provide sufficient detail to determine whether pesticides are applied to cottonwood (CA DPR, 2010). The United States Department of Agriculture (USDA) website (http://www.usda.gov/wps/portal/usda/usdahome) indicates that cottonwood is used for pulp production but does not specify whether this practice occurs in California. The US Forestry Service (http://www.fs.fed.us/), the California Department of Forestry and Fire Protection (http://www.fire.ca.gov/), the Natural Resources Conservation Service (http://www.nrcs.usda.gov/technical/forestry.html) and several pulp and paper industry web sites make no reference to cottonwood being used for pulp production in California. A personal communication (Mr. Kent Duysen) at the Sierra Forest Products Saw Mill, California, indicated that he was not aware of a commercial plantation of cottonwood in California. The Washington State Pest Management Resource Service indicated to EPA that dimethoate use is crucial in cottonwood and poplar trees grown for pulp in that State (WSPMRS, 2003). However, WSPMRS (2003) notes that cottonwood grown for pulp is a practice conducted in Alaska, Idaho, Oregon, Utah, and Washington. No reference was made to California. Thus, there is no information that suggests that cottonwood is grown commercially in California.

Conservative PRZM/EXAMS modeling suggests that sensitive aquatic invertebrate prey would be at risk in stagnant ponds located next to cottonwood monocultures treated with dimethoate at the maximum application rate. However, based on factors described above, this situation is highly unlikely to ever occur in CRLF habitats in California.

3.4.4 Mesocosm and Field Studies

The lack of replication and the low number of organisms in the Hessen et al. (1994) study make it difficult to determine if the results observed are statistically meaningful. Baekken and Aanes (1994) showed that the average number of drifting animals was equal or higher in the dimethoate-treated stream than in the reference stream. However, the differences observed between treated and reference streams could not be tested for statistical significance because of the lack of replication in the study. Similarly, the statistical significance of the differences in movement out of the trays between the treated and reference streams and abundance of certain taxa in the treated and reference streams is unknown because of the lack of replication in the study. The magnitude of the uncertainty from these two studies is considered high.

3.4.5 Incident Reports

Incident reports have a large degree of uncertainty associated with them. Tissue testing is not often performed, and exact cause of death is rarely established. Incident reports often present findings involving multiple pesticides, making the contribution of the individual pesticides to the reported effects uncertain. Thus, incident reports are not a very reliable source of information in the risk characterization process.

3.4.6 Monitoring Data

Drinking water and surface water samples collected for analysis of concentrations of dimethoate and other pesticides have been taken in regions of heavy agricultural use in California. Water samples have been taken over the course of nearly a decade. Dimethoate was infrequently detected. The highest concentration of dimethoate detected is more than 3-fold less than the effects metric for chronic effects to aquatic invertebrates. Monitoring data are considered a reliable source of information in the risk characterization process.

3.5 Summary and Conclusion of the Aquatic Effects Determination

The only aquatic exposure scenarios that required additional refined analyses were for chronic effects to aquatic invertebrates as a result of applying dimethoate via chemigation or aerially to cottonwood grown for pulp (2 lbs/A, maximum 3 treatments per season at a minimum of 10-day retreatment interval). Refined probabilistic analyses for these scenarios indicated that sensitive aquatic invertebrate prey would be at intermediate risk in stagnant ponds adjacent to treated cottonwood stands. However, over 75% of aquatic invertebrate species would not be at risk (i.e., NOEL not expected to be exceeded). As described in Section 2.1.4, it is highly unlikely that CRLFs would forage in stagnant ponds adjacent to cottonwood stands because they generally prefer habitats with in-flows and out-flows surrounded by dense riparian vegetation. These habitat characteristics would considerably reduce the concentrations of dimethoate in CRLF habitats compared to the "standard pond" modeled in PRZM/EXAMS. For reasons outlined in Section 3.4, even the refined analysis likely over-estimated risks of dimethoate to aquatic invertebrate prey. As with EPA's approach, the California Forestry PRZM scenario was used to estimate EECs for the application of dimethoate to cottonwood grown for pulp. This is a highly conservative scenario as this PRZM scenario uses a 40% slope, a slope that is much higher than most agricultural scenarios. Hybrid poplar plantations should be modeled as an agricultural scenario, such as the PRZM Christmas tree scenario (4% slope), rather than a forestry setting. The use of the PRZM Forestry scenario is exceptionally conservative and produces overestimates of EECs for the cottonwood grown for pulp use pattern. Most important, however, it is highly unlikely that cottonwood is grown for pulp in California. Thus, this use pattern likely does not exist in practice for dimethoate in California.

The USDA Pesticide Data Program (PDP) (2001-2007), the US Geological Survey (USGS) National Water Quality Assessment (NAWQA) Program (2001-2009) and the California Department of Pesticide Regulation (DPR) infrequently detected dimethoate in drinking water and surface water. In a more recent monitoring effort, the PDP found that the highest concentration of dimethoate measured was 11.3 µg/L, a concentration that is below the effects thresholds for aquatic invertebrates, the most sensitive aquatic species (Section 2.6.1). In addition, the new restrictions identified in the RED are expected to reduce the magnitude and frequency of detections of dimethoate in drinking and surface water (EPA, 2008c).

Incidents resulting from the legal, registered uses of dimethoate are infrequent. Moreover, the most recent aquatic incident involving registered use occurred in 1988. Changes in labeling, application rates and best management practices since then strongly suggest that aquatic incidents in the future will be even more infrequent.

The weight-of-evidence indicates that indirect effects to the CRLF due to direct effects to their aquatic prey and habitat are unlikely.

4.0 TERRESTRIAL EFFECTS DETERMINATION

This section describes the portion of the effects determination concerned with terrestrial exposure scenarios for CRLF, their terrestrial habitat and prey. Section 4.1 describes the screening-level assessment while Section 4.2 describes the refined assessment. Other lines of evidence are presented in Section 4.3. Section 4.4 describes the uncertainty in the assessment. The conclusion of the terrestrial effects determination is presented in Section 4.5.

4.1 Terrestrial Screening-Level Effects Determination

The terrestrial screening-level assessment consists of an assessment of effects (Section 4.1.1), exposure (Section 4.1.2) and risk characterization (Section 4.1.3).

4.1.1 Terrestrial Screening-Level Effects Assessment

The screening-level effects determination used the most sensitive and relevant measures of effect for the assessment endpoints under consideration. An evaluation of all available toxicity data was conducted to ensure that the best available data were used in the effects determination. The criteria used to evaluate studies and the study evaluations are presented in Appendix A, B and D. The only relevant plant toxicity study is presented below.

4.1.1.1 Terrestrial-phase Amphibians

Because there was no acceptable toxicity data available for terrestrial-phase amphibians, bird species were considered surrogates as is the standard practice by EPA (EPA, 2008a).

The selected acute toxicity study was conducted by Zok (2001c [MRID 47769705]) with northern bobwhite quail (*Colinus virginianus*). The study involved a five-day dietary exposure. With only one treatment eliciting partial mortality (i.e., not 0 or 100% mortality), it was not possible to compare goodness-of-fit of various dose-response models, nor was it possible to generate approximate confidence limits. A standard probit model was fit to the data using PROC PROBIT in SAS. The resulting LD50 estimate was 14.6 mg a.i./kg bw/d (Table 4-1). The dose-response curve is presented in Figure 4-1.

Table 4-1 Dose –response data for northern bobwhite quail exposed to dimethoate in their diet for five days[a]								
Group	*Dietary Concentration (mg a.i./kg diet)*	*Dead Birds*	*Total Birds*	*Mean Food Intake (g/bird/d)*	*Mean Body Weight (g/bird)*		*Mean of Day 0 and Day 5 Body Weights (g/bird)*	*Average Daily Dose (mg a.i./kg bw/d)*
					Day 0	*Day 5*		
0	0	0	20	2.6	19.5	25	22.3	0
1	36	0	10	2.9	18.5	23.8	21.2	4.94
2	75	0	10	2.4	18.9	22.4	20.7	8.72
3	150	4	10	1.9	19.3	20.2	19.8	14.4
4	300	10	10	1.3	19.1	15.7[b]	17.4	22.4
5	600	10	10	0.6	17.9	12.5[b]	15.2	23.7

[a] Data from Zok (2001c [MRID 47769705])
[b] Average of final body weights of birds that died during the exposure period

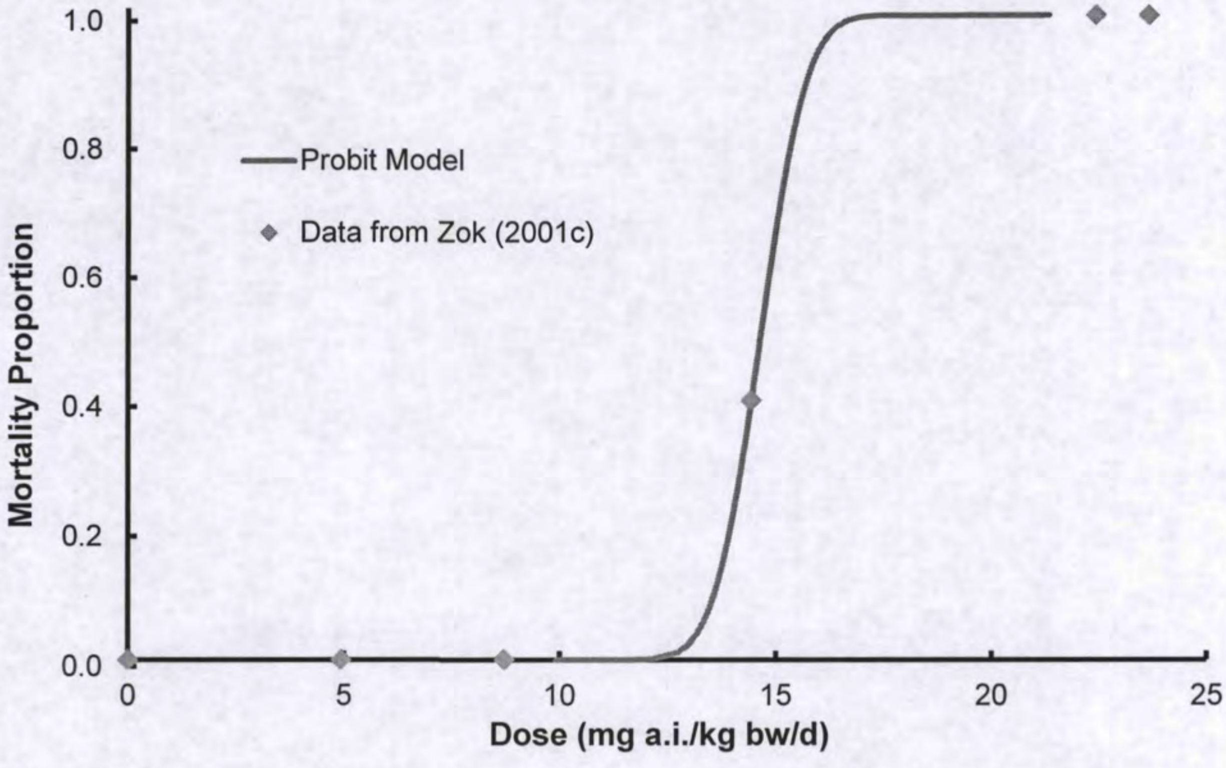

Figure 4-1 Dose-response curve for northern bobwhite quail exposed to dimethoate in their diet for 5 d. Data from Zok (2001c). Confidence limits could not be calculated due to only one partial effect treatment.

The chronic effects metric for birds used to assess risk to CRLF was derived from the dietary study conducted by Gallagher et al. (1996a [MRID 44049001]). The reproductive NOEL for northern bobwhite quail is 1.09 mg a.i./kg bw/d. The calculation involved multiplying the dietary NOEL (10.1 mg a.i./kg ww) reported by Gallagher et al. (1996a) by the average food consumption rate for both sexes during the 22-week trial (19.8 g/bird/d) and dividing the product by the average body weight for both sexes across the study duration (183 g/bird). Although the NOEL of 10.1 mg a.i./kg ww was for reproductive endpoints, it was not possible to calculate a NOEL specific to females because the reported feed consumption rates were not separated by sex. Thus, the calculated reproductive NOEL is for both sexes combined.

4.1.1.2 Terrestrial Plants

Porch et al. (2011a [MRID 48572802], 2011b [MRID 48572801]) examined the effects of dimethoate on vegetative vigor and seedling emergence and growth of 10 representative plant species. Test durations were 21 days. The studies were conducted following good laboratory practice (GLP) procedures (EPA 40 CFR Part 160, 17 August 1989) and standardized test protocols. The dates and times of quality assurance/quality control inspections and audits were included in the report. All methods and any deviations from standard protocol were included in the report or appropriately referenced to ensure that the study approach could be replicated. The methods used to conduct the studies were based on procedures described in the US Environmental Protection Agency Series 850 – Ecological Effects Test Guidelines OPPTS Number 850.4225 (Seedling emergence Tier II) and OPPTS number 850.4250 (Vegetative vigor, Tier II). Mean emergence, survival, shoot height, and shoot weight of the treatment groups were compared to the control group to determine if dimethoate application caused adverse effects. The calculated EC25 and NOEL reported in these two studies were >1.5 lb a.i./A and 1.5 lb a.i./A, respectively. The EC25 was calculated to be greater than the highest concentration tested, therefore, the observed NOEL was used to assess effects of dimethoate to terrestrial plants (Table 4-2).

A summary of key effects data can be found in Section 2.6. Measures of ecological effect selected for the terrestrial screening-level effects determination are presented in Table 4-2.

Table 4-2 Measures of ecological effect selected for the screening-level effects determination for dimethoate				
Species	***Exposure Duration***	***Endpoint***	***Concentration / Dose / Rate***	***Reference [MRID]***
Direct effects to CRLF and indirect effects via reduction in Pacific tree frog (prey)				
Northern bobwhite quail (*Colinus virginianus*)	Acute	LD50	14.6 mg/kg bw/d	Zok, 2001c [47769705]
Northern bobwhite quail (*Colinus virginianus*)	Chronic	NOEL	1.09 mg/kg bw/d	Derived from Gallagher et al., 1996a [44049001]
Indirect effects via habitat degradation				
10 crops (monocots and dicots)	Acute/chronic	21 d NOEL (seedling emergence)	>1.5 lb a.i./acre	Porch et al., 2011b [48572801]
10 crops (monocots and dicots)	Acute/chronic	21 d NOEL (vegetative vigor)	>1.5 lb a.i./acre	Porch et al., 2011a [48572802]

4.1.2 Terrestrial Screening-Level Exposure Assessment

For terrestrial-phase CRLFs and their terrestrial vertebrate prey (Pacific tree frog), exposure to dimethoate was assessed using a total daily intake (*TDI*) modeling approach. Exposure to terrestrial plants was assessed using TerrPlant (version 1.2.2), that compares estimated EECs derived using label application rates to effects metrics for plants. Risk was determined for use patterns with the highest application rates and number of applications per season, and shortest retreatment intervals (Table 4-3).

Table 4-3 Use patterns modeled in the exposure assessment for terrestrial-phase CRLF and their terrestrial amphibian prey (Pacific tree frog)				
Crop	***Application Method***	***Maximum Single Application Rate (lb a.i./A)***	***Maximum Number of Applications per Season***	***Minimum Retreatment Interval (d)***
Broccoli	Groundspray/aerial	0.5	3	7
Wheat	Groundspray/aerial	0.67	2	7
Turnip	Groundspray/aerial	0.25	7	3
Peppers	Groundspray/aerial	0.33	5	7
Christmas tree nurseries	Groundspray/airblast	1	3	14
Non-cropland areas adjacent to vineyards	Groundspray	2	2	14
Cottonwood grown for pulp	Aerial/chemigation	2	3	10

4.1.2.1 Wildlife Exposure Assessment Model

A *TDI* model was used to estimate acute and chronic dietary exposures of terrestrial-phase CRLFs and their amphibian prey, the Pacific tree frog, to dimethoate. To account for the different diets of juvenile and adult CRLFs, *TDI* was estimated separately for these life stages. Pacific tree frog *TDI* estimates were also used to estimate risk to adult CRLF consuming a diet containing small terrestrial-phase amphibian prey. Similarly, *TDI* modelling was used to estimate dimethoate residues in California mouse to model direct acute effects to adult CRLF consuming mice. The dietary items and residue calculations are presented in Section 4.1.2.2 below.

The model equation for total daily intake (*TDI*) was:

$$TDI = PDR * \sum_{i=1}^{k} NFIR_i * C_i$$

Equation 4-1

where,

PDR is the proportion of diet containing dimethoate residues (unitless)

$NFIR_i$ is the normalized food intake rate (kg ww/kg bw/d)

C_i is the concentration of dimethoate in each dietary item (i) (mg/kg ww)

k is the number of food items in the diet (unitless)

Measured food intake rates (*FIR*) are not available for CRLFs, Pacific tree frogs or other closely-related species, primarily due to the difficulties in measuring intake for free-ranging wildlife (EPA, 1993). Instead, an allometric equation developed from measurements of field metabolic rate (*FMR*) in free-ranging animals was used to estimate food intake rate for CRLFs, Pacific tree frog and California mouse. The normalized food intake rate ($NFIR_i$) of the i^{th} food item was derived from the normalized *FMR* using the following equation:

$$NFIR_i = \frac{FE_i * NFMR}{ME_i}$$

Equation 4-2

where,

NFMR is the field metabolic rate normalized to body weight (kcal/kg bw/d)

ME_i (= AE_i x GE_i) is metabolizable free energy for the k^{th} food item (kcal/kg)

AE_i is the assimilation efficiency of the ith food item (unitless)

GE_i is the gross energy of the ith food item (kcal/kg).

The proportion of free energy (FE_i) from each dietary item is calculated using Equation 4-3.

$$FE_i = \frac{P_i * ME_i}{\sum_{i=1}^{k} P_i * ME_i}$$ **Equation 4-3**

where,

P_i is the assumed daily proportion of the i th dietary item in the diet by mass.

4.1.2.2 Input Parameters for the Total Daily Intake Model

Field Metabolic Rate

Field metabolic rate (*FMR;* or free metabolic rate) represents the total energy requirements for animals in the wild, including energy required for feeding, reproduction and predator avoidance. It is often expressed in units of kcal/kg bw/d. There is a paucity of data on field metabolism rates of amphibians. Feder and Burggren (1992) describe the difficulties in estimating field metabolic rates for amphibians.

McNab (2002) presented allometric standard metabolic rate (SMR) equations for several taxa of amphibians and reptiles. SMR represents the minimum energy requirements of an organism in a post-absorptive state. The SMR equations were fit to data from several metabolism studies (Bennett and Dawson, 1976; Andrews and Pough, 1985; Chappell and Ellis, 1987; Gatten et al., 1992; Thompson and Withers, 1997). Although the raw data were not available, the models are presented in Figure 4-2, below, and suggest that amphibians, and specifically, anuran SMRs fall within the range of reptile SMRs. The CRLF is an anuran amphibian species.

In the absence of direct *FMR* measurements in CRLF or an amphibian surrogate, we used reptilian *FMR* estimates.

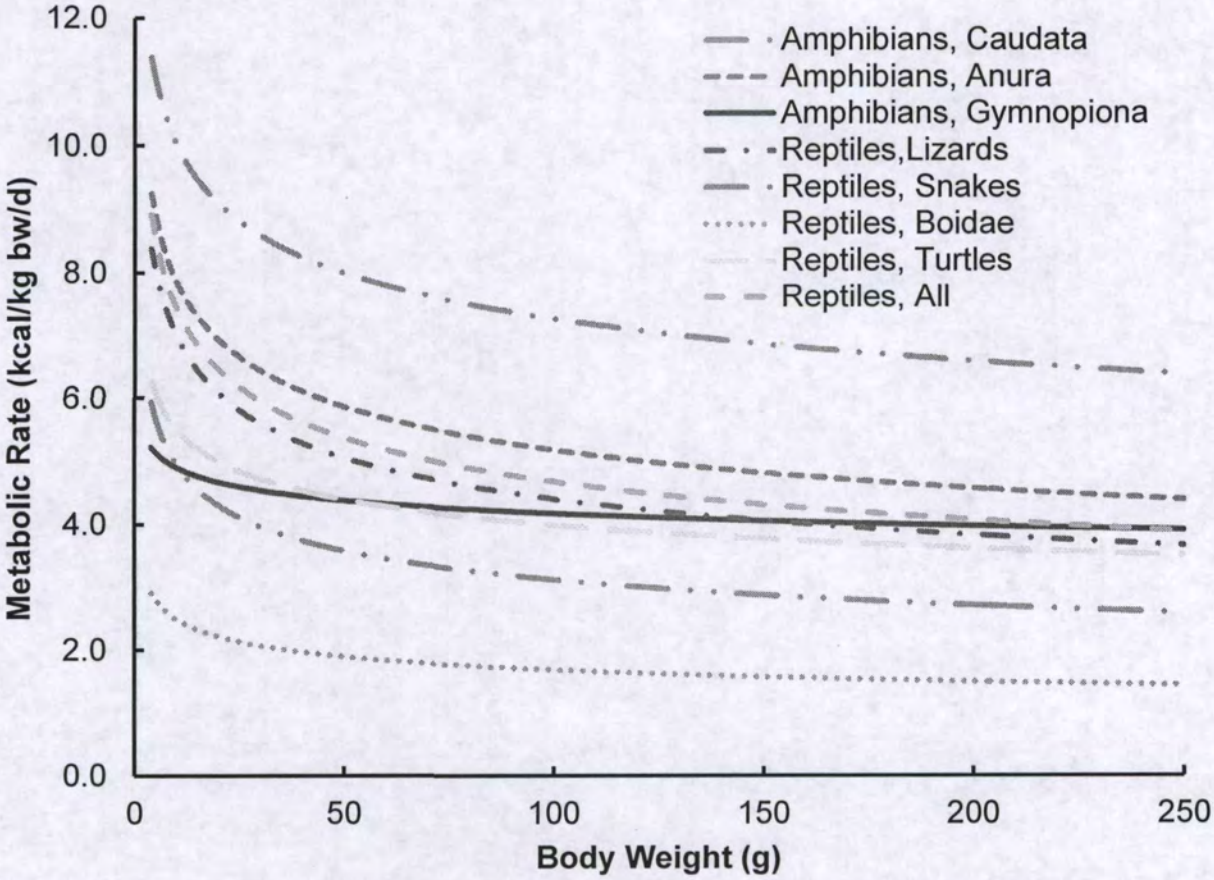

Figure 4-2 **Allometric SMR models for amphibians and reptile taxa from McNab (2002), assuming 1 mL of O_2 = 4.8 cal (EPA, 1993; original source: Dawson, 1974)**

In T-HERPS, EPA's model for estimating pesticide exposure for reptiles and amphibians, *FMR* is not considered (EPA, 2008e). The EPA uses a model for estimating food intake for insectivorous iguanid lizards from Nagy (1987). However, this model does not account for differences in gross energy and assimilation efficiencies of the dietary items of iguanids (primarily terrestrial arthropods) and CRLFs (aquatic and terrestrial arthropods, small mammals, fish and other amphibians). Further, Nagy et al. (1999) have updated estimates of field metabolic rates to include numerous reptilian species.

FMR was calculated using the following equation (Nagy et al., 1999):

$$Log(FMR) = a + b(log(bw))$$ **Equation 4-4**

In this calculation, *bw* is in units of g wet weight and *FMR* is in units of kJ/d. The model was fit to the data provided in Nagy et al. (1999) for 55 species of reptile. The intercept (*a*) and slope (*b*) parameters were calculated using simple linear regression with the PROC REG procedure in SAS Software® (SAS Version 9.1). The parameter estimates were a = -0.70658 and b = 0.88789. The model fit the data with an R^2 value of 0.945, F=911.49 with p<0.0001. The model is presented in Figure 4-3.

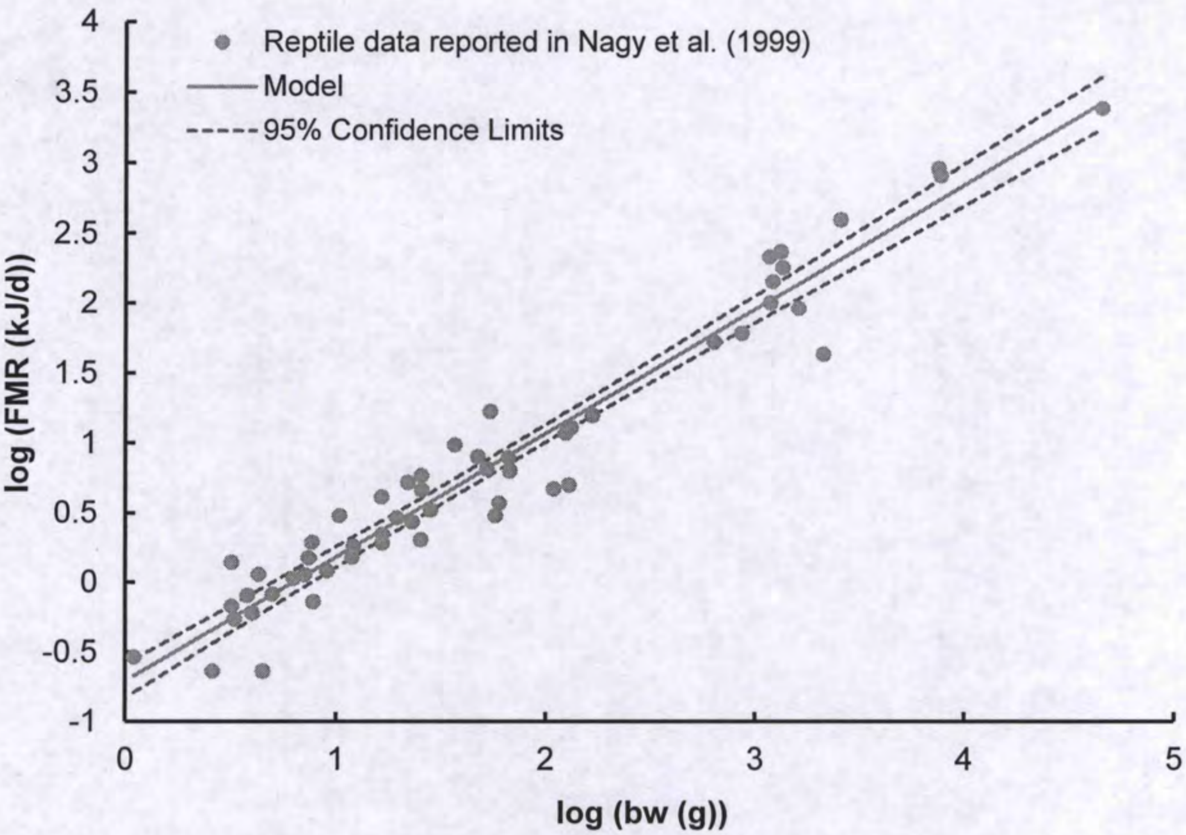

Figure 4-3 Linear model fit to *FMR* data presented in Nagy et al. (1999) for reptiles.

Body weight estimates for juvenile and adult CRLF, as well as their Pacific tree frog prey (see Section 4.1.2.2) were used to estimate *FMR*s for these receptors using the regression model described above. In the *TDI* model, the *FMR* estimate is converted to kcal standardized to unit body weight (i.e., kcal/kg bw/d).

No *FIR* or *FMR* data were found for the California mouse. Thus, a similar *FMR* estimation approach was applied for this species in the *TDI* model. *FMR* was estimated using the energetics data provided in Nagy et al. (1999) for 30 rodent species. A linear model was fit to the log of reported *FMR*s, in kJ/d, versus the log of associated rodent body weights, in g (see Figure 4-4; Nagy et al., 1999).

The intercept (*a*) and slope (*b*) parameters were estimated using simple linear regression with the PROC REG procedure in SAS Software® (SAS Version 9.1). The parameter estimates were $a = 0.7391$ and $b = 0.71214$. The model fit the data with an R^2 value of 0.847 (F=155.5, p<0.0001). The model is presented in Figure 4-4 below.

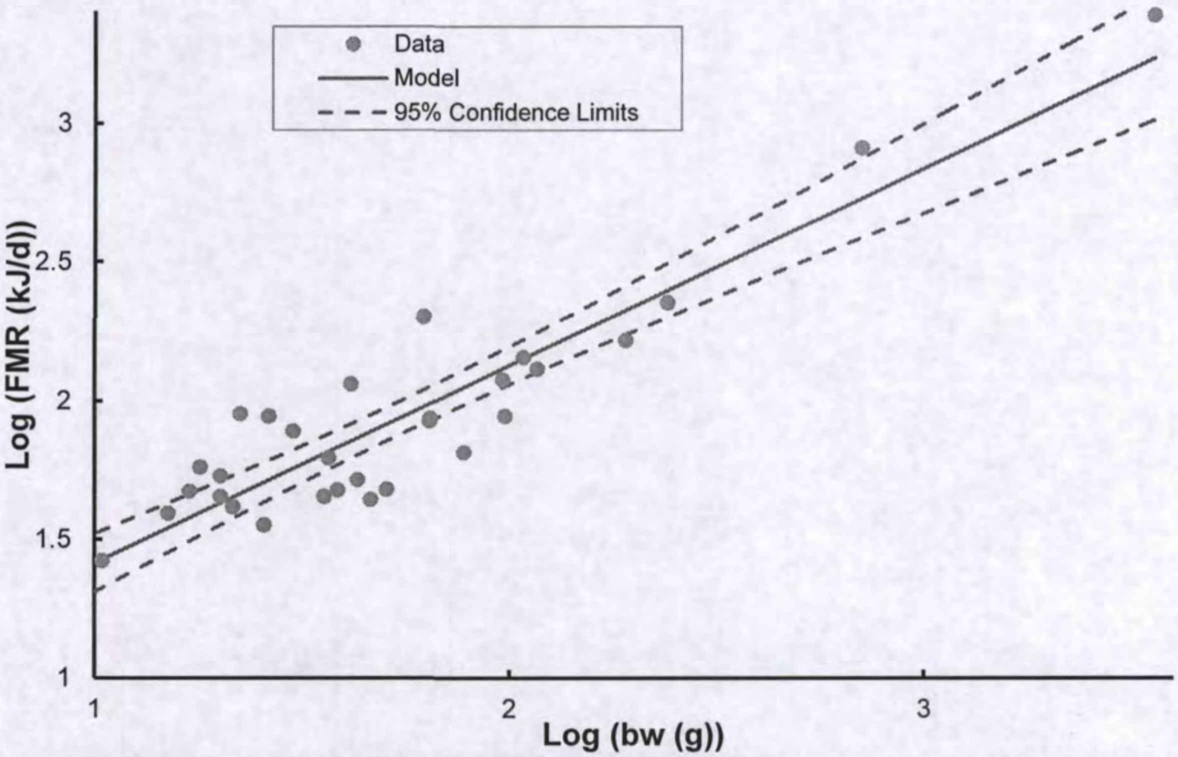

Figure 4-4 Linear model fit to *FMR* data presented in Nagy et al. (1999) for rodents

A body weight estimate for California mouse (see below) was used to estimate *FMR* for this prey species using the regression model presented above.

Body Weight

Body weight data for the CRLF were available from a 10-year (1991 to 2000) study from four streams in San Luis Obispo County, California (Scott and Rathbun, 2001). Body length and weight data were collected for 459 CRLFs. Body lengths ranged from 3.5 to 13.9 cm and weights ranged from 4.3 to 247 g. Juvenile and large adult CRLFs were ≤6.5 cm and ≥10 cm in length, respectively (Hayes and Tennant, 1985). The weights of juveniles ranged from 4.3 to 27 g with an average weight of 12.2 g (n = 72). The weights of adults ranged from 74 to 247 g with an average weight of 131.9 g (n = 387).

Adult Pacific tree frogs range in length from 2.5 to 5 cm (USGS, 2003). Jameson et al. (1970) sampled 10 Pacific tree frogs from each of nine locations in British Columbia, Oregon, California and Baja California. The body lengths and weights of the sampled frogs are presented in Table

4-4. They reported a mean wet weight of 2.27 g. Assuming that amphibians are 85% water, 2.27 g ww converts to a dry weight value of 0.341 g.

Table 4-4 Pacific tree frog body lengths and weights reported in Jameson et al. (1970)

Location	*Group Mean Wet Weight (g)*	*Snout-Vent Length (cm)*	*Shank Length (cm)*
British Columbia			
Chiliwack	1.60	2.96	1.52
Oregon			
Lee's Camp	4.45	3.87	2.09
Madras	3.22	3.32	1.74
California			
Crescent Mills	1.79	2.81	1.58
San Diego	2.38	3.34	1.68
Willows	1.68	2.93	1.47
Julian	2.22	3.32	1.61
Baja California			
Calamajue	1.62	2.79	1.36
Palmarito	1.47	2.70	1.43
Mean	**2.27**	**3.12**	**1.61**

The available data for California mouse body weights were limited, with only mean values or ranges reported in the literature. Grinnell and Orr (1934) reported average body weights of three subspecies of California mouse. The body weights of five *P. californicus mariposae* found on the lower western slope of southern Sierra Nevada were measured. The male (n=3) and female (n=2) average body weights were 47.6 g and 43.8 g, respectively, with an overall average of 46.1 g. The average body weight of nine adult (6 male and 3 female) *P. californicus benitoensis* was 42.8 g and the average weight of 11 adult *P. californicus insignis* from lower California was 33.2 g. Merritt (1974) reported a mean body weight of *P. californicus* of 57.01 ± 7.90 g for animals that were collected in the field but maintained in the laboratory for 110 days with a diet of prepared laboratory mouse food. The timing of the body weight measurements was not reported. Merritt (1978) reported *P. californicus* body weights ranging from 33.2 to 54.4 g. The mean of the three reported subspecies means (*P. californicus mariposae*, 46.1 g; *P. californicus benitoensis*, 42.8 g; *P. californicus insignis*, 33.2 g) of 40.7 g was used as a point estimate of California mouse weight in the assessment.

Proportion of Dietary Items

CRLFs are opportunistic feeders that prey on virtually anything available (Cook, 1997). Hayes and Tennant (1985) reported 196 prey items from 42 taxa in the digestive tract of 31 CRLFs. The most common prey groups were carabid and tenebrionid beetles, water striders, lycosid spiders, and larval neuropterans. The prey items identified in the frogs were distributed among the following categories: arachnida (7 of 196 prey items observed), amphipoda (2 of 196), isopoda (22 of 196), insecta (157 of 196), mollusca (6 of 196), fish (undigested dorsal spines observed in one frog), amphibia (2 of 196), and mammalia (1 of 196). The authors noted that prey occurrences in CRLFs reflect prey availability (e.g., current hatch of insects). Larger CRLFs (>8 cm) were observed consuming larger prey (>2 cm). Pacific tree frog (*Hyla regilla*) and California mouse (*Peromyscus californicus*) were the largest prey consumed by adult CRLFs (Hayes and Tennant, 1985).

Juvenile CRLFs do not consume terrestrial vertebrate species (e.g., mice, frogs) as do large adult CRLFs (Hayes and Tennant, 1985). Juvenile CRLFs consume aquatic and terrestrial invertebrates. No information is available on the proportions of these two prey items in the diet of juvenile CRLFs. To estimate the risk range to juvenile CRLF, best, intermediate and worst-case dietary exposure scenarios were modeled. The best-case dietary scenario consisted of a diet of 100% aquatic invertebrates as concentrations of dimethoate in aquatic invertebrates are less than those in terrestrial invertebrates. The worst-case dietary scenario for juvenile CRLFs consisted of a diet of 100% terrestrial invertebrates. The intermediate exposure scenario assumed a diet of 50% of each prey item.

The diet for adult CRLFs included aquatic and terrestrial invertebrates, fish, mammals and amphibians. The same approach for proportion diet was used for adult CRLF. The best and worst-case dietary exposure scenarios included 100% aquatic invertebrates (lowest dimethoate concentrations of all prey items) and 100% terrestrial invertebrates (expected highest concentrations of all prey items). The dietary proportions for the intermediate exposure scenarios was 25% for each of fish, amphibians, aquatic invertebrates and terrestrial arthropods. For amphibian prey, the corresponding peak acute or chronic *TDI* of the Pacific tree frog was used as an estimate of the residues in that feed item.

For acute exposures the consumption of one whole mouse was also considered. As with the amphibian prey, the peak acute or chronic *TDI* of the California mouse was used as an estimate of the residues in this prey.

Pacific tree frogs (*Hyla regilla*) primarily forage in shrubs and bushes for terrestrial and flying insects such as leaf hoppers, midges, and crane flies. They consume lesser quantities of ants, beetles and spiders (Owen, 2000; Herbert, 2002). Johnson and Bury (1965) observed that insects constituted 73.5% of the winter diet of 135 Pacific tree frogs. Their prey also includes a number of small invertebrate species that are associated with aquatic and moist habitats (Johnson and Bury, 1965). More adult insects were consumed than larvae, indicating that Pacific tree frogs prefer flying prey. According to frequency of occurrence data provided in Johnson and Bury (1965), approximately 81% and 19% of the Pacific tree frog diet consists of terrestrial and aquatic invertebrates, respectively. A significant portion of digestive tracts contained worms. These estimated proportions were used in the *TDI* model for the Pacific tree frog.

The California mouse primarily consumes fruits, seeds and flowers of shrubs. Arthropods also make up a small percentage of the California mouse diet (Meserve, 1976a,b). The only quantitative description of the California mouse diet available was reported by Merritt (1974) for three California mice foraging in northern California. The study reported volumetric percentages of various feed items of mice collected in two different sampling quadrats. These feed items were classed as seeds and nuts, berries, arthropods, leaves and herbaceous stems. Trace amounts were assumed 0.5% by volume. The percentages were then corrected to account for exclusion of other items found in the gut (e.g., small amounts of fur and unidentified material). The averages of the quadrats for each feed item were used in the exposure assessment, assuming equivalent densities of feed items. The following proportions of feed items were assumed in the diet of California mouse by wet weight: 52% seeds and nuts, 25% leaves and herbaceous stems, 12% arthropods, 6.9% berries, and 4.1% fungi.

Gross Energy

Gross energy (*GE*) values are reported in the Wildlife Exposure Factors Handbook (EPA, 1993). A mean *GE* value of 880 kcal/kg ww was used for aquatic invertebrates in the *TDI* model. This value was derived from the gross energies for bivalves (800 kcal/kg ww), isopods and amphipods (1100 kcal/kg ww), and cladocerans and insect larvae (740 kcal/kg ww) (Cummins and Wuycheck, 1971; Golley, 1961; Tyler, 1973; Jorgensen et al., 1991; Pierotti and Annett, 1987; Minnich, 1982; Thayer et al., 1973). The mean *GE* of 1200 kcal/kg ww for bony fish was used as a surrogate for all fish prey (Thayer et al., 1973). The gross energies of grasshoppers and crickets (1700 kcal/kg ww) and beetles (1500 kcal/kg ww) were averaged to derive the *GE* point estimate of 1600 kcal/kg ww for terrestrial invertebrates (Collopy, 1975; Bell, 1990). The estimated gross energies of mice and frogs are 1700 kcal/kg and 1200 kcal/kg ww, respectively (Gorecki, 1975; Golley, 1960; Koplin et al., 1980).

For California mouse, the *GE* in vegetation was considered. EPA (1993) reports a mean and standard deviation of 4200 and 490 kcal/kg ww, respectively, for dicot leaves from Golley (1961). These values were based on the results of 57 studies.

EPA (1993) reported single *GE* values of 1300 kcal/kg ww and 4200 kcal/kg dw (70-88% moisture content) for young grasses from Davis and Golley (1963) and Drozdz (1968). No measure of variability was associated with these values. However, EPA (1993) did report a mean and standard deviation of 4300 and 330 kcal/kg/dw for mature dry grasses based on the results of five studies (Cummins and Wuycheck, 1971; Davis and Golley, 1963; Golley, 1960; Kendeigh and West, 1965). To be conservative, the dry weight mean for young grass (4200 kcal/kg dw) was used in this assessment for foliar feed items.

EPA (1993) reported a mean and standard deviation of 5100 and 1100 kcal/kg dw for dicot seeds based on the results of 57 studies (Dice, 1922; Golley, 1961; Drozdz, 1968; Robel et al., 1979). The mean *GE* was used in this assessment for seeds and nuts consumed by California mouse.

EPA (1993) also reported both wet weight and dry weight *GE* values for fruit (pulp and skin; Levey and Karasov, 1989; Karasov, 1990). The reported percent moisture content was 77% with a standard deviation of 3.6% based on three studies. The mean and standard deviation for pulp and skin of fruit was 1100 and 300 kcal/kg ww from three studies, and 2000 and 3400 kcal/kg dw based on 28 studies, respectively. The dry weight mean of 2000 kcal/kg dw was selected for modeling because it was more conservative based on conversion to wet weight using the selected point estimate of 77% moisture (see Table 4-5).

Colak et al. (2009) investigated the nutritional composition of eight species of mushrooms. The authors reported a mean and standard deviation of 4141 and 291 kcal/kg dw, respectively. The mean was used in this assessment for fungi in the diet of California mouse.

Conversion of *GE* to wet weight was required for grass, seeds, fungi and fruits, the moisture content assumptions listed in Table 4-5 were applied. Unless stated otherwise, the values presented in Table 4-5 below are from EPA (1993) and were the values used in the registration eligibility document for carbofuran (EPA 2005b).

Table 4-5 Water content of dietary items used in this risk assessment

Item	*Percent Moisture*
Grass (young)	79
Seeds	9.3
Fruits	77
Fungi	86.8[a]

[a] The mean from Colak et al. (2009) was not used by EPA (2005b).

Assimilation Efficiency

Assimilation efficiency (*AE*) is the proportion of gross energy of a prey item that is actually obtained by the organism. The EPA Exposure Factors Handbook (EPA, 1993) reports *AE*s for the prey of birds and mammals, but not amphibians. In lieu of values for the prey of amphibians, the *AE*s reported for bird prey were used as surrogates for the CRLF and Pacific tree frog prey. For amphibians consuming aquatic invertebrates, terrestrial invertebrates, fish, other amphibians and mammals, *AE*s of 0.77, 0.72, 0.79, 0.79 and 0.78 were used, respectively (Ricklefs, 1974; Koplin et al., 1980; Stalmaster and Gessaman, 1982; Castro et al., 1989; Karasov, 1990). The *AE* for fish was used as a surrogate for amphibians because there were no data available for amphibian prey.

For the California mouse diet, mean *AE*s for mammals were obtained from EPA (1993). Reported mean *AE*s for mammals consuming arthropods and seeds/nuts were 0.87 and 0.85, respectively (Drozdz, 1968; Grodzinski and Wunder, 1975; Barrett and Stueck, 1976). The mean reported *AE* for rabbits, voles and mice consuming green forbs of 0.73 (Drozdz, 1968; Grodzinski and Wunder, 1975; Batzli and Cole, 1979) was assumed for California mouse consuming leaves, fungi and berries.

Proportion of Diet Containing Residues

Bulger et al. (2003) reported that CRLFs spend most of their time within five meters of their summer aquatic habitat. During rain events, they may move as far as 130 meters to upland areas where they remain for approximately four to six days. However, 90% of the individuals observed remained within 60 meters of water at all times. As such, it is not expected that CRLF regularly forage on agricultural fields.

Of their vertebrate prey, species from the genus *Peromyscus* (e.g., California mouse, and possibly other deer mice) and small amphibians (e.g. *Hyla regilla*) may be found in areas where dimethoate is applied. Although unlikely, there is a potential for CRLFs to consume mice or frogs that were exposed via diet at the site of dimethoate application.

The California mouse is semi-arboreal and is generally found in woodland and scrub covered regions (Clark, 1936; Merritt, 1978). Therefore, it is unlikely that California mice would spend a significant portion of their foraging time on treated fields following dimethoate application. Further, the home range of *P. californicus* is relatively small; from 150 to 3,788 m^2, with average ranges of 1,161 to 1,500 m^2 (Ribble and Salvioni, 1990; USC, 2006). Home ranges for other deer mice species (*P. maniculatus*; another potential small mammalian prey species) are of similar size from 242 to 3,000 m^2 (Bunker, 2001). Mean home ranges reported in the EPA Wildlife Exposure Factors Handbook for deer mice vary from 140 to 1,280 m^2 (EPA, 1993). Based on the maximum reported home range of 3,788 m^2 for *P. californicus*, and assuming a circular home range, an estimate of a maximum distance travelled from the centre of a home range is ~35 m. Given this information, it is unlikely that a CRLF would encounter California mice or other mice that might occur on fields treated with dimethoate.

Stebbins (1985) reported that Pacific tree frogs inhabit grasslands, chaparral, woodlands, forests, deserts, and farmlands. However, like CRLF, the preferred habitat of Pacific tree frog includes surface water (e.g., springs, ponds, streams, swamps) and moist environments (e.g., wells, rotting logs, burrows; Owen, 2000; Morey, 2005). Resident Pacific tree frogs have an average home range radius of 33 m and migratory frogs can range up to 400 m (Morey, 2005). As with small mammals, it seems unlikely that a CRLF would encounter tree frogs or other small amphibian prey that might occur on fields treated with dimethoate.

As discussed in the risk hypotheses section (Section 2.9), given the mode of action of dimethoate and the preferred habitat of CRLF, it is unlikely that the frogs will consume significant quantities of terrestrial arthropods on the field at the time of, or shortly after application. Many arthropods are expected to be immobilized due to the efficacy of the product at label application rates. Further, CRLF feeding seems to be triggered by movement (Hayes and Tennant, 1985).

The information suggests that the diet of CRLF may contain little to no dimethoate residues. However, there are insufficient data to suggest a point estimate percentage of each feed item that might contain residues. Therefore, we conservatively assumed that 100% of CRLFs diet contains dimethoate residues, and that 100% of their vertebrate prey (Pacific tree frog and

California mouse) diet also carries dimethoate residues. In addition, we assumed that their terrestrial arthropod prey are on the field at the time of, and shortly after application of dimethoate (Section 2.1.5). CRLF aquatic prey would only be exposed to dimethoate by direct contact in the water column if field runoff or drift reached their aquatic habitat. Although it is unlikely that field applications would result in dimethoate reaching all nearby waterbodies, in this assessment we assume that both runoff and drift reach the stagnant standard pond, and that this waterbody is the source of all aquatic prey for CRLF (see Section 3.1.2.3 for standard pond EECs). The assumptions above are highly conservative and will lead to overestimation of CRLF exposure.

Concentrations of Dimethoate in Prey

To account for multiple applications, first-order exponential degradation and dissipation of dimethoate in both the aquatic and terrestrial environment was assumed. For terrestrial arthropods and vegetation being consumed by California mouse prey 95th percentile residues were used for each application. Dissipation of these residues was modeled between applications with the estimated half-lives presented below. For aquatic prey (e.g., fish and invertebrates), BCFs were applied to screening-level aquatic EECs generated with PRZM/EXAMS (see Section 3.1.2.3).

Four days (96 hours) was selected as a conservative chronic averaging period because this duration represents less than 5% of the exposure period of the toxicity test (22-week dietary exposure of bobwhite quail; Gallagher et al., 1996a) used to derive the chronic effects metric for terrestrial-phase amphibians. Residue concentrations on feed items were averaged for four days for chronic exposure estimates.

<u>Residues Carried by Aquatic Prey</u>

Dimethoate concentrations in fish and aquatic invertebrates were estimated using a bioconcentration factor (BCF) approach. A BCF is the ratio of the average concentration of a substance in the tissues of an organism to the average concentration of the substance in the water in which the organism occurs. The concentration in fish and aquatic invertebrate prey was estimated using the following equation:

$$C_{aquatic\ prey} = C_{water} \times BCF \qquad \textbf{Equation 4-5}$$

where C_{water} is the peak or 4-day average concentration of dimethoate in surface water predicted by PRZM/EXAMS. Because no measured BCF values for fish and aquatic invertebrates were available, the approach of Arnot and Gobas (2004) was used to estimate the bioconcentration for dimethoate:

$$BCF = \frac{C_{aquatic\,prey}}{C_{water}} = F_{lipid} \times K_{ow} + OMF_{nl} \times OMOPC_{nl} \times K_{ow} + F_{water} \qquad \textbf{Equation 4-6}$$

where:

$C_{aquatic\,prey}$ is the concentration in the prey item (mg/kg ww)
C_{water} is the concentration in surface water predicted by PRZM/EXAMS (mg/L)
F_{lipid} is the lipid fraction (kg/L) of the prey item
K_{ow} is the octanol-water partitioning coefficient (unitless)
OMF_{nl} is the non-lipid organic matter fraction (i.e., carbohydrate and protein) (kg/L) of the prey item
$OMOPC_{nl}$ is the non-lipid organic matter-octanol proportionality constant (i.e., proportionality constant for the partitioning of carbohydrates and proteins (unitless)
F_{water} is the water fraction of the species calculated as 1 - (lipid fraction + non-lipid fraction) (kg/L).

The values for these input parameters are provided in Table 4-6 and Table 4-7. The Arnot and Gobas (2004) approach yielded BCFs of 0.92 and 1.04 for aquatic invertebrates and fish, respectively. The biotic constituents were assumed to have a density of 1 kg/L (Gobas et al., 1999; Arnot and Gobas, 2004). The calculated BCF was divided by this density to convert from kg/kg to L/kg.

Table 4-6 Input parameters for calculating the bioconcentration factor of dimethoate in fish

Parameter	*Abbreviation*	*Units*	*Value*
Lipid fraction[a]	$F_{lipid\text{-}fish}$	kg/kg	0.049
Octanol-water partitioning coefficient[b]	K_{ow}	unitless	5.06
Non-lipid organic matter fraction[c]	OMF_{nl}	kg/kg	0.2
Non-lipid organic matter-octanol proportionality constant[d]	$OMOPC_{nl}$	unitless	0.035
Water fraction of the prey item[e]	$F_{water\text{-}fish}$	kg/kg	0.75

[a] Averages from Morrison et al. (1997, 1999), Drouillard et al. (1996), Russell (1996) and Oliver and Niimi (1988). A summary of these studies is available in the SETAC Supplemental Data Archive, Item ETC-23-10-002 of Arnot and Gobas (2004).
[b] See Table 2-6.
[c] See Morrison et al. (1997), Oliver and Niimi (1988), Russell (1996) and Arnot and Gobas (2004).
[d] See Gobas et al. (1999) and Arnot and Gobas (2004).
[e] Calculated using 1 - (lipid fraction + non-lipid fraction).

Table 4-7 Input parameters for calculating the bioconcentration factor of dimethoate in aquatic invertebrates			
Parameter	***Abbreviation***	***Units***	***Value***
Lipid fraction[a]	$F_{lipid\text{-}invertebrates}$	kg/kg	0.016
Octanol-water partitioning coefficient[b]	K_{ow}	unitless	5.06
Non-lipid organic matter fraction[c]	OMF_{nl}	kg/kg	0.2
Non-lipid organic matter-octanol proportionality constant[d]	$OMOPC_{nl}$	unitless	0.035
Water fraction of the prey item[e]	$F_{water\text{-}invertebrates}$	kg/kg	0.78

[a] Averages from Morrison et al. (1997, 1999), Drouillard et al. (1996), Russell (1996) and Oliver and Niimi (1988). A summary of these studies is available in the SETAC Supplemental Data Archive, Item ETC-23-10-002 of Arnot and Gobas (2004).
[b] See Table 2-6.
[c] See Morrison et al. (1997), Oliver and Niimi (1988), Russell (1996) and Arnot and Gobas (2004).
[d] See Gobas et al. (1999) and Arnot and Gobas (2004).
[e] Calculated using 1 - (lipid fraction + non-lipid fraction).

The BCFs of 0.92 and 1.04 for aquatic invertebrates and fish, respectively, were used to estimate dimethoate concentrations in aquatic invertebrates and fish by multiplying the appropriate BCF by the 90th percentile of the 30-year peak concentrations in the standard (2 m deep) pond predicted by PRZM/EXAMs for each respective acute exposure scenario. For chronic exposure scenarios, the BCF was multiplied by the 90th percentile of the 30-year peak 96-hour average concentrations in the standard (2 m deep) pond predicted by PRZM/EXAMs for each respective chronic exposure scenario. The peak and 96-hour EECs are presented in Table 3-7. An explanation of the selected duration was provided above.

Residues Carried by Terrestrial Arthropods

Initial residues on terrestrial arthropods were estimated using the residue data presented in Barber et al. (2005 [MRID 47841001]), which collated the pesticide residue measurements for crop-dwelling, soil-dwelling and flying insects from 67 industry datasets found in 21 GLP compliant studies. Crop-dwelling arthropod residues were used as conservative estimates (as residues were typically much lower on flying insects and soil-dwelling arthropods; Barber et al., 2005). Orchard and vineyard crop-dwelling arthropods on average had slightly higher residues, but with lower variability than leafy crop-dwelling arthropods (see Table 4-8 and Table 4-9). The results of Knäbe (2004a [MRID 46486401], 2004b [MRID 46525902]), which were Cheminova commissioned studies of pesticide residues on arthropods in orchards, were added to the Barber et al. (2005) dataset for orchard/vineyard crop-dwelling arthropods.

Residue data were reported from Day 0 to Day 7 in Barber et al. (2005). However, depending on the trial values were not consistently reported for all days in this range. Peak residues were typically observed on Day 0 or Day 1. Where data were available (i.e., at least one of Day 0 or Day 1 residue values were measured and reported), the maximum of Day 0 and 1 RUDs reported in Barber et al. (2005) and Knäbe (2004a,b) were compiled. The data were tested for lognormality (using ProUCL Version 4, Shapiro-Wilks p>0.05). The maximum likelihood estimators (MLE; i.e., mean and standard deviation of data logarithms) were used to define RUD distributions, and the 95th percentiles of those estimated distributions were used as conservative point estimates for leafy crop-dwelling and orchard-dwelling arthropods. These results are summarized in Table 4-8 and Table 4-9 below, respectively.

The resulting 95th percentile single application RUDs for orchard/vineyards and leafy crops were 62.5 (n=17) and 66.6 (n=7) mg a.i./kg ww arthropod per lb a.i./A, respectively (See Table 4-8 and Table 4-9). The orchard/vineyard RUD 95th percentile estimates were used for Christmas tree nurseries airblast scenarios and cottonwood aerial and chemigation scenarios (Table 4-9). All other terrestrial-phase amphibian exposure scenarios used the leafy crop-dwelling RUD 95th percentile estimate (Table 4-8).

Peak and 96-hour average residues on terrestrial arthropods were estimated by multiplying each application rate in lb a.i./A by the dimethoate 95th percentile estimated RUD. These residue values were then degraded using the dissipation half-life (DT_{50} = 0.86 days) for crop-dwelling arthropods reported in Knäbe (2004a) assuming a first-order decay model. For multiple applications, the remaining residues from the previous application(s) were added to the residues resulting from the subsequent application and degraded in the same way. The highest four-day average residue concentration in the 365 days following the first application was used for each chronic exposure scenario. For acute exposures, the highest estimated residue concentrations in the 365 days following the first application were used in the calculation of the acute *TDI* exposure estimates.

Table 4-8 Terrestrial leafy crop-dwelling arthropod RUD data and distribution assumptions used in the exposure modeling for terrestrial-phase amphibians[a]

Sponsor	*Location*	*Pesticide Type*	*Application Rate (kg a.i./ha)*	*Crop*	*Maximum of Day 0 and Day 1 RUDs[b](mg a.i. /kg arthropod ww per kg a.i./ha)*	*Maximum of Day 0 and Day 1 RUDs (mg a.i./kg arthropod ww per lb a.i./A)*	*ln(mg a.i./kg arthropod ww per lb a.i./A)*
BASF	Germany	Fungicide	0.72	Vegetable (endive)	6.93	7.77	2.05
BASF	Italy	Fungicide	0.48	Vegetable (french beans)	75.6	84.7	4.44
BASF	USA	Insecticide	0.224	Cotton	5.71	6.40	1.86
BASF	USA	Insecticide	0.392	Cotton	6.33	7.09	1.96
Dow Agro-Sciences	USA	Insecticide	1.1	Alfalfa	0.93	1.04	0.04
Bayer	Germany	Insecticide	0.469	Potatoes	1.26	1.41	0.34
Bayer	Germany	Insecticide	0.469	Potatoes	7.68	8.60	2.15
						Mean (of ln data)	1.83
						Standard deviation (of ln data)	1.44
						95th percentile of maximum Day 0 and Day 1 combined RUD estimates (mg a.i./kg arthropod ww per lb a.i./A)	66.6

[a] Data from Barber et al., 2005 [MRID 47841001]

[b] Calculated by dividing the maximum of Day 0 and Day 1 residues by the application rate

Table 4-9 Terrestrial orchard/vineyard-dwelling arthropod RUD data and distribution assumptions used in the *TDI* modeling for terrestrial-phase amphibians[a]

Sponsor	*Location*	*Pesticide Type*	*Rate (kg a.i./ha)*	*Crop*	*Maximum of Day 0 and Day 1 RUDs[b](mg a.i. /kg arthropod ww per kg a.i./ha)*	*Maximum of Day 0 and Day 1 RUDs (mg a.i./kg arthropod ww per lb a.i./A)*	*ln(mg a.i./kg arthropod ww per lb a.i./A)*
BASF	Germany	Fungicide	0.72	Apple	14.4	16.2	2.78
BASF	Germany	Fungicide	0.48	Vine	1.58	1.77	0.57
BASF	Italy	Fungicide	0.72	Apple	12.5	14.1	2.64
BASF	Italy	Fungicide	0.96	Vine	5.82	6.53	1.88
Bayer	Italy	Fungicide	0.385	Apple	14.7	16.4	2.80
Bayer	Germany	Insecticide	0.105	Apple	48.6	54.4	4.00
Bayer	Germany	Insecticide	0.0995	Apple	13.0	14.5	2.68
Bayer	Germany	Insecticide	0.154	Vine	9.94	11.1	2.41

Table 4-9 Terrestrial orchard/vineyard-dwelling arthropod RUD data and distribution assumptions used in the *TDI* modeling for terrestrial-phase amphibians[a]

Sponsor	*Location*	*Pesticide Type*	*Rate (kg a.i./ha)*	*Crop*	*Maximum of Day 0 and Day 1 RUDs[b](mg a.i. /kg arthropod ww per kg a.i./ha)*	*Maximum of Day 0 and Day 1 RUDs (mg a.i./kg arthropod ww per lb a.i./A)*	*ln(mg a.i./kg arthropod ww per lb a.i./A)*
Aventis	UK	Insecticide	2.5	Apple	44.8	50.2	3.92
Aventis	UK	Insecticide	2.5	Apple	26.8	30.0	3.40
Dow AgroSciences	USA	Insecticide	2.3	Orange	2.88	3.23	1.17
Syngenta	France	Insecticide	0.05	Orchard	40.6	45.5	3.82
Cheminova	Spain	Insecticide	0.72	Orchard	7.78	8.72	2.17
Cheminova	Spain	Insecticide	1.81	Orchard	5.20	5.83	1.76
Syngenta	Spain	Insecticide	0.0216	Orchard	3.24	3.63	1.29
Syngenta	Spain	Insecticide	0.0216	Orchard	11.1	12.5	2.52
Syngenta	Spain	Herbicide	1.1	Orchard	1.69	1.90	0.64
Mean (of ln data)							2.38
Standard deviation (of ln data)							1.07
95th percentile of maximum Day 0 and Day 1 combined RUD estimates (mg a.i./kg arthropod ww per lb a.i./A)							62.5

[a] Data from Barber et al. (2005 [MRID 47841001]) and Knäbe (2004a [MRID 46486401], 2004b [MRID 46525902])
[b] Calculated by dividing the maximum of Day 0 and Day 1 residues by the application rate

Residues on Vegetation

Dimethoate-specific 95[th] percentile RUDs were estimated for vegetation in the diet of the California mouse. To calculate dimethoate specific RUDs, measured residue data from GLP field studies (Corden, 2000, 2001, 2005; Goodband, 2003; Knabe, 2004a; Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001a-l, 2002a-f, 2003 a,b) were sorted into feed item categories (i.e., short grass, long/tall grass, small fruit, large fruit and forage/leafy crop). The RUDs were determined for each trial within the database. For data where single applications of dimethoate were applied, the measured 0 DALA (days after the last application) residue was used. In many studies there were multiple applications of dimethoate on the field. To account for the possibility that some residual dimethoate could be on the field just prior to the next application, the calculated DT_{50} per trial (as described below) was used to degrade the pesticide between applications across each study. This information was used to subtract an estimate of residues remaining from previous applications from the 0 DALA residue measurement following a final, of multiple, applications. The 95[th] percentile RUD estimates for small fruits and short grass were used to estimate residues on feed items in the mouse diet (see Table 4-10).

Where there was 0 DALA residue data but no trial-specific DT_{50}, the mean DT_{50} from all trials was used to degrade the dimethoate between applications. To calculate the 95[th] percentile RUDs for each feed item, the average RUD distribution was tested in ProUCL for goodness of fit. The data were then plotted using the appropriate distribution (i.e. normal, lognormal, gamma). Based on the full distribution the 95[th], 90[th] and 50[th] percentile RUDs were calculated per feed item. Average DT_{50s} were calculated by averaging the full dataset DT_{50s} for each feed item category.

Half-lives for the feed item categories were estimated using the same measured residue data used to derived RUDs (Corden, 2000, 2001, 2005; Goodband, 2003; Knabe, 2004a; Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001a-l, 2002a-f, 2003 a,b). For each field trial, a linear model was fit to the logarithm of measured residues (mg/kg) over time from application. Prior to calculating the DT_{50}, the linear regression (assuming first order exponential degradation) for each trial was plotted to ensure that the assumption of linearity was met (by visual inspection of log residues vs. time). Feed item half-lives (DT_{50s}) were calculated using the slope from the linear regression model. Data that were below the limit of detection were not included in the calculation of the DT_{50}. The estimated half-lives for dimethoate on small fruits and short grass were used to model the dissipation of dimethoate on the non-arthropod feed items of the California mouse (see Table 4-10).

Table 4-10 California mouse diet 95th percentile dimethoate RUDs and dissipation half-life estimates		
Feed Item	*95th Percentile RUDs*	*Mean Half-Life (d)*
Short grass[a]	122	1.33
Small fruit[b]	12.2	4.90

[a] Used for leaves in the mouse diet and as a conservative surrogate for fungi.
[b] Used for berries, seeds and nuts in the diet of the mouse.

Residues Carried by Terrestrial Vertebrate Prey

Peak *TDI* estimates for Pacific tree frog (peak four-day average for chronic exposure in the diet) and California mouse were used directly as residue estimates (mg a.i./kg bw) for these adult CRLF prey. No evidence of significant dimethoate accumulation in animal tissue could be found. This is likely due to the fact that dimethoate is rapidly metabolised and excreted by birds and mammals, as discussed below.

Kirkpatrick et al. (1995) orally administered radiolabelled nominal doses of 10 and 100 mg/kg bw to rats (5 males and 5 females per treatment group). Patterns of excretion were similar following dose administration. Pre-treatment of rats with non-radiolabelled dimethoate for 14 days did not alter their pattern of excretion of a subsequent 10 mg/kg oral dose. Excretion was rapid. On average, 59-72% of radioactivity was excreted in urine within 6 hours of dosing, and 82-96% was excreted in urine within 24 hours of dosing. About 3% was expired in the air, found in the cage was or excreted in feces in the first 24 hours following dosing. Five days following final dosing kidney and liver tissues contained the highest levels of radioactivity. Dimethoate in the kidneys of sacrificed animals was estimated to be up to 0.3% of the original dose. Dimethoate in the livers of sacrificed animals was estimated to be 0.1 to 0.2% of the original dose, with other metabolites accounting for the majority of liver radioactivity. Sanderson and Edson (1964) reported that over 75% of radioactivity was excreted in the feces and urine of rats within 24 hours of being dosed with radiolabelled dimethoate. Similar findings were also reported for humans (Sanderson and Edson, 1964). Thus, the assumption that the California mouse peak *TDI* represents a conservative estimate of dimethoate residue in this prey is supported by available metabolism and excretion data in mammals.

Jalali et al. (1995) orally dosed white leghorn hens (three groups of five) with the 0.9 mg/kg bw for seven consecutive days. Metabolism was reportedly rapid, with no detection of dimethoate in tissues, egg, excreta or blood extracts following sacrifice 22 - 24 hours after the final dose. Mean cumulative radioactivity recovered in excreta and cage wash was 75% (Jalali et al., 1995). Similarly, pheasant reportedly excreted 70% within 24 hours of dosing (Sanderson and Edson, 1964).

No data were available for the rates of metabolism and/or excretion of dimethoate in terrestrial-phase amphibians.

The main *TDI* input parameters described above are summarized in Table 4-11 to Table 4-16.

Table 4-11 Residues assumed on dietary items in the screening-level effects determination for terrestrial-phase amphibians (mg a.i./kg ww feed item)[a]

Exposure Scenario			Terrestrial Arthropods		Aquatic Invertebrates		Fish		Mouse
Crop/Use	Application Rate (lb a.i./A) /Applications per Season/ Interval (d)	Application Method	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute
Broccoli	0.5/3/7	Groundspray	33.4	14.5	0.021	0.020	0.023	0.023	5.17
Broccoli	0.5/3/7	Aerial	33.4	14.5	0.023	0.022	0.026	0.025	5.17
Christmas tree nurseries	1/3/14	Groundspray	66.6	28.9	0.014	0.013	0.016	0.015	9.7
Christmas tree nurseries	1/3/14	Airblast	62.5	27.1	0.016	0.016	0.018	0.018	9.7
Cottonwood grown for pulp	2/3/10	Aerial	125.0	54.2	0.056	0.054	0.063	0.061	19.8
Cottonwood grown for pulp	2/3/10	Chemigation	125.0	54.2	0.053	0.051	0.060	0.058	19.8
Non-cropland areas adjacent to vineyards	2/2/14	Groundspray	133	57.8	0.009	0.008	0.010	0.009	19.3
Peppers	0.33/5/7	Groundspray	22.1	9.57	0.006	0.006	0.007	0.006	3.44
Peppers	0.33/5/7	Aerial	22.1	9.57	0.008	0.008	0.009	0.009	3.44
Turnip	0.25/7/3	Groundspray	18.3	7.93	0.002	0.002	0.003	0.002	3.43
Turnip	0.25/7/3	Aerial	18.3	7.93	0.005	0.005	0.006	0.005	3.43
Wheat (2)	0.67/2/7	Groundspray	44.8	19.4	0.015	0.015	0.017	0.017	6.80
Wheat (2)	0.67/2/7	Aerial	44.8	19.4	0.017	0.017	0.020	0.019	6.80

[a] The concentrations in amphibian prey of adult CRLF are presented in Table 4-21 (*TDI* model estimates for Pacific tree frog).

Table 4-12 Assumptions for calculating metabolizable energy of amphibian feed items in the screening-level *TDI* modeling

Dietary Item	Aquatic Invertebrates	Terrestrial Arthropods	Fish	Amphibians	Mammals
Gross energy (kcal/kg ww)	880	1600	1200	1200	1700
Assimilation efficiency (unitless)	0.77	0.72	0.79	0.79	0.78

Table 4-13 Assumptions for calculating metabolizable energy of California mouse feed items in the screening-level *TDI* modeling

Dietary Item	*Terrestrial Arthropods*	*Leaves*	*Fungi*	*Berries*	*Seeds and Nuts*
Gross energy (kcal/kg dw)	5161	4200	4141	2000	5100
Assimilation efficiency (unitless)	0.87	0.73	0.73[a]	0.73[a]	0.85

[a] Reported for voles and mice consuming green forbs, used as a surrogate for mice consuming fungi and berries.

Table 4-14 Input parameters specific to the CRLF

Input Parameter	*Juvenile*	*Adult*
Body weight (BW; g ww)	12.2	131.9
FMR (kcal/kg ww/d)	35.5	27.2
Best-case diet (by ww)	100% aquatic invertebrates	100% aquatic invertebrates
Intermediate-case diet (by ww)	50% aquatic invertebrates; 50% terrestrial arthropods	25% each of aquatic invertebrates, fish, amphibians and terrestrial arthropods
Worst-case diet (by ww)	100% terrestrial arthropods	100% terrestrial arthropods

Table 4-15 Input parameters specific to the Pacific tree frog

Input Parameter	*Value*
Body weight (BW; g ww)	2.27
FMR (kcal/kg ww/d)	42.8
Diet (by ww)	19% aquatic invertebrates; 81% terrestrial arthropods

Table 4-16 Input parameters specific to the California mouse

Input Parameter	*Value*
Body weight (BW; g ww)	40.7
FMR (kcal/kg ww/d)	451
Diet (by ww)	12% terrestrial arthropods; 25% leaves; 4% fungi; 7% berries; and 52% seeds and nuts

4.1.2.3 Terrestrial-Phase Amphibian Screening-Level Exposure Estimates

Screening-level exposure estimates for terrestrial-phase CRLF and their amphibian prey (Pacific tree frog) are presented below (see Table 4-17 to Table 4-21).

Acute dimethoate *TDI* estimates for the juvenile CRLF ranged from 1.16E-04 to 2.92E-03 mg a.i./kg bw/d for the best-case (100% aquatic invertebrate) diet, with the highest estimates seen for aerial application to cottonwood grown for pulp (2 lb a.i./A, 3 applications per season, 10-day retreatment interval).

Juvenile CRLF acute *TDI* estimates for the intermediate-case (50% aquatic invertebrate and 50% terrestrial arthropod) diet ranged from 0.355 to 2.58 mg a.i./kg bw/d with the highest estimate being ground application to non-cropland areas adjacent to vineyards (2 lb a.i./A, 2 applications per season, 14-day retreatment interval).

Juvenile CRLF acute *TDI* estimates for the worst-case (100% terrestrial arthropod) diet ranged from 0.563 to 4.10 mg a.i./kg bw/d, with the highest *TDI* calculated for ground application to non-cropland areas adjacent to vineyards (2 lb a.i./A, 2 applications per season, 14-day retreatment interval), followed by aerial and chemigation applications to cottonwood grown for pulp (2 lb a.i./A, 3 applications per season, 10-day retreatment interval).

Screening-level acute *TDI* estimates for juvenile CRLF are summarized in Table 4-17.

Table 4-17 Acute screening-level dimethoate *TDI* estimates for juvenile CRLF[a]

Crop/Use	*Scenario (lb. a.i./A)/No. Applications per Season/Retreatment Interval (d)*	*Application Method*	*Best-case TDI (mg a.i./kg bw/d)*[b]	*Intermediate-case TDI (mg a.i./kg bw/d)*[c]	*Worst-caseTDI (mg a.i./kg bw/d)*[d]
Broccoli	0.5/3/7	Aerial	1.18E-03	0.649	1.03
Broccoli	0.5/3/7	Groundspray	1.08E-03	0.649	1.03
Christmas tree nurseries	1/3/14	Airblast	8.54E-04	1.21	1.92
Christmas tree nurseries	1/3/14	Groundspray	7.29E-04	1.29	2.05
Cottonwood grown for pulp	2/3/10	Aerial	2.92E-03	2.43	3.85
Cottonwood grown for pulp	2/3/10	Chemigation	2.77E-03	2.43	3.85
Non-cropland areas adjacent to vineyards	2/2/14	Groundspray	4.49E-04	2.58	4.10
Peppers	0.33/5/7	Aerial	4.30E-04	0.428	0.680
Peppers	0.33/5/7	Groundspray	3.09E-04	0.428	0.680
Turnip	0.25/7/3	Aerial	2.61E-04	0.355	0.563
Turnip	0.25/7/3	Groundspray	1.16E-04	0.355	0.563
Wheat (2)	0.67/2/7	Aerial	9.07E-04	0.869	1.38
Wheat (2)	0.67/2/7	Groundspray	8.06E-04	0.869	1.38

[a] Based on estimated 95th percentile peak residues for terrestrial arthropods and residues in aquatic invertebrates based on modelled 90th percentile peak concentrations in water following application.

[b] Best-case diet for juvenile CRLF consists of 100% aquatic invertebrates

[c] Intermediate-case diet for juvenile CRLF consists of 50% aquatic invertebrates and 50% terrestrial arthropods by wet weight

[d] Worst-case diet for juvenile CRLF consists of 100% terrestrial arthropods

Chronic dimethoate *TDI* estimates for the juvenile CRLF ranged from 1.08E-04 to 2.83E-03 mg a.i./kg bw/d for the best-case diet, with the highest estimates seen for aerial application to cottonwood grown for pulp. *TDI* estimates for the intermediate-case and worst-case diets ranged from 0.154 to 1.12, and 0.295 to 1.78 mg a.i./kg bw/d, respectively, with the maximum values associated with groundspray applications to non-cropland areas adjacent to vineyards, followed by aerial and chemigation applications to cottonwood. Screening-level chronic *TDI* estimates for juvenile CRLF are summarized in Table 4-18.

Table 4-18 Chronic screening-level dimethoate *TDI* estimates for juvenile CRLF[a]

Crop/Use	*Scenario (lb. a.i./A)/No. Applications per Season/Retreatment Interval (d)*	*Application Method*	*Best-case TDI (mg a.i./kg bw/d)[b]*	*Intermediate-case TDI (mg a.i./kg bw/d)[c]*	*Worst-caseTDI (mg a.i./kg bw/d)[d]*
Broccoli	0.5/3/7	Aerial	1.14E-03	0.282	0.447
Broccoli	0.5/3/7	Groundspray	1.04E-03	0.282	0.447
Christmas tree Nurseries	1/3/14	Airblast	8.27E-04	0.526	0.835
Christmas tree Nurseries	1/3/14	Groundspray	7.06E-04	0.561	0.890
Cottonwood grown for pulp	2/3/10	Aerial	2.83E-03	1.05	1.67
Cottonwood grown for pulp	2/3/10	Chemigation	2.67E-03	1.05	1.67
Non-cropland Areas Adjacent to Vineyards	2/2/14	Groundspray	4.34E-04	1.12	1.78
Peppers	0.33/5/7	Aerial	4.14E-04	0.186	0.295
Peppers	0.33/5/7	Groundspray	3.00E-04	0.186	0.295
Turnip	0.25/7/3	Aerial	2.47E-04	0.154	0.373
Turnip	0.25/7/3	Groundspray	1.08E-04	0.154	0.373
Wheat (2)	0.67/2/7	Aerial	8.87E-04	0.377	0.598
Wheat (2)	0.67/2/7	Groundspray	7.88E-04	0.377	0.598

[a] Based on estimated 95th percentile peak four-day average residues on terrestrial arthropods and residues in aquatic invertebrates based on modelled 90th percentile four-day average peak concentrations in water following application.
[b] Best-case diet for juvenile CRLF consists of 100% aquatic invertebrates.
[c] Intermediate-case diet for juvenile CRLF consists of 50% aquatic invertebrates and 50% terrestrial arthropods by wet weight.
[d] Worst-case diet for juvenile CRLF consists of 100% terrestrial arthropods.

Acute dimethoate *TDI* estimates for the adult CRLF ranged from 8.87E-05 to 2.24E-03 mg a.i./kg bw/d for the best-case diet, with the highest estimates seen with aerial application to cottonwood grown for pulp.

Adult CRLF acute *TDI* estimates for the intermediate-case diet ranged from 0.138 to 1.00 mg a.i./kg bw/d with the highest estimate seen for non-cropland areas adjacent to vineyards, followed closely by aerial and chemigation applications to cottonwood grown for pulp.

Adult CRLF acute *TDI* estimates for the worst-case diet scenarios ranged from 0.431 to 3.14 mg a.i./kg bw/d, with the maximum *TDI* estimate associated with non-cropland areas adjacent to vineyards by ground application, followed by applications to cottonwood grown for pulp.

Modeling of the ingestion of a whole mouse resulted in *TDI* estimates of 1.06 to 6.12 mg a.i./kg bw/d. The highest estimates were for aerial and chemigation applications to cottonwood. Mouse dimethoate ingestion estimates were nearly twice the worst-case diet based on *FMR*. A CRLF consuming a mouse would likely be taking in more than twice their daily *FMR*.

Screening-level acute *TDI* estimates for adult CRLF are summarized in Table 4-19.

Table 4-19 Acute screening-level dimethoate *TDI* estimates for adult CRLF[a]

Crop/Use	*Scenario (lb. a.i./A)/No. Applications per Season/Retreatment Interval (d)*	*Application Method*	*Best-case TDI (mg a.i./kg bw/d)*[b]	*Intermediate-case TDI (mg a.i./kg bw/d)*[c]	*Worst-caseTDI (mg a.i./kg bw/d)*[d]	*Whole Mouse TDI (mg a.i./kg bw/d)*
Broccoli	0.5/3/7	Aerial	9.06E-04	0.252	0.788	1.60
Broccoli	0.5/3/7	Groundspray	8.28E-04	0.252	0.788	1.60
Christmas tree nurseries	1/3/14	Airblast	6.54E-04	0.471	1.47	2.99
Christmas tree nurseries	1/3/14	Groundspray	5.58E-04	0.502	1.57	2.99
Cottonwood grown for pulp	2/3/10	Aerial	2.24E-03	0.942	2.95	6.12
Cottonwood grown for pulp	2/3/10	Chemigation	2.12E-03	0.942	2.95	6.12
Non-cropland areas adjacent to vineyards	2/2/14	Groundspray	3.44E-04	1.004	3.14	5.96
Peppers	0.33/5/7	Aerial	3.29E-04	0.166	0.520	1.06
Peppers	0.33/5/7	Groundspray	2.37E-04	0.166	0.520	1.06
Turnip	0.25/7/3	Aerial	2.00E-04	0.138	0.431	1.06
Turnip	0.25/7/3	Groundspray	8.87E-05	0.138	0.431	1.06
Wheat (2)	0.67/2/7	Aerial	6.95E-04	0.338	1.06	2.10
Wheat (2)	0.67/2/7	Groundspray	6.17E-04	0.338	1.06	2.10

[a] Based on estimated 95[th] percentile peak residues on terrestrial arthropods and associated peak *TDI* estimates for amphibian and small mammal prey and residues in aquatic invertebrates based on modelled 90[th] percentile peak concentrations in water following application.
[b] Best-case diet for adult CRLF consists of 100% aquatic invertebrates.
[c] Intermediate-case diet for adult CRLF consists of 25% aquatic invertebrate, 25% fish, 25% terrestrial arthropods and 25% terrestrial-phase amphibians by wet weight.
[d] Worst-case diet for adult CRLF consists of 100% terrestrial arthropods.

Chronic dimethoate *TDI* estimates for the adult CRLF ranged from 8.25E-05 to 2.17E-03 mg a.i./kg bw/d for the best-case diet, with the highest estimates seen for use on cottonwood grown for pulp.

Adult CRLF chronic *TDI* estimates for the intermediate-case diet ranged from 0.0722 to 0.435 mg a.i./kg bw/d with the highest estimate for non-cropland areas adjacent to vineyards, followed closely by applications to cottonwood grown for pulp.

Adult CRLF chronic *TDI* estimates for the worst-case diet ranged from 0.226 to 1.36 mg a.i./kg bw/d, with the highest *TDI* estimates also associated with non-cropland areas adjacent to vineyards by ground application.

Screening-level chronic *TDI* estimates for adult CRLF are summarized in Table 4-20.

Table 4-20 Chronic dimethoate *TDI* estimates for adult CRLF[a]

Crop/Use	*Scenario (lb. a.i./A)/No. Applications per Season/Retreatment Interval (d)*	*Application Method*	*Best-case TDI (mg a.i./kg bw/d)*[b]	*Intermediate-case TDI (mg a.i./kg bw/d)*[c]	*Worst-caseTDI (mg a.i./kg bw/d)*[d]
Broccoli	0.5/3/7	Aerial	8.72E-04	0.110	0.342
Broccoli	0.5/3/7	Groundspray	7.98E-04	0.110	0.342
Christmas Tree Nurseries	1/3/14	Airblast	6.34E-04	0.204	0.639
Christmas Tree Nurseries	1/3/14	Groundspray	5.40E-04	0.218	0.682
Cottonwood grown for pulp	2/3/10	Aerial	2.17E-03	0.409	1.28
Cottonwood grown for pulp	2/3/10	Chemigation	2.05E-03	0.409	1.28
Non-cropland Areas Adjacent to Vineyards	2/2/14	Groundspray	3.32E-04	0.435	1.36
Peppers	0.33/5/7	Aerial	3.17E-04	0.0722	0.226
Peppers	0.33/5/7	Groundspray	2.30E-04	0.0722	0.226
Turnip	0.25/7/3	Aerial	1.89E-04	0.0912	0.285
Turnip	0.25/7/3	Groundspray	8.25E-05	0.0911	0.285
Wheat (2)	0.67/2/7	Aerial	6.79E-04	0.147	0.458
Wheat (2)	0.67/2/7	Groundspray	6.03E-04	0.147	0.458

[a] Based on estimated 95th percentile peak four-day average residues on terrestrial arthropods and residues in aquatic invertebrates based on modelled 90th percentile four-day average peak concentrations in water following application.

[b] Best-case diet for adult CRLF consists of 100% aquatic invertebrates.

[c] Intermediate-case diet for adult CRLF consists of 25% aquatic invertebrate, 25% fish, 25% terrestrial arthropods and 25% terrestrial-phase amphibians by wet weight.

[d] Worst-case diet for adult CRLF consists of 100% terrestrial arthropods.

Acute dimethoate *TDI* estimates for the Pacific tree frog ranged from 0.598 to 4.35 mg a.i./kg bw/d. Chronic *TDI* estimates ranged from 0.313 to 1.89 mg a.i./kg bw/d . The highest *TDI* estimates were calculated for groundspray application to non-cropland areas adjacent to vineyards, followed by applications to cottonwood grown for pulp.

Screening-level *TDI* estimates for the Pacific tree frog are summarized in Table 4-21 below.

Table 4-21 Screening-level dimethoate *TDI* estimates for Pacific tree frog

Crop/Use	*Scenario (lb. a.i./A)/No. Applications per Season/Retreatment Interval (d)*	*Application Method*[a]	*Acute TDI Estimate (mg a.i./kg bw/d)*[b]	*Chronic TDI Estimate (mg a.i./kg bw/d)*[c]
Broccoli	0.5/3/7	Aerial and groundspray	1.09	0.474
Christmas Tree Nurseries	1/3/14	Airblast	2.04	0.886
Christmas Tree Nurseries	1/3/14	Groundspray	2.18	0.945
Cottonwood grown for pulp	2/3/10	Aerial and chemigation	4.09	1.77
Non-cropland Areas Adjacent to Vineyards	2/2/14	Groundspray	4.35	1.89
Peppers	0.33/5/7	Aerial and Groundspray	0.721	0.313
Turnip	0.25/7/3	Aerial and Groundspray	0.598	0.395
Wheat (2)	0.67/2/7	Aerial and Groundspray	1.46	0.635

[a] At three significant digits, no difference in *TDI* values is seen between application methods for the same crop/use.
[b] Based on estimated 95th percentile peak terrestrial arthropods residues and residues in aquatic invertebrates based on modelled 90th percentile peak concentrations in water following application.
[c] Based on estimated 95th percentile peak four-day average terrestrial residues and residues in aquatic invertebrates based on modelled 90th percentile four-day average peak concentrations in water following application.

In general, *TDI* estimates for terrestrial-phase CRLF and their amphibian prey (Pacific tree frog) seemed most strongly influenced by diet, *FMR* and application rates. Retreatment intervals and number of applications per season seemed to have less influence on the *TDI* results.

4.1.2.4 Exposure of Terrestrial Plants to Dimethoate

The maximum application rates were used in TerrPlant (version 1.2.2) to estimate EECs (Table 3-3). EECs from single applications of dimethoate ranged from 0.002 to 1.1 lb a.i./A. EECs from multiple applications ranged from 0.002 lb a.i./A to 1.27 lb a.i./A. These EECs were then compared to the NOEL for 10 monocot and dicot crops to estimate risk to the structure of the plant community in terrestrial environments (Table 4-26 and Table 4-27 below).

4.1.3 Terrestrial Screening-Level Risk Characterization

Risk characterization integrates the exposure and effects assessments to determine the potential risk of exposure scenarios for both direct and indirect effects on the terrestrial-phase CRLF. The screening-level effects determination evaluated risks using RQs that were calculated by dividing estimated exposure metrics (e.g., estimated daily dose) by acute and chronic effects metrics (e.g., LC50, LD50, NOEL). For acute effects, the RQs for direct effects to adult CRLF were compared to the Agency's LOC's for endangered species (>0.1), while the LOC of 0.5 was used for amphibian prey (i.e., the Pacific tree frog). Chronic risk was assessed using the chronic LOC of >1 for all amphibians. For plants, the RQs were compared to EPA's LOC for non-listed plants (>1 for terrestrial plants).

4.1.3.1 Direct Risk to the Terrestrial-Phase CRLF

Direct acute and chronic risks to terrestrial-phase CRLFs were assessed using RQs derived for juvenile and adult CRLFs. The acute RQs (Table 4-22 and Table 4-23) were obtained by dividing acute total daily intake (Table 4-17 and Table 4-19) by the acute effects metric of 14.6 mg/kg bw. The chronic RQs (Table 4-22 and Table 4-23) were obtained by dividing the chronic total daily intake (Table 4-17 and Table 4-19) by the chronic effects metric of 1.09 mg/kg bw/d.

Acute screening-level RQs for terrestrial-phase juvenile CRLF ranged from 7.91E-06 to 0.280, with LOC exceedances occurring only for non-cropland areas adjacent to vineyards, cottonwood grown for pulp (for intermediate and worst-case diets) and Christmas tree nursery applications (for worst-case diet only). Under the assumption of the best-case diet, none of the RQs exceeded the acute LOC.

Chronic screening-level RQs for terrestrial-phase juvenile CRLF ranged from 9.88E-05 to 1.63, with LOC exceedances occurring only for applications to non-cropland areas adjacent to vineyards (intermediate and worst-case diets) and cottonwood grown for pulp (worst-case diet only). Despite the longer retreatment intervals (10-14 days), it was the use patterns with the highest rates that posed the highest estimated risk for direct effects to juvenile CRLF. Results are summarized in Table 4-22.

Table 4-22 Screening-level risk quotients for juvenile CRLF

Crop/Use	Scenario (lb. a.i./A)/No. Applications per season/Retreatment Interval (d)	Application Method	Acute RQs[a]			Chronic RQs[a]		
			Best-case[b]	Intermediate-case[c]	Worst-case[d]	Best-case[b]	Intermediate-case[c]	Worst-case[d]
Broccoli	0.5/3/7	Groundspray	7.38E-05	0.0443	0.0703	9.56E-04	0.258	0.410
Broccoli	0.5/3/7	Aerial	8.08E-05	0.0443	0.0703	1.04E-03	0.258	0.410
Christmas tree nurseries	1/3/14	Groundspray	4.98E-05	0.088	**0.140**	6.47E-04	0.514	0.82
Christmas tree nurseries	1/3/14	Airblast	5.83E-05	0.083	**0.131**	7.59E-04	0.483	0.77
Cottonwood grown for pulp	2/3/10	Aerial	2.00E-04	**0.166**	**0.263**	2.60E-03	0.97	**1.53**
Cottonwood grown for pulp	2/3/10	Chemigation	1.89E-04	**0.166**	**0.263**	2.45E-03	0.97	**1.53**
Non-cropland areas adjacent to vineyards	2/2/14	Groundspray	3.07E-05	**0.176**	**0.280**	3.98E-04	**1.03**	**1.63**
Peppers	0.33/5/7	Groundspray	2.11E-05	0.0292	0.0464	2.75E-04	0.170	0.270
Peppers	0.33/5/7	Aerial	2.93E-05	0.0292	0.0464	3.80E-04	0.170	0.270
Turnip	0.25/7/3	Groundspray	7.91E-06	0.0242	0.0385	9.88E-05	0.215	0.342
Turnip	0.25/7/3	Aerial	1.78E-05	0.0242	0.0385	2.26E-04	0.215	0.342
Wheat (2)	0.67/2/7	Groundspray	5.50E-05	0.0593	0.094	7.23E-04	0.346	0.549
Wheat (2)	0.67/2/7	Aerial	6.20E-05	0.0593	0.094	8.14E-04	0.346	0.549

[a] Bolded values indicate LOC exceedances. LOC are >0.1 and >1 for acute and chronic exposures, respectively.
[b] Best-case diet for juvenile CRLF consists of 100% aquatic invertebrates.
[c] Intermediate-case diet for juvenile CRLF consists of 50% aquatic invertebrates and 50% terrestrial arthropods by wet weight.
[d] Worst-case diet for juvenile CRLF consists of 100% terrestrial arthropods.

Acute screening-level RQs for terrestrial-phase adult CRLF ranged from 6.06E-06 to 0.418, with slight LOC exceedances occurring for applications to Christmas tree nurseries, non-cropland areas adjacent to vineyards and cottonwood grown for pulp assuming a worst-case diet. Ingestion of a whole mouse resulted in LOC exceedances for applications to broccoli, Christmas tree nuseries, non-cropland areas adjacent to vineyards, cottonwood grown for pulp and wheat. Under the assumption of the best-case diet and intermediate diet, none of the RQs exceeded the acute LOC.

Chronic screening-level RQs for terrestrial-phase adult CRLF ranged from 7.57E-05 to 1.25. Chronic RQs exceeded the LOC only for applications to cottonwood grown for pulp and non-cropland areas adjacent to vineyards assuming a worst-case diet. Under the assumptions of the best and intermediate-case diets, none of the chronic RQs exceeded the LOC. Results for adult CRLF are summarized in Table 4-23.

Table 4-23 Screening-level risk quotients for adult CRLF

Crop/Use	Scenario (lb. a.i./A)/No. Applications per season/Retreatment Interval (d)	Application Method	Acute RQs[a]				Chronic RQs[a]		
			Best-case[b]	Intermediate-case[c]	Worst-case[d]	Whole Mouse	Best-case[b]	Intermediate-case[c]	Worst-case[d]
Broccoli	0.5/3/7	Groundspray	5.65E-05	0.0172	0.0538	**0.109**	7.32E-04	0.1005	0.314
Broccoli	0.5/3/7	Aerial	6.18E-05	0.0172	0.0538	**0.109**	8.00E-04	0.1005	0.314
Christmas tree nurseries	1/3/14	Groundspray	3.81E-05	0.0343	**0.107**	**0.204**	4.96E-04	0.200	0.625
Christmas tree nurseries	1/3/14	Airblast	4.47E-05	0.0322	**0.101**	**0.204**	5.81E-04	0.188	0.587
Cottonwood grown for pulp	2/3/10	Aerial	1.53E-04	0.0644	**0.201**	**0.418**	1.99E-03	0.376	**1.17**
Cottonwood grown for pulp	2/3/10	Chemigation	1.45E-04	0.0644	**0.201**	**0.418**	1.88E-03	0.375	**1.17**
Non-cropland Areas Adjacent to Vineyards	2/2/14	Groundspray	2.35E-05	0.0685	**0.215**	**0.407**	3.05E-04	0.399	**1.25**
Peppers	0.33/5/7	Groundspray	1.62E-05	0.0114	0.0355	0.0726	2.11E-04	0.0662	0.207
Peppers	0.33/5/7	Aerial	2.25E-05	0.0114	0.0355	0.0726	2.91E-04	0.0662	0.207
Turnip	0.25/7/3	Groundspray	6.06E-06	9.41E-03	0.0294	0.0723	7.57E-05	0.0836	0.262
Turnip	0.25/7/3	Aerial	1.36E-05	9.41E-03	0.0294	0.0723	1.73E-04	0.0836	0.262
Wheat (2)	0.67/2/7	Groundspray	4.21E-05	0.0231	0.0721	**0.143**	5.54E-04	0.134	0.420
Wheat (2)	0.67/2/7	Aerial	4.74E-05	0.0231	0.0721	**0.143**	6.23E-04	0.134	0.420

[a] Bolded values indicate LOC exceedances. LOC are >0.1 and >1 for acute and chronic exposures, respectively.
[b] Best-case diet for adult CRLF consists of 100% aquatic invertebrates.
[c] Intermediate-case diet for adult CRLF consists of 25% aquatic invertebrate, 25% fish, 25% terrestrial arthropods and 25% terrestrial-phase amphibians by wet weight.
[d] Worst-case diet for adult CRLF consists of 100% terrestrial arthropods.

For indirect effects to terrestrial-phase CRLF via reduction in amphibian prey, direct effects to the Pacific tree frog were considered. Acute RQs for the Pacific tree frog ranged from 0.041 to 0.297, with no exceedances of the acute LOC of 0.5. Chronic RQs for the Pacific tree frog ranged from 0.287 to 1.73. Exceedances of the chronic LOC of 1 where observed only for applications to cottonwood grown for pulp and non-cropland areas adjacent to vineyards (Table 4-24). Again, these were the scenarios with the highest single application rate of 2 lb a.i./A.

Table 4-24 Screening-level risk quotients for Pacific tree frog

Crop/Use	***Scenario (lb. a.i./A)/No. Applications per Season/Retreatment Interval (d)***	***Application Method***	***Acute RQ[a]***	***Chronic RQ[a]***
Broccoli	0.5/3/7	Groundspray	0.075	0.435
Broccoli	0.5/3/7	Aerial	0.075	0.435
Christmas tree nurseries	1/3/14	Groundspray	0.149	0.87
Christmas tree nurseries	1/3/14	Airblast	0.139	0.81
Cottonwood grown for pulp	2/3/10	Aerial	0.279	**1.63**
Cottonwood grown for pulp	2/3/10	Chemigation	0.279	**1.63**
Non-cropland areas adjacent to vineyards	2/2/14	Groundspray	0.297	**1.73**
Peppers	0.33/5/7	Groundspray	0.049	0.287
Peppers	0.33/5/7	Aerial	0.049	0.287
Turnip	0.25/7/3	Groundspray	0.041	0.363
Turnip	0.25/7/3	Aerial	0.041	0.363
Wheat (2)	0.67/2/7	Groundspray	0.100	0.583
Wheat (2)	0.67/2/7	Aerial	0.100	0.583

[a] Bolded values indicate LOC exceedances. LOC are >0.5 and >1 for acute and chronic exposures, respectively.

A summary of the terrestrial-phase amphibian exposure scenarios that will be considered in the refined effects determination is presented in Table 4-25.

Table 4-25 Summary of exposure scenarios for terrestrial amphibians to be considered in the refined assessment

Crop (Use and Application Methods)	*Receptor*	*Exposure*	*Diet*
Broccoli	Adult CRLF	Acute	Whole mouse
Christmas tree nurseries (groundspray and airblast)	Juvenile CRLF	Acute	Worst case
	Adult CRLF	Acute	Worst case, whole mouse
Cottonwood grown for pulp (aerial and chemigation)	Juvenile CRLF	Acute and chronic	Intermediate (acute only) and worst case
	Adult CRLF	Acute and chronic	Worst case, whole mouse
	Pacific tree frog	Chronic	NA[a]
Non-cropland areas adjacent to vineyards (groundspray)	Juvenile CRLF	Acute and chronic	Intermediate and worst case
	Adult CRLF	Acute and chronic	Worst case, whole mouse
	Pacific tree frog	Chronic	NA[a]
Wheat (2)	Adult CRLF	Acute	Whole mouse

[a] The diet of 81% terrestrial arthropods and 19% aquatic invertebrates was assumed for all Pacific tree frog scenarios.

4.1.3.2 Terrestrial Plants

TerrPlant (Version 1.2.2) was used to estimate risk of dimethoate to terrestrial plants. EPA (2006a) recommends the use of an EC25 for the most sensitive tested monocot and dicot species as the measures of effect for non-listed species. An EC25 of >1.5 lb a.i./A was determined for dimethoate (Porch et al., 2011a,b). Seed germination/seedling emergence and vegetative vigor tests were conducted on four monocot and six dicot crop species over a period of 21 days at rates of 0.25, 0.5, 0.75, 1.0 and 1.5 lb a.i./A (Porch et al., 2011a,b). No adverse effects were observed at the highest rate of 1.5 lb a.i./A. Therefore, the unbounded NOEL of 1.5 lb a.i./A was used as the assessment endpoint in TerrPlant because there were no effects seen at the highest concentration.

Some of the application methods for dimethoate include airblast and chemigation. Because of the limitations of TerrPlant, these application methods could not be investigated. However, aerial application nearly always poses higher risks than do airblast and chemigation. Thus, it is assumed that there is little concern to terrestrial plants exposed to dimethoate if risk via aerial application is negligible.

TerrPlant EECs were compared to the NOEL to estimate the potential for risk to plant community structure in terrestrial environments, including breeding and non-breeding habitats that potentially contain the CRLF. There were no RQs that exceeded the LOC of 1 for any dimethoate use patterns (Table 4-26 and Table 4-27).

Table 4-26 Risk quotients for plant species exposed to a single application of dimethoate

Crop	*Application Rate (lb a.i./A)*	*Application Type*	*Estimated Exposure Rate (lb a.i./A)*			*RQ*		
			Dry Areas	*Semi-Aquatic Areas*	*Spray Drift*	*Dry Areas*	*Semi-Aquatic Areas*	*Spray Drift*
Peas (succulent), peas (not for use on field peas)	0.16	Groundspray	0.010	0.082	0.002	<0.1	<0.1	<0.1
		Aerial	0.016	0.088	0.008	<0.1	<0.1	<0.1
Endive, kale, lettuce, swiss chard, mustard greens, ornamentals (herbaceous), turnips	0.25	Groundspray	0.015	0.128	0.003	<0.1	<0.1	<0.1
		Aerial	0.025	0.138	0.013	<0.1	<0.1	<0.1
Pecans, peppers, wheat (5)	0.33	Groundspray	0.020	0.168	0.003	<0.1	0.11	<0.1
		Aerial	0.033	0.182	0.017	<0.1	0.12	<0.1
Alfalfa (forage and hay), alfalfa (seed), field corn, popcorn, asparagus, honeydew, lentils, melon, potato, sorghum, soybean, beans, cotton, safflower, broccoli, brussel sprouts, cauliflower, celery, grass for seed, tomato, wheat (3), wheat (4)	0.5	Groundspray	0.030	0.255	0.005	<0.1	0.17	<0.1
		Aerial	0.050	0.275	0.025	<0.1	0.18	<0.1
Wheat (1), wheat (2)	0.67	Groundspray	0.040	0.342	0.007	<0.1	0.23	<0.1
		Aerial	0.067	0.369	0.034	<0.1	0.25	<0.1
Christmas tree nurseries, conifer seed orchards, ornamentals (woody), citrus, pears	1	Groundspray	0.060	0.510	0.010	<0.1	0.34	<0.1
		Aerial	0.100	0.550	0.050	<0.1	0.37	<0.1
Cherries	1.33	Groundspray	0.080	0.678	0.013	<0.1	0.45	<0.1
		Aerial	0.133	0.732	0.067	<0.1	0.49	<0.1
Cottonwood for pulp, non-cropland areas adjacent to vineyards	2	Groundspray	0.120	1.020	0.020	<0.1	0.68	<0.1
		Aerial	0.200	1.100	0.100	0.13	0.73	<0.1

A more refined analysis was conducted in which peak amounts of dimethoate applied to a field were estimated for exposure scenarios that involved multiple applications of dimethoate to crops. The approach involved determining how much dimethoate remains immediately before the next application. These amounts were added to the subsequent amount applied to determine a "cumulative" application rate. The estimated 90^{th} percentile of mean soil aerobic half-lives of 3.5 days (Reiss, 2009a) was used to estimate cumulative peak amount applied. Using TerrPlant, the cumulative peak amounts applied were used to estimate risk to plant species. There were no risk quotients that exceeded the LOC of 1 (Table 4-27). Although dimethoate can be applied twice to citrus and safflower, these crops are not included in Table 4-27 because the maximum single application rate for these crops is equal to the maximum seasonal application rate. Thus, worst-case exposure would occur from a single application of the maximum single application rate (Table 4-27).

Because the LOC of 1 was not exceeded, CRLF terrestrial habitats are not considered to be at risk from dimethoate exposure, and are not considered further in this effects determination.

Table 4-27 Risk quotients for plant species exposed to more than one application of dimethoate

Crop	Application Rate (lb a.i./A) / Number of Applications / Re-application Interval (d)	Multiplier to Account for Dimethoate Remaining From Previous Applications	Peak Amount Applied (lb a.i./A)	Application Type	Estimated Exposure Rate (lb a.i./A)			RQs		
					Dry Areas	Semi-Aquatic Areas	Spray Drift	Dry Areas	Semi-Aquatic Areas	Spray Drift
Alfalfa (forage and hay)	0.5/3/30	1.00	0.50	Groundspray	0.030	0.255	0.005	<0.1	0.17	<0.1
				Aerial	0.050	0.275	0.025	<0.1	0.18	<0.1
Asparagus, honeydew, lentils, melon, potato, sorghum, soybean	0.5/2/7	1.25	0.63	Groundspray	0.038	0.321	0.006	<0.1	0.21	<0.1
				Aerial	0.063	0.347	0.032	<0.1	0.23	<0.1
Beans, cotton,	0.5/2/14	1.06	0.53	Groundspray	0.032	0.270	0.005	<0.1	0.18	<0.1
				Aerial	0.053	0.292	0.027	<0.1	0.19	<0.1
Broccoli, brussel sprouts, cauliflower, celery	0.5/3/7	1.31	0.66	Groundspray	0.040	0.337	0.007	<0.1	0.22	<0.1
				Aerial	0.066	0.363	0.033	<0.1	0.24	<0.1
Christmas tree nurseries, conifer seed orchards, ornamentals (woody)	1/3/14	1.07	1.07	Groundspray	0.064	0.546	0.011	<0.1	0.36	<0.1
				Aerial	0.107	0.589	0.054	<0.1	0.39	<0.1
Cottonwood grown for Pulp	2/3/10	1.16	2.31	Groundspray	0.139	1.178	0.023	<0.1	0.79	<0.1
				Aerial	0.231	1.271	0.116	0.15	0.85	<0.1
Endive	0.25/3/7	1.31	0.33	Groundspray	0.020	0.168	0.003	<0.1	0.11	<0.1
				Aerial	0.033	0.182	0.017	<0.1	0.12	<0.1
Grass for seed	0.5/2/90	1.00	0.50	Groundspray	0.030	0.255	0.005	<0.1	0.17	<0.1
				Aerial	0.050	0.275	0.025	<0.1	0.18	<0.1
Kale	0.25/2/14	1.06	0.27	Groundspray	0.016	0.138	0.003	<0.1	<0.1	<0.1
				Aerial	0.027	0.149	0.014	<0.1	<0.1	<0.1
Lettuce, swiss chard	0.25/3/14	1.07	0.27	Groundspray	0.016	0.138	0.003	<0.1	<0.1	<0.1
				Aerial	0.027	0.149	0.014	<0.1	<0.1	<0.1
Mustard greens	0.25/2/9	1.17	0.29	Groundspray	0.017	0.148	0.003	<0.1	<0.1	<0.1
				Aerial	0.029	0.160	0.015	<0.1	0.11	<0.1
Noncropland areas adjacent to vineyards	2/2/14	1.06	2.13	Groundspray	0.128	1.086	0.021	<0.1	0.72	<0.1
				Aerial	0.213	1.172	0.107	0.14	0.78	<0.1
Peas (succulent)	0.16/4/14	1.07	0.17	Groundspray	0.010	0.087	0.002	<0.1	<0.1	<0.1
				Aerial	0.017	0.094	0.009	<0.1	<0.1	<0.1
Peppers	0.33/5/7	1.33	0.44	Groundspray	0.026	0.224	0.004	<0.1	0.15	<0.1
				Aerial	0.044	0.242	0.022	<0.1	0.16	<0.1
Tomato	0.5/2/6	1.31	0.65	Groundspray	0.039	0.332	0.007	<0.1	0.22	<0.1
				Aerial	0.065	0.358	0.033	<0.1	0.24	<0.1

Table 4-27 Risk quotients for plant species exposed to more than one application of dimethoate

Crop	Application Rate (lb a.i./A) / Number of Applications / Re-application Interval (d)	Multiplier to Account for Dimethoate Remaining From Previous Applications	Peak Amount Applied (lb a.i./A)	Application Type	Estimated Exposure Rate (lb a.i./A)			RQs		
					Dry Areas	Semi-Aquatic Areas	Spray Drift	Dry Areas	Semi-Aquatic Areas	Spray Drift
Turnips	0.25/7/3	2.20	0.55	Groundspray	0.033	0.281	0.006	<0.1	0.19	<0.1
				Aerial	0.055	0.303	0.028	<0.1	0.2	<0.1
Wheat (2)	0.67/2/7	1.25	0.84	Groundspray	0.050	0.428	0.008	<0.1	0.29	<0.1
				Aerial	0.084	0.462	0.042	<0.1	0.31	<0.1
Wheat (4)	0.5/2/7	1.25	0.63	Groundspray	0.038	0.321	0.006	<0.1	0.21	<0.1
				Aerial	0.063	0.347	0.032	<0.1	0.23	<0.1
Wheat (5)	0.33/2/7	1.25	0.41	Groundspray	0.025	0.209	0.004	<0.1	0.14	<0.1
				Aerial	0.041	0.226	0.021	<0.1	0.15	<0.1

4.2 Refined Terrestrial Effects Determination

The only terrestrial exposure scenarios that required additional refined analyses were dimethoate applications to broccoli, cottonwood grown for pulp, non-cropland areas adjacent to vineyards, Christmas tree nurseries and wheat (Scenario 2 in Table 2-5).

For terrestrial-phase CRLF, the refined risk assessment involved integrating a dose-response curve from the selected dietary toxicity study with a distribution of estimated *TDI*s for each scenario. The result is a risk curve that shows the relationship between cumulative probability and magnitude of effect. Each risk curve was categorized using the criteria described in Section 2.10.5.2.

4.2.1 Refined Terrestrial Effects Assessment

A dose-response curve was fit to data from an acceptable avian GLP study for northern bobwhite. Ideally, a dose-response curve for CRLF would have been used. Acceptable toxicity data for terrestrial amphibians are not available for dimethoate. As a result, bird toxicity data were used, as per EPA guidance (EPA, 2004a). The selected study was an acute dietary study conducted with northern bobwhite (Zok, 2001c [MRID 47769705]). The data are presented in Table 4-1. PROC PROBIT in SAS Software® (SAS Version 9.1) was used to fit a probit model to the data. Because there was only one partial effect treatment (40% mortality in one treatment group), confidence limits could not be calculated for the model, nor could the assumptions of a regression analysis be tested. The fitted model has parameters $\mu = 14.6$ and $\sigma = 0.843$. The resulting dose-response curve is presented in Figure 4-1.

For chronic effects, a dose-response curve was fit to data from an acceptable avian GLP study for northern bobwhite. The selected study was a chronic reproductive dietary study (Gallagher et al., 1996a). The most sensitive endpoint in the study was the number of eggs laid. Nominal dietary concentrations, pre- and post-exposure body weights, and mean pen feed intake rates were used to estimate daily doses for each bird pair. The data are presented in Table 4-28. PROC PROBIT in SAS Software® (SAS Version 9.1) was used to fit several sigmoidal models to the data (probit, logit, two- and three-parameter Weibull, Burr Type III, Gompertz; with and without log transformation of the dose estimates where appropriate). By visual inspection and comparison of error terms, the two-parameter Weibull model (see Equation 4-7 and Figure 4-5) was selected as the best-fitting model.

$$proportion\ affected = 1 - e^{-\left(\frac{dose}{\alpha}\right)^{\gamma}}$$

Equation 4-7

Where γ is the shape parameter and α is the scale parameter. The fitted parameter values are $\gamma = 1.5759$ and $\alpha = 4.8470$.

The highest estimated dose in the study was 4.20 mg a.i./kg bw/d. Thus, estimates of levels of effect for doses beyond 4.20 mg a.i./kg bw/d are extrapolations beyond the available data.

Table 4-28 Estimated dose in northern bobwhite quail and observed reduction in the number of eggs laid relative to the mean of control birds[a]

Pen	*Nominal Concentration in Feed (mg a.i./kg ww)*	*Estimated Dose per Pen (mg a.i./kg bw/d)[b]*	*Eggs Laid*	*Percent Reduction Relative to Mean of Controls[c]*
101	0 (control)	0.00	66	-11.9
102	0 (control)	0.00	45	23.7
103	0 (control)	0.00	69	-17.0
104	0 (control)	0.00	58	1.69
106	0 (control)	0.00	46	22.0
107	0 (control)	0.00	65	-10.2
108	0 (control)	0.00	69	-17.0
109	0 (control)	0.00	52	11.9
110	0 (control)	0.00	61	-3.39
111	0 (control)	0.00	42	28.8
112	0 (control)	0.00	70	-18.6
113	0 (control)	0.00	46	22.0
114	0 (control)	0.00	62	-5.08
115	0 (control)	0.00	72	-22.0
116	0 (control)	0.00	62	-5.08
118	4	0.40	55	6.78
119	4	0.37	50	15.3
120	4	0.47	54	8.47
121	4	0.50	67	-13.6
122	4	0.43	72	-22.0
123	4	0.41	45	23.7
124	4	0.43	49	17.0
125	4	0.50	49	17.0
126	4	0.41	60	-1.69
127	4	0.40	63	-6.78
128	4	0.42	43	27.1
129	4	0.38	45	23.7
130	4	0.41	65	-10.2
131	4	0.42	64	-8.47
133	10.1	1.18	56	5.08
134	10.1	1.17	61	-3.39
135	10.1	1.16	65	-10.2
136	10.1	1.10	69	-17.0
137	10.1	1.06	65	-10.2
139	10.1	1.14	52	11.9
140	10.1	0.99	61	-3.39
141	10.1	0.95	59	0.00
142	10.1	1.03	1	98.3
143	10.1	1.02	64	-8.47
144	10.1	1.04	52	11.9
146	10.1	1.10	19	67.8
147	10.1	1.12	59	0.00
148	10.1	1.21	64	-8.47
149	35.4	3.77	30	49.1
150	35.4	3.81	17	71.2
151	35.4	3.84	36	39.0
152	35.4	3.26	36	39.0
154	35.4	3.40	40	32.2

Table 4-28	Estimated dose in northern bobwhite quail and observed reduction in the number of eggs laid relative to the mean of control birds[a]			
Pen	***Nominal Concentration in Feed (mg a.i./kg ww)***	***Estimated Dose per Pen (mg a.i./kg bw/d)[b]***	***Eggs Laid***	***Percent Reduction Relative to Mean of Controls[c]***
155	35.4	3.97	21	64.4
156	35.4	3.49	33	44.1
157	35.4	3.35	33	44.1
158	35.4	3.34	21	64.4
159	35.4	3.77	33	44.1
160	35.4	3.06	62	-5.08
162	35.4	3.32	32	45.8
163	35.4	4.17	18	69.5
164	35.4	3.82	22	62.7
153	35.4	4.20	39	33.9

[a] Original data from Gallagher et al. (1996a [MRID 44049001]). Pens in which mortalities occurred that were not due to dimethoate exposure were excluded from the analysis.
[b] Doses were estimated as they were for the chronic NOEL previously described in the screening-level assessment (see Section 4.1.1).
[c] The mean number of eggs laid by control birds was 59.

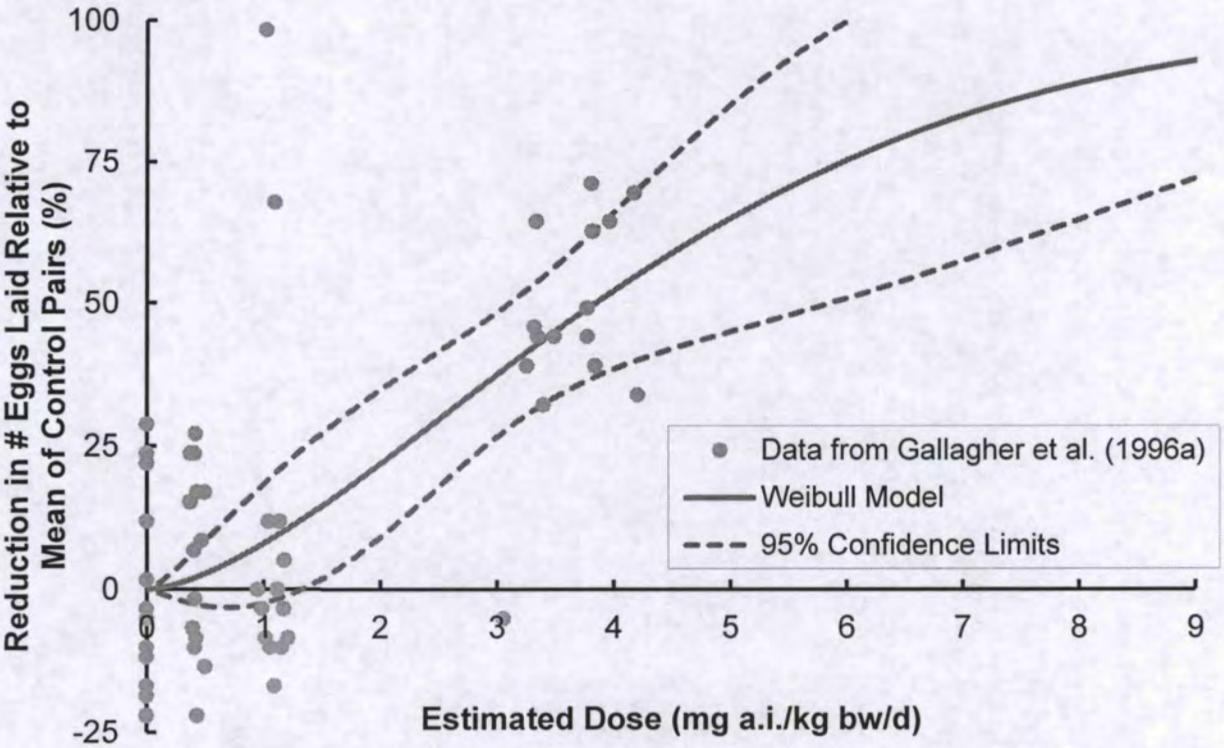

Figure 4-5 **Chronic dose-response curve for northern bobwhite quail exposed to dimethoate in their diet (Gallagher et al., 1996a)**

4.2.2 Refined Terrestrial Exposure Assessment

The exposure scenarios considered in this refined assessment were those that screened through from the screening-level assessment (Section 4.1) and are presented in Table 4-25.

As in the screening-level effects determination, total daily intake (*TDI*) models were used to estimate exposure for terrestrial-phase amphibians. However, instead of using point estimates for each input parameter (free metabolic rate, body weight, gross energy, assimilation efficiency and RUDs), distributions for many of the variables were used. *TDI* simulations were run in CrystalBall® Version 7.2 for each exposure scenario. Latin hypercube sampling from input parameter distributions was used to generate 10,000 *TDI* estimates for each exposure scenario. The input parameters and distribution for each *TDI* model parameter in the refined exposure assessment are discussed below.

4.2.2.1 *TDI* Model Inputs

Field Metabolic Rate

As in the screening-level assessment, an allometric equation derived using reptilian species data (from Nagy et al., 1999; n=55 spp.) was used (see Section 4.1.2.2) to estimate *FMR* for terrestrial-phase CRLF. The distribution of error terms about the regression line (see Figure 4-3) was used to capture the uncertainty about the modeled allometric equation. The root of the mean square error from the regression analysis (0.22887) was used the standard deviation for a normal error term distribution. Thus, in each iteration of the *TDI* simulation, *FMR* was estimated from the regression line plus or minus a randomly chosen value from a normal distribution for the regression equation error term.

Similarly, an allometric model equation derived using rodent species data (from Nagy et al., 1999; n=30 spp.) was used (see Section 4.1.2.2) to estimate *FMR* for the California mouse. The root of the mean square error from the regression analysis was 0.16163 and was used the standard deviation for a normal error term distribution.

Body Weight

The body weight data used in the screening-level effects determination (Jameson et al., 1970; Scott and Rathburn, 2001; see Section 4.1.2.2) were used to estimate body weight distributions for Pacific tree frog and CRLF (juvenile and adults separately).

Hayes and Tennant (1985) reported that juvenile and large adult CRLFs are ≤6.5 cm and ≥10 cm in length, respectively. The CRLF measurements reported by Scott and Rathburn (2001) were grouped according to lifestage (juvenile or adult) based on the length classes provided by Hayes and Tennant (1985). The weights of juveniles ranged from 4.3 to 27 g with an average weight of 12.2 g (n = 72). The weights of adults ranged from 74 to 247 g with an average weight of 132 g (n = 387). Distributions were fit to the body weight data.

Jameson et al. (1970) determined the mean body weight of 10 Pacific tree frogs at each of 10 locations in British Columbia, Oregon and California (see Table 4-6 in the study). Unfortunately, the raw data were not available. A distribution was fit to the reported mean body weights. As such, the variance for individual body weights is likely underestimated.

Four plausible distributions were fit to the body weight data for each of the Pacific tree frog, juvenile CRLF and adult CRLF (normal, three-parameter lognormal, three-parameter Weibull and three-parameter gamma distributions). The PROC UNIVARIATE procedure in SAS Version 9.1 was used for these analyses. Comparison of the observed and predicted percentiles for each distribution indicated that the three-parameter Weibull fit all three datasets better than the other distributions. For all refined *TDI* estimates, body weights were selected from the distributions described in Table 4-29. The form of the three-parameter Weibull probability density function is presented in Equation 4-8, below.

$$f(bw) = \frac{\gamma}{bw}\left(\frac{bw}{\alpha}\right)^{\gamma} e^{-\left(\frac{bw}{\alpha}\right)^{\gamma}}$$

Equation 4-8

where bw is in units of grams wet weight.

Table 4-29 Parameters for estimated body weight distributions (three-parameter Weibull) for terrestrial-phase amphibians			
Amphibian	***Scale Parameter (α)***	***Shape Parameter (γ)***	***Location Parameter (μ)***
Juvenile CRLF	8.89	1.42	4.10
Adult CRLF	66.0	1.79	73.3
Pacific tree frog	0.800	1.00	1.47

There were insufficient data to derive a distribution for body weight of the California mouse. Instead, the mean and standard deviation of three subspecies means reported in Grinnell and Orr (1934) were used to define a presumed normal distribution (see Section 4.1.2.2 for a discussion of the available body weight data for California mouse). The estimated mean and standard deviation were 40.7 and 6.70 g, respectively.

Proportion of Diet Containing Residues

A description of the home range and foraging behaviour of CRLF and their vertebrate prey is provided in the screening-level exposure assessment. Although it is highly unlikely that all, or even most of CRLF prey would contain peak dimethoate residues, there are insufficient data to quantify the proportion of CRLF diet that would contain residues. In light of this uncertainty, we assumedthat 100% of the diet of Pacific tree frogs and CRLFs was from fields treated with dimethoate(Section 4.1.2.1). It was also assumed that 100% of California mouse diet was from fields treated with dimethoate.

Proportion of Dietary Items

In the screening-level assessment, we concluded that there were insufficient data to estimate the proportions of various prey items in the diet of the CRLF. To estimate the range of risk to juvenile CRLF, best-, intermediate- and worst-case dietary exposure scenarios were modeled. The best-case diet consisted of 100% aquatic invertebrates. The worst-case diet for juvenile CRLFs consisted of 100% terrestrial invertebrates. The intermediate exposure scenario assumed a diet of 50% of each prey item. Because there were no data to refine a description of variability in the diet of juvenile CRLF, these categories were also used in the refined assessment.

In the screening-level assessment, the diets considered for adult CRLFs included aquatic invertebrates, terrestrial arthropods, fish, amphibians and small mammals. The best- and worst-case diets were the same as for juvenile CRLFs. The intermediate-case diet consisted of 25% of each of aquatic invertebrates, terrestrial arthropods, fish and terrestrial-phase amphibians. Ingestion of a whole mouse was considered only for acute exposure.

The estimated proportions of aquatic and terrestrial invertebrates assumed in the screening-level assessment for the Pacific tree frog diet were 19% and 81%, respectively. These values were also used in the refined assessment and were based on frequency of occurrence in digestive tracts of the Pacific tree frog (Johnson and Bury, 1965).

For the California mouse, the data provided in Merritt (1974) were used to determine their diet. The mean and standard deviations of feed item proportions were used to estimate alpha and beta parameters for the beta distribution. Beta distributions are often appropriate in the statistical modelling of proportions because they are defined on the interval (e.g., 0,1). We used the method-of-moments to estimate beta model parameters (NIST/SEMATECH e-Handbook of Statistical Methods, 2010; see Equation 4-9 and Equation 4-10). The statistics used to estimate the distributions for each of the dietary items are presented in Table 4-30.

$$\hat{\alpha} = \bar{x}\left(\frac{\bar{x}(1-\bar{x})}{s^2} - 1\right)$$

Equation 4-9

$$\hat{\beta} = (1-\bar{x})\left(\frac{\bar{x}(1-\bar{x})}{s^2} - 1\right)$$

Equation 4-10

where $\hat{\alpha}$ and $\hat{\beta}$ are alpha and beta estimates, respectively, $\bar{x}$ is the assumed mean feed item proportion and s is the assumed standard deviation of the feed item proportion.

Table 4-30 Summary of California mouse dietary distributions applied in the refined risk assessment[a]

Feed Item	*Proportion in Diet[b]*		*Beta Distribution Parameter Estimates[c]*	
	Mean	*Standard Deviation*	*Alpha*	*Beta*
Terrestrial arthropods	0.117	0.104	1.00	7.56
Leaves and herbaceous stems	0.252	0.0483	20.0	59.6
Fungi	0.0407	0.0501	0.59	14.0
Berries	0.0694	0.0366	3.27	43.9
Seeds and nuts	0.521	0.139	6.23	5.72

[a] Based on data provided in Merritt (1974).
[b] Non-feed items such as fur and unidentified material found in gut contents were excluded from the calculations. We assumed equivalent density of feed items as results were reported as volumetric percentages.
[c] Method-of-moments from NIST/SEMATECH e-Handbook of Statistical Methods (2010) was used to estimate alpha and beta parameters (see Equation 4-9 and Equation 4-10).

Gross Energy

Gross energy values for terrestrial and aquatic invertebrates are reported in the Wildlife Exposure Factors Handbook (EPA, 1993). In the screening-level assessment, mean values were used as *GE* estimates. In the refined assessment, reported means and standard deviations from EPA (1993) were used to parameterize lognormal distributions for *GE*, similar to the approach used by EPA (2005b). The statistics used to parameterize the *GE* distribution for each of the dietary items are presented in Table 4-31.

Table 4-31 Statistics used to parameterize lognormal distributions for gross energy of terrestrial-phase amphibian dietary items

Dietary Item	*Mean (kcal/kg ww)*	*Standard Deviation*	*Comments*	*References*
Terrestrial arthropods	1600	260	The mean gross energies of grasshoppers and crickets (1700 kcal/kg ww) and beetles (1500 kcal/kg ww) were averaged to estimate the mean. The standard deviation reported for grasshoppers and crickets of 260 kcal/kg ww was assumed. No variance was reported for *GE* in beetles.	Collopy, 1975; Bell, 1990
Aquatic invertebrates	880	190	The mean value was derived from mean gross energies for bivalves (800 kcal/kg ww), isopods and amphipods (1100 kcal/kg ww), and cladocerans and insect larvae (740 kcal/kg). No variance was reported for these means. The standard deviation of the three mean values was assumed (190 kcal/kg ww).	Cummins and Wuycheck, 1971; Golley, 1961; Tyler, 1973; Jorgensen et al., 1991; Pierotti and Annett, 1987; Minnich, 1982; Thayer et al., 1973.

For other feed items consumed by California mouse, data from the EPA (1993) were used to define lognormal distributions for *GE* (Table 4-32). The percent moisture values presented in Table 4-5 were used to convert *GE* from dry weight to wet weight.

Table 4-32 Statistics used to parameterize lognormal distributions for gross energy for dietary items specific to California mouse

Feed Item	*Mean (kcal/kg dw)*	*Standard Deviation*	*Comment*	*References*
Leaves	4200	330	Grasses	Davis and Golley, 1963; Cummins and Wuycheck, 1971; Drozdz, 1968; Golley, 1960; Kendeigh and West, 1965
Fungi	4141	291	Edible mushrooms	Colak et al., 2009[a]
Berries	2000	3400	Fruit pulp, skin	Karasov, 1990; Levey and Karasov, 1989
Seeds and nuts	5100	1100	Dicot seeds	Drozdz, 1968; Golley, 1961; Dice, 1922; Robel et al., 1979

[a] Not reported in EPA (1993).

Assimilation Efficiency

The EPA Exposure Factors Handbook (EPA, 1998) reports assimilation efficiencies for the prey of birds and mammals, but not amphibians. In lieu of values for the prey of amphibians, the assimilation efficiencies reported for the prey of birds were used as surrogates for the prey of CRLFs and the Pacific tree frog. The mean and standard deviations presented EPA (1993) were used to estimate alpha and beta parameters for the beta distribution using the method-of-moments equations (NIST/SEMATECH e-Handbook of Statistical Methods, 2010; see Equation 4-9 and Equation 4-10). The statistics used to estimate the *AE* distribution for each of the dietary items are presented in Table 4-33 and Table 4-34 for terrestrial-phase amphibians and mice, respectively.

Table 4-33 Statistics used to parameterize beta distributions for assimilation efficiencies of terrestrial-phase amphibian dietary items

Feed Item	*Mean(proportion)*	*Standard Deviation*	*Alpha Estimate*	*Beta Estimate*	*Comments*	*References*
Terrestrial invertebrates	0.720	0.0510	55.1	21.4	Birds consuming terrestrial insects used as surrogate for frogs consuming terrestrial insects, n= 16 studies	Karasov, 1990; Ricklefs, 1974; Bryant and Bryant, 1988
Aquatic invertebrates	0.770	0.0840	18.6	5.54	Waterfowl consuming aquatic invertebrates used as surrogate for frogs consuming aquatic invertebrates. Three studies used to generate sample mean and standard deviation	Karasov, 1990

Table 4-34 Statistics used to parameterize beta distributions for assimilation efficiencies of California mouse dietary items in the refined exposure assessment

Feed Item	*Mean(proportion)*	*Standard Deviation*	*Alpha Estimate*	*Beta Estimate*	*Comments*	*References*
Terrestrial arthropods	0.87	0.049	40.1	5.99	Based on six studies reporting on small mammals consuming insects	Grodzinski and Wunder, 1975; Barrett and Stueck, 1976
Leaves Fungi Berries	0.73	0.076	24.2	8.94	Based on eight studies reporting on rabbits, voles and mice consuming green forbs	Grodzinski and Wunder, 1975; Drozdz, 1968; Batzli and Cole, 1979
Seeds and nuts	0.85	0.073	19.5	3.44	Based on eight studies reporting on voles and mice consuming seeds and nuts	Grodzinski and Wunder, 1975; Drozdz, 1968

Concentrations of Dimethoate in Prey

It was clear from the screening-level assessment that aquatic invertebrates are expected to have residues that are negligible in comparison to those in terrestrial arthropods on treated fields following dimethoate application. Thus, in the refined assessment, concentrations of dimethoate in aquatic invertebrates were not modified from the screening assessment.

As in the screening-level assessment, residues on terrestrial arthropods were estimated using residue data presented in Barber et al. (2005). This study collated the results for crop-dwelling, soil-dwelling and flying insects from 67 industry datasets found in 21 GLP-compliant studies. Residues in crop-dwelling arthropods were used as conservative estimates as residues were typically much lower on soil-dwelling arthropods (Barber et al., 2005). The results of Knäbe (2004a,b), which were Cheminova-commissioned studies of pesticide residues on arthropods in orchards, were added to the Barber et al. (2005) dataset for orchard/vineyard crop-dwelling arthropods. The data were tested for lognormality using ProUCL Version 4 (Shapiro-Wilks $p>0.05$). The maximum likelihood estimators (i.e., the mean and standard deviation of data natural logarithms) were used to define assumed RUD distributions.

As in the screening-level assessment, peak and 96-hour average residues on terrestrial arthropods were estimated by multiplying each application rate by the dimethoate RUD selected from the appropriate distribution for each trial. These residues were then degraded using the dissipation half-life (DT_{50} = 0.86 days) for crop-dwelling arthropods reported in Knäbe (2004a) assuming a first-order decay model.

For feed items specific to the California mouse, RUD distributions were generated with dimethoate-specific residue data collected on vegetation (Corden, 2000, 2001, 2005; Goodband, 2003; Knäbe, 2004a; Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001a-l, 2002a-f, 2003a,b). Section 4.1.2.2 describes how the data were processed. Residues were typically higher on short grass and were used as surrogate data for feed items for which no residue data were available (e.g., fungi). Residue data for small fruit were used as a surrogate for seeds and nuts. The appropriate parametric distribution for each feed item RUD was determine with ProUCL Version 4.0. Both short grass and small fruit residue data were well described by a lognormal distribution. Maximum likelihood estimates of location and scale parameters were used to define the distributions used in the refined exposure assessment (see Table 4-35).

First-order exponential dissipation following applications was assumed, as it was in the screening-level assessment. Residues on seeds and fruits were degraded assuming the dissipation half-life of 4.9 days previously derived for small fruit (Table 4-10). Residues on other vegetation feed items (e.g., fungi and leaves) were degraded assuming a dissipation half-life of 1.33 days (Table 4-10). Half-life calculations are described in Section 4.1.2.2. As was done for amphibians the dissipation half-life estimate of 0.86 days (Knäbe, 2004a) was assumed for arthropods in the mouse diet.

Table 4-35 Summary of RUD statistics and lognormal distribution parameters for California mouse dietary items

Feed Item	*Number of Trials*	*Day 0 RUD (mg a.i./kg ww per lb a.i./A)*		*Lognormal Distribution Parameters*		
		Mean	*Standard Deviation*	*Location Parameter Estimate*[a]	*Scale Parameter Estimate*[b]	*95th Percentile*[c]
Short grass	3	59.3	31.4	4.00	0.492	122
Small fruits	22	5.09	3.75	1.41	0.665	12.2

[a] Mean of logarithms of reported Day 0 RUD values.
[b] Standard deviation of logarithms of reported Day 0 RUD values.
[c] Value used at screening-level exposure assessment.

4.2.2.2 Refined Exposure Estimates

Refined *TDI* exposure estimates for terrestrial-phase CRLF and their amphibian prey (Pacific tree frog) are summarized in Table 4-36.

Ground and aerial applications to broccoli (0.5 lb a.i./A three times per year with a minimum retreatment interval of 7 days) were considered for adult CRLF consuming mice (i.e., whole California mouse). The *TDI* simulation estimates for this exposure scenario had a mean of 0.844 mg a.i/kg bw/d and a standard deviation of 0.730 (Table 4-36).

Christmas tree nurseries can receive up to 1 lb a.i./A three times per year, with a minimum retreatment interval of 14 days. This use pattern was considered for juvenile and adult CRLF acutely exposed via a worst-case diet (100% terrestrial arthropods from a dimethoate-treated field) and adult CRLF acutely exposed via ingestion of a whole mouse. Mean acute *TDI* estimates ranged from 0.500 mg a.i./kg bw/d for adult CRLF consuming a worst-case diet following ground application to 1.59 mg a.i./kg bw/d for adult CRLF consuming whole mice following either ground or airblast application (Table 4-36).

Applications to cottonwood grown for pulp (2 lb a.i./A three times per year, with a minimum retreatment interval of 10 days) were considered for juvenile and adult CRLF for acute and chronic exposures assuming a worst-case diet. For acute exposures only, this use pattern was also considered for juvenile CRLF consuming an intermediate-case diet (half terrestrial arthropods and half aquatic invertebrates) and for adult CRLF consuming mice. Chronic mean *TDI* estimates for juveniles and adults consuming a worst-case diet were 0.611 mg a.i./kg bw/d and 0.467 mg a.i./kg bw/d, respectively. Mean acute *TDI* estimates ranged from 0.879 mg a.i./kg bw/d for juvenile CRLF consuming an intermediate-case diet to 3.24 mg a.i./kg bw/d for adult CRLF consuming whole mice (Table 4-36).

Non-cropland adjacent to vineyards can receive up to 2 lb a.i./A twice per year, with a minimum retreatment interval of 14 days. This use pattern was considered for juvenile and adult CRLF consuming a worst-case diet, and juveniles consuming an intermediate-case diet. Mean acute *TDI* estimates ranged from 0.818 mg a.i./kg bw/d for juvenile CRLF consuming an intermediate-case diet to 3.17 mg a.i./kg bw/d for adult CRLF consuming mice. Mean chronic *TDI* estimates for this use pattern ranged from 0.355 mg a.i./kg bw/d for juvenile CRLF consuming a intermediate-case diet to 0.566 mg a.i./kg bw/d for juvenile CRLF consuming a worst-case diet (Table 4-36).

Applications to wheat (Scenario 2; 0.67 lb a.i./A twice a year with a seven-day retreatment interval) were only considered for adult CRLF consuming mice. The mean *TDI* estimate for this scenario was 1.11 mg a.i./kg bw/d with a standard deviation of 0.970 (Table 4-36).

For indirect effects to adult CRLF via reduced amphibian prey, direct effects to the Pacific tree frog were investigated for chronic dietary exposures following applications to cottonwood grown for pulp and non-cropland adjacent to vineyards. Mean *TDI* estimates were 0.638 and 0.600 mg a.i./kg bw/d for cottonwood and non-cropland adjacent to vineyards applications, respectively (Table 4-36).

As in the screening-level assessment, *TDI* estimates for terrestrial-phase CRLF and their amphibian prey (Pacific tree frog) were strongly influenced by diet, *FMR* and application rate. Retreatment intervals and number of applications per season had less influence on the *TDI* results (Table 4-36).

Table 4-36 Summary of *TDI* estimates for refined terrestrial exposure scenarios

Exposure Scenario						*TDI Estimates (mg a.i./kg bw/d)*						
								Percentiles				
Crop/Use	***Application Method***	***Scenario (lb. a.i./A)/ No. Applications per Year/ Retreatment Interval (d)***	***Receptor***	***Diet***	***Exposure Duration***	***Mean***	***Standard Deviation***	***5***	***25***	***50***	***75***	***95***
Broccoli	Aerial/groundspray[a]	0.5/3/7	Adult	Whole mouse	Acute	0.844	0.730	0.208	0.406	0.647	1.04	2.13
Christmas trees	Airblast	1/3/14	Juvenile CRLF	Worst	Acute	0.704	1.31	0.0484	0.153	0.343	0.758	2.48
Christmas trees	Groundspray	1/3/14	Juvenile CRLF	Worst	Acute	0.653	2.15	0.0158	0.0705	0.199	0.552	2.61
Christmas trees	Airblast	1/3/14	Adult CRLF	Worst	Acute	0.538	0.959	0.0355	0.115	0.261	0.580	1.93
Christmas trees	Groundspray	1/3/14	Adult CRLF	Worst	Acute	0.500	1.73	0.0120	0.0537	0.152	0.424	1.85
Christmas trees	Airblast/groundspray	1/3/14	Adult CRLF	Whole mouse	Acute	1.59	1.40	0.386	0.754	1.21	1.95	4.04
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Juvenile CRLF	Worst	Acute	1.41	2.62	0.0969	0.306	0.686	1.52	4.96
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Juvenile CRLF	Worst	Chronic	0.611	1.13	0.0420	0.133	0.298	0.658	2.15
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Adult CRLF	Worst	Acute	1.08	1.92	0.0710	0.231	0.522	1.16	3.86
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Adult CRLF	Worst	Chronic	0.467	0.832	0.0308	0.100	0.226	0.503	1.67
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Juvenile CRLF	Intermediate	Acute	0.879	1.61	0.0612	0.193	0.429	0.948	3.08
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Adult CRLF	Whole mouse	Acute	3.24	2.84	0.796	1.55	2.47	3.99	8.21
Cottonwood grown for pulp	Aerial/ chemigation[a]	2/3/10	Pacific tree frog	NA	Chronic	0.638	1.14	0.0432	0.140	0.319	0.698	2.15
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Worst	Acute	1.31	4.30	0.0316	0.141	0.397	1.10	5.21
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Worst	Chronic	0.566	1.87	0.0137	0.0612	0.172	0.479	2.26
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Intermediate	Acute	0.818	2.77	0.0203	0.0890	0.247	0.688	3.22
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Intermediate	Chronic	0.355	1.20	0.00886	0.0387	0.107	0.299	1.40

Table 4-36 Summary of *TDI* estimates for refined terrestrial exposure scenarios

Exposure Scenario						*TDI Estimates (mg a.i./kg bw/d)*						
								Percentiles				
Crop/Use	*Application Method*	*Scenario (lb. a.i./A)/ No. Applications per Year/ Retreatment Interval (d)*	*Receptor*	*Diet*	*Exposure Duration*	*Mean*	*Standard Deviation*	*5*	*25*	*50*	*75*	*95*
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Adult CRLF	Worst	Acute	1.00	3.47	0.0240	0.107	0.304	0.848	3.69
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Adult CRLF	Worst	Chronic	0.434	1.51	0.0104	0.0466	0.132	0.368	1.60
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Adult CRLF	Whole mouse	Acute	3.17	2.80	0.769	1.50	2.41	3.88	8.05
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Pacific tree frog	NA	Chronic	0.600	1.89	0.0145	0.0626	0.182	0.515	2.31
Wheat (2)	Aerial/groundspray[a]	0.67/2/7	Adult CRLF	Whole mouse	Acute	1.11	0.970	0.273	0.533	0.849	1.37	2.82

[a] Application method did not significantly affect *TDI* estimates for these scenarios.

4.2.3 *Refined Terrestrial Risk Characterization*

Risk curves were generated by integrating the dose-response curves with the exposure distributions. Section 2.10.5.2 describes the criteria used to categorize risk based on the area under the risk curve (AUC), which is equivalent to the probability of a randomly selected exposure dose exceeding a randomly selected level of effect. Only exposure scenarios that resulted in a RQ>LOC in the screening-level assessment were considered in the refined risk characterization (Table 4-25).

The AUC for adult CRLF consuming California mice was 6.87E-04%, which is classified as *de minimis* risk. The probability of causing 5% or greater mortality for acute exposures is 0.01%, or 1 in 10,000 exposures (Figure 4-6 and Table 4-37).

Applications to Christmas tree nurseries were considered for juvenile and adult CRLF acutely exposed via a worst-case diet and adult CRLF acutely exposed via ingestion of a whole mouse. Results indicate that this use pattern poses *de minimis* risk to all receptors considered, with AUC estimates ranging from 0.037 to 0.22%. For all Christmas tree nursery exposure scenarios considered, the probability of exceeding a 5% effect level was ≤0.28% (Table 4-37).

Applications to cottonwood grown for pulp pose *de minimis* risk for all acute exposures considered with AUCs ranging from 0.189 to 0.480%. The probability of an acute exposure leading to >5% effect is ≤ 0.61% for this use pattern. For the two chronic exposure scenarios associated with this use pattern (adult and juveniles consuming 100% terrestrial arthropods), AUC estimates range from 3.26 to 5.12%. These AUC estimates are classified as low risk, and the probability of >5% chronic effect (i.e., >5% reduction in reproduction) is approximately 23 and 25%, for juveniles and adult CRLF, respectively (Figure 4-6, Figure 4-9 and Table 4-37).

The results indicate *de minimis* risk for all acute exposures considered following applications to non-cropland adjacent to vineyards, with AUC estimates ranging from 0.392 to 0.970%. The probability of exceeding the 5% effect level was ≤1.15% for acute exposures. For chronic exposures, AUC estimates ranged from 2.7 to 4.67%, and the probability of exceeding the 5% chronic effect level was between 11.4 and 19.9% (Figure 4-6, Figure 4-10 and Table 4-37).

Applications to wheat were only considered for adult CRLF consuming mice. The estimated AUC for the acute exposure scenario was 0.0101% with a 0.01% (or 1-in-10,000) probability of exposure exceeding the estimated 5% effect level (Figure 4-6 and Table 4-37).

For indirect effects to adult CRLF via reduced amphibian prey, direct effects to the Pacific tree frog were investigated for chronic dietary exposures following applications to cottonwood grown for pulp and non-cropland adjacent to vineyards. These scenarios pose low risk to the Pacific tree frog, with estimated AUCs of 5.35 and 5.37% for non-cropland adjacent to vineyards and cottonwood grown for pulp, respectively (Figure 4-11 and Table 4-37).

The risk curves generated for each exposure scenario are presented in Appendix G.

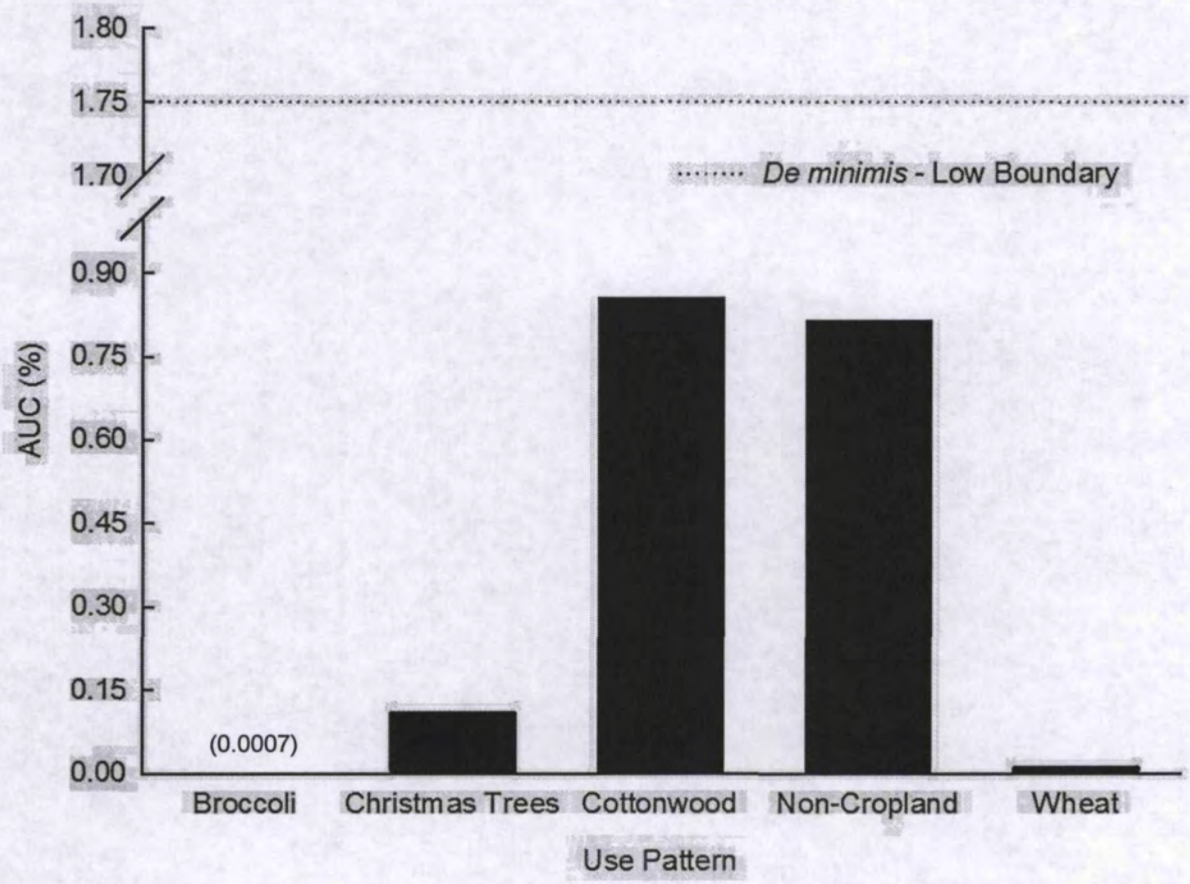

Figure 4-6 **Refined risk characterization demonstrating *de minimis* risk for adult CRLF acutely exposed via ingestion of whole California mice.**

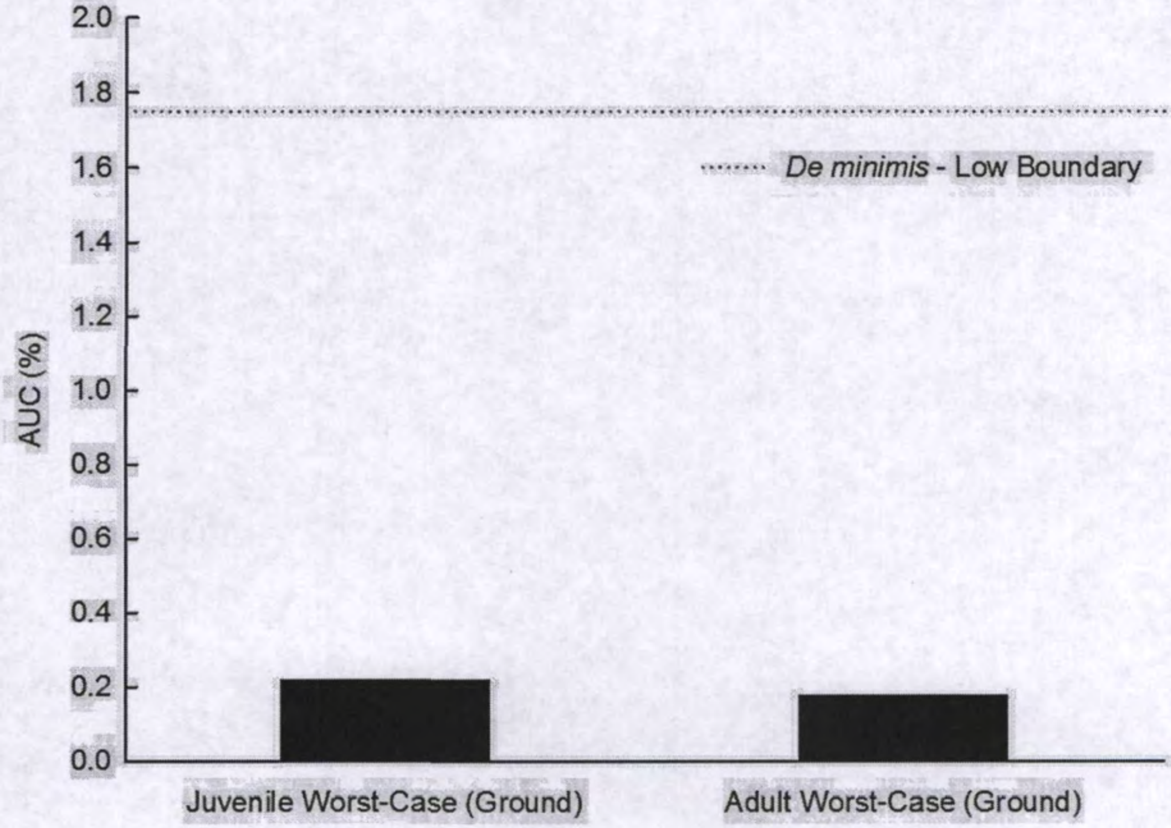

Figure 4-7 Refined risk characterization demonstrating *de minimis* risk for juvenile CRLF acutely exposed via a worst-case diet in Christmas tree plantations receiving ground application of 1 lb a.i./A three times per growing season, with a minimum retreatment interval of 14 days.

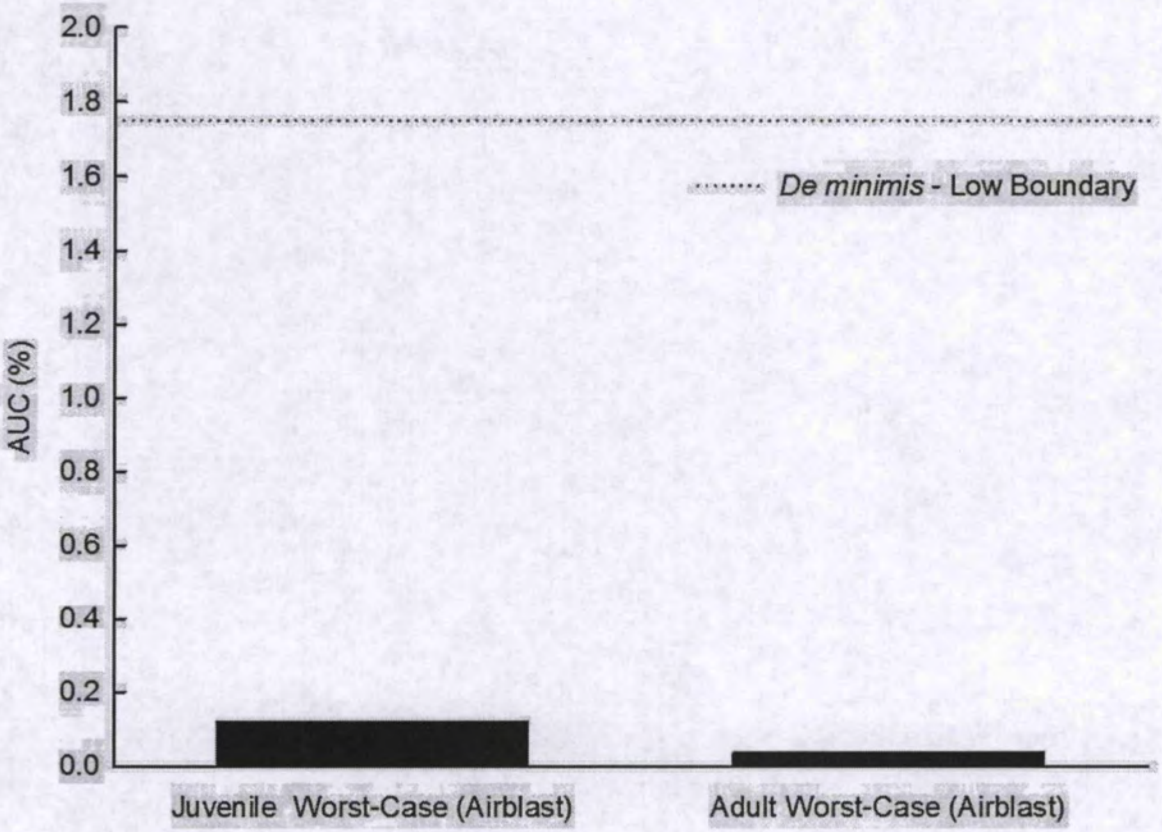

Figure 4-8 **Refined risk characterization demonstrating *de minimis* risk for juvenile CRLF acutely exposed via a worst-case diet in Christmas tree plantations receiving airblast application of 1 lb a.i./A three times per growing season, with a minimum retreatment interval of 14 days.**

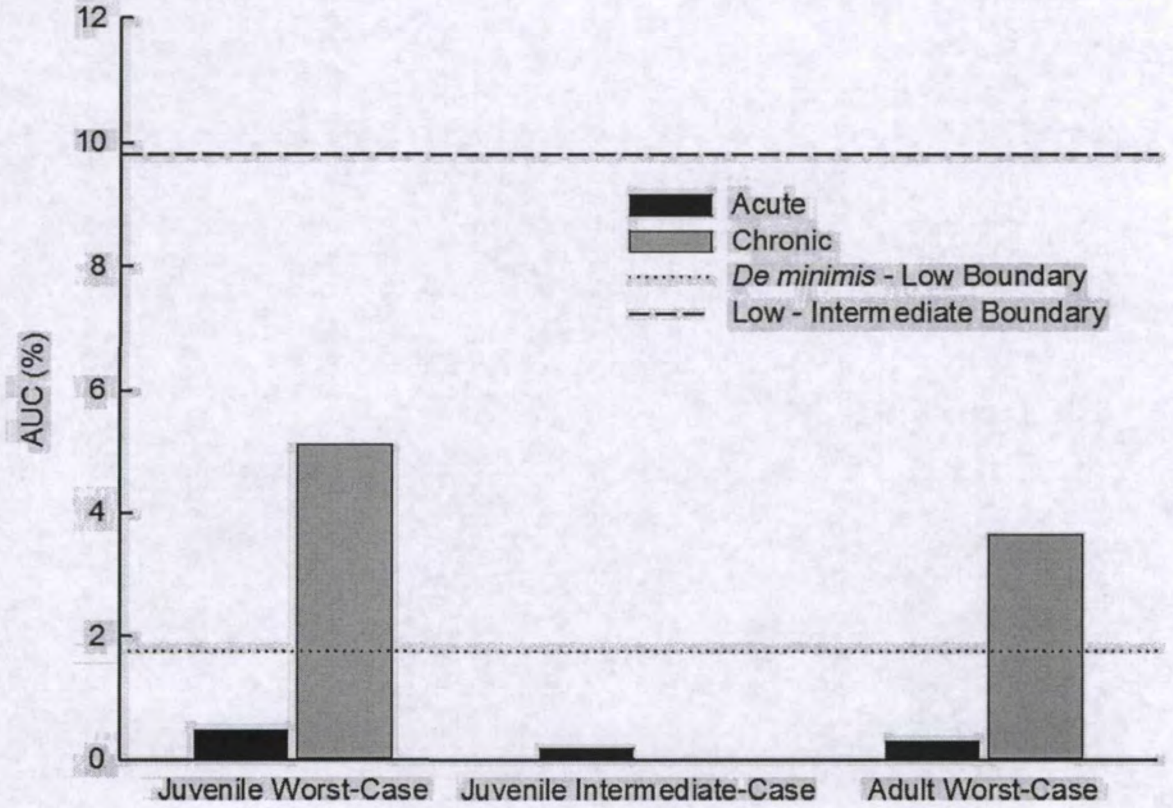

Figure 4-9 **Refined risk characterization demonstrating *de minimis* and low risk for CRLF exposed via intermediate and worst-case diets, respectively, in cottonwood plantations receiving 2 lb a.i./A three times per growing season, with a minimum retreatment interval of 10 days.**

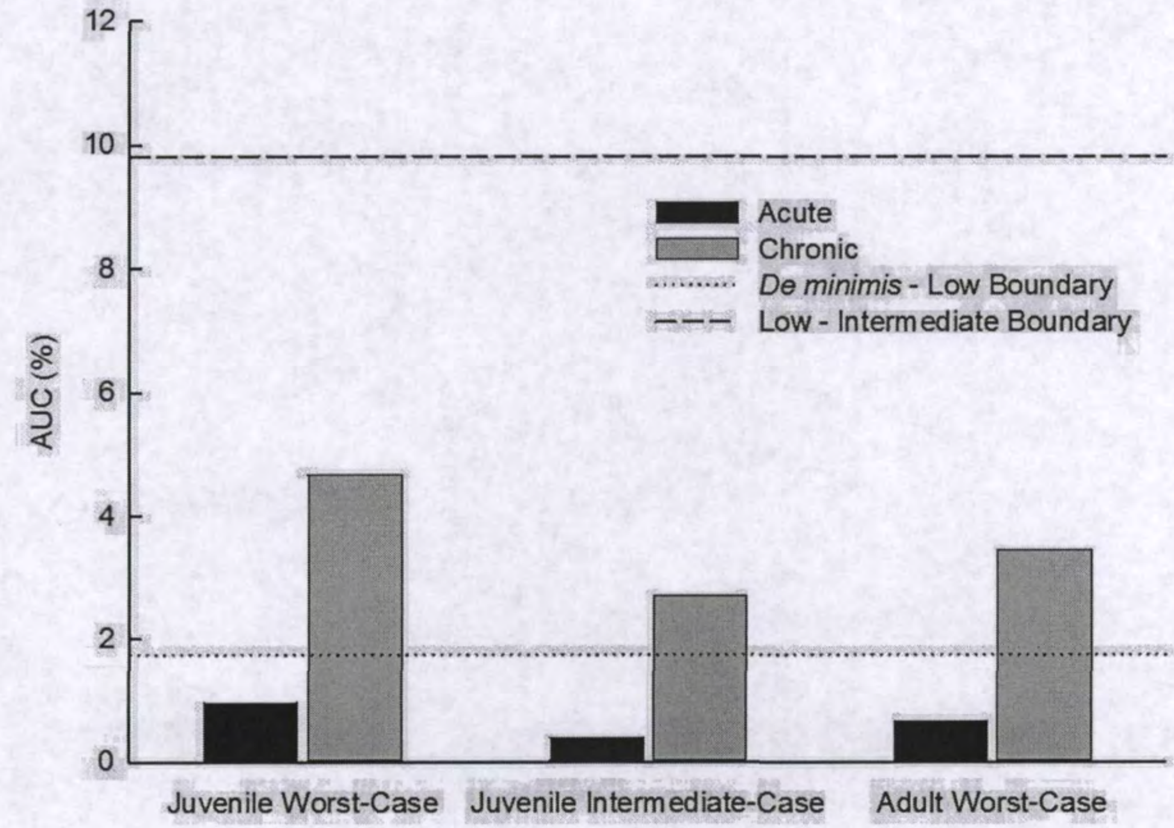

Figure 4-10 **Refined risk characterization demonstrating *de minimis* and low risk for CRLF exposed via intermediate-case and worst-case diets, respectively, on non-cropland adjacent to vineyards receiving 2 lbs a.i./A twice per growing season, with a minimum retreatment interval of 14 days.**

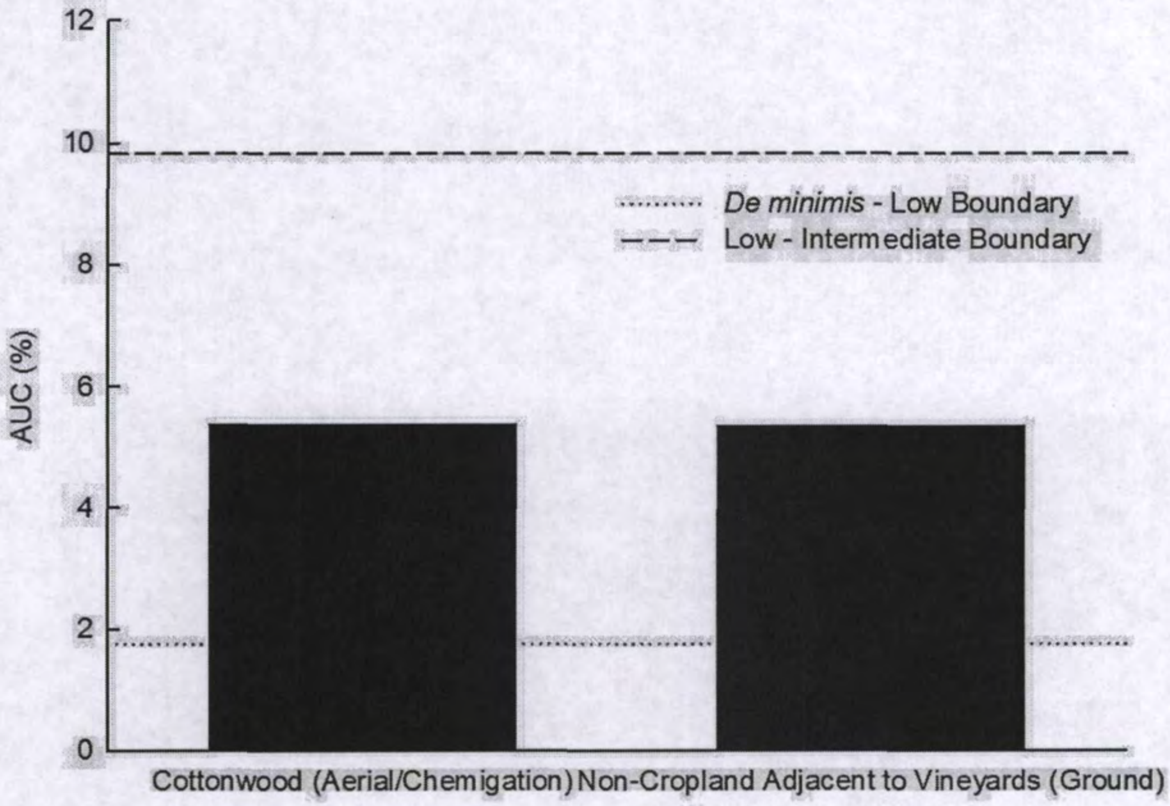

Figure 4-11 Refined risk characterization demonstrating low risk for Pacific tree frog chronically exposed via diet on fields with highest potential exposure.

Table 4-37 Summary of quantitative refined risk characterization for terrestrial-phase CRLF

Crop/Use	*Application Method*	*Scenario (lb. a.i./A)/ No. Applications per Year/ Retreatment Interval (d)*	*Receptor*	*Diet*	*Exposure Duration*	*Estimated Probability of Exceeding 5% Effect Level (%)*	*AUC (%)[a]*	*Risk Category*
Broccoli	Aerial/groundspray	0.5/3/7	Adult	Whole mouse	Acute	0.0100	6.87E-04	*De minimis*
Christmas trees	Airblast	1/3/14	Juvenile CRLF	Worst	Acute	0.140	0.122	*De minimis*
Christmas trees	Groundspray	1/3/14	Juvenile CRLF	Worst	Acute	0.280	0.218	*De minimis*
Christmas trees	Airblast	1/3/14	Adult CRLF	Worst	Acute	0.0600	0.0372	*De minimis*
Christmas trees	Groundspray	1/3/14	Adult CRLF	Worst	Acute	0.210	0.178	*De minimis*
Christmas trees	Airblast/groundspray	1/3/14	Adult CRLF	Whole mouse	Acute	0.140	0.109	*De minimis*
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Juvenile CRLF	Worst	Acute	0.610	0.480	*De minimis*
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Juvenile CRLF	Worst	Chronic	23.4	5.12	Low
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Adult CRLF	Worst	Acute	0.330	0.290	*De minimis*
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Adult CRLF	Worst	Chronic	16.5	3.65	Low
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Juvenile CRLF	Intermediate	Acute	0.190	0.189	*De minimis*
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Adult CRLF	Whole mouse	Acute	1.17	0.855	*De minimis*
Cottonwood grown for pulp	Aerial/ chemigation[b]	2/3/10	Pacific tree frog	NA	Chronic	24.6	5.37	Low
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Worst	Acute	1.15	0.970	*De minimis*
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Worst	Chronic	18.6	4.67	Low
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Intermediate	Acute	0.500	0.392	*De minimis*
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Juvenile CRLF	Intermediate	Chronic	11.4	2.70	Low

Table 4-37 Summary of quantitative refined risk characterization for terrestrial-phase CRLF

Crop/Use	*Application Method*	*Scenario (lb. a.i./A)/ No. Applications per Year/ Retreatment Interval (d)*	*Receptor*	*Diet*	*Exposure Duration*	*Estimated Probability of Exceeding 5% Effect Level (%)*	*AUC (%)[a]*	*Risk Category*
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Adult CRLF	Worst	Acute	0.770	0.670	*De minimis*
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Adult CRLF	Worst	Chronic	14.7	3.46	Low
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Adult CRLF	Whole mouse	Acute	1.07	0.814	*De minimis*
Non-cropland adjacent to vineyards	Groundspray	2/2/14	Pacific tree frog	NA	Chronic	19.9	5.35	Low
Wheat (2)[c]	Aerial/groundspray	0.67/2/7	Adult CRLF	Whole mouse	Acute	0.0100	0.0101	*De minimis*

[a] A description of the AUC approach to risk categorization is described in Section 2.10.5.2
[b] Aerial and chemigation exposure concentrations were not significantly different, and are thus presented together here.
[c] Wheat (2) refers to a specific wheat use pattern of several presented in Table 2-5.

4.3 Other Lines of Evidence in the Terrestrial Effects Determination

4.3.1 Incident Reports

A copy of the dimethoate incident reports in the Ecological Incident Information System (EIIS) was provided to Intrinsik Environmental Sciences by the US EPA (EPA, 2010a). There have been 26 incidences from 1972 to 2006 (Table 4-38). Only three incidences were reported after 2000. The EIIS report provides general information on the incident location, data, county and state, certainty, legality, formulation type, application method and total magnitude. Certainty is ranked on a scale from 0 to 4 where 0 is considered unrelated and 4 is considered highly probable. The legality code indicates whether the incident was due to a registered use, misuse (not applied as per label), accidental misuse (e.g., spill), intentional misuse (e.g., baiting) or unknown. In some incident reports, information is also available that describes the affected species, response observed (e.g., mortality, behavioral), and the identified route of exposure. Additional information on application rate and type, and local meteorological conditions was not provided.

Two incidents were reported for observed damage to corn and lentils following direct application. Both of these incidents were the result of dimethoate misuse (EPA, 2010a) and will not be considered further.

The EIIS for dimethoate contained 19 reported terrestrial incidents involving wildlife. Of these, three were the result of misuse of the pesticide, and nine were the result of a registered use (EPA, 2010a). For the remaining seven incidents, it is unknown whether the adverse effects to wildlife were from misuse or registered use of dimethoate. Of the registered use incidents, four had a high probability of being due to dimethoate use. The remaining six registered use incidents were given certainty scores of two (possible). The four incidents with a high probability of being caused by dimethoate use occurred in 1972 (two incidents), 1993 and 2000. Thus, these four incidents likely do not reflect current labelled uses, application rates, and protections. Moreover, two of these four incidents involved additional pesticides along with dimethoate. Thus, it is not possible to determine if wildlife were adversely affected by dimethoate or by one or a combination of the other pesticides.

In the IRED, EPA stated that, "The primary ecological risks of concern are to birds and mammals on a chronic basis. The Agency is attempting to reduce those risks by reducing application rates and numbers of applications, and increasing application intervals." In addition, the Agency stipulated that best management practices (BMPs) be added to labels, with the purpose of reducing the amount of dimethoate that enters surface water bodies through spray drift (EPA, 2006b). These BMPs include requiring medium or coarser sprays for aerial applications and prohibiting aerial sprays when wind speeds are greater than 10 miles per hour. To further reduce the amount of dimethoate entering surface water bodies as runoff, the Agency recommended use of vegetative filter strips, if practical. The label changes included some reductions of application rates, limiting the number of applications per year, and increasing some retreatment intervals. Label changes were required in response to the IRED (EPA, 2006b) and took effect in 2006-2008. There have been no incident reports, aquatic (or terrestrial), since the mitigations imposed by EPA took place. The risk mitigation imposed in the recent IRED should continue to reduce the probability of the occurrence of ecological incidents.

EPA (2008b) suggested that Canada geese (*Branta canadensis*) were frequently affected by dimethoate use on alfalfa. Of the four incidents involving Canada geese, two were due to accidental misuse (i.e., spills). The two remaining incidents occurred in 1986 and 1993 (Table 4-38). Significant changes to dimethoate labelling and application rates and incorporation of best management practices on the label have occurred since that time to reduce risk to gorge-feeding birds such as the Canada goose. Specifically, for alfalfa hay, the frequency of applications has been reduced to 1/cutting and no more than three applications per year. For alfalfa seed, no more than two applications per year (one at least 10 days before flowering and one after flowering) are permitted. Thus, incidents are much less likely to be an issue for gorge feeders that frequent treated alfalfa fields.

There are two primary sources of incident reports. The first source is Section 6(a)(2) of FIFRA, under which pesticide registrants are required to report to EPA allegations or other information the registrant receives regarding adverse effects associated with registered pesticides. Investigative reports voluntarily submitted to the EPA from state and other federal agencies that oversee agriculture, wildlife, natural resources, and environmental quality are the second major information source. Diagnostic reports are also obtained from the National Wildlife Health Institute (USGS), the Patuxent Wildlife Research Center (USGS), the Southwest Wildlife Cooperative Disease Study, and state wildlife forensic laboratories (EPA, 2010b). Information is also extracted from accounts of ecological incidents reported in newspapers and reliable internet sources (EPA, 2010b). One of the issues with the development of the EIIS based on these sources is the proper tracking and quality control of each incident. Within the EIIS, each incident is assigned a unique incident number. However, in the dimethoate EIIS reports there is a high probability that duplicate incidents exist. For example, the following incidents appear to be duplicates (Table 4-38):

I014341-015 and I014341-016	Identical date, location, species affected, crop, certainty code, etc.
I013884-020 and I013884-024	Exposure route and date differ, but otherwise incidents are identical. Suspect transcription error.
I005754-003 and B0000-219-02	Minor differences, uncertain magnitude.

Table 4-38 Ecological Incident Information System (EIIS) summary for dimethoate (Accessed April 28th, 2010)[a]

Incident #	*Date*	*General Description*	*County, State*	*Certainty Code[b]*	*Legality Code[c]*	*Other Pesticides Involved*	*Application Method*	*Organism Affected*	*Magnitude[d]*	*Exposure Route*
I016940-010	3/3/2005	Corn	Imperial, CA	4	M	Cyfluthrin	Spray[e]	Corn (*Zea mays*)	30 Acres	Direct treatment
I013587-025	7/17/1999	Lentils	Spokane, WA	3	M	None	Spray	Grass (no species name)	--	Spray drift
I005524-004	2/10/1986	Alfalfa	Imperial, CA	2	RU	Carbofuran	--	Canada goose (*Branta canadensis*)	25	Ingestion
I005751-001	5/1/1988	Alfalfa	ID	3	MA	Carbofuran, Disulfoton	--	Canada goose (*Branta canadensis*)	>100	Ingestion
I005572-003	5/22/1988	Alfalfa	ID	3	MA	Carbofuran, Disulfoton	Seed Treatment	Canada goose (*Branta canadensis*)	150	Ingestion
I000920-001	6/10/1993	Alfalfa	Canyon, ID	4	RU	Carbofuran	--	Canada goose (*Branta canadensis*)	40	
I010916-001	8/9/2000	Bait	Onond-aga, NY	4	MI	None	Bait	Rock dove (*Columbia livia*)	1	
I014341-015	1/1/1998	Bean	Grant, WA	2	UN	Naled	--	Bee (Apidae spp.)	20 Hives	Ingestion
I014341-016	1/1/1998	Bean (Phaseolus sp.)	Grant, WA	2	UN	Bentazon	--	Bee (Apidae spp.)	20 Bee Hives	Ingestion
I013884-033	7/8/1998	Bean	Yakima, WA	2	RU	None	Spray	Bee (Apidae spp.)	--	Spray Drift
I013587-012	7/14/1999	Not reported	Grant, WA	2	UN	Carbaryl, chlorothal-onil, methamido-phos	--	Bee (Apidae spp.)	150 Bee Hives	Spray Drift
I003826-009	4/28/1995	Orchard	Hender-son, NC	3	UN	Captan, carbaryl, endosulfan, methyl parathion	--	Bee (Apidae spp.)	Unknown	Drift
I014341-006	1/1/1996	Orchard	Benton, WA	2	UN	Chlorpyrifos	--	Bee (Apidae spp.)	1256	Ingestion

Table 4-38 Ecological Incident Information System (EIIS) summary for dimethoate (Accessed April 28th, 2010)[a]

Incident #	*Date*	*General Description*	*County, State*	*Certainty Code[b]*	*Legality Code[c]*	*Other Pesticides Involved*	*Application Method*	*Organism Affected*	*Magnitude[d]*	*Exposure Route*
I013884-028	4/15/1998	Orchard	Yakima, WA	2	RU	Chlorpyrifos	--	Bee (Apidae spp.)	Unknown	Ingestion
I013883-018	7/15/1997	Potato	Grant, WA	2	RU	Carbofuran, methamido-phos	--	Leafcutter bee (*megachile sp.*)	Unknown	Ingestion
I013884-020	8/12/1998	Bean	Adams, WA	2	RU	None	--	Honey bee (*Apis millifera*)	20 colonies	Ingestion
I013884-024	8/21/1998	Bean	Adams, WA	2	UN	Naled	--	Honey bee (*Apis millifera*)	20 colonies	Drift
I020741-001	7/19/2006	Corn	Larimer, CO	3	UN	Not available	--	Honey bee (*Apis millifera*)	22 bee hives	Spray drift
B0000-219-03	5/1/1972	Garden	Contra costa, CA	4	RU	Diazinon, dieldrin	--	Cedar waxwing (*Bombycilla cedrorum*)	--	Ingestion
I005754-003	3/22/1972	Not reported	CA	2	RU	None	--	Cedar waxwing (*Bombycilla cedrorum*)	6 or 60[f]	Ingestion
B0000-219-02	3/22/1972	Ornamental, woody	Tulare, CA	4	RU	None	--	Cedar waxwing (*Bombycilla cedrorum*)	60-80[f]	Ingestion

[a] An e-mail was sent to the EPA (Mastrota.Nicholas@epa.gov – May 5th, 2010) to enquire about the potential for duplicate records in the EIIS database for dimethoate. No response had been received as of June 28th, 2012. Unless otherwise noted, the formulation was not reported for the incidents presented in this table

[b] Certainty Code: 0 = Unrelated, 1=Unlikely, 2=Possible, 3=Probable, 4=Highly Probable

[c] Legality Code: RU = Registered Use, M=Misuse, MA=Misuse (Accidental), MI=Misuse (Intentional), UN=Unknown.

[d] The magnitude of the incident in the number of organisms of the reported taxa affected, unless otherwise noted

[e] reported EC formulation

[f] Estimate likely due to transcription error in the EIIS database. Actual number unknown.

4.4 Uncertainties in the Terrestrial Effects Determination

4.4.1 Effects Assessment

The screening-level effects determination for terrestrial-phase CRLFs, their prey and their habitat used the most sensitive and relevant measures of effect for each assessment endpoint. There are uncertainties associated with the selection of acceptable studies of good quality to derive the measures of effects. The uncertainties were reduced by using data-screening criteria to identify best available data. In the end, GLP studies were selected to derive the effects metrics. Raw data are typically available in GLP studies to confirm the calculations and reported results. Also, the test material used in recent GLP studies is more representative of the dimethoate currently produced by Cheminova. As a result, the magnitude of the uncertainty stemming from data quality issues is considered low.

4.4.1.1 Extrapolation From Birds to Amphibians

In the absence of toxicity data for terrestrial-phase amphibians, EPA uses the toxicity test results from bird studies as surrogate effects metrics for amphibians (EPA, 2004a, 2008e). This approach was followed in the current effects determination for CRLF.

The extrapolation of toxicity test results for pesticides from birds to terrestrial-phase amphibians has little, if any, empirical support, primarily because of the paucity of toxicity data for the latter. That is, the extrapolation is made of necessity, not because it has been scientifically justified by EPA or anyone else. Birds and herptiles belong to different taxonomic classes. Allard et al. (2009) found that there was no empirical basis for extrapolating toxicity benchmarks between taxonomic classes. Studies with acute toxicity data demonstrated that uncertainty in toxicity extrapolations increased as taxonomic relatedness decreased (Suter et al., 1986; Suter and Rosen, 1988; Raimondo et al., 2007). Raimondo et al., observed that 100% of extrapolations were within the range 1 to 5-fold accuracy when done within a genus. The success rate, however, declined to 92% for within-family extrapolations and 85% for within-class extrapolations. The classes being compared in the Raimondo et al. (2007) study were birds and mammals, both of which are homeotherms. Comparisons of sensitivities to toxicants between homeotherms and poikilotherms have not been done. Luttik and Aldenberg (1997) concluded that differences between birds and mammals preclude extrapolations between these two classes based on LD50 values. Sample and Arenal (1999) similarly concluded that extrapolations between birds and mammals should be approached with extreme caution. The concerns expressed regarding extrapolations between birds and mammals almost certainly apply to toxicity extrapolations between birds and terrestrial-phase amphibians.

4.4.1.2 Terrestrial-Phase Dose-Response Curves

The acute dose-response curve for northern bobwhite was generated with a dataset that contained only one partial effect treatment (i.e., with the exception of one treatment group, mortality was either 0% or 100%; Zok, 2001c). This meant that a model could not be selected based on goodness-of-fit, error terms do not exist for most plausible sigmoidal models and confidence limits could not be calculated. This results in a high degree of uncertainty in the estimated levels of effect (mortality) corresponding to intermediate doses for northern bobwhite.

The chronic dose-response curve was estimated by fitting a model to percent reduction in eggs laid (Gallagher et al., 1996a) versus estimated daily dose. Some uncertainty was introduced in the conversion of dietary concentrations to estimated daily doses (e.g., food intake rates were measured on a pen-by-pen basis, as opposed to individual birds). Also, there was a high degree of variability in the response variable. Even at the highest treatment levels, some pairs of birds produced more eggs than the mean of control birds. Uncertainty was also introduced at the high end of the dose-response curve because effects were extrapolated beyond those observed in the highest treatment. The highest observed dose achieved was 4.2 mg a.i/kg bw/d. This latter source of uncertainty is not that important given that *TDI* modeling results suggest a less than a 3% probability of exceeding this average daily dose for all chronic exposure scenarios.

4.4.2 Exposure Assessment

4.4.2.1 Total Daily Intake (*TDI*) Model

Measured concentrations of dimethoate in aquatic prey of terrestrial-phase CRLFs were not available. Dimethoate residues in prey were calculated using estimated BCFs. The approach by Arnot and Gobas (2004) was used to estimate conservative concentrations of dimethoate in aquatic prey. The approach yielded BCFs of 0.92 and 1.04 for aquatic invertebrates and fish, respectively. Percent lipid content in aquatic invertebrates and fish used to estimate these BCFs were obtained from measurements in aquatic invertebrates and fish from the Great Lakes. Thus, it was assumed that lipid contents in aquatic species in the Great Lakes are similar to lipid contents in prey in California. The BCF values were then multiplied by conservative surface water concentrations estimated by PRZM/EXAMS modeling to derive concentrations of dimethoate in prey. Based on this information, the estimated concentrations in aquatic prey of CRLFs and Pacific tree frogs were likely overestimated. However, this uncertainty likely had a negligible effect on the results of the refined effects determination given that estimated residues in terrestrial arthropods were orders of magnitude greater than those in aquatic invertebrates.

Residue values on terrestrial arthropod feed items from Barber et al. (2005) and Knäbe (2004a,b) were used to estimate potential exposure of Pacific tree frogs and CRLFs to dimethoate. The studies presented in these documents were conducted according to GLP and generally recognized modern agricultural practices. Cheminova's peak residue unit doses following application for terrestrial arthropods are consistent with recently published data on arthropod residues (e.g., Fischer et al., 1997; EPA, 2012). This suggests that the uncertainty related to the use of these calculated RUD values is minor.

The dissipation half-life on crop-dwelling arthropods reported by Knäbe (2004a) was used to model the degradation of dimethoate. This was a GLP study conducted in an apple orchard in Spain. Thus, there is some uncertainty in extrapolating results from an apple orchard in Spain to a variety of crops in California. This source of uncertainty is likely to have a larger impact on the chronic *TDI* results than would be the case with the acute *TDI* results.

Residue estimates and dissipation half-lives on the vegetation feed items of the California mouse were based on a large database of dimethoate-specific GLP field residue studies (Corden, 2000, 2001, 2005; Goodband, 2003; Knäbe, 2004a, Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001 a-l; 2002a-f, 2003a,b; see Section 4.1.2.2). Thus, uncertainty is low with regard to vegetative RUDs and dissipation half-lives.

In the screening-level assessment, concentrations of dimethoate in terrestrial vertebrate prey of terrestrial-phase CRLFs were not available. Dimethoate residues in mice and terrestrial-phase amphibian prey were predicted using the Total Daily Intake (*TDI*) model. As with any modelled estimate, this source of uncertainty could be reduced by direct measurements of tissue concentrations in Pacific tree frogs and California mice. However, given the high rates of metabolism and excretion of dimethoate in birds and mammals (Jalali et al., 1995; Kirkpatrick et al., 1995), it is likely that *TDI* estimates do not significantly underestimate dietary concentrations in these prey.

No measurements of free metabolic rate or food intake rate were available for the CRLF or their vertebrate prey (Pacific tree frog and California mouse). Therefore, free metabolic rates were estimated using allometric equations for reptilian species as a surrogate for the frogs and rodentia for the California mouse. A comparison of standard metabolic rates of reptiles and amphibians suggests that these organisms have similar base metabolic needs. However, there is uncertainty in assuming that energy demands would be similar among these taxa when they are actively foraging, escaping predators, searching for mates, defending territories, etc.

There are two variables that strongly influence *TDI* estimates and thus are particularly important in the interpretation of the quantitative results of the refined terrestrial risk characterization. These variables are: (1) the proportion of diet containing pesticide residues, and (2) the proportions of various items in the diet. Due to a lack of quantitative data for these variables, highly conservative assumptions were applied in both the screening-level and refined exposure assessments for terrestrial-phase CRLF and their amphibian prey.

We assumed that 100% of the terrestrial-phase amphibian diet consists of feed items carrying dimethoate residues (i.e., terrestrial prey found on the treated field, or aquatic prey exposed to dimethoate via drift and runoff). However, dimethoate is an acute contact and systemic insecticide. As such, it is designed to kill crop-dwelling terrestrial arthropod pests. At the maximum applications the majority of terrestrial arthropods coming in contact with the spray would be rapidly killed or immobilized. This leads to two important points: (1) most terrestrial arthropods on a field at the time of dimethoate application would not be able to travel to the preferred riparian habitat of CRLF, and (2) immobilized terrestrial arthropods are not desirable prey for the CRLF because their predatory instincts are triggered by movement (Hayes and Tennant, 1985). Thus, the assumption that CRLFs are consuming terrestrial arthropods exclusively found on treated fields immediately after application is highly conservative. Further, non-migrant terrestrial-phase CRLFs forage in close proximity to a water source (Bulger et al., 2003). Bulger et al. (2003) reported that over 75% of the individual CRLF monitored traveled short distances to upland areas following rain events, but returned to aquatic habitat after a short period. The remaining 25% of CRLFs were non-migratory. Tatarian (2008) corroborated these results. Thus, the majority of frogs are found near water most of the time. Given that dimethoate is not applied to riparian habitat or directly to water bodies, very few CRLF, if any, would have a diet consisting largely comprised of feed items with peak dimethoate residues.

Because no appropriate data were available on the proportions of prey consumed by CRLFs, risk was modeled using best-, intermediate- and worst-case dietary exposure scenarios. For acute exposures, the consumption of a whole mouse was also considered. Although there is considerable uncertainty regarding the CRLF diet, we modelled the possible range of diets in this assessment.

Diets containing 50% or 100% terrestrial arthropods were considered in the refined assessment (diets consisting of only aquatic invertebrates were found to pose negligible risk to CRLFs). However, there are some data suggesting that a diet of 100% terrestrial arthropods is unlikely. CRLFs consume a variety of invertebrate and vertebrate species found along the shoreline and on the water surface. A study examining the gut contents of 35 CRLFs reported prey from 42 taxa (Hayes and Tennant, 1985). The prey groups observed most often included carabid and tenebrionid beetles, water striders, lycosid spiders, and larval neuropterans (Hayes and Tennant, 1985). The most commonly observed prey species were larval alderflies (*Sialis cf. californica*; aquatic), pillbugs (*Armadillidrium vulgare*; moist terrestrial), and water striders (*Gerris sp.*; aquatic; Hayes and Tennant, 1985). These taxa represent a mix of terrestrial and aquatic prey. A preference for particular prey species was not observed in this study, and CRLFs appeared to select prey based on availability (Hayes and Tennant, 1985). Hayes and Tennant (1985) concluded that CRLFs are not good at identifying prey and tend to forage in an indiscriminant manner (Hayes and Tennant, 1985). Thus, terrestrial-phase CRLF are unlikely to consume the worst-case diet of 100% terrestrial arthropods.

The consumption of a whole mouse by an adult CRLF was also considered in the exposure assessment. We assumed that the mouse spent 100% of its time foraging on treated fields following dimethoate application. However, CRLF small mammal consumption is expected to be infrequent (Hayes and Tennant, 1985). Further, it is extremely unlikely that a mouse foraging all day on a treated field would subsequently be consumed by an individual of a species with preference for riparian and aquatic habitat.

The dietary composition of the Pacific tree frog was estimated using frequency of occurrence data from gut content analyses. Estimates of 81% and 19% for terrestrial and aquatic invertebrates, respectively, were calculated based on data provided in Johnson and Bury (1965). Much of the frogs' diets consisted of worms. Because residues are lower in terrestrial worms than in crop-dwelling arthropods (likely due to interception by soil and/or crop; Barber et al., 2005), we expect that exposure to Pacific tree frogs was over-estimated in our assessment.

Gross energy assumptions were from EPA (1993), and are expected to introduce minor uncertainty given that they are based on measured data of closely-related surrogate prey items. Assimilation efficiencies for dietary items as they are consumed by CRLF and Pacific tree frog are, however, more uncertain. There were no available assimilation efficiency data for amphibians consuming prey. As a result, we assumed that assimilation efficiencies for CRLFs and Pacific tree frogs were the same as for birds consuming the same prey. Although these assumptions are somewhat uncertain, they are not expected to have a major impact on the risk estimates.

The duration assumed for the chronic effects determination is uncertain. A chronic exposure study was selected in which reproductive effects were observed (reduced number of eggs laid relative to control animals) at the end of a 22-week exposure period (Gallagher et al., 1996a). The study did not report, and there is no post hoc way of assessing, at what point in the exposure period the physiological changes resulting in the impacts on number of eggs laid occurred. A chronic exposure averaging period of four days was selected for this effects determination (which is less than 5% of the exposure duration in the toxicity study used for the effects assessment). This is a highly conservative assumption given the small fraction that four days represents compared to the full duration of the study. However, there is no way to confirm the level of conservatism.

4.4.2.2 TerrPlant

The Terrestrial Plants Model (TerrPlant) is a screening-level model that estimates the risk of pesticides to non-target plants. TerrPlant estimates pesticide residues in runoff and drift to non-target areas and calculates risk quotients for non-listed and listed threatened and endangered terrestrial plant species that occupy dry and semi-aquatic areas. The model can be used for both monocot and dicot species. TerrPlant considers a non-target area to be the space adjacent to the treated field that receives runoff and spray drift following pesticide application. Dry areas are assumed to receive sheet runoff (1 to 1 ratio of areas), whereas semi-aquatic areas are assumed to receive channel runoff (10 to 1 ratio of areas). With these assumptions, TerrPlant estimates pesticide concentrations or application rates and then compares these values to the corresponding application rates for effects to plant survival and growth.

The limitations, assumptions and sources of uncertainty in the TerrPlant model include (Trask et al., 2010a,b):

- The semi-aquatic non-target area is assumed to be one-tenth the size of the target application area. This assumption is based on observations of aquatic areas in Georgia.

However, the size ratio is likely to be highly variable across agricultural areas in California.

- The spray drift component of TerrPlant only considers the application method and does not include additional factors such as wind speed, droplet size and height of pesticide release that may affect the quantity of pesticide moving off the field as spray drift.
- The model conservatively assumes that runoff occurs at the time of application, an unlikely event given that farmers generally avoid applying pesticides on rainy days.
- Both runoff and spray drift are assumed to be distributed uniformly throughout the non-target area. In reality, there is typically a decrease in the quantities of runoff and spray drift reaching areas of increasing distance from the application area.
- TerrPlant assumes that runoff and spray drift reach the non-target area at the same time, and that non-target plants exposed to the pesticide residues are in the sensitive, early emergent life stages. Both of these assumptions are conservative.
- The fraction of pesticide in runoff is based upon estimates of pesticide solubility. Other environmental fate parameters that would likely affect the fraction of pesticide in runoff, such as K_d of the pesticide, are not considered.
- Currently, there are no field data to evaluate the exposure estimates generated by TerrPlant. Thus, there is uncertainty concerning model performance in the real world.
- TerrPlant can only simulate single applications. However, a more refined analysis was conducted herein in which peak amounts of dimethoate on a field were estimated for exposure scenarios that involved multiple applications of dimethoate to crops. The approach involved determining how much dimethoate remains immediately before the next application. This amount was then added to the new amount applied to determine a "cumulative" application rate. The soil aerobic half-life of 3.5 days (EPA, 2005a) was used to estimate cumulative peak amount applied (Section 4.1.2.4).

The TerrPlant analyses described herein showed that dimethoate poses no risk to non-targe plants. Given the conservativeness of TerrPlant, there is very little uncertainty regarding this conclusion.

4.4.3 Incident Reports

Incident reports have a large degree of uncertainty associated with them. Tissue testing is not often performed, and exact cause of death is rarely established. Incident reports often present findings involving multiple pesticides, making the contribution of the individual pesticides to the reported effects uncertain. Thus, incident reports are not a very reliable source of information in the risk characterization process.

4.5 Summary and Conclusions of the Terrestrial Effects Determination

Five use patterns were considered in the refined terrestrial effects determination for direct effects to juvenile and adult CRLF and indirect effects to the CRLF via reduction of terrestrial amphibian prey (Pacific tree frog) given the results of the screening-level assessment. These use patterns were:

- Broccoli (groundspray and aerial applications of 0.5 lb a.i./A applied three times per year with a minimum retreatment interval of 7 days)
- Non-cropland areas adjacent to vineyards (groundsprayed with 2 lb a.i./A twice per year with a minimum retreatment interval of 14 days)
- Cottonwood grown for pulp (chemigated or aerially treated with 2 lb a.i./A three times per year with a minimum retreatment interval of 10 days)
- Christmas tree nurseries (airblast or groundsprayed with 1 lb a.i./A three times per year with a minimum retreatment interval of 14 days), and
- Wheat (groundspray and aerial applications of 0.67 lb a.i./A applied twice per year with a minimum retreatment interval of 7 days).

All of these use patterns pose *de minimis* acute risk to adult CRLF consuming whole California mice.

Applications to Christmas tree nurseries pose *de minimis* risk to CRLF. Both cottonwood grown for pulp and non-cropland adjacent to vineyards applications pose low chronic risk and *de minimis* acute risk to CRLF. Pacific tree frog is estimated to be at low chronic risk in cottonwood plantations and non-cropland adjacent to vineyards.

We assumed that CRLFs forage for prey on treated fields immediately after application at maximum label application rates. These assumptions are highly conservative as the scientific literature indicates that most frogs remain in close proximity to a water body most of the time, and that they forage opportunistically on mobile prey (see Section 2.1.5). The feed item with the highest residues, terrestrial arthropods, is the target of the insecticide and thus will be unavailable to off-field CRLF. Thus, the assumption that CRLFs are consuming terrestrial arthropods exclusively found on treated fields immediately after application is highly conservative.

Given these conservative assumptions and that, at most, low risk to terrestrial-phase CRLF was found, we expect that risk is more likely negligible for the two use patterns producing the highest potential exposure (i.e., non-cropland adjacent to vineyards and cottonwood grown for pulp at maximum yearly label application rates).

Based on the California Pesticide Use Reporting (PUR) database, the use patterns considered in the refined assessment account for a very small proportion of the total dimethoate used and the total area treated in California between 2000 and 2009 (see Table 2-1). We could find no evidence to suggest that cottonwood grown for pulp was treated with dimethoate during those years. There is no record of uncultivated agricultural areas, which would include non-cropland adjacent to vineyards, being treated with dimethoate from 2006 to 2009.

Further, the application rates and number of applications considered in the refined terrestrial assessment were estimated to result in the highest exposure concentrations based on registered labels. However, based on the PUR database (2000-2009), much lower application rates and number of treatments are typically applied in fields. Incidents resulting from the legal, registered uses of dimethoate are infrequent. Moreover, the most recent registered use incident occurred in 1993 and changes in labeling, application rates and best management practices since then strongly suggest that incidents in the future will be even less likely.

The weight-of-evidence indicates that direct effects to terrestrial-phase CRLF, and indirect effects to the CRLF due to direct effects to their amphibian prey and habitat are unlikely.

5.0 FINAL CONCLUSION OF THE CRLF EFFECTS DETERMINATION

The refined risk assessment results suggest that CRLF are unlikely to be at significant risk as a result of dimethoate use in California, either via direct or indirect effects. Based on the results of this effects determination and the effects determination conducted by EPA (2008a), risks of direct effects to aquatic-phase and terrestrial-phase CRLFs are negligible. Similarly, risk is negligible for indirect effects to CRLF via reduction of prey and/or their habitat. Thus, the overall conclusion of this effects determination is that dimethoate use in California may affect, but is not likely to adversely affect CRLF.

6.0 REFERENCES

AAFC (Agriculture and Agri-Food Canada). 2012. Considerations for Hybrid Poplar Productions. Canadian AgroForestry Development Center. http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1192561823602&lang=eng. Accessed July 2012.

Aboul-Ela, I.A. and M.T. Khalil. 1987. The acute toxicity of three pesticides on organisms of different trophic levels as parameters of pollution in Lake Wadi El Rayan. Ei Fayoum. Egypt Proc Zool Soc AR Egypt 13:31-26.

Allard, P., A. Fairbrother, B.K. Hope, R.N. Hull, M.S. Johnson, L. Kapustka, G. Mann, B. McDonald and B.S. Sample. 2009. Recommendations for the development and application of wildlife toxicity reference values. Integr Environ Assess Manage 6:28-37.

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

Andersen, T.H., R. Tjørnhøj, L. Wollenberger, T. Slothuus and A. Baun. 2006. Acute and chronic effects of pulse exposure of *Daphnia magna* to dimethoate and pirimicarb. Environ Tox Chem 25(5):1187–1195.

Anderson, T.D. and K.Y. Zhu. 2004. Synergistic and antagonistic effects of atrazine on the toxicity of organophosphorodithioate and organophosphorothioate insecticides to *Chironomus tentans* (Diptera: Chironomidae). Pest Biochem Phys 80:54–64.

Andrews, R.M. and F.H. Pough. 1985. Metabolism of squamate reptiles: allometric and ecological relationships. Physiol Zool 58:214-231.

Arnot, J.A. and F.A.P.C. Gobas. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. Environ Tox Chem 23(10):2343-2355.

ASTM (American Society for Testing and Materials). 1992. Standard Guide for Conducting Static Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. E 729-88a. In: Annual Book of ASTM Standards, Vol. 11.04. Philadelphia, PA, pp. 403–422.

Baekken, T. and K.J. Aanes. 1991. Pesticides in Norwegian agriculture. Their effects on benthic fauna in lotic environments. Preliminary results. Verh Int Ve. Limnol 24(4):2277-2281.

Baekken T. and K.J. Aanes. 1994. Sublethal effects of the insecticide dimethoate on invertebrates in experimental streams. Norw J Agr Sci Suppl. 13:163-177.

Bakre, P., and M. Rajasekaran. 1989. Acute toxicity of certain pesticides to house sparrow, *Passer domesticus*. Geobios; 16(6): 249-251

Barber, I., M. Ebeling, P. Edwards, M. Riffel, J. Schabacker, K. Welter, J. Pascual and C. Wolf. 2005. Review on Initial Residue Levels of Pesticides in Arthropods Sampled in Field Studies. RIFCON GmbH. Report No. RC05-029. CropLife America Report Number 3151957. MRID 47841001.

Barnthouse, L.W. 2004. Quantifying population recovery rates for ecological risk assessment. Environ Toxicol Chem 23:500–508.

Barrett, G.W. and K.L. Stueck. 1976. Caloric ingestion rate assimilation efficiency of the short-tailed shrew, Blarina brevicauda. Ohio J Sci 76:25-26.

Baskin, Y. 1994. Ecosystem function of biodiversity. Bioscience 44:657–660.

Batzli, G.O., and F.R. Cole. 1979. Nutritional ecology of microtine rodents: Digestibility of forage. J Mammal 60(4):740-750.

Becker, V.S. 1991. Dissipation of Dimethoate From Soil Following Application to Bean, Grape and Bareground Plots Located in Fresno County, CA, USA. EPL Bio-Analytical Services, Inc., Decatur, IL. USA; Doc. No. 922-003; MRID 42884403.

Bell, G.P. 1990. Birds and mammals on an insect diet: A primer on diet composition analysis in relation to ecological energetics. Stud Avian Biol 13:391-415. Cited in: EPA. 1993.

Bennett, A.F. and W.R. Dawson. 1976. Metabolism: Chapter B. In: Biology of the Reptilia. Vol 5. London Academic Press, pp 127-223.

Beusen, J.M. and B. Neven. 1989. Toxicity of dimethoate to *Daphnia magna* and freshwater fish. Bull Environ Contam Toxicol 42:126-133.

Birchfield, N. 2003. Washington Toxics Coalition, Northwest Coalition for Alternatives to Pesticides, Pacific Coast Federation of Fisherman's Associations, and Institute for Fisheries Resources (Plaintiffs) vs. Environmental Protection Agency and Christine T. Whitman (Defendants) vs. American Crop Protection Association et al. (Intervenor-Defendants). Case No. C01-0123C in the United States District Court for the Western District of Washington.

Bobzien, S., J.E. DiDonato and P.J. Alexander. 2000. Status of the California Red-legged Frog (*Rana aurora* draytonii) in the East Bay Regional Park District, California. Oakland, CA. Cited In: FWS, 2002a.

Bogen, K.T., and R. Reiss. 2011. Generalized Haber's law for exponential concentration decline, with application to riparian-aquatic pesticide ecotoxicity. Risk Anal August 13, 2011.

Bold, H.C. and M.J. Wynne. 1985. Introduction to the Algae: Structure and Function. Prentice-Hall, Englewood Cliffs, NJ.

Breton, R.L., G. Gilron, R. Thompson, S. Rodney and S. Teed. 2009. A new quality assurance system for the evaluation of ecotoxicity studies submitted under the New Substances Notification Regulations in Canada. Integr Environ Assess Manage 5:127-137.

Brougher, D.S., T.Z. Kendall, S.P. Gallagher and H.O. Krueger. 2012. Dimethoate: A 96-hour Static-renewal Acute Toxicity Test with the Rainbow Trout (Onccorhynchus mykiss). Wildlife International, Ltd. Easton, Maryland. Wildlife International Ltd. Project Number 232A-136A. 61 pp.

Brunet, R., C. Girard, and A. Cyr. 1997. Comparative study of the signs of intoxication and changes in activity level of red-winged blackbirds (*Agelaius phoeniceus*) exposed to dimethoate. Agr Ecosyst Environ 64:201-209.

Bryant, D.M. and V.M. Bryant. 1988. Assimilation efficiency and growth of nestling insectivores. Ibis 130: 268-274.

Bulger, J.B., N.J. Scott Jr. and R.B. Seymour. 2003. Terrestrial activity and conservation of adult California red-legged frogs *Rana aurora* draytonii in coastal forests and grasslands. Biol Conserv 110:85-95.

Bunker, A. 2001. Peromyscus maniculatus. Animal Diversity Web. Accessed January 17, 2007. http://animaldiversity.ummz.umich.edu/site/accounts/information /Peromyscus_maniculatus.html

Burden, A.N. 1991. A Study on the Decomposition of Dimethoate Following Application to Three Soils. Hazleton, UK. DTF Doc. No. 921-004, MRID 46719202.

Burns, L.A. 2000. Exposure Analysis Modeling System (EXAMS). Environmental Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Athens, GA.

CaDFG (California Department of Fish and Game). 2011. California Natural Diversity Database (CNDDB). November, 2011 update. Accessed December 01, 2011.

CA DPR (California Department of Pesticide Regulation). 2000. Pesticide Use Reporting: An Overview of California's Unique Full Reporting System. California Department of Pesticide Regulation. Sacramento, CA.

CA DPR (California Department of Pesticide Regulation). 2010. California Pesticide Information Portal - California Pesticide Use Data 2003-2007. http://calpip.cdpr.ca.gov/cfdocs/calpip/prod/main.cfm Accessed December 2009.

CA DPR (California Department of Pesticide Regulation). 2011. California Pesticide Information Portal - California Pesticide Use Data 2000-2009. http://calpip.cdpr.ca.gov/cfdocs/calpip/prod/main.cfm Accessed November 29, 2011.

Caley, C.Y., B.D. Cameron, B. Knight, K. Armstrong and B.E. Hall. 1992a. Determination of Acute Toxicity (LC50) of EC Formulation of Dimethoate Containing 400 g/L to Bluegill Sunfish (96 h, semi static). Inverest Research International, Scotland. Report No. 6944. CHA Doc. No. 121 DMT.

Caley, C.Y., B.D. Cameron, B. Knight and B. E. Hall. 1992b. EC Formulation of Dimethoate Containing 400g/L: Determination of Acute Toxicity (LC50) to Rainbow Trout (96 h, semi static). Inverest Research International, Scotland. Report No. 6912. CHA Doc. No. 120 DMT.

Canton, J.H., R.C.C. Wegman, A. Van Oers, A.H.M. Tammer, E.A.M. Mathijssen-Spiekman and H.H. Van den Broek. 1980. Environmental Toxicological Research with Dimethoate and Omethoate Rep. No.121/80, Natl. Inst. Public Health Environ Hyg.

Cantox Environmental. 2007. Generic Problem Formulation for California Red-Legged Frog. A Report Prepared by Cantox Environmental Inc. for CropLife America, Washington, DC. CLA Report Number 05232007.

Carsel, R.F., J.C. Imhoff, P.R. Hummel, J.M. Cheplick and J.S. Donigian, Jr. 1997. PRZM-3, A Model for Predicting Pesticide and Nitrogen Fate in Crop Root and Unsaturated Soil Zones: Users Manual for Release 3.0. Environmental Research Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Athens, GA.

Castro, G., N. Stoyan and J.P. Myers. 1989. Assimilation efficiency in birds: a function of taxon or food type? Comp Biochem Physiol A Comp Physiol 92: 271-278.

Chappell, M.A. and T.M. Ellis. 1987. Resting metabolic rates in boid snakes: allometric relationships and temperature effects. J comp Physiol B 157:227-235.

Chaudhari, T.R., M.L. Jadhav and V.S. Lomte. 1988. Acute toxicity of organophosphates to fresh water snails from Panzara Rive at Dhule, MS. Environ Ecol 6(1):244-246.

Clark, F.H. 1936. Geotropic behavior on a sloping plane of arboreal and non-arboreal races of mice of the genus Peromyscus. J Mammal 17:44-47.

Colak, A., Ö. Faiz and E. Sesli. 2009. Nutritional composition of some wild edible mushrooms. Turk J Biochem 34(1): 25-31.

Collopy, M.W. 1975. Behavioral and Predatory Dynamics of Kestrels Wintering in the Arcata Bottoms. Master's Thesis, Humboldt State University, Arcata, CA. Cited in: EPA, 1993.

Cook, D. 1997. Biology of the California red-legged frog: A synopsis. Trans W Sec Wild Soc 33:79-82.

Corden, M.T. 2000. C14-Dimethoate Metabolism in Potatoes. Project Number: SCI/021. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 145 p. DMT 410.

Corden, M.T. 2001. C14-Dimethoate Metabolism in Wheat, Volume 1. Project Number: SCI/049. Unpublished study prepared by huntingdon Life Sciences Ltd. 250 p. DMT 474.

Corden, M.T. 2005. C14-Dimethoate Metabolism in Olives. Project Number: SCI/088. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 315 p. DMT 692.

Crump, K., B. Allen, E. Faustman, M. Donison, C. Kimmel, and H. Zenich. 1995. The Use of the Benchmark Dose Approach in Health Risk Assessment. Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, DC. EPA/630/R-94/007.

Cummins, K.W. and J.C. Wuycheck. 1971. Caloric Equivalents for Investigations in Ecological Energetics. International Association of Theoretical and Applied Limnology, Stuttgart, West Germany. Cited in: EPA, 1993.

CWHR (California Wildlife Habitat Relationships) Program. 2008. California Red-legged Frog, *Rana draytonii*, A071. California Department of Fish and Game, California Interagency Wildlife Task Group.

Davis, D.E. and F.B. Golley. 1963. Principles in Mammalogy. New York, NY: Van Nostrand Rheinhold. [Citeds in EPA, 1993].

Dawson, W.R. 1974. Appendix: conversion factors for units used in the symposium. In: Paynter, R.A. ed. Avian Energetics. Publication no. 15. Nuttal Ornithological Club, Cambridge, MA.

Deneer, J.W., W. Seinen and J.L.M. Hermens. 1988. Growth of *Daphnia magna* exposed to mixtures of chemicals with diverse modes of action. Ecotox. Environ. Safety 15:72-77.

Denslow, J.S. 1985. Disturbance-mediated Coexistence of Species. In: The Ecology of Natural Disturbance and Patch Dynamics. Academic Press, San Diego, CA.

Dice, L.R. 1922. Some factors affecting the distribution of the prairie vole, forest deer mouse, and prairie deer mouse. Ecology 3:29-47.

Dickman, M. 1968. The effect of grazing by tadpoles on the structure of a periphyton community. Ecology 49:1188-1190.

Drickamer, L.C. and B.M. Vestal. 1973. Patterns of reproduction in a laboratory colony of Peromyscus. J Mammal 54:523-528.

Drouillard, K.G., J.J.H. Ciborowski, R. Lazar and D.G. Haffner. 1996. Estimation of the uptake of organochlorines by the mayfly Hexagenia limbata (Ephemeroptera: Ephemeridae). J Great Lakes Res 22: 26-35.

Drozdz, A. 1968. Digestibility and assimilation of natural foods in small rodents. Acta Theriol. 13:367-389.

Duchemin, M.B., C. Durou, B. Journel, P. Adrian, and P.C. Thomas. 2010. Reliability assessment process of standard and non standard data for the environmental risk assessment for the purpose of regulations of chemicals. Presented at the SETAC EU meeting, Seville, Spain, May 23-27, 2010.

Duellman, W.E. and L. Trueb. 1986. Biology of Amphibians. McGraw-Hill Book Co., New York, NY.

ECOFRAM (Ecological Committee on FIFRA Risk Assessment Methods). 1999. Terrestrial Draft Report. May 10, 1999. http://www.epa.gov/oppefed1/ecorisk/terrreport.pdf

EPA (United States Environmental Protection Agency). 1975. Methods for Acute Toxicity with Fish, Macroinvertebrates and Amphibians. EPA-660/3-75-009. Ecological Research Series, Washington, DC. pp 1-61.

EPA (United States Environmental Protection Agency). 1983. Dimethoate Registration Standard.

EPA (United States Environmental Protection Agency). 1993. Wildlife Exposure Factors Handbook. Volumes I and II. Office of Research and Development. Washington, DC. EPA EPA/600/R-93/187a, EPA/600/R-93/187b.

EPA (United States Environmental Protection Agency). 1998. Guidelines for Ecological Risk Assessment. Office of Research and Development, Washington, DC. EPA/630/R-95/002F.

EPA (United States Environmental Protection Agency). 2000. Benchmark Dose Technical Guidance Document. External Review Draft, October 2000. EPA/630/R-00/001.

EPA (United States Environmental Protection Agency). 2002a. Water Models; Guidance for Selecting Input Parameters. Version II. Office of Pesticide Programs, Environmental Fate and Effects Division. February 28, 2002. www.epa.gov/oppefed1/models/water/input_guidance2_28_02.htm

EPA (United States Environmental Protection Agency). 2002b. Calcasieu Estuary Remedial Investigation/Feasibility Study (RI/FS): Baseline Ecological Risk Assessment (BERA).Region 6, Dallas, TX. DCN: 3282-941-RTZ-RISKZ-14858.

EPA (United States Environmental Protection Agency). 2002c. Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides. Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Environmental Fate and Effects Division, Washington, DC. http://www.epa.gov/oppefed1/models/water/input_guidance2_28_02.htm

EPA (United States Environmental Protection Agency). 2003a. Water Models. Office of Pesticide Programs, Environmental Fate and Effects Division, Washington, DC. http://www.epa.gov/oppefed1/models/water

EPA (United States Environmental Protection Agency). 2003b. Pesticide Root Zone Model Field and Orchard Crop Scenario Metadata. Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Environmental Fate and Effects Division. http://www.epa.gov/oppefed1/models/water/index.htm

EPA (United States Environmental Protection Agency). 2004a. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs. Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances Office of Pesticide Programs, Washington, DC.

EPA (United States Environmental Protection Agency). 2004b. Ecological Risk Assessment for General Electric (GE)/Housatonic River Site, Rest of River. New England Region, Boston, MA. DCN: GE-100504-ACJS.

EPA (United Stated Environmental Protection Agency). 2005a. A Supplement to the Environmental Fate and Ecological Risk Assessment for the Re-registration of Dimethoate (O,O-dimethyl S-[2-(methylamino)-2-oxoethyl] phosphorodithioate).CAS Registry Number 60-51-5. PC Code 035001. July 27, 2005. Environmental Fate and Effects Division, Office of Pesticide Products, Washington, DC.

EPA (United States Environmental Protection Agency). 2005b. Reregistration Eligibility Science Chapter for Carbofuran, Environmental Fate and Effects Chapter. Environmental Risk Assessment and Human Drinking Water Exposure Assessment. Authors: E. Fite, D. Randall, D. Young, E. Odenkirchen and C. Salice. June 3, 2005.

EPA (United States Environmental Protection Agency). 2006a. User's Guide TerrPlant Version 1.2.2. December 26, 2006. Environmental Fate and Effects Division, Office of Pesticide Programs, US Environmental Protection Agency, Washington, DC.

EPA (United States Environmental Protection Agency). 2006b. Interim Re-registration Eligibility Decision for Dimethoate. June 12th, 2006. Office of Pesticide Programs, Washington, DC. EPA-HQ-OPP-2009-0059-0005.

EPA (United States Environmental Protection Agency). 2008a. Risks of Dimethoate Use to the Federally-Listed California Red Legged Frog (*Rana aurora* draytonii). Environmental Fate and Effects Assessment Division, Office of Pesticide Programs, Washington, DC.

EPA (United States Environmental Protection Agency). 2008b. Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species and Drinking Water Assessments in Support of the Registration Review of Dimethoate. Office of Prevention, Pesticides, and Toxic Substances Washington, DC. HQ-OPP-2009-0059-0002.

EPA (United States Environmental Protection Agency). 2008c. Revised Interim Reregistration Eligibility Decisions for Dimethoate. Environmental Fate and Effects Division, Office of Pesticide Products, Washington, DC.

EPA (United States Environmental Protection Agency). 2008d. Benchmark Dose Software v. 2.0. http://www.epa.gov/NCEA/bmds/

EPA (United States Environmental Protection Agency). 2008e. T-Herps Version 1.0 User's Guide. Terrestrial Herpetofaunal Exposure Residue Program Simulation. Environmental Fate and Effects Division, Office of Pesticide Programs, Washington, DC.

EPA (United States Environmental Protection Agency). 2010a. Ecological Incident Information System (EIIS) Summary Reports (General Information and Species Information). Provided by USEPA. April, 2010.

EPA (United States Environmental Protection Agency). 2010b. Pesticides Environmental Effects: Databases. Web Site: Accessed April 2010. http://www.epa.gov/oppefed1/general/databasesdescription.htm

EPA (United States Environmental Protection Agency). 2012. User's Guide T-REX Version 1.5 (Terrestrial Residue EXposure model). Appendix B. Initial Pesticide Residues on Arthropods. Environmental Fate and Effects Division, Office of Pesticide Programs U.S. Environmental Protection Agency, Washington, D.C. March 22, 2012. http://www.epa.gov/oppefed1/models/terrestrial/trex/t_rex_user_guide_app_b.htm

Estes, T.L. and P. Hendley. 2002. The sensitivity of PRZM-EXAMS to key assumptions – Implications for pesticide aquatic risk assessments. 21st Annual Meeting of the Society of Environmental Toxicology and Chemistry, Nashville, TN.

EU Joint Submission Group. 2002. Fate and Behavior in the Environment. Dimethoate EU Joint Submission Group, Section 5, Chapter 7, April 2002.

Feder, M.E. and W.W. Burggren. 1992. Environmental Physiology of the Amphibians. University of Chicago Press; ISBN: 0226239446.

Felsot, A.S., J.B. Unsworth, J.B.H.J. Linders, G. Roberts, D. Rautman, C. Harris and E. Carazo. 2011. Agrochemical spray drift; assessment and mitigation – A review. Journal of Environmental Science and Health Part B 46: 1-23.

Finney, D.J. 1952. Probt Analysis. Cambridge University Press, 2nd ed. 1952.

Finney, D.J. 1971. Probit Analysis. Cambridge University Press, 3rd ed. 1971.

Fischer, D.L., L.M. Bowers and C.V. Lam. 1997. Summary of Field Measurements of Pesticide Concentrations in Invertebrate Prey of Birds. 18th Annual Meeting of the Society of Environmental Toxicology and Chemistry, San Francisco, CA.

Fletcher, J.S., J.E. Nellessen and T.G. Pfleeger. 1994. Literature review and evaluation of the EPA food-chain (Kenega) nomogram, an instrument for estimating pesticide residues on plants. Environ. Toxicol Chem 13(9):1383-1391.

Frear, D.E.H. and J.E. Boyd. 1967. Use of *Daphnia magna* for the microbioassay of pesticides. I. Development of standardized techniques for rearing Daphnia and preparation of dosage-mortality curves for pesticides. J Econ Entomol 60(5):1228-1236.

Friis, M. 1992. Product Chemistry--Chemathoate Technical: Lab Project Number: MVF/01.06.92/DMT-USA. Report prepared by Cheminova Agro A/S. MRID 42730901; 42730902.

FWS (United States Fish and Wildlife Service). 1996. Endangered and Threatened Wildlife and Plants; Determination of Threatened Status for the California Red-legged Frog. Federal Register 61(101):25813-25833.

FWS (United States Fish and Wildlife Service). 2002a. Recovery Plan for the California Red-legged Frog (*Rana aurora* draytonii). U.S. Fish and Wildlife Service, Portland, OR.

FWS (United States Fish and Wildlife Service). 2002b. Notice of Availability of the Final Recovery Plan for the California Red-legged Frog. Federal Register 67(177):57830-57831.

FWS (United States Fish and Wildlife Service). 2006. Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the California Red-Legged Frog, and Special Rule Exemption Associated With Final Listing for Existing Routine Ranching Activities; Final Rule. Federal Register 71(71):19244-19346.

FWS (United States Fish and Wildlife Service). 2010. Endangered and Threatened Wildlife and Plants; Revised Designation of Critical habitat for the California Red-Legged Frog. 50CFR Part 17. Department of the Interior. Federal Register 75(51) Wednesday March 17th, 2010.

Gallagher, S., J. Foster, J. Beavers and M. Jaber. 1996a. Dimethoate: A Reproduction Study with the Northern Bobwhite (Colinus platyrhynchos): Amended Report. Lab Project Number: 232-115. Wildlife International Ltd., Easton, MD. CHA Doc. No. 318 DMT. MRID 44049001.

Gallagher, S., J. Foster, J. Beavers and M. Jaber. 1996b. Dimethoate: A Reproduction Study with the Mallard (Anas virginianus). Lab Project Number: 232-116. Wildlife International Ltd., Easton, MD. CHA Doc. No.: 321 DMT. MRID 43967101.

Gallagher, S.P., J. Grimes and J.B. Beavers. 2003a. Omethoate: An Acute Oral Toxicity Study With the Northern Bobwhite. Wildlife International, Ltd, Easton, MD. Study No. 542-101. CHA Doc. No. 581 DMT. Final report submitted to EPA on May 15, 2009. MRID 47769703.

Gallagher, S.P., J. Grimes and J.B. Beavers. 2003b. Omethoate: An Acute Oral Toxicity Study With the Ring-necked Pheasant. Wildlife International, Ltd., Easton, MD. Study No. 542-102.DTF – Omethoate Doc. No. O811-001. CHA Doc. No. 580 DMT. Final report submitted to EPA on May 15, 2009. MRID 47769704.

Gathmann, A. and T. Tscharntke. 2002. Foraging ranges of solitary bees. Ecology 71:757-764.

Gatten, R.E., K. Miller, and R.J. Full. 1992. Energetics at rest and during locomotion. In: Feder, M.E. W.W. Burggren (Eds). Environmental Physiology of the Amphibians. University of Chicago Press, Chicago, pp. 314-377.

Giddings, J.M., R.C. Biever, M.F. Annunziato and A.J. Hosmer. 1996. Effects of diazinon on large outdoor pond microcosms. Environ Toxicol Chem 15:618-629.

Giddings, J.M., L. Hall Jr., K. Solomon, W. Adams, D. Vogel, L. Davis and R. Smith. 1997. An Ecological Risk Assessment of Diazinon in the Sacramento and San Joaquin River Basins. Novartis Crop Protection Technical Report 11/97, Greensboro, NC.

Giddings, J.M., T.A. Anderson, L.W. Hall, A.J. Hosmer, R.J. Kendall, R.P. Richards, K.R. Soloman and W.M. Williams. 2005. Atrazine in North American Surface Waters: A Probabilistic Aquatic Ecological Risk Assessment. Society of Environmental Toxicology and Chemistry (SETAC), Pensacola, FL.

Giesy, J.P., K.R. Soloman, J.R. Coats, K.R. Dixon, J.M. Giddings and E.E. Kenaga. 1999. Chlorpyrifos: Ecological risk assessment in North American aquatic environments. Rev Environ Contam Toxicol 160:1-129.

Gobas, F.A.P.C, J. Wilcockson, R.W. Russel and G.D. Haffner. 1999. Mechanism of biomagnification in fish under laboratory and field conditions. Environ Sc Technol 33:1330141.

Golley, F.B. 1960. Energy dynamics of a food chain of an old-field community. Ecol Monogr 30:187-206. Cited in: EPA, 1993.

Golley, F.B. 1961. Energy values of ecological materials. Ecology 42:581-584. (Cited in: EPA, 1993).

Goodband, T. 2003. Decline of Dimethoate Residues in the Raw Agircultural Commodity Spring Wheat Resulting from a Single Application of an EC Formulation Containing 400 g/L Dimethoate in the UK and Germany During 2002. Project Number:AF/6738/DC. Unpublished study prepared by Agrisearch UK, Ltd. 136 p. DMT 582.

Gorecki, A. 1975. Calorimetry in Ecological Studies. In: Grodzinski, W., R.Z. Klekowski, A. Duncan (Eds.). IPB Handbook No. 24: Methods of Ecological Energetics. Blackwell Scientific Publications, London, UK. Cited in: EPA, 1993.

Graves, W.C. and J.P. Swigert. 1993a. Dimethoate: A 96-Hour Static acute Toxicity Test With the Saltwater Mysid (*Mysidopsis bahia*). Wildlife International Ltd., Easton, MD. Project Number: 242A-102, FIFRA Subdivision E, Series 72-3. CHA Doc. No.: 137 DMT. MRID 42760003.

Graves, W.C. and J.P. Swigert. 1993b. Dimethoate: A 96-Hour Shell Deposition Test With the Eastern Oyster (*Crassostrea virginica*). Wildlife International Ltd., Easton, MD. Project Number: 242A-104, FIFRA Subdivision E, Series 72-3. CHA Doc. No.: 138 DMT. MRID 42760002.

Grinnell, J. and R.T. Orr. 1934. Systematic review of the Californicus group of the rodent genus Peromyscus. J Mammal 15(3): 210-220.

Grodzinski, W., and B.A. Wunder 1975. Ecological energetic of small mammals. In: Golley, F.B., K. Petrusewicz, L. Ryszkowski., eds. Small mammals: their productivity and population dynamics. Cambridge, MA: Cambridge University Press; pp. 173-204.

Gupta, P.K. 1984. Acute toxicity of three insecticides to the freshwater snail *Viviparus bengalensis*. Environ Ecol 2(3):168-170.

Guzzella, L., A. Gronda and L. Colombo. 1997. Acute toxicity of organophosphorus insecticides to marine invertebrates. Bull Environ Contam Toxicol 59:313-320.

Hamitou 2009a. Dimethoate 400 g/L EC (CHA 3621-04): Acute Toxicity to Water Fleas (*Daphnia magna*) Under Static Conditions. Springborn Smithers Laboratories (Europe) Study No. 1005.028.110. CHA Doc. No. 765 DMT.

Hamitou, M. 2009b. Dimethoate 400 g/L EC (CHA 3621-04): Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Conditions. Springborn Smithers Laboratories (Europe) Study No. 1005.028.100. CHA Doc. No. 764 DMT.

Hawkins, D.R., D. Kirkpatrick, C.P. Till, D. Shaw and S.R. Biggs. 1986a. The Hydrolysis of 14C-Dimethoate. Huntingdon Research Centre, Ltd., UK. DTF Doc. No. 911-002. MRID 00159761.

Hawkins, D.R., D. Kirkpatrick, C.P. Till and D. Shaw. 1986b. The Photodegradation of 14C-Dimethoate in Water. Huntingdon Research Centre, Ltd., UK.. DTF Doc. No. 914-001. MRID 00159762.

Hawkins, D.R., D. Kirkpatrick, C.P. Till and D. Shaw. 1986c. The Mobility of 14C-Dimethoate in Soil. Huntingdon Research Center, Ltd., UK. Study No. 6e/86806. Unpublished report, CHA Doc. No. 139 DMT. MRID No. 00164959.

Hawkins, D.R., D, Kirkpatrick, C.P. Till, and D. Shaw. 1986d. The Metabolism of 14C-Dimethoate in Soil Under Anaerobic Conditions. Huntingdon Research Center, Ltd., UK. Study No 6d/86368. Unpublished report. CHA Doc No. 29 DMT.

Hawkins, D.R., D. Kirkpatrick, D. Shaw and J.A. Mobbs. 1988. The Metabolism of 14C-dimethoate in Soil Under Aerobic Conditions. Huntington Research Center, Ltd., UK. Study No. HRC/DTF '7/881515. Unpublished report, CHA Doc.: 89 DMT. MRID 42843201.

Hawkins, D.R., D. Kirkpatrick, D. Shaw and S. C. Chan. 1990. The Metabolism of 14C-dimethoate in Sandy Loam Soil Under Anaerobic Conditions. Huntingdon Research Centre, Ltd., UK. DTF Doc. No. 632-003.; CHA Doc. No. 96 DMT. MRID 42884402.

Hayes, M.P. and M.R. Jennings. 1988. Habitat correlates of distribution of the California red-legged frog (*Rana aurora* draytonii) and the foothill yellow-legged frog (Rana boylii): Implications for management. In: R. Sarzo, K.E. Severson and D.R. Patton (technical coordinators). Proceedings of the symposium on the management of amphibians, reptiles, and small mammals in North America. USDA Forest Service General Technical Report RM-166. pp. 144-158. Cited In: FWS, 2002a.

Hayes, M.P. and M.M. Miyamoto. 1984. Biochemical, behavioral and body size difference between *Rana aurora* aurora and R.a. draytonii. Copeia 1984(4):1018-1022. Cited In: FWS, 2002a.

Hayes, M.P. and M.R. Tennant. 1985. Diet and feeding behavior of the California red-legged frog, *Rana aurora* dryatonii. Southewestern Naturalist 30:601-605. http://www.dfg.ca.gov/whdab/html/cnddb.html

Heintze, A. 2002. Assessment of side effects of dimethoate on the larvae of the midge, Chironimus riparius, with the laboratory test method. GAB Biotechnologie GmbH & IFU Umweltanalytik. GmbH study number 20011123/01-ASCr. CHA Doc. No. 521 DMT. MRID 48298309.

Herbert, P.D.N. (Ed.). 2002. Canada's Aquatic Environments. Cybernatural Software, University of Guelph, Guelph, ON. www.aquatic.uoguelph.ca.

Hermens, J., H. Canton, N. Steyger and R. Wegman. 1984. Joint effects of a mixture of 14 chemicals on mortality and inhibition of reproduction of *Daphnia magna*. Aquat Toxicol 5:315-322.

Hertl, J. 2001a. Acute toxicity of O-desmethyl Dimethoate, Potassium Salt to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-hour Static Test (Final Report Revision No.1). Company Report No. 8553230. DTF Doc No 442-010 GLP. CHA Doc. No.: 422 DMT.

Hertl, J. 2001b. Toxicity of O-desmethyl Dimethoate, Potassium Salt to *Daphnia magna* in a 48-hour Immobilization Test (Final Report Revision No.1). Company Report No. 8552220. DTF Doc No 443-010 GLP. CHA Doc. No.: 419 DMT.

Hertl, J. 2001c. Toxicity of O-desmethyl Dimethoate, Potassium salt to *Scenedesmus subspicatus* in an Algal Growth Inhibition Test (Final Report Revision No.1). Company Report No. 8551210. DTF Doc No 443-009 GLP. CHA Doc. No.: 420 DMT.

Hertl, J. 2002a. Final Report. Acute toxicity of Dimethylthiophosphoric Acid, Na Salt to *Daphnia magna* in a 48-hour Immobilization Test. Company Report No. 10562220/10562220A/10562220. DTF Doc No 443-012 GLP. CHA Doc. No.: 485 DMT.

Hertl, J. 2002b. Final report. Acute toxicity of Dimethylthiophosphoric Acid, NaSalt to Rainbow Trout (*Oncorhynchus mykiss*) in a 96-hour Static Test. Company Report No. 10561230/10561230A/10561230. DTF Doc No 442-011 GLP. CHA Doc. No.: 485 DMT.

Hertl, J. 2002c. Acute Toxicity of Dimethoate to *Daphnia magna* in a 48-hour Immobilization Test.IBACON - Institut für Biologische Analytik und Consulting. IBACON GmbH Study No: 10591220, 10591220A. CHA Doc. No. 482 DMT.

Hessen D.O., T. Kallqvist, M.I. Abdel-Hamid and D. Berge. 1994. Effects of pesticides on different zooplankton taxa in mesocosm experiments. Norw J Agri Sci Suppl. 13:153-161.

Hill, E.F., R.G. Heath, J.W. Spann and J.D. Williams. 1975. Lethal Dietary Toxicities of Environmental Pollutants to Birds. Special Scientific Report: Wildlife No. 191. US Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center. Laurel, Maryland. MRID 00022923.

Hoshino, T. 1989. [Methylene-14C-]Omethoate: General Metabolism Study in the Rat. Bayer AG M 01810019. Final report dated Dec 18, 1989. 143 p. MRID 46099808.

Hubbard, P.M., K.H. Martin, and J.B. Beavers. 2009a. Omethoate: A Dietary LC50 Study With the Northern Bobwhite. Wildlife International, Ltd., Easton, MD. Project Number 232-141. MRID 47709501.

Hubbard, P.M., K.H. Martin, and J.B. Beavers. 2009b. Omethoate: A Dietary LC50 Study With the Mallard. Wildlife International, Ltd., Easton, MD. Project Number 232-142. MRID 47709502.

Hubbard, P.M., K.H. Martin, and J.B. Beavers. 2009c. Dimethoate: A Dietary LC50 Study With the Mallard. Wildlife International, Ltd., Easton, MD. Project Number 232-148. MRID 47744401.

Hubbard, P.M., J.B. Beavers, and K.H. Martin. 2010. Dimethoate Technical: A One-day Acute Dietary Exposure Study with the Northern Bobwhite Including an Assessment of Avoidance Behavior. Wildlife International Ltd., Easton, Maryland. Wildlife International Ltd. Project Number 542-107. 105 pp.

Hudson, R.H., R.K. Tucker and K. Haegele. 1984. Handbook of Acute Toxicity of Pesticides to Wildlife, Resource Publication 153. U.S. Department of Interior, Fish and Wildlife Service, Washington, DC. MRID 00160000.

Intrinsik, In Preparation(a). Comments on EPA's Problem Formulation for Dimethoate. Prepared for Cheminova by Intrinsik Environmental Sciences Inc., Ottawa, Ontario, Canada. Project #60230.

Intrinsik, In Preparation(b). Refined Effects Determination for California Red-Legged Frog Potentially Exposed to Malathion. Prepared for Cheminova, Arlington, VA by Intrinsik Environmental Sciences Inc., Ottawa, Ontario, Canada. Project #60275.

Intrinsik, 2012. Cheminova's Comments on EPA's Dimethoate Effects Determination for the California Red-Legged Frog. Prepared for Cheminova by Intrinsik Environmental Sciences Inc., Ottawa, Ontario, Canada. Project #60190. Docket ID: EPA-HQ-OPP-2009-0059-0020.1.

Jacobson, B. and B.B. Williams. 1994a. Dissipation of Dimethoate in Soil Under Field Conditions With Grain Sorghum in Texas. ABC Laboratories, Inc., Analytical Chemistry and Field Studies, Columbia, MO. Doc. No. 922-004. MRID 43388001.

Jacobson, B. and B.B. Williams. 1994b. Dissipation of Dimethoate in Soil Under Field Conditions When Applied to Bare Ground in New York. ABC Laboratories, Inc., Analytical Chemistry and Field Studies, Columbia, MO. Doc. No. 922-005. MRID 43388002.

Jalali, K., G.R. Krautter and J.E. Cassidy. 1995. The Metabolism of [14C] Dimethoate in Laying Helns Following Oral Administration for 7 Consecutive d. PTRL East, Inc. Richmond, Kentucky and PTRL West, Inc., Richmond, California. Sponsored by Cheminova Agro A/S, Lemvig, Denmark.

Jameson, D.L., T. William and J. Mountjoy. 1970. Metabolic and morphological adaptation to heterogenous environments by the Pacific tree toad, *Hyla regilla*. Evolution 24:75-89.

Jennings, M.R. 1988. Natural History and Decline of Native Ranids in California. In: H.F. DeLisle, P.R. Brown, B. Kaufman and B.M. McGurty (Eds.). Proceedings of the Conference on California Herpetology. Southwestern Herpetologists Society Special Publication. pp. 61-72. Cited In: FWS, 2002a.

Jennings, M.R. and M.P. Hayes. 1994. Amphibian and Reptile Species of Special Concern in California. Report prepared for the California Department of Fish and Game, Inland Fisheries Division, Rancho Cordova, CA.

Jenssen, T.A. 1967. Food habits of the green frog, Rana clamitans, before and during metamorphosis. Copeia 1967:214-218.

Johnson, C.R. and R.B. Bury. 1965. Food of the Pacific treefrog, *Hyla regilla* Baird and Girard, in northern California. Herpetologica 21:56-58.

Johnson, W. and M. Finley. 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. Resource Publication 137. US Fish and Wildlife Service, Washington, DC. 106 p. MRID 40094602.

Jorgensen, S.E., S.N. Nielsen and L.A. Jorgensen. 1991. Handbook of Ecological Parameters and Ecotoxicology. Elsevier Science Publishers, Amsterdam, The Netherlands.

Karasov, W.H. 1990. Digestion in birds: chemical and physiological determinants and ecological implications. Stud Avian Biol 13: 391-415.

Kendeigh, S.C. and G.C. West. 1965. Caloric values of plant seeds eaten by birds. Ecology 46:553-555.

Klimisch, H.J., M. Andreae, and U. Tillmann. 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regul Toxicol Pharm 25:1-5.

Kirkpatrick, D., D. Shaw, J. Nicholson, C.D. O'Hara, D. Watson and T. Beeby. 1995. ^{14}C-Dimethoate: The Biokinetics and Metabolism in the Rat. Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, England. Sponsored by the Dimethoate Task Force, Ingelheim, Germany.

Knäbe, S. 2004a. Residues of Dimethoate and Omethoate in Different Feed Sources for Wild Birds After Application of an EC Formulation Containing 400 g/L Dimethoate (Spain 2003). Report Amendment No. 1 included. GAB Biotechnologie GmbH & GAB Analytik GmbH. Study No. 20031130/S1-FNto. CHA Doc. No. 612 DMT. MRID No. 46486401. Unpublished report. 239 p.

Knäbe, S. 2004b. Residues of malathion and malaoxon in different feed sources for wild birds after application of CHA 3110 (Germany 2004). GAB Biotechnologies GmbH & GAB

Analytik GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany. Study code 20041219/G1-FNTO. CHA Doc No.: 493 FYF. MRID 46525902.

Koplin, J.R., M.W. Collopy and A.R. Bammann. 1980. Energetics of two wintering raptors. Auk 97:795-806. Cited in: EPA, 1993.

Kubiak, R. 1992. Volatilization of 14C-dimethoate From Plant and Soils Surfaces Under Laboratory Conditions. LLFA, Abt. Phytomedizin, Neustadt/Weinstraße, Germany. DTF Doc. No. DTF01. CHA Doc. No.: 133 DMT.

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

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

Levey, D.J. and W.H. Karasov. 1989. Digestive responses of temperate birds switched to fruit or insect diets. Auk 106:675-686.

Levinskas, G.J. 1965. Dimethoate: Demyelination Studies in White Leghorn Hens. American Cyanamid Company. Report number 65-56. Unpublished study. Liess, M. and R. Schulz. 1999. Linking insecticide contamination and population response in an agricultural stream. Environ. Toxicol Chem 18:1948–1955.

Liess, M. and R. Schulz. 1999. Linking insecticide contamination and population response in an agricultural stream. Environ. Toxicol Chem 18:1948–1955.

Lisker, E.B., M.P. Ensminger, S.L. Gill and K.S. Goh. 2011. Detections of eleven organophosphorus insecticides and one herbicide threatening Pacific salmonids, Oncorhynchus spp., in California, 1999-2010. Bull Environ Contam Toxicol 87(4):355-360.

Luttik, R. and T. Aldenberg. 1997. Extrapolation factors for small samples of pesticide toxicity data: Special focus on LD50 values for birds and mammals. Environ Toxicol Chem 16:1785-1788.

Mangels, G. 1987. Dimethoate (CL 12,880): The Determination of the n-Octanol/Water Partition Coefficient. Lab Project Number: 0108: 1627. Prepared by American Cyanamid Co. 81 p. MRID 43274001.

Mangels, G. 1994. Dimethoate (CL 12,880): The Determination of the Water Solubility. Lab Project Number: 0108: PD/M. Prepared by American Cyanamid Co. 13 p. MRID 43461402.

Mansour, S.A. and T.M. Hassan. 1993. Pesticides and Daphnia. 3. An analytical bioassay method, using *Ceriodaphnia quadrangula*, for measuring extremely low concentrations of insecticides in waters. Int J Toxicol Occup Environ Health 2:34-39.

Mary, A. Sr., R. Nagabhushanam and R. Sarojini. 1986. Toxicity evaluation of organophosphorus and chlorinated hydrocarbon pesticides in freshwater prawn *Macrobrachium lamerrii*. J Environ Biol 7(3):189-195.

Mayer F.L. 1987. Acute Toxicity Handbook of Chemicals to Estuarine Organisms. Gulf Breeze, FL. EPA, 600/8-87/017. MRID 40228401.

Mayer, F.L. and M.R. Ellersieck. 1986. Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. Resour. Publ. No.160. US

Department of the Interior, Fish and Wildlife Service, Washington, DC. 505 p. MRID 40098001

McCabe, T. T. and B. D. Blanchard. 1950. Three species of Peromyscus. Rood Association, Santa Barbara, Ca. 136pp.

McCarty, L.S., C.J. Borgert, and E. M. Mihaich. 2012. Information quality in regulatory decision-making: Peer review versus good laboratory practice. Environ Health Perspect doi:10.1289/ehp.1104277.

McNab, B.K. 2002. The Physiological Ecology of Vertebrates: A View from Energetics. Cornell University Press, New York; ISBN: 0801439132.

Merritt, J.F. 1974. Factors influencing the local distribution of *Peromyscus californicus* in Northern California. J mammal 55(1):102-114.

Merritt, J.F. 1978. *Peromyscus californicus*. Mammalian Species 85:1-6.

Meserve, P. L. 1976a. Habitat and resource utilization by rodents of a California coastal sage scrub community. J Anim Ecol 45:647-666.

Meserve, P. L. 1976b. Food relationships of a rodent fauna in a California coastal sage scrub community. J Mammal 57:300-319.

Minnich, J.E. 1982. The Use of Water. In: C. Gans, and F.H. Pough (Eds.). Biology of the Reptilia: V. 12, Physiology C; Physiological Ecology. Academic Press, New York, NY. pp. 325-395.

Moore, D.R.J. 1998. The ecological component of ecological risk assessment: Lessons from a field experiment. Hum Ecol Risk Assess 3:1-21.

Moore, D.R.J., R.P. Thompson and S.I. Purbrick. 2006a. Refined Aquatic Risk Assessment for Aldicarb. Prepared for Bayer CropScience, Research Triangle Park, NC.

Moore, R.J.M., R.P. Thompson, S.I Rodney, D. Fischer, T. Ramanarayanan and T. Hall. 2006b. Refined aquatic risk assessment for aldicard in the United States. IEAM 6:102-118.

Moore, D.R.J., R.S. Teed, S.I. Rodney, R.P. Thompson and D.L. Fischer. 2010a. Refined avian risk assessment for aldicarb. IEAM 6(1):83-101.

Moore, D.R.J., R.L. Breton, T.R. DeLong, S. Ferson, G. Lawrence, J.P.Lortie, D.B. MacDonald, R. McGrath, A. Pawlisz, S.C. Svirsky, R.S. Teed, R.P.Thompson and T. Tucker. 2010b. Ecological risk assessment for wildlife in the Housatonic river area. I. Overview of approach and methods. IEAM (forthcoming).

Morey,S. 2005. Pacific Treefrog *Hyla regilla*. California Department of Fish and Game. California Interagency Wildlife Task Group. California Wildlife Habitat Relationships, Version 8.1 Personal Computer Program. Sacramento, CA.

Morrison, H.A., F.A.P.C Gobas, R. Lazar, D.M. Whittle and D.G. Haffner. 1997. Development and verification of a benthic/pelagic food web bioaccumulation model for PCB congeners in western Lake Erie. Environ Sci Technol 31:3267-3273.

Morrison, H.A., D.M. Whittle, C.D. Metcalfe and A.J. Niimi. 1999. Application of a food web bioaccumulation model for the prediction of polychlorinated biphenyl, dioxin and furan congener concentrations in Lake Ontario aquatic biota. Can J Fish Aquat Sci 56:1389-1400.

Muncy, R.J. and A.D. Oliver Jr. 1963. Toxicity of ten insecticides to the Red Crawfish, *Procambarus clarki* (Girard). Trans Am Fish Soc 92(4):428-431.

Nagy, K. A. 1987. Field metabolic rate and food requirement scaling in mammals and birds. Ecol Monogr 57: 111-128.

Nagy, K.A., I.A. Girard, and T.K. Brown. 1999. Energetics of free-ranging mammals, reptiles and birds. Annual reviews in Nutrition 19:247-277.

NatureServe. 2006. NatureServe Explorer: An Online Encyclopedia of Life. Version 4.7. NatureServe, Arlington, VA. http://www.natureserve.org/explorer.

NIST/SEMATECH e-Handbook of Statistical Methods. 2010. http://www.itl.nist.gov/div898/handbook/, accessed July 12, 2011.

NRCS (National Resources Conservation Service). 2012. Use of the NRCS STATSGO database for regional interpretations. http://www.id.nrcs.usda.gov/technical/soils/hybrid.html. Accessed July, 2012.

Oliver, B.G. and A.J. Niimi. 1988. Trophodynamic analysis of polychlorinated biphenyl congeners and other chlorinated hydrocarbons in the Lake Ontario ecosystem. Environ Sci Technol 22:388-397.

Osborne, J.L., S.J. Clark, R.J. Morris, I.H. Williams, J.R. Riley, A.D. Smith, D.R. Reynolds and A.S. Edwards. 1999. A landscape-scale study of bumble bee foraging range and constancy, using harmonic radar. J Appl Ecol 36:519-533.

Oteifa, B.A., A.H. Moussa, A.A. Abou-El-Hassan, A.M. Mohamed and M.A. El-Emam. 1975. Effect of certain insecticides in the control of the fresh water snails *Biomphalaria alexandrina* and *Bulinus trancatus*. Egypt J Bilh 2:221-243.

Owen, P. 2000. *Hyla regilla*. Animal Diversity Web. Accessed January 29, 2007 at http://animaldiversity.ummz.umich.edu/site/accounts/information/Hyla_regilla.html.

Pantani, C., G. Pannunzio, M. De Cristofaro, A.A. Novelli and M. Salvatori. 1997. Comparative acute toxicity of some pesticides, metals, and surfactants to *Gammarus italicus* Goedm. and *Echinogammarus tibaldii* Pink. and Stock (Crustacea: Amphipoda). Bull Environ Contam Toxicol 59:963-967.

Parra, G., R. Jiménez-Melero and F. Guerrero. 2005. Agricultural impacts of Mediterranean wetlands: The effect of pesticides on survival and hatching rates in copepods. Ann Limnol – Int J Lim 41(3):161-167.

Pierotti, R. and C. Annett. 1987. Reproductive Consequences of Dietary Specialization and Switching In an Ecological Generalist. In: Kamil, A.C., J. Krebs and H.R. Pulliam (Eds.).Foraging Behavior. Plenum Press, New York, NY. Cited in: EPA, 1993.

Plafkin, J.L., M.T. Barbour, K.D. Porter, S.K. Gross and R.M. Hughes. 1989. Rapid Bioassessment Protocols for Use in Streams and Rivers: Benthic Macroinvertebrates and Fish. US Environmental Protection Agency, Washington, D.C. EPA/444/4-89-001.

Pollman, B. 2006. Residue Behaviour of Winter Barley After Application of Dimethoate 400 g/L EC – 4 Sites in Northern Europe 2004. Project Number 20044016/E1-FRWB. Unpublished study prepared by GAB Biotechnologie GmbH & GAB Analytik GmbH. 106 p. DMT 679.

Porch, J.R., T.Z. Kendall and H.O. Krueger. 2009. Dimethoate: A 7-day Static-Renewal Toxicity Test With Duckweed (*Lemna gibba* G3). Wildlife International Project Number 232A-118. Wildlife International, Easton, MD. MRID 47709703.

Porch, J.R., H.O. Krueger, and K.H. Martin. 2011a. Dimethoate TEP and TGAI: A Tier II Toxicity Test to Determine the Effects of the Test Substances on Vegetative Vigor of Ten Species of Plants. Wildlife International, Ltd. Project number: 232-152. Study conducted according to OPPTS 850.4250. Final report dates August 12, 2011. MRID 48572802.

Porch, J.R., H.O. Krueger, and K.H. Martin. 2011b. Dimethoate TEP and TGAI: A Tier II Toxicity Test to Determine the Effects of the Test Substance on Seedling Emergence of Ten Species of Plants; Wildlife International Ltd. Project number: 232-151. Study conducted according to OPPTS 850.4225. Final report dated August 12, 2011. MRID 48572801; 48628101.

Posthuma, L. G.W. Suter II and T.P. Traas. 2002. Species Sensitivity Distributions in Ecotoxicology. Lewis Publishers, Boca Raton, FL.

Pryor, G.S. 2003. Growth rates and digestive abilities of bullfrog tadpoles (Rana catesbeiana) fed algal diets. J Herpetol 32:560-566.

Raimondo, S., P. Mineau and M.G. Barron. 2007. Estimation of chemical toxicity to wildlife species using interspecies correlation models. Environ. Sci. Technol. 41:5888-5894.

Rapport, D.J., H.A. Regier and T.C. Hutchinson. 1985. Ecosystem behavior under stress. Am Nat 125:617–640.

Raufer, B. 2009a. Determination of Residues of Dimethoate and Omethoate After One Application of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries at 3 Sites in Northern Europe 2008. Project Number: S08-02100. Unpublished study prepared by Eurofins-GAB GmbH. 128 p. DMT 835.

Raufer, B. 2009b. Determination of Residues of Dimethoate and Omethoate After One Application of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries at 3 Sites in Southern Europe 2008. Project Number: S08-02098. Unpublished study prepared by Eurofins-GAB GmbH. 137 p. DMT 975.

Raufer, B. 2009c. Determination of Residues of Dimethoate and Omethoate After Two Applications of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries at 4 Sites in Northern Europe 2008. Project Number: S08-2099. Unpublished study prepared by Eurofins-GAB GmbH. 139 p. DMT 976.

Raufer, B. 2009d. Determination of Residues of Dimethoate and Omethoate After One Application of an EC Formulation Containing 400 g/L Dimethoate in Sweet Cherries in 1 Site in Northern Europe 2009. Project Number: S08-2039. Unpublished study prepared by Eurofins-GAB GmbH. 100 p. DMT 977.

Reddy, M.S. and K.V. R. Rao. 1992. Toxicity of selected insecticides to the Penaeid prawn *Metapenaeus monoceros* (Fabricius). Bull Environ Contam Toxicol 48:622-629.

Redgrave, V.A., A.J. Johnson, C. Gopinath, J.C. Hadley, A. Anderson, and I.S. Dawe. 1991. Dimethoate: Acute Delayed Neurotoxicity in the Domestic Hen. Huntingdon Research Centre Ltd. Cambridgeshire, England. CHA Doc. No. 100 DMT. 71 pp.

Reiss, R. 2009a. Dimethoate: Initial Response to the Agency's Assessment of Potential Risks to Endangered and Threatened Salmon and Steelhead in the Pacific Northwest. Prepared by Exponent, Inc., Alexandria, VA. July 22, 2009. Docket ID: EPA-HQ-OPP-2009-0059-0015.1.

Reiss, R. 2009b. Updated Summary of Recent Drinking Water Monitoring Data for Dimethoate and Omethoate. Prepared for Cheminova by Dr. Richard Reiss of Exponent, Inc, Alexandria, VA. Final report dated July 7, 2009. Docket ID: EPA-HQ-OPP-2009-0059-0012.2.

Reiss, R. 2009c. Benchmark Dose Analysis of a Bobwhite Quail Reproduction Study for Dimethoate. Prepared for Cheminova by Exponent, Inc, Alexandria, VA. Final report dated July 8, 2009. Docket ID: EPA-HQ-OPP-2009-0059-0012.3 & EPA-HQ-OPP-2009-0059-0012.4.

Ribble, D.O. and M. Salvioni. 1990. Social organization and nest co-occupancy in *Peromyscus californicus*, a monogamous rodent. Behav Ecol Sociol 26:1-15.

Ricklefs, R.E. 1974. Energetics of Reproduction in Birds. In: R. Paynter, ed. Avian Energetics. Nuttal Ornithological Club, Cambridge, MA.

Risher, J.F., F.L. Mink and J.F. Stara. 1987. The toxicologic effects of the carbamate insecticide aldicarb in mammals: A review. Environ Health Perspect 72:267-281.

RIVM (Rijksinstituut voor Volksgezondheid en Milieu [National Institute of Public Health and the Environment]). 2008. Environmental Risk Limits for Dimethoate. RIVM report number 601714001/2008, Bilthoven, The Netherlands.

Roast S.D., R.S. Thompson, P. Donkin, J. Widdows and M.B. Jones. 1999. Toxicity of the organophosphate pesticides chlorpyrifos and dimethoate to *Neomysis integer* (Crustacea: Mysidacea). Wat Res 33(2):319- 326.

Robel, R.J., A.R. Bisset, A.D. Dayton, and K.E. Kemp. 1979. Comparative energetic of bobwhites on six different foods. J Wildl Manage 43:987-992.

Rodney, S.I, R.S. Teed, and D.R.J. Moore. 2008. Development of an Excel-Based Tool for Fitting and Evaluating Species Sensitivity Distributions. Prepared for Environment Canada by Intrinsik Environmental Sciences Inc., Ottawa, ON.

Rood, J.P. 1966. Observations on the reproduction of Peromyscus in captivity. Am Midl Nat. 76:496-503.

Russell, R.W. 1996. Bioavailability and Biomagnification of Organochlorinated Chemicals in Aquatic Ecosystems. PhD Thesis. University of Windsor, Windsor, ON, Canada.

Sample, B.E. and C.A. Arenal. 1999. Allometric models for interspecies extrapolation of wildlife toxicity data. Bull Environ Contam Toxicol 62:653-663.

Sanders, H.O. 1969. Toxicity of Pesticides to the Crustacean *Gammarus lacustris*. Tech Paper No. 25, US Department of the Interior, Bureau of Sport Fisheries and Wildlife, Fish and Wildlife Service, Washington, DC. 18 p.

Sanders, H.O. and O.B. Cope. 1968. The relative toxicities of several pesticides to naiads of three species of stoneflies. Limnol Oceanogr 13(1):112-117.

Sanderson, D.M. and E.F. Edson. 1964. Toxicological properties of the organo-phosphorus insecticide dimethoate. Brit J Ind Med 21: 52-64.

Schafer, E.W. 1972. The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicol Appl Pharmacol 21:315-330. MRID 00020560.

Schanné, C. 1992. Adsorption/Desorption of (14-Carbon) Dimethoate on Six Soils. Project Number: 283342. Prepared by RCC Umweltchemie Ag. 140 p. CHA Doc. No.: 118 DMT. MRID 47477301.

Schmitzer, S. 2005. Toxicity Testing of an EC Formulation Containing 400g/L Dimethoate (BAS 152 11 I) on Honey Bees (Apis mellifera L.) in the field. Final Report. IBACON Project 21551039. MRID 48101302.

Scott, N.J. and G.B. Rathbun. 2001. Declining and Sensitive Aquatic Vertebrates of Coastal Streams, San Luis Obispo County. Western Ecological Research Center, Biological Resources Division, U.S. Geological Survey to the California Department of Transportation, San Luis Obispo, CA.

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

Segal Ranch. 2012. Hybrid Poplars. http://www.hybridpoplar.com/home/sr2/growing_main.html. Accessed July 2012.

Serrano, R., F. Hernández, J.B. Peña, V. Dosca and J. Canales. 1995. Toxicity and bioconcentration of selected organophophorus pesticides in *Mytilus galloprovincialis* and *Venus gallina*. Arch Environ Contam Toxicol 29:284-290.

Sherratt, T.N., G. Roberts, P. Williams, M. Whitfield, J. Biggs, N. Shillabeer and S.J. Maund. 1999. A life-history approach to predict the recovery of aquatic invertebrate populations after exposure to xenobiotic chemicals. Environ Toxicol Chem 18:2512–2518.

Siepmann, S., and S.B. Slater. 1998. Hazard assessment of the insecticide malathion to aquatic life in the Sacramento-San Joaquin river system. State of California, Office of Spill Prevention and Response. Pesticides Investigations Unit. Administrative Report 98-2. Rancho Cordova, California.

Singh, A. and R.A. Agarwal. 1990. Molluscicidal properties of synthetic pyrethroids. J Med App Malacol 2:141-144.

Skinner, W. and Shepler, K. 1994. Photodegradation of [14C] Dimethoate in/on Soil by Natural Sunlight. PTRL West, Inc., Richmond, CA. CHA Doc. No.: 173 DMT. MRID 43276401.

Slooff, W. and J.H. Canton. 1983. Comparison of the susceptibility of 11 freshwater species to 8 chemical compounds. II. (Semi) Chronic toxicity tests. Aquat Toxicol 4(3):271-282.

Solecki, R., L. Niemann, C. Gericke, and I. Chahoud. 2001. Dietary administration of dimethoate to the japanese quail: Reproductive effects and successful hatchability of eggs. Bull Environ Contam Toxicol 67:807-814.

Solomon, K.R., D.B. Baker, R.P. Richards, K.R. Dixon, S.J. Klaine, T.W. La Point, R.J. Kendall, C.P. Weisskopf, J.M. Giddings, J.P. Giesy, L.W. Hall Jr and M.W. Williams. 1996. Ecological risk assessment of atrazine in North America surface waters. Environ Toxicol Chem 15:31–76.

Song, M.Y. and J.J. Brown. 1998. Osmotic effects as a factor modifying insecticide toxicity on Aedes and Artemia. Ecotoxicol Environ Saf 41:195-202.

Song, M.Y., J.D. Stark, and J.J. Brown. 1997. Comparative toxicity of four insecticides, including imidacloprid and tebufenozide, to four aquatic arthropods. Environ Toxicol Chem 16(12):2494–2500.

Srivastava, V.K. and A. Singh. 2001. Toxicity of alphamethrin, dimethoate and carbaryl pesticides to the freshwater snails *Lymnaea acuminata* and *Indoplanorbis exustus*. Iberus 19(1):1-5.

Stalmaster, M.V. and J.A. Gessaman. 1982. Food consumption and energy requirements of captive bald eagles. J Wildl Manage 46: 646-654.

Stebbins, R.C. 1985. Peterson Field Guide to Western Reptiles and Amphibians. Houghton Mifflin Co., Boston, MA. 336 p.

Stephan, C.E. 2002. Use of Species Sensitivity Distributions in the Derivation of Water Quality Criteria for Aquatic Life by the U.S. Environmental Protection Agency. In: Posthuma, L., G.W. Suter II and T.P. Traas (Eds.). Species Sensitivity Distributions in Ecotoxicology. Lewis Publishers, Boca Raton, FL.

Stone Environmental Inc. 2012. Refined Exposure Modeling of Malathion for the California Red-Legged Frog. Prepared for Intrinsik Environmental Sciences, Inc., Ottawa, ON by Stone Environmental Inc., Montpelier, VT. Stone Project ID 112482-F.

Storer, T.I. 1925. A synopsis of the amphibia of California. Univ Calif Pub Zool 27:1-342. Cited In: FWS, 2002a.

Suárez, L. A. 2005. PRZM-3, A Model for Predicting Pesticide and Nitrogen Fate in the Crop Root and Unsaturated Soil Zones: Users Manual for Release 3.12.2. U.S. Environmental Protection Agency, National Exposure Research Laboratory, Athens, GA. EPA/600/R-05/111.

Suter G.W. Jr and A.E. Rosen. 1988. Comparative toxicology for risk assessment of marine fishes and crustaceans. Environ Sci Technol 22:548–556.

Suter G.W. Jr, A.E. Rosen and E. Linder. 1986. Analysis of Extrapolation Error. In: Barnthouse L.W. and G.W. Suter Jr, editors. User's Manual for Ecological Risk Analysis. Oak Ridge National Laboratory, Oak Ridge, TN. ORNL-6251. pp 49-81.

Suter II, G.W., L.W. Barnthouse, S.M. Bartell, T. Mill, D. Mackay and S. Paterson. 1993. Ecological Risk Assessment. Lewis Publishers, Boca Raton, FL.

Suter II, G.W., R.A. Efroymson, B.E. Sample and D.S. Jones. 2000. Ecological Risk Assessment for Contaminated Sites. Lewis Publishers, Boca Raton, FL.

Tatarian, P.J. 2008. Movement patterns of California red-legged frogs (*Rana draytonii*) in an inland California environment. Herptol Conserv Biol 3(2):155-169.

Teeter, D. 1988. Determination of Vapor Pressure of Dimethoate: Lab Project Number: 36211. Prepared by Analytical Bio-Chemistry Laboratories, Inc. 265 p. CHA Doc. No. 86 DMT. MRID 42261203.

Temple, D.L., K.H. Martin, J.B. Beavers, and M. Jaber. 2010. Omethoate and Dimethoate: A Comparative Reproduction Study with the Northern Bobwhite. Wildlife International, Ltd. Project Number 232-149. August 31, 2010. Unpublished report.

Thayer, G.W., W.E. Schaaf and J.W. Angelovic. 1973. Caloric measurements of some estuarine organisms. Fishery Bull 71:289-296. Cited in: EPA, 1993.

Thybaud, É., S. Le Bras and R.P. Cosson. 1987. Étude comparée de la sensibilité d'*Asellus aquaticus* L. (Crustacé, Isopode) vis-ā-vis de quelques insecticides et de divers métaux lourds. Acta Ecologica 8(4):355-361.

Thompson, G.G. and P.P. Withers. 1997. Comparative morphology of western Australian varanid lizards (Squamata: Varanidae). J Morphol 233(2):127-152.

Trask, J.R., W.M. Williams and A.M. Ritter. 2010a. Overview of USEPA-OPP's Terrestrial Risk Assessment Models. Prepared by Waterborne Environmental, Inc., Leesburg, VA for CropLife America, Washington DC.

Trask, J.R., W.M. Williams, and A.M. Ritter. 2010b. Options for Refining the Exposure Component of USEPA-OPP's Terrestrial Risk Assessment Models. Prepared by Waterborne Environmental, Inc., Leesburg, VA for CropLife America, Washington DC.

Tripathi, P.K. and A. Singh. 2003. Toxic effects of dimethoate and carbaryl pesticides on reproduction and related enzymes of the freshwater snail *Lymnaea acuminata*. Bull Environ Contam Toxicol 71:535-542.

Tyler, A.V. 1973. Caloric values of some North Atlantic invertebrates. Mar Biol 19:258-261. Cited in: EPA, 1993.

USC (University of South Carolina). 2006. Perobase - A Comprehensive Database for Peromyscus. University of South Carolina. Accessed January 17, 2007. http://wotan.cse.sc.edu/perobase/index.html

USDA (United States Department of Agriculture). 2007. Frog Fact. United States Department of Agriculture, Forest Service. Orgen, UT. http://www.fs.fed.us/r4/amphibians/frog_fact.htm

USDA (United States Department of Agriculture). 2011. Pesticide Data Program – Annual Summary Calendar Year 2009. Agricultural Marketing Service. 194 pg.

USGS (United States Geological Survey). 2003. A Field Guide to the Reptiles and Amphibians of Coastal Southern California. USGS, Western Ecological Research Center, San Diego Field Station, CA. http://www.werc.usgs.gov/fieldguide/index.htm.

USGS (United Stated Geological Survey). 2009. USGS National Water Quality Assessment Data Warehouse. http://infotrek.er.usgs.gov/traverse/f?p=NAWQA:HOME:0. Accessed June 2011.

Van den Brink, P.J., R.P.A. van Wijngaarden, W.G.H. Lucassen, T.C.M. Brock and P. Leeuwangh.1996. Effects of the insecticide Dursban 4E (active ingredient chlorpyrifos) in outdoor experimental ditches: II. Invertebrate community responses and recovery. Environ Toxicol Chem 15:1143–1153.

Versteeg, D.J., S.E. Belanger and G.J. Carr. 1999. Understanding single species and model ecosystem sensitivity: A data-based comparison. Environ Toxicol Chem 18:329-1346.

Völkl, S. 1993. 14C-Dimethoate: Degradation and Metabolism in Aquatic Systems. RCC Umweltchemie AG, Itingen, Switzerland. DTF Doc. No. 621-002. CHA Doc. No.: 141 DMT. MRID 47784101.

Wassersug, R. 1984. Why tadpoles love fast food. Nat Hist 4:84.

WHO (World Health Organization). 1991. Environmental Health Criteria No. 121. Aldicarb. World Health Organization, Geneva, Switzerland. http://www.inchem.org/documents/ehc/ehc/ehc121.htm

Willis, G.H. and L.L. McDowell. 1987. Pesticide persistence on foliage. Rev Environ Contam Toxicol 100:23-73.

Wilson, A. 2000. Residue Decline Curve Study With an EC Formulation Containing 400 g/L Dimethoate Applied to Cherries in Spain and Italy, 1999. Project Number: SCI/024. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 94 p. DMT 426.

Wilson, A. 2001a. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Wheat in Spain and Italy in 2002. Project Number: SCI/046. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 133 p. DMT 453. MRID 46678001.

Wilson, A. 2001b. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Wheat in Spain and Italy in 2002. Project Number: SCI/037. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 144 p. DMT 459. MRID 46678010.

Wilson, A. 2001c. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Wheat in United Kingdom and Germany in 2001. Project Number: SCI/080. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 133 p. DMT 484.

Wilson, A. 2001d. Residue Decline Curve Study With an EC Formulation Containing 400 g/L Dimethoate Applied to Lettuce in Italy, Spain and Greece in 2000. Project Number: SCI/041. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 112 p. DMT 438. MRID 46678007.

Wilson, A. 2001e. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Tomatoes in Spain and Italy in 2000. Project Number: SCI/040. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 112 p. DMT 448. MRID 46678008.

Wilson, A. 2001f. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Celery in Italy in 2000. Project Number: SCI/043. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 91 p. DMT 439.

Wilson, A. 2001g. Residue Decline Curve Study With and EC Formulation Containing 400 g/L Dimethoate Applied to Sugar Beet in Italy and Spain in 2000. Project Number: SCI/045. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 109 p. DMT 541. MRID 46678004.

Wilson, A. 2001h. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Asparagus in Spain in 2001. Project Number: SCI/076. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 76 p. DMT 479.

Wilson, A. 2001i. Residue Decline Curve Study With an EC Formulation Containing 400 g/L Dimethoate Applied to Citrus in Spain, Italy and Greece in 1999. Project Number: SCI/022. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 291 p. DMT 460.

Wilson, A. 2001j. Residue Study (Decline Curve and at Harvest) With an EC Formulation Containing 400 g/L Dimethoate Applied to Citrus in Spain, Italy and Greece in 2000. Project Number: SCI/039. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 186 p. DMT 467.

Wilson, A. 2001k. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Melons in Italy, Spain and Greece in 2000. Project Number:

SCI/047. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 131 p. DMT 456. MRID 46678002.

Wilson, A. 2001l. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Globe Artichokes in Italy in 2000. Project Number: SCI/044. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 100 p. DMT 472.

Wilson, A. 2002a. Residue Study (Decline Curve and at Harvest) With an EC Formulation Containing 400 g/L Dimethoate Applied to Sugar Beet in Spain and Italy in 2001. Project Number SCI/069. Unpublished study prepared by Huntingdon Life Sciences Ltd. 127 p. DMT 483.

Wilson, A. 2002b. Residue Study (Decline Curve and at Harvest) With an EC Formulation Containing 400 g/L Dimethoate Applied to Wheat in the United Kingdom and Germany in 2001. Project Number SCI/080. Unpublished study prepared by Huntingdon Life Sciences Ltd. 131 p. DMT 484.

Wilson, A. 2002c. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Asparagus in Italy in 2000. Project Number SCI/042. Unpublished study prepared by Huntingdon Life Sciences Ltd. 98 p. DMT 527.

Wilson, A. 2002d. Residue Study (Decline Curve and at Harvest) With an EC Formulation Containing 400 g/L Dimethoate Applied to Citrus in Spain, Italy and Greece in 2001. Project Number SCI/073. Unpublished study prepared by Huntingdon Life Sciences Ltd. 150 p. DMT 551.

Wilson, A. 2002e. Residue Study (Decline Curve) With an EC Formulation Containing 400 g/L Dimethoate Applied to Asparagus in Italy in 2002. Project Number SCI/087. Unpublished study prepared by Huntingdon Life Sciences Ltd. 76 p. DMT 572.

Wilson, A. 2002f. Residue Study (Decline Curve and at Harvest) With an EC Formulation Containing 400 g/L Dimethoate Applied to Wheat in the United Kingdom and Germany in 2002. Project Number SCI/086. Unpublished study prepared by Huntingdon Life Sciences Ltd. 108 p. DMT 573.

Wilson, A. 2003a. Residue Study (Processed Commodity) With an EC Formulation Containing 400 g/L Dimethoate Applied to Wheat in the United Kingdom and Germany in 2001. Project Number SCI/079. Unpublished study prepared by Huntingdon Life Sciences Ltd. 216 p. DMT 576.

Wilson, A. 2003b. Residue Study (At Harvest) With an EC Formulation Containing 400 g/L Dimethoate Applied to Citrus in Italy in 2002. Project Number SCI/091. Unpublished study prepared by Huntingdon Life Sciences Ltd. 89 p. DMT 585.

Wolf, T.M. and B.C. Caldwell. 2001. Development of a Canadian spray drift model for the determination of buffer zone distances. Expert Committee on Weeds Annual Meeting, Quebec City, QC, Nov. 26-29, 2001.

Wright, A.H. and A.A. Wright. 1949. Handbook of Frogs and Toads of the United States and Canada. Comstock Publishing Company, Inc., Ithaca, NY. 640 p. Cited In: FWS, 2002a.

WSPMRS (Washington State Pest Management Resource Service). 2003. Response to EPA's Request for Information on the Use of Dimethoate for Reregistration Purpose. Pacific Northwest Coalition Comment Coordinator, Washington State Pest Management Resource Service, Washington State University Tri-Cities, Richland, WA.

Wüthrich, V. 1990. Influence of Dimethoate on the Reproduction of *Daphnia magna*. RCC Umweltchemie AG Study No. 264464. CHA Doc. No. 97 USA DMT (Amendment 2 – raw data included). MRID 42864701.

Zok, S. 2001a. Dimethoate: Acute Toxicity in the Northern Bobwhite Quail (*Colinus virginianus*) After Single Oral Administration (LD50). BASF - Experimental Toxicology and Ecology Study No. 11W0466/99128. DTF Doc. No. 441-008. CHA Doc. No. 470 DMT. Final report submitted to EPA on May 15, 2009. MRID 47769701.

Zok, S. 2001b. Dimethoate: Acute Toxicity in the Ring-necked Pheasant (*Phasianus colchicus*) After Single Oral Administration (LD50). BASF - Experimental Toxicology and Ecology Study No. 12W0466/99126. DTF Doc. No. 441-007. CHA Doc. No. 471 DMT. Final report submitted to EPA on May 15, 2009. MRID 47769702.

Zok, S. 2001c. Dimethoate: Avian Dietary LC50 Test in Chicks of the Bobwhite Quail (*Colinus virginianus*). BASF - Experimental Toxicology and Ecology Study No. 31W0466/99127. DTF Doc. No. 445-010. CHA Doc. No. 469 DMT. Final report submitted to EPA on May 15, 2009. MRID 47769705.

Zok, S. 2001d. Dimethoate: Avian Dietary LC50 Test in Chicks of the Ring-necked Pheasant (*Phasianus colchicus*). OPPTS Guideline 850.2200. BASF Project No.: 36W0466/99130. Final report submitted to EPA on May 15, 2009. U.S. EPA MRID 47769706.

APPENDIX A
STUDY EVALUATION CRITERIA

Background

Regulatory authorities such as the U.S. Environmental Protection Agency (US EPA) , the Pest Management Regulatory Agency and the California Department of Pesticide Regulation often rely on "best professional judgment" in evaluating ecotoxicological studies. In some cases, little evaluation is done at all. This is particularly true for peer-reviewed journal articles. A scientific evaluation of the quality of these studies is often lacking and authorities simply use the most sensitive endpoint to drive their ecological risk assessments. A "best professional judgment" approach or no evaluation at all lacks transparency, objectivity and is not scientifically defensible. Reliance on best professional judgment, in the absence of rigorous criteria, can also lead to different reviewers arriving at different conclusions.

The objective of this position paper is to provide an approach for evaluating the quality of ecotoxicological studies conducted on aquatic, avian and mammalian species that is rigorous and consistent. The goal is to ensure the use of the most scientifically defensible results in ecological risk assessments. This paper includes:

- A background section describing why such a system is needed;
- Types of studies available;
- Existing study quality evaluation approaches;
- Cheminova's approach for assessing study quality; and
- Appendices of the specific criteria for each toxicity test.

Intrinsik developed a scoring system for Environment Canada aimed at evaluating the quality of ecotoxicity studies submitted under the New Substance Notification Regulations (Breton et al., 2009). The scoring system focused on fish, Daphnia and algae acute toxicity studies conducted following OECD Testing Guidelines (OECD 201, 202, and 203). The approach described herein builds upon the Breton et al. (2009) approach, as well as the Klimisch et al. (1997) evaluation scheme. The latter scheme is used in various jurisdictions and applied under REACH. The Klimisch et al. (1997) scheme assesses the reliability of data, particularly toxicological and ecotoxicological data. The intention of the system is to harmonize data evaluation worldwide. However, the interpretation of Klimisch et al. (1997) criteria by evaluators is overly subjective and can lead to different reliability codes (Duchemin et al., 2010). This paper applies aspects of these schemes and also considers the US EPA Ecotox and The California Department of Fish and Game (CDFG) Pesticides Unit schemes to developed criteria to identify studies that can be used in risk assessment.

In the evaluation scheme described herein, each study is categorized as acceptable (core), supplemental or unacceptable. A generic set of criteria was developed to cover all types of toxicity tests. If the study meets the generic criteria, then the study is further evaluated against what is called "acceptability" criteria. If the study satisfies the acceptability criteria then the study is categorized as acceptable. If the study only meets the generic criteria, then the study is categorized as supplemental. If the study does not meet the generic set of criteria, then the study is unacceptable.

This paper reflects Cheminova's position for evaluating the quality of ecotoxicity studies for use in ecological risk assessment (ERA).

Types of Studies Available

An important point to consider when collecting studies is the application of such data. The source, methodology, data presentation, interpretation and study review process are all factors that influence the appropriateness of the information for a particular use (McCarty et al., 2012).

Good Laboratory Practice Studies

Studies conducted under Good Laboratory Practice (GLP) using widely accepted protocols and guidelines should be considered "best available data". Guidelines are based on current and well-tested analytical methods and have been through rigorous scientific review. Good Laboratory Practice Standards (40 CFR Part 160) require thorough documentation and verification of study conduct. The identity of the substance tested must be confirmed, its purity must be reported, and test concentrations or doses are typically verified by appropriate methods. Study methods must be documented in a manner that allows the experiment to be reproduced. GLP studies are particularly good for use in risk assessment and regulatory decisions due to the standardized methodology used within testing protocols, and the availability of raw data (McCarty et al., 2012). Methods used in GLP studies may not always include the newest technology, but the methods used have been validated across many jurisdictions (McCarty et al., 2012). Registrant studies conducted after October 16, 1989 are required to have been GLP compliant.

Peer-Reviewed Journals

The peer-review process provides credibility to the information contained in a journal article. However, this does not necessarily mean a study is high quality or appropriate for application in regulatory decision-making. In addition, the process of peer review is not consistent between journals, or even within a field (McCarty et al., 2012). Studies in the peer-reviewed scientific literature seldom follow GLP, and may or may not follow an acceptable guideline. However, a study following appropriate guidelines can be scientifically valid without GLP compliance. Peer reviewed journal articles are typically selected for publication due to their stimulation of scientific debate (McCarty et al., 2012). With this in mind, it is less likely that "negative" results are readily published in peer review journals, therefore leaving data gaps in toxicological information available in peer reviewed literature. Such information is critical to risk assessment.

Grey Literature Studies

Graduate studies and studies conducted in research centers and contract laboratories are examples of grey literature studies. Such studies may not follow an acceptable guideline or follow GLP. Similar to peer-reviewed journals, grey literature studies need to be evaluated for quality using the same criteria as with other types of studies.

Review Articles and Handbooks

Review articles and handbooks usually provide a compilation of results from previous studies. Most often insufficient experimental details are available in these sources to verify the quality of the original studies. Original sources are sometimes not even provided. The primary documents need to be consulted and verified for quality. If the original studies are not available, then data from review articles and handbooks should not be used in an ecological risk assessment.

Existing Study Quality Evaluation Approaches

Breton et al. (2009)

Environment Canada and Health Canada must be notified of new substances being manufactured in, or imported to, Canada. Notification is legislated under the New Substances Notification Regulations (Chemicals and Polymers) (NSNR). Using information provided by the notifier, and other complementary information available to the two departments, the New Substances Program conducts ecological and human health risk assessments. Between 2000 and 2009, more than 750 ecotoxicity studies have been submitted to the New Substances Program of Environment Canada under the NSNR.

On behalf of Environment Canada, Breton et al. (2009) developed scoring methods used by regulators to assess the quality and validity of ecotoxicity studies on fish, Daphnia spp. and green algae based on the OECD Test Guidelines 203 (OECD, 1992), 202 (OECD, 2004) and 201 (OECD, 2002), respectively. Criteria for each of the test species were developed to evaluate the quality of the studies. Each of the criteria are weighted (a numeric value) in terms of importance with the objective of calculating an overall numeric score for studies.

The criteria are grouped in the following five categories:

- Test Method;
- Test Species;
- Test Substance;
- Test Design and Conditions; and,
- Validity of Test.

The overall study quality score is then used to assign the study to a quality or reliability level. These reliability levels are: 1) very good, 2) good, 3) acceptable, or 4) unacceptable.

The consistency of the Breton et al. (2009) approach was tested by evaluating the quality of 614 ecotoxicity studies (270 fish, 213 Daphnia spp. and 131 green algae). The consistency of the Breton et al. (2009) methods among different evaluators was validated by re-scoring 20% of the 614 studies by different evaluators. This led to the refinement of the criteria and guidance. Most scores by different evaluators were identical. In cases where discrepancies occurred, scores obtained were typically within +/- 5% overall study quality score with the exception of one re-scoring study for fish, Daphnia and algae (i.e., 5.02% for fish, 6.98% for Daphnia, and 5.71% for algae). The minor discrepancies in scores were attributed to the following factors:

- Differences in interpretation of the information provided in the test report;
- Ambiguity of the information provided in the test reports; and,
- Information that was overlooked by the user upon reviewing the test report (e.g., information provided in an appendix or footnote).

Klimisch et al. (1997)

The Klimisch et al. (1997) evaluation scheme is used in various regulatory programs, including REACH, to evaluate the reliability of scientific studies. The scheme is extensively used for toxicological and ecotoxicological studies. The intention of this scheme is to harmonize data evaluation worldwide. Klimisch et al. (1997) proposed four categories of reliability codes (Table A-1).

Table A-1 Klimisch et al. (1997) categories and justification

Code	*Category*	*Justification*
1	Reliable without restrictions	Guideline study or comparable to guideline study, preferably performed according to GLP Test parameters documented according to a specific or comparable guideline
2	Reliable with restrictions	Acceptable, well documented publication/study report Basic data provided[a] but test parameters documented do not totally comply with guideline but are comparable to guideline Comparable to guideline study with acceptable restrictions
3	Not reliable	Method not validated or acceptable Documentation insufficient for assessment Does not meet criteria of today's standard methods Relevant methodological deficiencies Unsuitable test system (e.g., inappropriate pathway of application or exposure)
4	Not assignable	Only short abstract available Only secondary literature (e.g., review, table, books, etc.) Insufficient experimental details

[a] Basic data include test organisms, data on the method, purity of the substance (necessary as impurities may have a substantial influence on the toxicity), and dose/concentration data.

Studies rated as "reliable without restrictions" and "reliable with restrictions" may be used in a risk assessment. Klimisch et al. (1997) suggested that data with lower reliability may be used as supporting information, especially if the results are comparable or in the similar range. In cases where only data with limited reliability are available, they suggested that these data may be used for definitive assessments of risk if the assessor considers these data as relevant (plausible) for risk assessment.

Klimisch et al. (1997) provided a checklist that evaluators can use to evaluate studies. This list comprises information for avian and mammalian studies, in vitro studies and ecotoxicity studies. However, even with this checklist, interpretation of the Klimisch et al. (1997) criteria by evaluators is overly subjective. This can lead to the assignment of different reliability codes for the same studies (Duchemin et al., 2010). As a result, Cheminova developed an approach to categorize the quality of studies that we believe can provide consistent results.

EPA Ecotox

U.S. EPA ECOTOX, Version 4, is a scientific database comprised of mostly peer-reviewed ecotoxicological reports on the toxicity of single chemicals to aquatic life, terrestrial plants and wildlife. The database is intended to provide quality studies from open-literature for use in environmental risk assessments necessary for registration of chemicals. ECOTOX was created and is maintained by the U.S. EPA, Office of Research and Development (ORD), and the National Health and Environmental Effects Research Laboratory's (NHEERL's) Mid-Continent Ecology Division (MED).

Studies in the open literature are obtained via specific search strategies conducted by EPA's ORD and MED. This search generally includes manual and electronic searches (i.e., references obtained from review article reference sections, or from searches on Cambridge Scientific Abstracts) (EPA, 2004).

For a study to be accepted into the ECOTOX database, it must report: 1) toxic effects related to a single chemical exposure; 2) toxic effects on an aquatic or terrestrial plant or animal species; 3) a biological effect on live, whole organisms; 4) a concurrent environmental chemicals concentration/dose or application rate; and 5) an explicit duration of exposure.

Studies that are considered acceptable for ECOTOX are then further assessed to determine if a particular paper may be potentially useful for hazard identification of a chemical. Some additional criteria required are:

- Toxicological information of the chemical is reported
- The study is reported in the English language
- Full study must be available (no abstracts are accepted)
- It is a publicly available paper

- The paper is the primary source of the data
- Controls are included in the study
- The location of the study is reported (e.g., laboratory of field)
- All studies that do not meet the criteria are kept and reasons for rejection are noted.
- All of the eligible studies are then organized based on taxonomic groups, and available details about the study are entered into a standardized format. All measurement units are converted to be consistent.

The ECOTOX database is a good starting point for identifying available open-literature studies and toxicological endpoints for many species of concern. However, for use of a study in ecological risk assessments, further professional judgement should be made as to the appropriateness of their use.

California

The California Department of Fish and Game (CDFG) Pesticides Unit conducts assessments to determine the risk of pesticides to aquatic organisms. An important part of hazard assessment is the evaluation of toxicological information from scientific studies (Siepmann and Slater, 1998). The CDFG primarily assesses studies that have been published in the scientific literature and laboratory reports that are required for pesticide registration (conducted and/or provided by registrants).

Studies are assessed for compliance with standards for test type, method, design, species, water chemistry, and toxicant monitoring. Studies are rejected from use if they fail to follow certain fundamental procedures. Examples of criteria include:

- Four or more tested concentrations
- Oxygen levels >60% during test
- Formulation has a high percent of active ingredient
- Mortality in test must be <30 to >60% mortality
- Effect criteria (e.g., LC/EC50) must be provided
- Control survival must be reported
- Measured concentrations in exposure water

A test does not have to comply with every standard, however, a study may be rejected if it fails to meet certain fundamental procedures (i.e., no effect criteria) or if it fails to meet many of the test standards. Acceptable studies are considered for use in hazard identification.

Cheminova's Approach for Assessing Study Quality

Cheminova's approach builds upon the Breton et al. (2009), the Klimisch et al. (1997), the EPA ECOTOX and the California schemes. Three categories or quality levels were developed under the Cheminova scheme: acceptable, supplemental, and unacceptable. Criteria were developed for: (1) fish, aquatic invertebrates and amphibians, (2) birds (3) mammals and (4) algae and aquatic plants.

Acceptable studies are more likely to comprise those conducted with widely accepted guidelines under GLP. These studies are preferred when conducting an ecological risk assessment and for deriving effects metrics. Acceptable guideline GLP studies are selected over supplemental studies when both types of studies are available for the same species endpoint. In the absence of such studies, other acceptable studies are selected followed by supplemental studies. Supplemental studies could include peer-reviewed journal articles and grey literature studies. Both acceptable and supplemental studies can be included in the development of species sensitivity distributions (SSDs), and other analyses used in refined assessment. Such analyses require more data and are typically less sensitive to the additional uncertainty introduced when using supplemental data.

The criteria were developed with the goal of ensuring high quality while minimizing misclassification as can happen with the Klimisch et al. (1997) scheme. Table A-2 presents general information that is required before evaluating the quality of a study. Table A-3 provides the study quality acceptability criteria and guidance to help consistently address these criteria. A generic set of criteria was developed to cover all types of toxicity tests. If the study meets all of the generic criteria (answer Yes to all criteria), then the study is further evaluated against what is called "acceptability" criteria. If the study satisfies all the acceptability criteria (answer Yes to all criteria) then the study is categorized as acceptable. If the study only meets the generic criteria, then the study is categorized as supplemental. If the study fails to meet (answer No to any criteria) any of the generic criteria, then the study is unacceptable.

Table A-2 General information and guidance required before evaluating the quality of a study.

General Information	*Guidance*
Compound Name	Required
Study Preference (Primary)	Primary sources of information are preferred to secondary sources (e.g., review articles, databases) when reviewing a source.

Table A-2 General information and guidance required before evaluating the quality of a study.

General Information	*Guidance*
Secondary Reference	Secondary sources, such as those presented below, often lack the experimental details to be able to conduct a proper evaluation of the study. Hudson, R.H., R.K. Tucker and M.A. Haegle. 1984. Handbook of Toxicity of Pesticides to Wildlife. USFWS Publication No. 153 Johnson, W.W. and M.T. Finley. 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USFWS Publication No. 137 Mayer, F.L. and M.R. Ellersieck. 1986. Manual of Acute Toxicity: Interpretation and Database for 410 Chemicals and 66 Species of Freshwater Animals. USFWS Publication No. 160. Mayer, F.L. 1987. Acute Toxicity Handbook of Chemicals to Estuarine Organisms. USEPA Environmental Research Laboratory, Gulf Breeze, Florida. EPA Publication 600/x-86/231.
GLP study?	To meet this criterion, a GLP Compliance Statement needs to be provided in the study report. The statement must provide, at a minimum: a dated Study Director's sign-off; and identification of which GLP standards were followed (e.g., OECD, U.S. EPA).

Table A-3 Study quality evaluation scheme for aquatic species, birds and mammals.	
Generic Criteria	***Guidance***
Single chemical exposure?	Single chemical exposure can be verified, technical or formulated product indicated here. Tests conducted with mixtures of active ingredients are not acceptable.
Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?	It must be clearly stated in the study report that the study followed a standard. Terms such as "in general agreement with", "comparable to", "similar to", "closely follows" and "in general accordance with" indicate that the study did not necessarily follow a standard. Studies that followed a recognized international standard meet this generic criterion.
If study did not follow an international recognized standard, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?	Deviations from a standard should be presented. Determining whether the study meets "acceptable laboratory practices" is subjective and requires some level of experience. Sufficient details must be provided to meet this criterion.
Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?	Chemical identification must be reported (e.g. product trade name, CAS number etc.). A wide range of impurities can be produced when manufacturing pesticides. Some impurities are known to potentiate, or have synergistic or antagonistic effects on toxicity. As such, the purity of a chemical based on the latest production technology should be considered the benchmark when addressing this criterion. For example, Cheminova is the only company that sells technical dimethoate (>94% in North America). Dimethoate-based products manufactured decades ago or produced by other companies have a different set of inerts and impurities than formulations or technical grades manufactured today. For this reason, Cheminova's GLP studies should be considered the best available data for risk assessment. Evaluators must be aware of the level of purity expected for the chemical under investigation when assessing technical grade chemicals. When assessing formulations, only GLP studies should be considered acceptable for risk assessment. Open literature studies are considered unreliable because inerts in formulations can vary widely between manufacturers and can strongly influence the toxicity of the tested material. Open literature studies for formulations with unknown impurities are classified as unacceptable. The source of the chemical needs to be provided, or verified, as different production technologies can produce different types and amounts of impurities. Studies that use technical products similar to or the same as currently manufactured technical products meet this criterion.
Were effects endpoints ecologically relevant?	Mortality, growth and reproduction are ecologically relevant endpoints. Verify that the exposure pathway was appropriate (e.g., injection is not an environmentally relevant exposure pathway).

Table A-3 Study quality evaluation scheme for aquatic species, birds and mammals.

Generic Criteria	*Guidance*
Aquatic: Was an appropriate exposure duration used and reported? **Avian and mammalian: Were an appropriate exposure duration and post-exposure observation period used and reported?**	Acute fish and amphibian studies are typically 96 h and acute invertebrate studies are typically 48 h in duration. Chronic studies are typically much longer (e.g., 21 d) or involve more than one life stage. Algae studies are typically 72 - 96 h, and aquatic plant tests with *Lemna sp.* are typically 7 d in duration. Acute gavage, single dose studies should have a minimum of 14 days observation for both birds and mammals. Exposure duration for an acute dietary avian study is generally 5 days followed by a 3 day observation period. Chronic avian tests are generally conducted over a 22-week period (but can vary depending on endpoint being measured (i.e. egg production measured at 10 weeks).Chronic mammalian tests are generally ≥12 months, however, subchronic tests exist that can last up to 90 days. The post observation period should be reported if conducted in the study. However a post-observation period is not required for all study durations (i.e. chronic studies).

Table A-3 Study quality evaluation scheme for aquatic species, birds and mammals.	
Generic Criteria	*Guidance*
Were appropriate controls included, reported and results adequate?	If control mortality is greater than 20%, the study should be rejected. If there was control mortality, it may be corrected (i.e., Abbott's formula). Some guidelines for acute studies (e.g., OECD and EPA mammalian or avian testing guidelines) may not require use of controls depending on the standard protocol that is followed. If the objective of the test is to generate a concentration- or dose-response curve, then the use of controls may not be necessary. If the study shows that the range of treatments produced very low to very high responses with some partial responses in between, then this would generate an appropriate dose-response curve to derive the endpoint of interest (e.g., LC50 or LD50). If this is the case, the LC50 or LD50 is reliable. If the goal of the study is to generate a NOEL and LOEL, then controls are necessary. The use of appropriate controls for some guidelines for chronic reproduction tests (e.g. EPA) may only be validated for reproductive effects, and not mortality. In these cases, this criterion is met as long as the test validity criteria for reproductive effects, as recommended in the protocol, is met. For example, this criterion is met if a control group met the ASTM E 1191-03a and OPPTS 850.1350 guideline validity criteria that 75% of 1st generation females must produce young and that ≥3 young must be produced per 1st generation female. For algal studies, according to OECD and EC guidelines, the number of control cells should increase by a factor of at least 16 within 72 h, and according to EPA guidelines controls should reach log growth phase by 96 h. OECD 201 (2004) validity criteria include coefficients of variation for daily growth rates in control cultures of less than 35% and for average growth in replicate controls of less than 15% (not applicable for OECD tests prior to 2004, or for other standardized test methods). For tests with the aquatic plant *Lemna sp.* OECD 221 (2006) validity criteria require doubling time of control frond number be less than 60 h. If a co-solvent was used, was a control group tested with the vehicle? The study must have verified that the toxicity of the solvent to test organisms was negligible through use of a positive control treatment.

Table A-3 Study quality evaluation scheme for aquatic species, birds and mammals.

Generic Criteria	*Guidance*
Were the statistical procedures reported and appropriate?	For NOEL and LOEL endpoints to be derived, appropriate significance tests must be carried out. Typically, Dunnett's test is used to compare treatment groups to controls. Tukey's test is appropriate when comparing all groups. If the measure of effect is continuous, a Mann-Whitney U (also known as the Wilcoxon sum-rank) test or t-test (if data are normally distributed) may be appropriate. However, a Bonferroni (or other) correction to the significance level would be required if multiple comparisons were made. There are numerous tests suggested in the literature. Expert judgement should be used if a non-standard statistical test is applied. For dose- or concentration-response curve-fitting, a plausible sigmoidal-shaped model is fit to the data. Often data are log-transformed for better fit, and to meet the assumptions of the regression analysis. Possible models include: normal (probit), logistic (logit), Gompertz, Weibull, Fisher-Tippett and Burr. The evaluator should use professional judgement if other models are presented. Models should not be fit if no dose- or concentration- response is demonstrated. Probit and logistic models can be linearly transformed. Historically, models were graphed on probit paper by "eye-balling" a best-fitting line through the data. This approach is no longer an acceptable practice. Studies using this approach are deemed unacceptable.
Criteria For an Acceptable Study	**Guidance**
Were test concentrations or doses provided?	At a minimum, the range of concentrations or doses tested should be reported.
<u>**Aquatic**</u>**: Were the test concentrations or doses measured and maintained?** <u>**Avian and mammalian**</u>**: Were test diet concentrations or doses measured (acute and chronic) and maintained (chronic)?**	Maintaining implies that exposure concentrations or doses remained constant and were measured and analyzed at regular intervals (e.g., every 24 hours) over the duration of the exposure period. Concentrations in aquatic tests can also be maintained via flow-through or static renewal exposures. If a static test was conducted, were test concentrations measured to ensure constant exposure? Consider the physical and chemical properties of the chemical to determine if a static test would maintain constant exposure. Bird and mammal studies conducted via oral gavage may not report measured doses since the organism is being exposed via direct dosing (e.g. via intubation, catheter etc.)

Table A-3 Study quality evaluation scheme for aquatic species, birds and mammals.

Generic Criteria	*Guidance*
Was the test species acclimated and characteristics of the test species reported (e.g., strain, sex, age, life stage, length, weight)? **Algal and aquatic plant: Were characteristics of the test species reported and appropriate (e.g., strain, age, initial cell concentration/frond number, weight)?**	To be acceptable, the study must describe acclimation period or state that the organism was reared under laboratory conditions similar to those of the study. The results should indicate that the species had properly acclimated to experimental conditions. Typically, algal cultures should be between 3 and 7 d old and in exponential growth phase prior to inoculation. Initial cell concentrations should typically be 10^4 cells/mL, but may vary depending on the species. For example, OECD guidelines recommend 2-5 x 10^3 for *S. subspicatus*, 5 x 10^3 – 10^4 for *P. subcapitata*,and 5 X10^4-10^5 for *S. leopoldensis*, and EPA recommends 7.7 x 10^4 for *S. costatum*. Healthy *L. minor* plants will typically have colonies with 2-5 fronds, while *L. gibba* may contain up to 7 fronds.
Algal and aquatic plant: Was the method and medium of cultivation reported and appropriate?	The study should describe culture conditions and composition, as well as if test organisms were adapted to the test medium.
Aquatic species: Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges? **Algal and aquatic plant: Were appropriate test conditions (e.g., pH, light intensity, photoperiod, temperature) measured, reported and within acceptable ranges?** ***Avian and mammalian*: Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured and within acceptable ranges?**	Typically, acceptable temperatures are within the preferred range of the test species and are constant throughout the test (± 1°C during testing) and pH between 6 and 9 (± 1.5 unit during testing) depending on test protocol. In aquatic tests, dissolved oxygen should be reported and maintained (± 20% during testing). Lighting period typically varies from 12 to 16 hours per day. For algal and aquatic plant tests, temperature should be within the preferred range of the test species (± 2 °C during testing) and measured at least at the beginning and end of the test. The pH range should be ±1.5 unit during testing and measured at least at the beginning and end of the test. Guidelines recommend a light intensity ranging from 4000-10 000 lux. Studies are to be conducted under continuous light, with the exception of the species S. costatum. Typically, lighting period is 8 hours for avian and 12 hours for mammalian testing. Adherence to testing guideline must be verified for each parameter. Water quality conditions outside the acceptable range of the test species could enhance the toxicity of the tested chemical. Studies with such conditions are not considered acceptable.
Avian and mammalian: Were individual body weights measured during testing and observation periods?	Animals should be weighed at least before and after testing, and preferably during the observation period.
Avian and mammalian: For dietary studies, was feeding consumption measured, or at least estimated, during the study?	This is necessary to determine whether effects occurred due to the testing chemical, or lack of food consumption by the tested animal.

Table A-3 Study quality evaluation scheme for aquatic species, birds and mammals.	
Generic Criteria	*Guidance*
Avian: For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated? **Mammalian: For reproduction tests, were the number of pups, development of the pups, viability of the pups, percent offspring survival and growth measured and evaluated?**	A study can meet this criterion even if only one endpoint was investigated. List endpoints measured.
Was a concentration- or dose-response relationship demonstrated?	If a relationship was not demonstrated, it is statistically inappropriate to calculate an endpoint. The study may be found to be unacceptable even if it meets the generic criteria. Studies in which the highest concentration tested elicits no response can be deemed acceptable, however, technically dose response was not demonstrated (i.e. NOEC > 1000 mg/L) .
Comment Section	Use expert judgment to support or refute study acceptability for risk assessment.

In Table A-4 a list of test species recommended by or acceptable in standardized toxicity test methods can be found. For the purposes of ecological risk assessment, studies were evaluated based on their accordance with the evaluation criteria from Table A-3, regardless of the species tested. However, application of the study data to the ecological risk assessment was dependent on the relevance of the species tested to the assessment being conducted.

Table A-4. Test species recommended by or acceptable in standardized toxicity test methods[a].

Common Name	*Scientific Name*	*Test Method*
Algae/Aquatic Plants		
Diatom	*Phaeodactylum tricomutum*	ISO 10253 (2006)
Diatom	*Skeletonema costatum*	ISO 10253 (2006), OPPTS 850.5400 (1996)
Duckweed	*Lemna sp.*	OECD 221 (2006), OPPTS 850.4400 (1996)
Green Algae	*Pseudokirchneriella subcapitata* (formerly *Selenastrum capricomutum*)	OECD 201 (2011), EC EPS1/RM25 (2007), OPPTS 850.5400 (1996)
	Scenedesmus subspicatus	OECD 201 (2011)
	Chlorella vulgaris	OECD 201 (1984)
	Navicula pelliculosa	OECD 201 (2011), OPPTS 850.5400 (1996)
	Anabaena flos aquae	OECD 201 (2011), OPPTS 850.5400 (1996)
	Synechococcus leopoldensis	OECD 201 (2011)
Macroalgae	*Ceramium tenuicome*	ISO 10710 (2010)
Amphibians		

Table A-4. Test species recommended by or acceptable in standardized toxicity test methods[a].

Common Name	Scientific Name	Test Method
African Clawed Frog	*Xenopus laevis*	Some GLP studies cite fish toxicity test methods from OECD 203 (1992) and OPPTS 850.1075 (1996) for amphibian test procedures
Aquatic Invertebrates		
Bay Mussel	*Mytilus edulis*	OPPTS 850.1055 (1996)
Brown Shrimp	*Penaeus aztecus*	OPPTS 850.1045 (1996)
Cladoceran	*Ceriodaphnia dubia*	EC EPS1/RM/21 (2007), ISO 20665 (2008)
Eastern Oyster	*Crassostrea virginica*	OPPTS 850.1055 (1996)
Gammarid	*Gammarus fasciatus*	OPPTS 850.1020 (1996)
	Gammarus pseudolimnaeus	OPPTS 850.1020 (1996)
	Gammarus lacustris	OPPTS 850.1020 (1996)
Midge	*Chironomus sp.*	OECD 218 (2004) (sediment-water toxicity test)
Mysid	*Mysidopsis bahia*	OPPTS 850.1035 (1996), OPPTS 850.1350 (1996)
Pacific Oyster	*Crassostrea gigas*	OPPTS 850.1055 (1996)
Pink Shrimp	*Penaeus duorarum*	OPPTS 850.1045 (1996)
Quahog	*Mercenaria mercenaria*	OPPTS 850.1055 (1996)
Water Flea	*Daphnia sp.*	OECD 202 (2004), OECD 211 (2008), EC EPS1/RM/11 (1996), EC EPS1/RM/14 (2000), ISO 6341 (1996), ISO 10706 (2000), OPPTS 850.1010 (1996), OPPTS 850.1300 (1996)
White Shrimp	*Penaeus setiferus*	OPPTS 850.1045 (1996)
Fish		
Atlantic Salmon	*Salmo salar*	OECD 210 (1992), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Bluegill	*Lepomis macrochirus*	OECD 203 (1992), OECD 204 (1984), OECD 210 (1992), OECD 212 (1998), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Brook Trout	*Salvelinus fontinalis*	OECD 210 (1992), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Brown Trout	*Salmo trutta*	OECD 210 (1992), OPPTS 850.1400 (1996)
Carp	*Cyprinus carpio*	OECD 203 (1992), OECD 204 (1984), OECD 210 (1992), OECD 212 (1998), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Channel Catfish	*Ictalurus punctatus*	OECD 210 (1992), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Chinook Salmon	*Oncorhynchus tschawytscha*	OECD 210 (1992), OPPTS 850.1400 (1996)
Cod	*Gadus morhua*	OECD 212 (1998)
Coho Salmon	*Oncorhynchus kisutch*	OECD 210 (1992), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Fathead Minnow	*Pimephales promelas*	OECD 203 (1992), OECD 204 (1984), OECD 210 (1992), OECD 212 (1998), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Flagfish	*Jordanella floridae*	OECD 210 (1992), OPPTS 850.1400 (1996)

Table A-4. Test species recommended by or acceptable in standardized toxicity test methods[a].

Common Name	***Scientific Name***	***Test Method***
Goldfish	*Carassius auratus*	OECD 212 (1998)
Guppy	*Poecilia reticulate*	OECD 203 (1992), OECD 204 (1984), OPPTS 850.1075 (1996)
Herring	*Clupea harengus*	OECD 212 (1998)
Lake Trout	*Salvelinus namaycush*	OECD 210 (1992), OPPTS 850.1400 (1996)
Northern Pike	*Esox lucius*	OECD 210 (1992), OPPTS 850.1400 (1996)
Rainbow Trout	*Oncorhynchus mykiss* (formerly *Salmo gairdneri*)	OECD 203 (1992), OECD 204 (1984), OECD 210 (1992), OECD 212 (1998), OECD 215 (2000), EC EPS1/RM/09 (2007), EC EPS1/RM13 (2007), EC EPS1/RM/22 (2011), EC EPS1/RM/28 (1998), ISO 10229 (1994), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
Ricefish (Medaka, Red Killifish)	*Oryzias latipes*	OECD 203 (1992), OECD 204 (1984), OECD 210 (1992), OECD 212 (1998, OECD 215 (2000), OPPTS 850.1075 (1996)
Sheepshead Minnow	*Cyprinodon variegatus*	OECD 210 (1992), OECD 212 (1998), OPPTS 850.1400 (1996)
Silverside	*Menidia menidia*	OECD 210 (1992), OPPTS 850.1400 (1996)
	Menidia beryllina	OPPTS 850.1400 (1996)
	Menidia peninsulae	OECD 210 (1992), OECD 212 (1998), OPPTS 850.1400 (1996)
Threespine Stickleback	*Gasterosteus aculeatus*	OECD 210 (1992), EC EPS/1/RM10 (2000), OPPTS 850.1075 (1996), OPPTS 850.1400 (1996)
White sucker	*Catostomus commersoni*	OECD 210 (1992), OPPTS 850.1400 (1996)
Zebra-fish	*Brachydanio rerio*	OECD 203 (1992), OECD 204 (1984), OECD 210 (1992), OECD 212 (1998), OECD 215 (2000), ISO 7346 (1996), OPPTS 850.1075 (1996)
Birds		
Bobwhite Quail	*Colinus virginianus*	OECD 205 (1984), OECD 206 (1984), OPPTS 850.2100 (1996), OPPTS 850.2200 (1996), OPPTS 850.2300 (1996)
Japanese Quail	*Coturnix coturnix* japonica	OECD 205 (1984), OECD 206 (1984)
Mallard Duck	*Anas platyrhynchos*	OECD 205 (1984), OECD 206 (1984), OPPTS 850.2100 (1996), OPPTS 850.2200 (1996), OPPTS 850.2300 (1996)
Pigeon	*Columba livia*	OECD 205 (1984)
Red-legged Partridge	*Alectoris rufa*	OECD 205 (1984)
Ring-necked Pheasant	*Phasianus colchicus*	OECD 205 (1984)
Mammals		
Mouse	--	OECD 415 (1983)

Table A-4. Test species recommended by or acceptable in standardized toxicity test methods[a].

Common Name	Scientific Name	Test Method
Rat	--	OECD 415 (1983), 420 (2002), 421 (1995) 423 (2002), 425 (2008), OPPTS 870.1100 (1998), OPPTS 870.6300 (1998)

[a] Studies included in the table are for ecologically relevant effects and methods of test substance administration.

Conclusions

There is a need to develop an approach for evaluating the quality of ecotoxicological studies. Relying on a "best professional judgment" without reference to data quality criteria lacks transparency, objectivity and is not scientifically defensible.

Cheminova has developed data acceptability criteria for aquatic, avian and mammalian species. The approach builds upon the Breton et al. (2009), the Klimisch et al. (1997), the EPA ECOTOX and California schemes. In the evaluation scheme described herein, each study is categorized as acceptable (core), supplemental or unacceptable.

Fish , Aquatic Invertebrates and Amphibians

Study Quality and Acceptability Evaluation

Compound:

Study reference (Primary):

Secondary reference:

Is the primary reference study a GLP study?:

Species tested:

Endpoint(s):

	GENERIC CRITERIA	Y/N	COMMENTS
1	Single chemical exposure?		
2	Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?		
3	If NO to 2, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?		
4	Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?		
5	Were effects endpoints ecologically relevant?		
6	Was an appropriate exposure duration used and reported?		
7	Were appropriate controls included, reported and results adequate?		
8	Were the statistical procedures reported and appropriate?		

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**		
10	**Were the test species acclimated and characteristics of the test species reported (e.g., strain, sex, age, life stage, length, weight)?**		
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**		
12	**Was a dose/response relationship demonstrated?**		
13	**Were the concentrations/doses provided?**		

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Avian

Study Quality and Acceptability Evaluation

Compound:

Study reference (Primary):

Secondary reference:

Is the primary reference study a GLP study?:

Species tested:

Endpoint(s):

	GENERIC CRITERIA	Y/N	COMMENTS
1	Single chemical exposure?		
2	Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?		
3	If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?		
4	Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?		
5	Were the effects endpoints ecologically relevant?		
6	Were an appropriate exposure duration and post-exposure observation period used and reported?		
7	Were appropriate controls included, reported and the results adequate?		
8	Were statistical procedures reported and appropriate?		

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	Were test diet concentrations or doses provided?		
10	Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?		
11	Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?		
12	Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?		
13	Were individual body weights measured during testing and observation periods?		
14	For dietary studies, was feeding consumption measured, or at least estimated, during the study?		
15	For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?		
16	Was a concentration- or dose-response relationship demonstrated?		

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Mammalian

Study Quality and Acceptability Evaluation

Compound:

Study reference (Primary):

Secondary reference:

Is the primary reference study a GLP study?:

Species tested:

Endpoint(s):

	GENERIC CRITERIA	Y/N	COMMENTS
1	Single chemical exposure?		
2	Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?		
3	If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?		
4	Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?		
5	Were the effects endpoints ecologically relevant?		
6	Were an appropriate exposure duration and post-exposure observation period used and reported?		
7	Were appropriate controls included, reported and the results adequate?		
8	Were statistical procedures reported and appropriate?		

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	Were test diet concentrations or doses provided?		
10	Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?		
11	Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?		
12	Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, and reported within acceptable ranges?		
13	Were individual body weights measured during testing and observation periods?		
14	For dietary studies, was feeding consumption measured, or at least estimated, during the study?		
15	For reproduction tests, were the number of pups, development of the pups, viability of the pups, percent offspring survival and growth measured and evaluated?		
16	Was a concentration- or dose-response relationship demonstrated?		

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Algae and Aquatic Plants

Study Quality and Acceptability Evaluation

Compound:

Study reference (Primary):

Secondary reference:

Is the primary reference study a GLP study?:

Species tested:

Endpoint(s):

GENERIC CRITERIA		Y/N	COMMENTS
1	Single chemical exposure?		
2	Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?		
3	If NO to 2, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?		
4	Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?		
5	Were effects endpoints ecologically relevant?		
6	Was an appropriate exposure duration used and reported?		
7	Were appropriate controls included, reported, and the results adequate?		
8	Were the statistical procedures reported and appropriate?		

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	Were the test concentrations measured / maintained?		
10	Were characteristics of the test species reported and appropriate (e.g., strain, age, initial cell concentration/frond number, weight)?		
11	Was the method and medium of cultivation reported and appropriate?		
12	Were appropriate test conditions (e.g., pH, light intensity, photoperiod, temperature) measured, reported and within acceptable ranges?		
13	Was a concentration/response relationship demonstrated?		
14	Were the concentrations provided?		

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

APPENDIX B
DATA QUALITY EVALUATION OF AQUATIC INVERTEBRATE TOXICITY STUDIES

Aquatic Invertebrates (Freshwater)

Acceptable Studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Hamitou, M. 2009a. Dimethoate 400 g/L EC (CHA 3621-04): Acute Toxicity to Water Fleas (*Daphnia magna*) Under Static Conditions. Unpublished report by Springborn Smithers Laboratories (Europe). Switzerland. Study No. 1005.028.110. CHA Doc. No. 765 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Water flea (*Daphnia magna*)

Endpoint(s): 48 h EC50 (immobilization) 8.9 mg/L (3.4 mg a.i./L)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	OECD Guideline for testing of chemicals #202, *Daphnia sp.* Acute immobilization test (OECD, 2004).
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (400 g/L EC) CHA 3621-04, 37.7% w/w (400 g/L), Cheminova A.A., Lemvig, Denmark.
5	**Were effects endpoints ecologically relevant?**	Y	EC50 (Immobility/survival)
6	**Were an appropriate exposure duration used and reported?**	Y	24 and 48 h
7	**Were appropriate controls included, reported and results adequate?**	Y	No control mortality.
8	**Were the statistical procedures reported and appropriate?**	Y	EC50 calculated using Bootstrap analysis, using TOXSTAT® ver. 3.5.

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	**Y**	Samples were measured for a.i. prior to start of test and at the end. The sample with the highest concentration at the end of test was lost and therefore not measured (this did not not affect results of the test). All samples were within 91-104% of nominal concentrations.
10	**Were the test species acclimated and characteristics of the test species reported (e.g., strain, sex, age, life stage, length, weight)?**	**Y**	Daphnia were obtained from lab cultures maintained at Springborn Smithers Labs (Europe). Daphnids used were <24 h old, Daphnia were left for a 30 min transition period before start of test.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y**	Hardness 154 mg/L $CaCO_3$, alkalinity 29 mg/L $CaCO_3$, pH ~7.5, DO ~ 8.6 mg/L, conductivity 410 µS/cm, temperature ~20 °C, 200-500 lux lighting, 16 h light: 8 h dark, 5 daphnids/200mL.
12	**Was a dose/response relationship demonstrated?**	**Y**	Dose-response demonstrated, raw data provided.
13	**Were the concentrations/doses provided?**	**Y**	0.625, 1.25, 2.5, 5.0, 10 mg test item/L

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Heintze, A. 2002. Assessment of Side Effects of Dimethoate on the Larvae of the Midge, Chironimus riparius, With the Laboratory Test Method. GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH Study Number 20011123/01-ASCr. Unpublished report, CHA Doc. No. 521 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species Tested: Midge (*Chironomus riparius*)

Endpoint(s): 28 d EC50 (emergence) 0.162 mg/L
28 d NOEC (emergence) 0.1 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	OECD 219
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Solid, white, 99.1% w/w, 39.8 mg/L, source Cheminova.
5	**Were effects endpoints ecologically relevant?**	Y	EC50, NOEC
6	**Was an appropriate exposure duration used and reported?**	Y	28 d
7	**Were appropriate controls included, reported and results adequate?**	Y	Control mortality 3.3%.
8	**Were the statistical procedures reported and appropriate?**	Y	NOEC and LOEC calculated using t-test and Dunnett test; Probit used for EC50.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static, measured at 1 h, 7 d, 28 d
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	2-3 d old, sediment-dwelling life stage, acclimated 24 h before testing.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	25 larvae/1600mL, 16 h light: 8 h dark, pH 7.5, hardness 260 mg/L, DO > 60%, conductivity 540 µS/cm (these parameters were measured during testing, temperature 20°C +/- 2°C.
12	**Was a dose/response relationship demonstrated?**	Y	Raw data available, dose-response relationship demonstrated.
13	**Were the concentrations/doses provided?**	Y	Six test concentrations and a control, 0.05, 0.1, 0.2, 0.4, 0.8, 1.6 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE () SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Hertl, J. 2002c. Acute Toxicity of Dimethoate to *Daphnia magna* in a 48-hour Immobilization Test IBACON - Institut für Biologische Analytik und Consulting IBACON GmbH Study No: 10591220, 10591220A. Unpublished report, CHA Doc. No. 482 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 48 h EC50 (immobilization) 2 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Commission Directive 92/69/EEC; OECD 202 and OPPTS 850.1010
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Solid, white, commercial technical grade produced by Cheminova, 99.1% w/w, 39.8 g/L (25°C).
5	**Were effects endpoints ecologically relevant?**	Y	EC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Control mortality did not exceed 10%.
8	**Were the statistical procedures reported and appropriate?**	Y	Calculated using Moving average interpolation.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static, measured at 0, 24 and 48 h
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	6.5 -22 h old, acclimated 6.5 h before beginning of test.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	5 daphnids/50 mL, 4 replicates, 16 h light: 8 h dark, temperature maintained at 21°C, pH ranged between 7.8 to 8.1, DO at least 9.5 mg/L or higher, at the end of the test DO was > 60% of the air saturation value.
12	**Was a dose/response relationship demonstrated?**	Y	Raw data provided, dose-response demonstrated.
13	**Were the concentrations/doses provided?**	Y	Six test concentrations and control, 0, 0.5, 1, 2, 4, 8, 16 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE () SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Wüthrich, V. 1990. Influence of Dimethoate on the Reproduction of *Daphnia magna*. RCC Umweltchemie AG Study No. 264464. Unpublished Report. CHA Doc. No. 97 USA DMT (Amendment 2 – raw data included). MRID No. 42864701.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 96 h EC50 (survival) 0.465 mg/L
21 d NOEC (growth/reproduction) 0.04 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	OECD 202 and EPA Subdivision E Guideline 72-4.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate, white to greyish-yellow solid, 99% purity, Batch 611A, supplied by Dimethoate Task Force.
5	**Were effects endpoints ecologically relevant?**	Y	EC50, NOEC
6	**Was an appropriate exposure duration used and reported?**	Y	96 h, 21 d
7	**Were appropriate controls included, reported and results adequate?**	Y	No mortality up to 7 d, between 8 - 12 d the mortality rate was 2.5%, day 13 to the end of the test the mortality rate was 5%.
8	**Were the statistical procedures reported and appropriate?**	Y	Dunnett-test and the Logit-model

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static renewal, measured.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Less than 24 h old (4.06 to 4.89 mm); 8 replicates. Study report does not mention if daphnids were acclimated (according to OECD 202, a 24 h period is recommended), however daphnids were <24 h old when used in test and were bred in the laboratory.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	5 daphnids/200 mL, 16 h light: 8 h dark, 500-1000 Lux lighting, temperature maintained at 19.1-21.7°C, pH maintained at 8-8.5, oxygen saturation at the beginning of the test was 8.6 - 9.5 mgO_2/L, and during testing to the end was 7.5- 8.7 mgO_2/L, the oxygen concentration was > 60% of the saturation concentration at the end of the test (> 5 mg/L), conductivity 606 µS/cm.
12	**Was a dose/response relationship demonstrated?**	Y	Raw data available, dose-response relationship demonstrated.
13	**Were the concentrations/doses provided?**	Y	Five concentrations and a control, 0.04, 0.1, 0.25, 0.6 and 1.5 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE () SUPPLEMENTAL () UNACCEPTABLE

Comments:

Supplemental Studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Andersen, T.H., R. Tjørnhøj, L. Wollenberger, T. Slothuus and A. Baun. 2006. Acute and chronic effects of pulse exposure of *Daphnia magna* to dimethoate and pirimicarb. Environ Toxicol Chem 25(5):1187–1195.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 48 h EC50 (immobilization) 1.1 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	ISO 6341, OECD Guideline 211.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS no. 60-51-5; purity, 99.8%) purchased from Sigma-Aldrich A/S (Copenhagen, Denmark).
5	**Were effects endpoints ecologically relevant?**	Y	EC50
6	**Was an appropriate exposure duration used and reported?**	Y	Acute exposure of 2, 4, 6, 12, 24, and 48 h. Long terms effects were also examined for 21 d following a single pulse exposure.
7	**Were appropriate controls included, reported and results adequate?**	Y	30 control daphnids, ≥ 80% survival
8	**Were the statistical procedures reported and appropriate?**	Y	Probit; t-tests

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Continuous and pulse exposures conducted. Test concentrations within the static tests were not measured. The endpoint of 1.1 mg/L is for continuous exposure (not pulsed).
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	In house culture of *Daphnia magna*. Less than 1 d old used for testing. Media as in test.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	pH 7.5, DO ≥ 6 mg/L, temperature 20 +/- 0.5 °C, 12 h light:12 h dark, four replicates of 5 Daphnia, 6 replicates of 5 animals in control. For chronic, 400 daphnids in 8 replicates.
12	**Was a dose/response relationship demonstrated?**	Y	No raw data reported, but graphs demonstrate dose-responses.
13	**Were the concentrations/doses provided?**	Y	Acute: six concentrations ranged 0.75 to 1.75 mg/L; Chronic: single pulsed exposure at 10, 20, and 30 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Anderson, T.D. and K.Y. Zhu. 2004. Synergistic and antagonistic effects of atrazine on the toxicity of organophosphorodithioate and organophosphorothioate insecticides to *Chironomus tentans* (Diptera: Chironomidae). Pest Biochem Phys 80:54–64.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Midge (*Chironomus tentans*)

Endpoint(s): 48 h EC50 (immobilization) 0.249 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y/N	Partly to USEPA sediment guideline
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate, 99.5%. Source: Chem Service,West Chester, PA.
5	**Were effects endpoints ecologically relevant?**	Y	EC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Solvent control included, no control mortality.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static test, not measured.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Midge, *Chironomus tentans*, fourth instar larvae; Acclimation not indicated, but cultured and tested under similar conditions.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	No test conditions reported other than temperature (25 ºC) and photoperiod (16 h light:8 h dark). Loading density was 10 midges/L, 4 replicates.
12	**Was a dose/response relationship demonstrated?**	N	No raw data to verify.
13	**Were the concentrations/doses provided?**	N	Description of preparation only; five treatments, concentrations not given.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Beusen, J.M. and B. Neven. 1989. Toxicity of dimethoate to *Daphnia magna* and freshwater fish. Bull Environ Contam Toxicol 42:126-133.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 48 h LC50 1.7 mg/L (open system), 2 mg/L (closed system)
48 h EC50 (immobilization) 1.5 mg/L (open system), 1.8 mg/L (closed system)

23 d LC50 0.23 mg/L, 0.11 mg/L (For chronic tests, results are reported for two individual tests at the same exposure concentrations with the same species using the same methods.)
23 d EC50 (immobilization) 0.11 mg/L, 0.19 mg/L
23 d MATC (reproduction) 0.13 mg/L, 0.085 mg/L
23 d NOEC (immobilization) 0.08 mg/L, 0.1 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Methods for the determination of ecotoxicity. Official Journal of the European Communities No L251:147-154. 1984.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (99%) from Riedel-de Haen PESTANAL ®.
5	**Were effects endpoints ecologically relevant?**	Y	LC50/EC50/NOEC/MATC (Survival, reproduction)
6	**Was an appropriate exposure duration used and reported?**	Y	Acute: 48 h, Chronic: 23 d.
7	**Were appropriate controls included, reported and results adequate?**	Y	Controls included. No control mortality.

GENERIC CRITERIA		Y/N	COMMENTS
8	**Were the statistical procedures reported and appropriate?**	Y	Reported use of graphical method of Litchfield and Wilcoxon (1949). The reproductive data from the *Daphnia magna* life-cycle test were analyzed by analysis of variance and the one-tailed Student t-test.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static-renewal. Analysis by GC; 90% of the initially added amount of dimethoate was found after 48 h.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	*Daphnia magna* Straus obtained from a laboratory brood stock maintained at 19 ± 1°C and 14 h light: 10 h dark. (Daphnids used in test less than 24 h old.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable range?**	Y/N	Daphnia tested at 20 ºC. pH and DO reportedly measured but results not reported. In acute open tests 5 animals per 50 mL (4 replicates), in acute closed tests 10 animals per 100 mL, in chronic tests, 1 per replicate in 50 mL, 10 replicates, 14 h light:10 h dark.
12	**Was a dose/response relationship demonstrated?**	N	No data given to evaluate dose-response.
13	**Were the concentrations/doses provided?**	N	At least 5 concentrations plus control used but no test concentration ranges reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Song, M.Y., J.D. Stark and J.J. Brown. 1997. Comparative toxicity of four insecticides, including imidacloprid and tebufenozide, to four aquatic arthropods. Environ Toxicol Chem 16(12):2494–2500.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: water flea (*Daphnia magna*), yellow fever mosquito (*Aedes aegypti*), brine shrimp (*Artemia salina*), black saltmarsh mosquito (*Aedes taeniorhynchus*)

Endpoint(s): 48 h LC50 3.32 mg/L (27°C) (*Daphnia magna*)
48 h LC50 3.12 mg/L (20°C) (*Daphnia magna*)
48 h LC50 5.04 mg/L (27°C) (*Aedes aegypti*)
48 h LC50 6.41 mg/L (20°C) (*Aedes aegypti*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	ASTM (1992), EPA (1975)
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate technical (>95%) from Alltech, San Jose, CA.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 h, 72 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Control mortality <10%; mortality data were corrected for mortality in the controls prior to probit analysis. No raw data presented.
8	**Were the statistical procedures reported and appropriate?**	Y	Reported use of probit analysis.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Not measured, Static.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	*Aedes aegypti* and *Daphnia magna* less than 24 h old born in the laboratory used in test.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	Tested at both 20 ºC and 27 ºC. No indication of other measurements during test. 10 animals tested per replicate; 4 replicates.
12	**Was a dose/response relationship demonstrated?**	N	No data given to evaluate dose-response.
13	**Were the concentrations/doses provided?**	N	Four test concentrations plus control were used but test concentrations themselves were not reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Unacceptable Studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Aboul-Ela, I.A. and M.T. Khalil. 1987. The acute toxicity of three pesticides on organisms of different trophic levels as parameters of pollution in Lake Wadi El Rayan. Ei Fayoum. Egypt Proc Zool Soc AR Egypt 13:31-26.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Cladoceran (*Daphnia longispina*), copepod (*Cyclops strenuus*), amphipod (*Gammarus pulex*), snails (*Biomphalaria alexandrina* and *Bulinus truncatus*) and fish (*Tilapia niloticam* and mullet fry).

Endpoint(s): 96 h LC50 0.0022 mg/L (*Gammarus pulex*)
96 h LC50 0.002 mg/L (*Cyclops strenuus*)
96 h LC50 0.0031 mg/L (*Biomphalaria alexandrina*)
96 h LC50 0.0029 mg/L (*Bulinus truncatus*)
96 h LC50 0.0026 mg/L (*Daphnia longispina*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Not reported
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	N	Not reported
8	**Were the statistical procedures reported and appropriate?**	N	Semi-logarithmic graph

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Cladoceran (*Daphnia longispina*) (average length 1.3 mm), copepod (*Cyclops strenuus*) (average length 1.1 mm), amphipod (*Gammarus pulex*) (average length 0.90 cm), snails (*Biomphalaria alexandrina* (average MD was 11.6 ± 0.33 mm) and *Bulinus truncatus* (average shell length 10.8 ± 0.4 mm)) and fish (*Tilapia niloticam* (average length 15.3 ± 2.3 cm) and mullet fry (average length 5.2 ±1.2 cm)), acclimated for 5 d.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	Photoperiod 14 h light:10 h dark, temperature 27 ± 2°C, 10-20 animals/test concentration, 2 replicates.
12	**Was a dose/response relationship demonstrated?**	N	Not reported
13	**Were the concentrations/doses provided?**	N	Not reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Baekken, T. and K.J. Aanes. 1991. Pesticides in Norwegian agriculture. Their effects on benthic fauna in lotic environments. Preliminary results. Verh Int Ve. Limnol 24(4):2277-2281.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Snail (*Physa fontinalis*), crustacean (*Gammarus lacustris*), mayflies (*Baetis rhodani* and *Heptagenia sulphurea*) and caddisfly (*Hydropsyche siltalai*)

Endpoint(s): 96 h LC50 0.023 mg/L (*Hydropsyche siltalai*)
96 h LC50 0.007 mg/L (*Baetis rhodani*)
96 h LC50 0.081 mg/L (*Heptagenia sulphurea*)
96 h LC50 0.18 mg/L (*Gammarus lacustris*)
(tests were conducted using a formulation, effect concentration in mg a.i./L could not be calculated because purity of formulation was not provided)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y/N	Insufficient data available.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Dimethoate Rogor L 20 (200g a.i./L), source not provided.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Control used, control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	Y	Logit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	**Y**	Flow-through
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	**Y/N**	Last instar, acclimation period not reported.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y/N**	Temperature 15 ± 1°C, pH 6.3, hardness 11 mg/L, additional water chemistry properties provided. Loading density, photoperiod and DO not provided.
12	**Was a dose/response relationship demonstrated?**	**N**	Raw data not available.
13	**Were the concentrations/doses provided?**	**Y**	Five test concentrations (0.002, 0.02, 0.05, 0.2 and 2 mg/L).

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Canton, J.H., R.C.C. Wegman, A. Van Oers, A.H.M. Tammer, E.A.M. Mathijssen-Spiekman and H.H. Van den Broek. 1980. Milieutoxicologisch Onderzoek met Dimethoaat en Omethoaat. Intern Rapport 121/80 CBS VI/RA. RIJKS Instituut voor de Volkgezondheid, Bilthoven. [Dutch]. English title: Ecotoxicological Studies with Dimethoate and Omethoate.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*); green algae (*Chlorella pyrenoidosa*), guppy (*Poecilia reticulate*), Japanese killifish (*Oryzias latipes*), rainbow trout (*Salmo gairdneri*).

Endpoint(s): 48 h LC50 6.4 mg/L (*Daphnia magna*)
48 h EC50 (immobilization) 2.9 mg/L (*Daphnia magna*)
20 d LC25 0.145 mg/L (*Daphnia magna*)
20 d LC50 0.31 mg/L (*Daphnia magna*)
20 d NOEC (mortality) 0.032 mg/L (*Daphnia magna*)
20 d NOEC (reproduction) 0.1 mg/L (*Daphnia magna*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Dutch Normalisation Institute
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (98%) obtained from Luxan; obtained from Bayer.
5	**Were effects endpoints ecologically relevant?**	Y	EC50, LC25, LC50, NOEC
6	**Was an appropriate exposure duration used and reported?**	Y	48 h (acute), 20 d (chronic).
7	**Were appropriate controls included, reported and results adequate?**	N	Control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	N	Statistics not reported.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Stability study performed separately and endpoint values corrected for the stability results.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	No acclimation procedure reported. Daphnids less than 1 d old.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	Hardness (5.5° DH) and pH (7.9 ±0.2) reported on media, but no water quality from tests. Authors state that pH and DO were measured during tests and no influence was observed during experiments.12 h light: 12 h dark, 25 organisms per group, 1 litre of test solution per group.
12	**Was a dose/response relationship demonstrated?**	N	No raw data reported to verify dose-response.
13	**Were the concentrations/doses provided?**	N	Test concentrations not reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Chaudhari, T.R., M.L. Jadhav and V.S. Lomte. 1988. Acute toxicity of organophosphates to fresh water snails from Panzara Rive at Dhule, MS. Environ Ecol 6(1):244-246.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Freshwater snails (*Lymnaea acuminata*, *Thiara scabra* and *Thiara lineate*)

Endpoint(s): 24 h LC50 0.0359 mg/L (*Lymnaea acuminata*)
48 h LC50 0.0245 mg/L (*Lymnaea acuminata*)
24 h LC50 0.0444 mg/L (*Thiara scabra*)
48 h LC50 0.0358 mg/L (*Thiara scabra*)
24 h LC50 0.0359 mg/L (*Thiara lineate*)
48 h LC50 0.0245 mg/L (*Thiara lineate*)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	APHA (American Public Health Association), American Water Works Association and Water Pollution Control Federation. 1980. Standard methods for analysis of water and wastewater, 15th edition, APHA, New Your, USA.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**		
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Rogor EC dimethoate 30%, Rallis India Ltd., Bombay.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	24 h, 48 h
7	**Were appropriate controls included, reported and results adequate?**	N	Control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	N	Not provided
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	10 daphnids in 5 L, five replicates, photoperiod not provided, temperature maintained at 36±1 °C, DO 0.58 mg/L, pH 7.4, alkalinity 60 mg/L.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	N	Five concentrations used, values not reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: **() ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE**

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Deneer, J.W., W. Seinen and J.L.M. Hermens. 1988. Growth of *Daphnia magna* exposed to mixtures of chemicals with diverse modes of action. Ecotox. Environ. Safety 15:72-77.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 16 d NOEC (growth) 0.029 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	NEN 6502 (Dutch Standard Organisation, 1980).
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Not reported
5	**Were effects endpoints ecologically relevant?**	Y	NOEC
6	**Was an appropriate exposure duration used and reported?**	Y	16 d
7	**Were appropriate controls included, reported and results adequate?**	N	Not reported
8	**Were the statistical procedures reported and appropriate?**	Y	Student's t-test

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	Were the test concentrations or doses measured / maintained?	N	Static
10	Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?	N	Less than 24 h old
11	Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?	Y/N	20-25 daphnids/L, duplicates, 19 ± 1°C, 12 h light dark cycle.
12	Was a dose/response relationship demonstrated?	N	No data available
13	Were the concentrations/doses provided?	Y	8 test concentrations, values reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Frear, D.E.H. and J.E. Boyd. 1967. Use of *Daphnia magna* for the microbioassay of pesticides. I. Development of standardized techniques for rearing Daphnia and preparation of dosage-mortality curves for pesticides. J Econ Entomol 60(5):1228-1236.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 26 h LC50 2.5 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Not provided
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	26 h
7	**Were appropriate controls included, reported and results adequate?**	N	Not reported
8	**Were the statistical procedures reported and appropriate?**	N	Logarithmic-probability paper

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	Were the test concentrations or doses measured / maintained?	N	Static
10	Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?	N	2-26 h old
11	Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?	N	10 daphnids/120 mL, 10 replicates, water chemistry provided.
12	Was a dose/response relationship demonstrated?	N	Not provided
13	Were the concentrations/doses provided?	N	Not clear

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Gupta, P.K. 1984. Acute toxicity of three insecticides to the freshwater snail *Viviparus bengalensis*. Environ Ecol 2(3):168-170.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Freshwater snail (*Viviparus bengalensis*)

Endpoint(s): 12 h LC50 29.31 mg/L
24 h LC50 20.23 mg/L
48 h LC50 11.07 mg/L
72 h LC50 6.88 mg/L
96 h LC50 5.36 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	APHA (American Public Health Association), American Water Works Association and Water Pollution Control Federation. 1971. Standard methods for analysis of water and wastewater, 13th edition, American Public Health Association, Washington, USA.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**		
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Rogor 30EC; source not provided
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	12, 24, 48, 72 and 96 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Controls used; controls appeared normal.
8	**Were the statistical procedures reported and appropriate?**	Y	Litchfield and Wilcoxon method

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static renewal
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Acclimated 15 d; 2.58 +/- 0.73 cm shell height and 1.95 +/- 0.25 cm wet weight.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	10 snails per concentration, three replicates, photoperiod not provided, temperature maintained at 29 ±2 °C, DO 7.5 +/- 0.3 mg/L, pH 7.9 +/- 0.2, total hardness 212 +/- 0.6.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	N	Not reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Hermens, J., H. Canton, N. Steyger and R. Wegman. 1984. Joint effects of a mixture of 14 chemicals on mortality and inhibition of reproduction of *Daphnia magna*. Aquatic Toxicol 5:315-322.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*)

Endpoint(s): 48 h LC50 6.4 mg/L
16 d EC50 (reproduction) 0.31 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Single and multiple chemical exposures performed
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Concept NEN reports 6501 and 6502 of Dutch Standard Organization (ca. 1980).
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**		
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Dimethoate source, purity not reported. Referred to publication of previous work.
5	**Were effects endpoints ecologically relevant?**		LC50/EC50
6	**Was an appropriate exposure duration used and reported?**	Y	Acute 48 h, chronic 16 d
7	**Were appropriate controls included, reported and results adequate?**	Y	Assume they were included as required in guideline that was followed and that control mortality, if applicable, was negligible or corrected.
8	**Were the statistical procedures reported and appropriate?**	Y	Assume appropriate statistics were used based on guideline.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	The highest and lowest tested concentrations were analyzed. Acute was static, chronic was renewal 3x/wk.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	*Daphnia magna* (<1 d old). Acclimation not reported.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	Temperature 19 ºC, test medium "Dutch Standard Water". Loading density was 25 daphnids/L for static and 15 daphnids/L for chronic.
12	**Was a dose/response relationship demonstrated?**	N	No raw data given. Unable to verify dose-response.
13	**Were the concentrations/doses provided?**	N	Concentration range not reported. Ratio of concentrations reported as 3.2.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Mansour, S.A. amd T.M. Hassan. 1993. Pesticides and Daphnia. 3. An analytical bioassay method, using *Ceriodaphnia quadrangula*, for measuring extremely low concentrations of insecticides in waters. Int J Toxicol Occup Environ Health 2:34-39.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Ceriodaphnia quandrangula*)

Endpoint(s): 1 h EC20 (survival) 4 mg/L (formulation), 1.6 mg a.i./L
1 h EC90 (survival) 7.8 mg/L (formulation), 3.12 mg a.i./L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y/N	Makes reference to an earlier publication for methods; water properties provided.
4	**Were the identification, purity and source of test substance given and comparable to the technical material and formulation?**	Y/N	EC dimethoate 40%; source not provided.
5	**Were effects endpoints ecologically relevant?**	N	EC20; EC90 (data not available to calculate EC50).
6	**Was an appropriate exposure duration used and reported?**	N	1 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Controls used; control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	N	Not provided

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static, measured at end of test.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	24-48 h old, acclimation period not discussed.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	5 daphnids in 5 mL, temperature maintained at 21±1 °C, DO not provided, pH 7.3 to 8.4.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	N	Not reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments: Test conducted with a formulation.

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Mary, A. Sr., R. Nagabhushanam and R. Sarojini. 1986. Toxicity evaluation of organophosphorus and chrlorinated hydrocarbon pesticides in freshwater prawn *Macrobrachium lamerrii.* J Environ Biol 7(3):189-195.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Freshwater prawn (*Macrobrachium lamerrii*)

Endpoint(s): 24 h LC50 4.275 mg/L (formulation), 1.283 mg a.i./L
48 h LC50 3.459 mg/L (formulation), 1.04 mg a.i./L
72 h LC50 2.63 mg/L (formulation), 0.789 mg a.i./L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	Insufficient details provided.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Dimethoate 30%EC, no source provided.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	24, 48 and 72 h
7	**Were appropriate controls included, reported and results adequate?**	N	Not reported
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static renewal
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Acclimation period not provided; 12-17 mm carapace length.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	Loading density and photoperiod not provided, temperature maintained at 27 ±2 °C, DO 4.5 ml/L, pH 6.5-7.0.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	N	Not reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Muncy, R.J. and A.D. Oliver Jr. 1963. Toxicity of ten insecticides to the Red Crawfish, *Procambarus clarki* (Girard). Transactions of the American Fisheries Society 92(4):428-431.

Secondary reference:

Is the primary reference study a GLP study?: No

Species tested: Red Crawfish

Endpoint(s): 72 h LC50 >20 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?**	N	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Dimethoate, chemical source and purity (technical) not reported.
5	**Were effects endpoints ecologically relevant?**	Y	LC50 Mortality
6	**Were an appropriate exposure duration used and reported?**	Y	24, 48, 72 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Controls were included, results not reported.
8	**Were the statistical procedures reported and appropriate?**	N	Straight line graphical interpolation.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	**N**	Not reported
10	**Were the test species acclimated and characteristics of the test species reported (e.g., strain, sex, age, life stage, length, weight)?**	**Y/N**	Crawfish were captured from a pond in Louisiana, were sorted by sex and size (4-10 g), used both males and females, acclimation period not reported.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y/N**	Used tap water for exposures, pH 7.6, alkalinity 8 ppm, total dissolved solids of 205 ppm, 16-32°C (high temperatures apparently not unusual in the normal habitat).
12	**Was a dose/response relationship demonstrated?**	**N**	No effects seen at the highest concentration tested.
13	**Were the concentrations/doses provided?**	**N**	Provided concentrations for other substances but dimethoate was only reported to be tested in 20 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Oteifa, B.A., A.H. Moussa, A.A. Abou-El-Hassan, A.M. Mohamed and M.A. El-Emam. 1975. Effect of certain insecticides in the control of the fresh water snails *Biomphalaria alexandrina* and *Bulinus trancatus*. Egypt J Bilh 2:221-243.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Freshwater snails (*Biomphalaria alexandrina* and *Bulinus trancatus*)

Endpoint(s): 24 h LC50 23 mg/L (*Biomphalaria alexandrina*)
24 h LC50 18.9 mg/L (*Bulinus trancatus*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	Insufficient details provided.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Rogor 40% L; source not provided.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	24 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Controls used; control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	N	Not reported

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Adult snails, 3 mo acclimation period.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	10 adult snails/L, 4 replicates, photoperiod not provided, temperature maintained at 25-27°C, DO and pH not reported.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available
13	**Were the concentrations/doses provided?**	N	Not reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Pantani, C., G. Pannunzio, M. De Cristofaro, A.A. Novelli and M. Salvatori. 1997. Comparative acute toxicity of some pesticides, metals, and surfactants to *Gammarus italicus* Goedm. and *Echinogammarus tibaldii* Pink. and Stock (Crustacea: Amphipoda). Bull Environ Contam Toxicol 59:963-967.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Amphipod (*Gammarus italicus* and *Echinogammarus tibaldii*)

Endpoint(s): 96 h LC50 3.8 mg/L (*Gammarus italicus*)
96 h LC50 4.1 mg/L (*Echinogammarus tibaldii*)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	**Y**	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	**N**	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	**N**	Insufficient details provided.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	**Y**	99% purity, Riedel-de-Kaën
5	**Were effects endpoints ecologically relevant?**	**Y**	LC50
6	**Was an appropriate exposure duration used and reported?**	**Y**	96 h
7	**Were appropriate controls included, reported and results adequate?**	**Y/N**	Controls used; control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	**Y**	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	3 d of acclimation
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	10 animals/250 mL, 2 replicates for *E. Tibaldii*, photoperiod not provided, water hardness 55 mg/L, pH 7.9 ± 0.5, temperature 8 ± 0.5°C, DO not reported.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	N	Six test concentrations, data not reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: **() ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE**

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Parra, G., R. Jiménez-Melero and F. Guerrero. 2005. Agricultural impacts of Mediterranean wetlands: The effect of pesticides on survival and hatching rates in copepods. Ann Limnol – Int J Lim 41(3):161-167.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Copepod (*Arctodiaptomus salinus*)

Endpoint(s): 24 h LC50 16 mg/L
48 h LC50 9.56 mg/L
72 h LC50 4.88 mg/L
96 h LC50 3.16 mg/L
96 h NOEC (hatching rate) 2 mg/L
96 h NOEC (100% nauplius mortality) 20 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	Single chemical exposure?	Y	Dimethoate
2	Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?	N	
3	If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?	N	Insufficient data provided.
4	Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?	N	No information provided.
5	Were effects endpoints ecologically relevant?	Y	LC50
6	Was an appropriate exposure duration used and reported?	Y	24, 48, 72 and 96 h
7	Were appropriate controls included, reported and results adequate?	Y	No mortality in controls.
8	Were the statistical procedures reported and appropriate?	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	1 d acclimation period
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	15 females carrying egg sacs/50 mL, loading for egg sac tests not provided, 3 replicates, photoperiod not provided, temperature maintained at 20°C, DO and pH not reported.
12	**Was a dose/response relationship demonstrated?**	N	Not reported.
13	**Were the concentrations/doses provided?**	Y	Test concentrations for egg sac carrying females tests ranged from 0 to 50 mg/L. Two test concentrations for the egg sacs tests were used (2 and 20 mg/L).

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Sanders, H.O., and O.B. Cope. 1968. The relative toxicity of several pesticides to naiads of three species of stoneflies. Limnol Oceanography 13(1):112-117.

Secondary reference: 1) Johnson W.W. and M.T. Finley. 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. United States Fish and Wildlife Service; Resource Publication 137. 2) Mayer, F.L. Jr., and M.R. Ellersieck. 1986. Manual of Acute Toxicity: Interpretation and Database for 410 Chemicals and 66 Species of Freshwater Animals. United States Department of the Interior, U.S. Fish and Wildlife Service, Publication 160.

Is the primary reference study a GLP study?: No

Species tested: Stonefly (*Pteronarcys californica*)

Endpoint(s): 24 h LC50 0.51 mg/L
48 h LC50 0.14 mg/L
96 h LC50 0.043 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	Random placement of test chambers and organisms not indicated.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Technical grade (Sanders and Cope, 1968); 97.4% (Johnson and Finley, 1980); source not reported.
5	**Were effects endpoints ecologically relevant?**	Y	LC50, mortality
6	**Was an appropriate exposure duration used and reported?**	Y	24 h, 48 h, 96 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Control included, control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	N	Plotted on logarithmic-probability paper; Litchfield and Wilcoxon used to determine the confidence limits.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static exposure. Nominal test concentrations.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Stonefly (*Pteronarcys californica*) naiads (wild caught). Short acclimation time (48 h) to test conditions (reconstituted water, test temperature). Body length (30-35 mm) and age (second year class) reported.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	Water quality (pH, DO, Alkalinity) taken at initiation, then only DO was measured at other times. Low DO at 96 h (~30% saturated at test temperature of 15.5 °C). Loading density was 10 animals/0.25 to 4L.
12	**Was a dose/response relationship demonstrated?**	N	No raw data to verify dose-response.
13	**Were the concentrations/doses provided?**	N	Four or five concentrations and untreated control (concentrations not given). Quantity of solvent used (ethanol) not indicated.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Sanders, H.O. 1969. Toxicity of Pesticides to the Crustacean *Gammarus lacustris.* Bureau of Sport Fisheries and Wildlife, Fish-Pesticide Research Laboratory, Columbia, Missouri. Technical Paper 25.

Secondary reference: 1) Johnson W.W. and M.T. Finley. 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. United States, Fish and wildlife service; Resource Publication 137. 2) Mayer, F.L. Jr., and M.R. Ellersieck. 1986. Manual of Acute Toxicity: Interpretation and Database for 410 Chemicals and 66 Species of Freshwater Animals. United States Department of the Interior, U.S. Fish and Wildlife Service, Publication 160.

Is the primary reference study a GLP study?: No

Species Tested: Scud (*Gammarus lacustris*)

Endpoint(s): 24 h LC50 0.9 mg/L
48 h LC50 0.4 mg/L
96 h LC50 0.2 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	Random placement of test chambers and organisms not indicated.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Technical grade (Sanders and Cope, 1968); 97.4% (Johnson and Finley, 1980), source: American Cyanamid.
5	**Were effects endpoints ecologically relevant?**	Y	LC50, mortality
6	**Was an appropriate exposure duration used and reported?**	Y	24, 48, 96 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Controls included, but control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	N	Plotted on logarithmic-probability paper; Litchfield and Wilcoxon used to determine the confidence limits.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static exposure. Nominal test concentrations.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Mature and ten 2 mo old *Gammarus lacustris* per concentration. Organisms added to test chambers 2 h before toxicant added. Species cultured in test medium (reconstituted water).
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	Water quality (pH, TDS, alkalinity, hardness) measured for dilution water, but no indication of measurements during test. No DO measured. Loading density was 10 animals/0.25 to 4L.
12	**Was a dose/response relationship demonstrated?**	N	No raw data reported, unable to verify dose-response.
13	**Were the concentrations/doses provided?**	N	Four or five treatments, concentrations not specified. Solvent used (ethanol) at 1 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Slooff, W., and J.H. Canton. 1983. Comparison of the susceptibility of 11 freshwater species to 8 chemical compounds. II. (Semi) Chronic toxicity tests. Aquat Toxicol 4(3):271-282.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Guppy (*Poecilia reticulata*), medaka (*Oryzias latipes*), African clawed frog (*Xenopus laevis*),water flea (*Daphnia magna*),mosquito (*Culex pipiens*), brown hydra (*Hydra oligactis*),great pond snail (*Lymnaea stagnalis*), blue-green algae (*Microcystis aeruginosa*), blue-green algae (*Scenedesmus pannonicus*), duckweed (*Lemna minor*), bacteria (*Pseudomonas fluorescens*)

Endpoint(s): 21 d NOEC (growth) 100 mg/L (*Hydra oligactis*)
40 d NOEC (mortality) 32 mg/L (*Lymnaea stagnalis*)
40 d NOEC (reproduction) 10 mg/L (*Lymnaea stagnalis*)
7 d NOEC (hatch) 32 mg/L (*Lymnaea stagnalis*)
25 d NOEC (mortality/ development) 0.32 mg/L (*Culex pipiens*)
21 d NOEC (mortality) 0.032 mg/L (*Daphnia magna*)
21 d NOEC (reproduction) 0.1 mg/L (*Daphnia magna*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	Not stated.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	Multiple tests on different species; Static or static renewal. Duration varies 0.3 to 100 d, Table of experimental methods provided.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Source and purity not reported.
5	**Were effects endpoints ecologically relevant?**	Y	NOEC
6	**Was an appropriate exposure duration used and reported?**	Y	0.3d , 4 d, 7 d, 21 d, 25 d, 28 d, 40 d, 100 d
7	**Were appropriate controls included, reported and results adequate?**	N	Not reported
8	**Were the statistical procedures reported and appropriate?**	N	Statistical procedure is not reported.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y/N	Not measured, but some renewal of test solutions.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Age or life stage reported. No details on rearing, acclimation.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	Temperature and loading density reported. Water quality parameters not reported.
12	**Was a dose/response relationship demonstrated?**	N	No data given to evaluate dose response.
13	**Were the concentrations/doses provided?**	N	Stated that concentrations in all tests varied by 3.2 factor. No specific concentrations given.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Srivastava, V.K. and A. Singh. 2001. Toxicity of alphamethrin, dimethoate and carbaryl pesticides to the freshwater snails *Lymnaea acuminata* and *Indoplanorbis exustus*. Iberus 19(1):1-5.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Freshwater snails (*Lymnaea acuminata* and *Indoplanorbis exustus*)

Endpoint(s): 96 h LC50 (18°C) 14.31 mg/L, 12.69 mg/L, 11.78 mg/L, 11.24 mg/L (*Lymnaea acuminata*)
96 h LC50 (28°C) 19.65 mg/L, 18.13 mg/L, 15.26 mg/L, 10.81 mg/L (*Lymnaea acuminata*)
96 h LC50 (18°C) 13.09 mg/L, 11.65 mg/L, 11.57 mg/L, 10.03 mg/L (*Indoplanorbis exustus*)
96 h LC50 (28°C) 16.23 mg/L, 14.26 mg/L, 11.96 mg/L, 9.41 mg/L (*Indoplanorbis exustus*)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y/N	Singh and Agarwal (1990); insufficient details.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Commercial grade Rogohit purchased from local market.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Controls used. Control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	Y/N	POLO programme

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	**N**	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	**Y**	1.8 cm shell length, 0.8 cm shell height.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y**	20 animals/3L, 6 replicates; tests conducted under 2 conditions: 1) temperature 18°C, pH 6.7-7.05, DO 6.5-7.2, alkalinity 105-109 mg/L and 2) temperature 28°C, pH 7.2-7.4, DO 6.8-7.4, alkalinity 106-109 mg/L.
12	**Was a dose/response relationship demonstrated?**	**N**	No data provided
13	**Were the concentrations/doses provided?**	**Y**	Five test concentrations (11, 14, 17, 20 and 23 mg/L).

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: **() ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE**

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Thybaud E., S. Le Bras and R.P. Cosson. 1987. Étude comparée de la sensitivité d'*Asellus aquaticus* L. (Crustacé, Isopode) vis-á-vis de quelques insecticides et de divers métaux lourds. [Comparative study of the susceptibility of *Asellus aquaticus* L. (Crustacea, Isopoda) to some insecticides and heavy metals]. Acta Aecol 8:355-361.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Isopod (*Asellus aquaticus*)

Endpoint(s): 48 h LC50 2.96 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	N	Incomplete
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Source of dimethoate unknown; purity unknown.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Control included, but control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static test
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Age unknown, acclimated 3 wk.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	10 animals per concentration, water quality determined and reported on dilution water, but not during test. 12 h light: 12 h dark.
12	**Was a dose/response relationship demonstrated?**	N	24 and 48 h LC10, LC50, LC90. No raw data, unable to verify dose-response.
13	**Were the concentrations/doses provided?**	Y	1, 2, 3, 4 and 5 mg/L

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Tripathi, P.K. and A. Singh. 2003. Toxic effects of dimethoate and carbaryl pesticides on reproduction and related enzymes of the freshwater snail *Lymnaea acuminata*. Bull Environ Contam Toxicol 71:535-542.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Freshwater snail (*Lymnaea acuminata*)

Endpoint(s): 96 h LOEC (number of eggs and number of hatched eggs) 1 mg/L
7 d LOEC (survivability of hatchlings) 1 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	Sufficient details on testing method provided.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Technical, purity and source not provided.
5	**Were effects endpoints ecologically relevant?**	Y	LOEC
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y/N	Controls used, control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	Y	Student t-test

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Static
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Acclimated 96 h, adult snails (37.1 +/- 1.9 mm shell height and 20.6 +/- 1.4 mm shell width).
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	30 snails in 10 L, six replicates, photoperiod not provided, temperature maintained at 23±1 °C, DO not provided, pH ranged not provided.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	Y	Four concentrations used (1, 3, 6 and 9 mg/L).

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Aquatic Invertebrates (Marine)

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Graves, W.C. and J.P. Swigert. 1993a. Dimethoate: A 96-Hour Static Acute Toxicity Test With the Saltwater Mysid (*Mysidopsis bahia*). Wildlife International Ltd. Project Number: 242A-102, FIFRA Subdivision E, Series 72-3. MRID 42760003.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species Tested: Saltwater mysid (*Mysidopsis bahia*)

Endpoint(s): 48 h LC50 22 mg/L
96 h LC50 15 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Followed ASTM standard E 729-88 and US. EPA OPP in 40 CFR part 160, August, 1989 and OECD ISBN 92-84-12367-9, Paris, 1982.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Solid with a white crystalline color, Technical grade produced by Cheminova A/S, 99.1% purity.
5	**Were effects endpoints ecologically relevant?**	Y	EC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y	No control mortality
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static, measured at beginning and end of test.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Less than 24h old obtained from cultures maintained by Wildlife International Ltd. Adult mysids in the cultures were held in water from same source and at same temperature as that used in the test. Adults held for at least 14 d prior to collection of juveniles for testing..
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	10 mysids in 2 L, 2 replicates, 16 h light: 8 h dark, temperature maintained at 25±1 °C, DO ranged between 7.2- 6 mg/L during the test and DO concentrations exceeded 60% of saturation throughtout the test, pH ranged between 8.2 to 8.4 during the test.
12	**Was a dose/response relationship demonstrated?**	Y	Raw data available. Dose-response relationship demonstrated.
13	**Were the concentrations/doses provided?**	Y	Six concentrations and a control, 1.2, 2.5, 5.1, 10, 18 and 38 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE () SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Graves, W.C. and J.P. Swigert. 1993b. Dimethoate: A 96-Hour Shell Deposition Test With the Eastern Oyster (*Crassostrea virginica*). Wildlife International Ltd. Project Number: 242A-104, FIFRA Subdivision E, Series 72-3. MRID 42760002.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species Tested: Eastern oyster (*Crassostrea virginica*)

Endpoint(s): 96 h EC50 (shell deposition) 113 mg/L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Followed ASTM standard E 729-88 and US EPA OPP in 40 CFR part 160, August, 1989 and OECD ISBN 92-84-12367-9, Paris, 1982.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Solid with a white crystalline color; technical grade produced by Cheminova A/S, 99.1% purity.
5	**Were effects endpoints ecologically relevant?**	Y	EC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y	No control mortality
8	**Were the statistical procedures reported and appropriate?**	Y	Binomial method

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Flow-through, measured at beginning and end of test.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	25 to 41 mm with average of 29 mm. All oysters from the same year class. 13 d holding period prior to test.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	16 h light: 8 h dark, 495 Lux lighting, 20 oysters in test chamber, flow of saltwater into each test chamber, 1 L of water/oyster/h, temperature maintained at 22±1 °C, DO ranged between 7.3- 7.6 mg/L during the test and DO concentrations exceeded 60 % of saturation through the test, pH ranged between 8.1 to 8.2 during the test.
12	**Was a dose/response relationship demonstrated?**	Y	Raw data available, dose-response relationship demonstrated.
13	**Were the concentrations/doses provided?**	Y	Five concentrations and a control, 15.6, 25.9, 43.2, 72 and 120 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE () SUPPLEMENTAL () UNACCEPTABLE

Comments:

Supplemental Studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Guzzella, L., A. Gronda and L. Colombo. 1997. Acute toxicity of organophosphorus insecticides to marine invertebrates. Bull Environ Contam Toxicol 59:313-320.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Brine shrimp (*Artemia salina*); Rotifer (*Brachionus plicatilis*)

Endpoint(s): 24 h LC50 303 mg/L (*Artemia salina*)
24 h LC50 244 mg/L (*Brachionus plicatilis*)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y/N	Standardized by using Toxkit (Rototox Kit M & Artoxkit M) supplied by Creasel Ltd, Belgium.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	≥ 95% pure; Source: Chem. Service, West Chester, PA.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	24 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Controls included, 100% survival reported.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit analysis using EPA Probit software.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Stock solutions analyzed only.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	N	Brine shrimp, *Artemia sp* and rotifer, *Brachionus plicatus* neonates.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	10 animals in 3 replicates for Artemia, 6 animals in 5 replicates for rotifers. Tests performed in "standard seawater" (formula given) as supplied with kits. 24 h dark.
12	**Was a dose/response relationship demonstrated?**	N	No raw data given to verify dose-response
13	**Were the concentrations/doses provided?**	N	5 concentrations plus control, but values not given.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Serrano, R., F. Hernández, J.B. Peña, V. Dosca and J. Canales. 1995. Toxicity and bioconcentration of selected organophophorus pesticides in *Mytilus galloprovincialis* and *Venus gallina*. Arch Environ Contam Toxicol 29:284-290.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Mollusc (*Mytilus galloprovincialis* and *Venus gallina*)

Endpoint(s): 96 h LC50 >56 mg/L (*Mytilus galloprovincialis*) (no effects seen at highest test concentration)
96 h LC50 >32 mg/L (*Venus gallina*) (no effects seen at highest test concentration)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Cygon, Perfekthion (93-99%); Dr. Ehrenstorfer reference Materials (Germany).
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Controls used; no control mortality.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static, measured at beginning and end of test.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Acclimation for 7 d, adult *M. galloprovincialis* (6.95 ± 2.13 g mean weight soft tissue) and mean size of major axis (5.13 ± 0.49 cm) and *V. gallina* (1.31 ± 0.53 g mean weight soft tissue) and mean size of major axis (2.43 ± 0.29 cm).
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	Six *M. galloprovincialis*/30L and ten *V. gallina*/30L, 3 replicates, photoperiod not provided, salinity 38 g/L, pH 7.1-7.9, temperature 18 ± 1°C. DO measured twice daily and ranged between 90-100%.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available
13	**Were the concentrations/doses provided?**	Y	Six test concentrations (1, 3.2, 5.6, 10, 32 and 56 mg/L).

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Song, M.Y. and J.J. Brown. 1998. Osmotic effects as a factor modifying insecticide toxicity on Aedes and Artemia. Ecotoxicol Environ Saf 41:195-202.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Brine shrimp (*Artemia salina*), black saltmarsh mosquito (*Aedes taeniorhynchus*)

Endpoint(s): 48 h LC50 0.031 mg/L (27°C) (*Aedes taeniorhynchus*)
48 h LC50 15.73 mg/L (27°C) (*Artemia salina*)
72 h LC50 10.14 mg/L (*Artemia salina*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (Cygon), purity >95%; source: Alltech Company, San Jose, CA.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 to 72 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Reported results of tests with ≤10% mortality in solvent control, but also indicated use of Abbott's correction prior to Probit analysis.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Not reported
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Brine shrimp, *Artemia sp.* (stage 4 nauplii) & mosquito, *Aedes taeniorhynchus* (24 h old larvae).
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	15 organisms per replicate, 4 replicates. Tests performed in full strength and diluted artificial seawater (12.7 and 33 ppt, pH 8.0, temperature of 27 ºC, constant light, fed Tetramin).
12	**Was a dose/response relationship demonstrated?**	N	No raw data given to verify dose-response.
13	**Were the concentrations/doses provided?**	N	Five concentrations indicated but values not given.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Song, M.Y., J.D. Stark and J.J. Brown. 1997. Comparative toxicity of four insecticides, including imidacloprid and tebufenozide, to four aquatic arthropods. Environ Toxicol Chem 16(12):2494–2500.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species Tested: Water flea (*Daphnia magna*), yellow fever mosquito (*Aedes aegypti*), brine shrimp (*Artemia salina*), black saltmarsh mosquito (*Aedes taeniorhynchus*)

Endpoint(s): 48 h LC50 0.031 mg/L (27°C) (*Aedes taeniorhynchus*)
48 h LC50 15.73 mg/L (27°C) (*Artemia salina*)
72 h LC50 10.14 mg/L (*Artemia salina*)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	ASTM (1992), EPA (1975)
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate technical (>95%) from Alltech, San Jose, CA.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 h, 72 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Control mortality <10%, mortality data were corrected for mortality in the controls prior to probit analysis.
8	**Were the statistical procedures reported and appropriate?**	Y	Probit analysis

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	N	Not measured, static.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	*Aedes aegypti*, *Aedes taeniorhynchus*, *Daphnia magna*, 24 h old. *Artemia sp.*,48 h old. Acclimation to 20º or 27 ºC unclear.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	10 animals tested per replicate, 4 replicates. Tested at both 20 ºC and 27 ºC. No indication of other measurements during test.
12	**Was a dose/response relationship demonstrated?**	N	No data given to evaluate dose response.
13	**Were the concentrations/doses provided?**	N	Four test concentrations plus control used but no test concentrations reported.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE (X) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Unacceptable Studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Mayer F.L. 1987. Acute Toxicity Handbook of Chemicals to Estuarine Organisms. United States Environmental Protection Agency, Environmental Research Laboratory, Sabine Island, Gulf Breeze, FL. April 1987. EPA 600/8-87/017.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Brown Shrimp (*Penaeus aztecus*) and Longnose killifish (*Fundulus similis*)

Endpoint(s): 48 h EC50 (effect not specified) >1 mg/L (*Penaeus aztecus*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Document indicates, for the most part, research was conducted by methods of the American Society for Testing and Materials (1980) or Committee on Methods for Toxicity Tests with Aquatic Organisms 1975). Older studies would pre-date guidelines.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**		
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Technical grade, purity 99.3%. Source not reported.
5	**Were effects endpoints ecologically relevant?**	Y	EC50
6	**Was an appropriate exposure duration used and reported?**	Y	48 h
7	**Were appropriate controls included, reported and results adequate?**	N	Control mortality not reported.
8	**Were the statistical procedures reported and appropriate?**	N	No statistics. Limit test only.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Flow through exposure. Dimethoate is water soluble and does not volatilise, and the test was conducted in 48 h, it was assumed that the test concentrations were maintained.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y/N	Brown shrimp (*Penaeus aztecus*) (35-75 mm) and Longnose killifish (*Fundulus similis*) juveniles. No specific details on weight and number tested. Acclimated to laboratory conditions before testing.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	Temperature 22 ºC, salinity 30 ppt. No indication of other measurements during test. No DO reported.
12	**Was a dose/response relationship demonstrated?**	n/a	EC/LC50>1.0 mg/L. Limit test, no dose-response
13	**Were the concentrations/doses provided?**	N	Data not provided. Solvent used (acetone, ethanol, polyethylene glycol, or triethylene glycol) at 1 ml/L. Test limited to one concentration, 1.0 mg/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Reddy, M.S. and K.V. R. Rao. 1992. Toxicity of selected insecticides to the Penaeid prawn *Metapenaeus monoceros* (Fabricius). Bull Environ Contam Toxicol 48:622-629.

Secondary reference:

Is the primary reference study a GLP study?: No

Species Tested: Penaeid prawn (*Metapenaeus monoceros*)

Endpoint(s): 96 h LC50 2.31 mg/L (formulation), 0.69 mg a.i./L
96 h LC50 2.47 mg/L (formulation), 0.74 mg a.i.L
96 h LC50 2.08 mg/L (formulation), 0.62 mg a.i./L
96 h LC50 2.86 mg/L (formulation), 0.86 mg a.i.L

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	N	
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**	Y	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	30% purity; Hyderabad Chemicals Supplies Pvt Ltd., Hyderadad.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	N	Not reported
8	**Were the statistical procedures reported and appropriate?**	Y	Probit

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	Y	Static renewal every 24 h.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	Y	Acclimation conducted but period of time not provided, 75 ± 5 mm in length, 2.5 ± 0.2g weight.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y/N	20 animals per test concentration, 5 replicates, photoperiod not provided, aeration reported but DO not provided. 15 ± 1 ppt salinity, pH 7.1 ±0.2, temperature 23 ±2°C.
12	**Was a dose/response relationship demonstrated?**	N	Raw data not available.
13	**Were the concentrations/doses provided?**	N	Not reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Roast S.D., R.S. Thompson, P. Donkin, J. Widdows and M.B. Jones. 1999. Toxicity of the organophosphate pesticides chlorpyrifos and dimethoate to *Neomysis integer* (Crustacea: Mysidacea). Wat Res 33(2):319-326.

Secondary reference:

Is the primary reference study a GLP study?: Yes/No (United Kingdom Compliance Programme (ca. 1989), but data lacking.

Species Tested: Mysid (*Neomysis integer*)

Endpoint(s): 96 h LC50 0.543 mg/L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Procedures of the Department of Health's UK Compliance program, Department of Health, 1989. Good description of the methods.
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used acceptable laboratory practices?**		
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Source and purity not reported.
5	**Were effects endpoints ecologically relevant?**	Y	LC50
6	**Was an appropriate exposure duration used and reported?**	Y	96 h
7	**Were appropriate controls included, reported and results adequate?**	Y	Controls included, < 10% mortality.
8	**Were the statistical procedures reported and appropriate?**	Y	Moving average angle method.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were the test concentrations or doses measured / maintained?**	**Y/N**	Static renewal. Not measured, but 24 h aged solutions gave similar results.
10	**Was the test species acclimated and characteristics of test species reported (e.g., strain, sex, age, life stage, length, weight)?**	**N**	15 ± 1 mm body length. No details on age, acclimation.
11	**Were appropriate test conditions (e.g., pH, conductivity, salinity, light intensity, temperature, DO, hardness of water, feeding, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y/N**	Temperature was 12 ºC; salinity 7 ppt. Photoperiod given as 18 h light:6 h dark. 10 mysids in 1500 mL. No indication of other measurements during test. No DO reported. Fed Artemia nauplii twice daily.
12	**Was a dose/response relationship demonstrated?**	**Y/N**	96 h LC50 0.543 mg/L (0.403-0.683). Not enough data given to evaluate dose-response.
13	**Were the concentrations/doses provided?**	**Y**	0.28, 0.5, 0.88, 1.56, 2.81 and 5000 mg dimethoate/L. Solvent used (acetone, ethanol, polyethylene glycol, or triethylene glycol) at 1 ml/L. Current OPPTS guideline max <100 mg/L or OECD <0.1 ml/L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE () SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

APPENDIX C
DATA QUALITY EVALUATION OF AQUATIC VASCULAR PLANT TOXICITY STUDY

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Porch, J.R., T.Z. Kendall, and H.O. Krueger. 2009. Dimethoate: A 7-Day Static-Renewal Toxicity Test With Duckweed (*Lemna gibba* G3). Wildlife International Ltd. Project Number 232A-118. Wildlife International Easton, MD.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Duckweed (*Lemna gibba*)

Endpoint(s): Formulation:
7 d EC50 (frond number) >100 mg/L (>41.5 mg a.i./L)
7 d EC50 (frond number growth rate) >100 mg/L (>41.5 mg a.i./L)
7 d EC50 (biomass) >100 mg/L (>41.5 mg a.i./L)
7 d EC50 (biomass growth rate) >100 mg/L (>41.5 mg a.i./L)
7 d NOEC (biomass, frond number, growth rate based on frond number, biomass) 100 mg/L (41.5 mg a.i./L)

Technical:
7 d EC50 (frond number) >41.5 mg a.i./L
7 d EC50 (frond number growth rate) >41.5 mg a.i./L
7 d EC50 (biomass) >41.5 mg a.i./L
7 d EC50 (biomass growth rate) >41.5 mg a.i./L
7 d NOEC (biomass, frond number, growth rate based on frond number, biomass) 41.5 mg a.i./L

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical and formulation
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, ETC.)?**	Y	Procedures based on EPA Ecological Test Guidelines OPPTS 850.4400, ASTM Standard Guide 1415-91 E "Standard Guide for Conducting Static Toxicity Tests with *Lemna gibba*" (1991), draft of OECD guideline 221 "*Lemna sp.* Growth Inhibition Test" and Series 123 of the EPA's "Pesticide Assessment Guidelines FIFRA, Subdivision J, Hazard Evaluation: Non-target Plants".
3	**If NO to 2, was a complete description given of the test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	

	GENERIC CRITERIA	Y/N	COMMENTS
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	**Y**	Dimethoate 400 (41.5% dimethoate) received from Platte Chemical and Dimethoate technical (99.1% dimethoate), received from Cheminova A/S. Purity was taken into account when authors calculated exposure concentrations.
5	**Were effects endpoints ecologically relevant?**	**Y**	Biomass, growth, frond number.
6	**Was an appropriate exposure duration used and reported?**	**Y**	7 d
7	**Were appropriate controls included, reported, and the results adequate?**	**Y**	Controls included, doubling time of frond number was 1.79 d (meeting validity criteria of this test of <2.5 d).
8	**Were the statistical procedures reported and appropriate?**	**Y**	Evaluated for normality and homogeneity of variances using Shapiro-Wilk's and Levene's tests, treatment groups compared to controls using ANOVA and Dunnett's one-tailed tests.

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were the test concentrations measured / maintained?**	**Y**	Measured at start of test and at renewal periods (days 3 and 5). Analytical method was HPLC. Measured concentrations of technical ranged from 90-92% of nominal and of formulation ranged from 88-93%.
10	**Were characteristics of the test species reported and appropriate (e.g., strain, age, initial cell concentration/frond number, weight)?**	**Y**	*Lemna gibba* G3, 4 plants totaling 12 fronds added to each replicate test chamber.
11	**Was the method and medium of cultivation reported and appropriate?**	**Y**	Lemna grown in culture medium for at least 2 weeks prior to test initiation. Cultured and tested in 20X Algal Assay Procedure medium, pH adjusted to 7.5 ±1.
12	**Were appropriate test conditions (e.g., pH, light intensity, photoperiod, temperature) measured, reported and within acceptable ranges?**	**Y**	Continuous lighting, ranged from 4280 to 5680 lux. Temperature ranged from 24.0 to 24.4°C, pH ranged from 7.6-9.0
13	**Was a concentration/response relationship demonstrated?**	**n/a**	No adverse effects observed at any concentration tested.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
14	Were the concentrations provided?	Y	For formulation: control, 6.25, 12.5, 25, 50 and 100 mg/L. For technical: control, 2.59, 5.19, 10.4, 20.8, and 41.5 mg a.i./L.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

APPENDIX D
DATA QUALITY EVALUATION OF AVIAN TOXICITY STUDIES

Avian

Acceptable Studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Gallagher, S.P., J. Foster, J.B. Beavers, M. Jaber. 1996a. Dimethoate: A Reproduction Study with the Northern Bobwhite (*Colinus virginianus*). Wildlife International Ltd. Project No. 232-115. June 19, 1996. Unpublished report. CHA Doc. No. 318 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Northern Bobwhite (*Colinus virginianus*)

Endpoint(s): 22 wk NOEL (reduction in adult body weight and feed consumption, egg production and hatching survivorship) 10.1 mg/kg diet (1.092 mg/kg bw/g)
22 wk LOEL (reduction in adult body weight and feed consumption, egg production and hatching survivorship) 35.4 mg/kg diet

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	Methods followed EPA Registration Guidelines "Pesticide Assessment Guidelines" Subsection 71-4, and OECD Test Guideline 206.
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5), Purity: 99.1%. Received from: Analytical Bio-Chemistry Laboratories Batch No. 20522-00.
5	**Were the effects endpoints ecologically relevant?**	Y	NOEL, LOEL Many reproductive endpoints.
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	1-generation: Exposed to test substance in feed for 22 wk. Post-adult termination (final incubation, hatching and 14 d offspring rearing period) phase was 5 wk.

GENERIC CRITERIA		Y/N	COMMENTS
7	**Were appropriate controls included, reported and the results adequate?**	Y	Control birds fed diet containing an amount of solvent (acetone) equivalent to the amount in the treated diets. Only one single mortality in the controls.
8	**Were statistical procedures reported and appropriate?**	Y	Difference from controls: Dunnett's method. Necropsy results: Fisher's Exact test.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 4, 10.1 and 35.4 mg active ingredient/kg diet
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	The concentration of the test substance in the diet was verified at Day 0, Day 7 of week 1, and weeks 6, 12 and 18.
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Birds were acclimated. Supplier: Top Flight Quail Farm, Belvidere, NJ Sex: 64 male and 64 female birds Age: 19 wk at test initiation
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y*	Temperature (adult birds): 21.8°C ± 3.0°C; Temperature (brooding pens): approx. 38°C; Temperature (hatchlings): approx. 37.2°C ± 0.0°C; Deviation: Temporary excursions below normal temperature were observed. Average Humidity (adult birds): 64 ± 15% Average Humidity (chicks): approx. 76% Photoperiod: 8 h light until week 8, when the photoperiod was increased to 17 h light to induce egg laying in adults. The photoperiod of hatchlings was16 h light: 8 h dark Density: 1 adult bird/pen
13	**Were individual body weights measured during testing and observation periods?**	Y	Reported at test initiation and on weeks 2, 4, 6, 8 and at adult termination.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y	Ad libitum. Feed consumption was measured weekly for each pen; no attempt was made to quantify the amount of feed wasted by the birds.
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	Y**	Measures were made of eggs laid, eggs cracked, eggs set, viable embryos, live 3 wk embryos, hatchlings, body weight of hatchlings, 14 d old survivors, body weight of 14 d old survivors, and eggshell thickness. Deviations: There were several minor deviations from the Study Protocol.
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for gross pathology, feed consumption, body weight, eggshell thickness, reproductive parameters. Dose response demonstrated.

* The Study Director stated these deviations caused no adverse impact on study outcome

**Not all measures were as per Study Protocol. The Study Director states these deviations caused no adverse impact on the outcome of the study.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments: There was an incubator accident (see page 19) that resulted in some eggs from Lot A being destroyed. Egg production and % cracked eggs were calculated using this Lot. Values for all other reproductive parameters were calculated without this lot. OECD and EPA Acceptability Criteria still were met by the data. There were minor deviations from the Study Protocol noted (see table above, and report), not expected to adversely affect the outcome of the study.

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Gallagher, S.P., J.W. Foster, J.B. Beavers, M. Jaber. 1996b. Dimethoate: A Reproduction Study with the Mallard (*Anas platyrhynchos*). Wildlife International Ltd. Project No. 232-116. March 26, 1996. Unpublished report. CHA Doc. No. 321 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Mallard (*Anas platyrhynchos*)

Endpoint(s): 22 wk NOEL (reduction in adult body weight and feed consumption, egg production and embryo viability) 35.4 mg/kg diet
22 wk LOEL (reduction in adult body weight and feed consumption, egg production and embryo viability) 152 mg/kg diet

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	**Y**	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	**Y**	Methods followed EPA Registration Guidelines "Pesticide Assessment Guidelines", 2) ASTM E1062-86, and 3) OECD Test Guideline 206.
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	**n/a**	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	**Y**	Dimethoate (CAS 60-51-5), Purity: 99.1%, Received from: Analytical Bio-Chemistry Laboratories Batch No. 20522-00.
5	**Were the effects endpoints ecologically relevant?**	**Y**	NOEL, LOEL Many reproductive endpoints.
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	**Y**	1-generation: Exposed to test substance in feed for 22 wk.
7	**Were appropriate controls included, reported and the results adequate?**	**Y**	Control birds fed diet containing an amount of solvent (acetone) equivalent to the highest amount in the treated diets. There were no control mortalities.
8	**Were statistical procedures reported and appropriate?**	**Y**	Difference from controls: Dunnett's method Necropsy results: Chi-square test

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 10.1, 35.4 and 152 mg active ingredient/kg diet
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	The concentration of the test substance in the diet was verified at Day 0, and weeks 6, 12 and 18.
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Birds were acclimated. Supplier: Whistling Wings, Hanover, IL Sex: 64 male and 64 female birds Age: 24 wk at test initiation
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y*	Temperature (adult birds): 22.2°C ± 2.5°C; Temperature (brooding pens): approx. 38°C; Temperature (hatchlings): approx. 29°C; Deviation: Temporary excursions from normal temperature were observed. Average Humidity (adult birds): 70 ± 16% Average Humidity (chicks): 54 ± 18% Photoperiod: 8 h light: 16 h dark or less until beginning of week 10, when the photoperiod was increased to 17 h light: 7 h dark to induce egg laying. Deviation: Photoperiod was 13 h light for 1 d (instead of 17 h) due to equipment malfunction. Photoperiod for hatchlings was 16 h light: 8 h dark. Density: 1 adult bird/pen
13	**Were individual body weights measured during testing and observation periods?**	Y**	Reported at test initiation and on weeks 2, 4, 6, 8 and at adult termination. Deviation: Feed consumption was not recorded at the end for pen 151 in the 152 mg/kg diet test group.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y***	Ad libitum. Feed consumption was measured for each pen for a 7 d period; no attempt was made to quantify the amount of feed wasted by the birds.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	Y	Measures were made of eggs laid, eggs cracked, eggs set, viable embryos, live 3 wk embryos, hatchlings, body weight of hatchlings, 14 d old survivors, body weight of 14 d old survivors, and eggshell thickness. Eggs not cracked or used for eggshell thickness were incubated.
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for gross pathology, feed consumption, body weight, reproductive parameters. Dose response demonstrated. No treatment-related mortality or overt signs of toxicity occurred.

* The Study Director stated these deviations caused no adverse impact on study outcome.

** Body weight for hatchlings from two pens was not weighed according to the protocol. This resulted in some data being excluded. The Study Director states this deviation caused no adverse impact on the outcome of the study.

*** Feed consumption was measured in other test pens. Therefore, Study Director stated this deviation is expected to cause no adverse impact on study outcome.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments: There was an incubator accident (see page 18) that resulted in some eggs from Lots A and B being destroyed. Egg production and % cracked eggs were calculated using both Lots A and B, as these parameters were not impacted by the accident. Values for all other reproductive parameters were calculated without those lots. OECD and EPA Acceptability Criteria still were met by the data. Four other deviations from the Study Protocol were noted (see table above).

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Hubbard, P.M., Martin, K.H. and J.B. Beavers. 2009c. Dimethoate: A Dietary LC50 Study with the Mallard. Wildlife International Ltd. Project No. 232-148. April 23, 2009. Unpublished report.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Mallard (*Anas platyrhynchos*)

Endpoint(s): 5 d (3 d observation) LC50 1066 mg/kg diet
5 d (3 d observation) NOEL (body weight) 94 mg/kg diet (42 mg a.i./kg diet/d)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	Protocol based on procedures specified in: 1) OPPTS 850.2200 (Ecological Effects Test Guidelines) 2) Section 71-2 of EPA's, Pesticide Assessment Guidelines 3) ASTM E857-87, and 4) OECD Test Guideline 205 (Avian Dietary Toxicity Test).
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5), Purity: 99.1%, with 0.05% isodimethoate and <0.02% omethoate Cheminova Batch No. 20522-00
5	**Were the effects endpoints ecologically relevant?**	Y	LC50, NOEL Mortality, body weight, feed consumption
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Exposed to test substance in feed for 5 consecutive days, followed by 3 d of observation.
7	**Were appropriate controls included, reported and the results adequate?**	Y	Untreated control, no control mortalities.

	GENERIC CRITERIA	Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	Y	Mortality - probit Body weight – Dunnett's t-test and Bonferroni t-test Bartlett's and Hartley's tests for homogeneity of variance and an ANOVA test also performed.

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 11.8, 23.5, 47, 94, 188, 375, 750 and 1500 mg active ingredient/kg diet
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	The concentration of the test substance in the diet was verified at day 0, 1 and 4.
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Birds were acclimated. Supplier: Whistling Wings, Hanover, IL Sex: not determined Age: 10 d old at study start
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	Temperature: 28.5°C ± 1.1°C in the brooding compartment; average ambient room temperature was 18.7°C ± 1.2°C Average Humidity: 41 ± 6% Photoperiod: 16 h light: 8 h dark Loading density: 5 juveniles/pen
13	**Were individual body weights measured during testing and observation periods?**	Y	Reported on days 0, 5 and 8
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y	Ad libitum. Average feed consumption was measured daily for all 8 d.
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for mortality, clinical signs, mean feed consumption, body weight. Dose-response for mortality demonstrated.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Redgrave, V.A., C. Gopinath, and A. Anderson. 1991. Dimethoate: Acute Delayed Neurotoxicity in the Domestic Hen. Huntington Research Centre, Ltd. Unpublished study (DTF 15/901429).

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Domestic hen (*Gallus Gallus domesticus*)

Endpoint(s): 1 dose (14 d) LD50 55 mg/kg bw

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	EPA Guideline 81-7 and modifications proposed in 12/18/89 draft revisions.
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Batch number 611/A; 96.42% purity; supplied by sponsor (Dimethoate Task Force).
5	**Were the effects endpoints ecologically relevant?**	Y	Mortality (LD50), changes in body weight
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	For assessment of mortality, 14 d pre treatment followed by 14 d observation post dosing.
7	**Were appropriate controls included, reported and the results adequate?**	Y	No mortalities occurred in control group.
8	**Were statistical procedures reported and appropriate?**	Y	LD50 calculated by probit analysis

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 30, 45, 67.5, 101.25, 151.875 mg/kg bw (n=10 at each dose level). Concentrations of dimethoate in dose formulations analyzed and mean results within 2% of nominal.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	n/a	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	72 adult female hens, 12 mo of age, between 1935 and 2295 g, supplied by Atkinson Bros. Ltd. Acclimation period of 14 d. Birds were randomly allocated to treatment groups based on body weight.
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	Room temperature: 23-25°C (±1.4-1.5) Relative humidity: 70% (±7.3) Acceptable ranges not provided for temperature/humidity but are in line with OPPTS 850.2100 Photoperiod: 12 h light: 12 h dark
13	**Were individual body weights measured during testing and observation periods?**	Y	Measured at day -14, -7, 0, 7 and 14
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	n/a	Gavage study
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Four (of 10) mortalities occurred in the 45 mg/kg group, six (of 10) at the 67.5 mg/kg group and 10 (all birds) at the 101.25 and 151.875 mg/kg groups. Body mass decreased in treated birds over first week of dosing followed by an increase in second week; controls increased over both weeks.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Solecki, R., L. Niemann, C. Gericke, and I. Chahoud. 2001. Dietary Administration of Dimethoate to the Japanese Quail: Reproductive Effects and Successful Hatchability of Eggs. Bull Environ Contam Toxicol 67:807-814.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species tested: Japanese quail (*Coturnix c. japonica*)

Endpoint(s): 6 wk NOEL (adult body weight gain (growth)) 10 mg/kg diet
6 wk LOEL (adult body weight gain (growth)) 35 mg/kg diet
6 wk NOEL (reproductive success) 35 mg/kg diet
6 wk LOEL (reproductive success) 70 mg/kg diet

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	N	Not specified.
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	Y	Detail provided on test methodology.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (99.1% pure) was manufactured and provided by Cheminova (Lemvig/Denmark; Batch 20522-00.
5	**Were the effects endpoints ecologically relevant?**	Y	Reproduction (# eggs, egg shell thickness, egg weight, hatchability), mortality, body weight gain, brain cholinesterase activity.
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	6 wk of exposure, birds were mated once per day during this time (5 d/wk).
7	**Were appropriate controls included, reported and the results adequate?**	Y	Control birds were fed standard diets ("Club-Wachtelfutter") over the 6 wk period, there were no mortalites during study.

	GENERIC CRITERIA	Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	Y	Used Students t-test, Chi-square test and Fishers exact test for testing differences obtained for statistical significance, Dunnett test for statistical differences, ANOVA .

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	10, 35, 70 mg/kg diet
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	Diet test concentrations were subject to regular (weekly) analytical examinations and were found to be similar to nominal concentrations, stability was verified for at least 14 d (considered sufficient because diets were prepared each week).
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Obtained from breeder (Küberich, Geesdorf/Wiesentheid, Bavaria, FRG) at 5 wk of age, 7 wk acclimation period before being transferred to testing groups, maintained in testing groups without test diet to ensure conditions were right, male and female birds were used for mating.
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	Housed singly in wire pens, temperature 22±2°C, 55±10% relative humidity, 16 h light:8 h dark, 65-120 lux lighting.
13	**Were individual body weights measured during testing and observation periods?**	Y	Weights of surviving chicks were measured, weights of parents were measured at start and end of acclimation and at termination.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y	Feeding consumption was estimated weekly based on replicates of three pairs each.
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	Y	Eggshell thickness measured weekly in one intact egg per pen at five sites, number of eggs, number of viable eggs, weight of survivors.

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Provide mean data for body weight gain, brain cholinesterase activity, egg weight, cracked eggs, eggshell thickness, hatchling body weight. Dose response demonstrated.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Temple, D.L., K.H. Martin, J.B. Beavers, M. Jaber. 2010. Omethoate and Dimethoate: A Comparative Reproduction Study with the Northern Bobwhite. Wildlife International, Ltd. Project Number 232-149. August 31, 2010. Unpublished report.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Northern Bobwhite (*Colinus virginianus*)

Endpoint(s): 10 wk NOEL (weight gain, reproduction) 12 mg/kg diet (1.1 mg a.i./kg/d)
10 wk LOEL (weight gain, reproduction) 30 mg/kg diet
10 wk NOEL (survival) 30 mg/kg diet
10 wk LOEL (survival) 75 mg/kg diet

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	Protocol based in part on 1) EPA Registration Guidelines "Pesticide Assessment Guidelines" Subsection 71-4, 2) OECD Test Guideline 206 3) ASTM E1062-86 and 4) EPA Guideline 850.2300 "Avian Reproduction Test".
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5), Purity: 98.0% Received from: Cheminova Batch No. 611/A
5	**Were the effects endpoints ecologically relevant?**	Y	NOEL, LOEL Many reproductive endpoints.
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Exposed to test substance in feed for 10 wk, with 8 wk of egg production. Post-adult termination (final incubation, hatching and 14 d offspring rearing period) phase was 6 wk.
7	**Were appropriate controls included, reported and the results adequate?**	Y	Control birds fed diet comparable to treatment groups but without test substance. One control animal mortality.

GENERIC CRITERIA		Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	Y	Differences between groups: ANOVA Comparison of treatment means for omethoate and dimethoate with control group mean: two-sided Dunnett's t-test multiple comparison procedure Necropsy results: Fisher's Exact test

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 5, 12 and 75 mg active ingredient/kg diet)
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	The concentration of the test substance in the diet was verified at day 0, day 7 of week 1, and weeks 4 and 8.
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Birds were acclimated. Supplier: M & M Quail Farm, Gillsville, GA Sex: 108 male and 108 female birds Age: 27 wk at test initiation
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y	Temperature (adult birds): 21.8°C ± 0.6°C Temperature (brooding pens): approx. 38°C Average Humidity (adult birds): 24 ± 8% Average Humidity (chicks): approx. 27% ± 8% Photoperiod: 8 h light: 16 h dark during acclimation, then increased to 17 h light: 7 h dark to induce egg laying (start of Week 1). Photoperiod for hatchlings was 16 h light: 8 h dark. Density: 1 adult bird/pen
13	**Were individual body weights measured during testing and observation periods?**	Y	Reported at test initiation and adult termination.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y	Ad libitum. Feed consumption of adults was measured daily for a 4 d period each week. No attempt was made to quantify the amount of feed wasted by the birds.

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	Y	Measures were made of eggs laid, eggs cracked, eggs set, viable embryos, live 3 wk embryos, hatchlings, body weight of hatchlings, 14 d old survivors, body weight of 14 d old survivors, and eggshell thickness.
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for clinical observations, gross pathology, feed consumption, body weight, eggshell thickness, reproductive parameters. Dose-response relationship demonstrated.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL () UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Zok, S. 2001d. Avian Dietary LC50 Test in Chicks of the Ring-necked Pheasant (*Phasianus colchicus*). BASF Aktiengesellschaft. Project ID 36W0466/99130. October 31, 2001. Unpublished report. CHA Doc. No. 468 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Ring-necked Pheasant (*Phasianus colchicus*)

Endpoint(s): 5 d (3 d observation) LD50 396 mg/kg diet
5 d (3 d observation) NOEL (survival) 150 mg/kg diet

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	Test guidelines: 1) US EPA EPA-540/9-82-024 (Avian dietary LC50 test), 2) EPA-540/9-85-008 (Standard Evaluation Procedure), 3) EPA 712-C-96-1409, OPPTS 850.2200 (Avian Dietary Toxicity Test) and 4) OECD Test Guideline 205 (Avian Dietary Toxicity Test).
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5), Purity: 99.1%, Cheminova Batch No. 20522-00
5	**Were the effects endpoints ecologically relevant?**	Y	LC50, NOEL Mortality, body weight, feed consumption, necropsy
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Exposure in feed for 5 d, plus a 3 d post-exposure period.
7	**Were appropriate controls included, reported and the results adequate?**	Y	Untreated control, 1/20 control animals died.

GENERIC CRITERIA		Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	Y	LD50 – probit analysis according to Finney, 1971. Body weight – one-way ANOVA followed by Dunnett's test.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 36, 75, 150, 300, and 600 mg active ingredient/kg diet Test substance was dissolved in 20 ml of acetone, then mixed with the diet.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	The concentration of the test substance in the test substance preparations was checked analytically at the beginning and end of exposure.
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Birds were acclimated for 7 d to test cages and conditions. Supplier: Gibis SARL, Chatte, France Sex: not determined Age: 12 d old at study start
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y*	Temperature: 21°C ± 2°C (an area with higher temperature was maintained by ceramic radiant heaters so that chicks could find their optimum conditions). Humidity: 50-75% (two slight deviations, at 46-49% for 18 h, and 48% for 3 h) Photoperiod: 16 h light: 8 h dark Density: 10 birds/pen
13	**Were individual body weights measured during testing and observation periods?**	Y	Individual body weights were recorded. Mean body weight was calculated for each pen on days 0, 5 and 8.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y	Ad libitum. Feed consumption was measured daily.
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for mortality, clinical signs, mean feed consumption, body weight. Dose-response for mortality demonstrated.

*See comments below

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:. Although the humidity fell outside the protocol range, the deviation was not large.

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Zok, S. 2001c. Avian Dietary LC50 Test in Chicks of the Bobwhite Quail (*Colinus virginianus*). BASF Aktiengesellschaft. Project ID 31W0466/99127. October 31, 2001. Unpublished report. CHA Doc. No. 469 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Northern Bobwhite Quail (*Colinus virginianus*)

Endpoint(s): 5 d (3 d observation) LD50 154 mg/kg diet (14.6 mg/kg bw/d)
5 d (3 d observation) NOEL (survival) 36 mg/kg diet

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	US EPA protocols: EPA/9-82-024 (Avian single-dose oral LD50 test), EPA-540/9-85-008 (Standard Evaluation Procedure), and EPA 712-C-96-140, OPPTS 850.2200 (Avian Dietary Toxicity Test), and OECD Test Guideline 205 (Avian Dietary Toxicity Test).
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5), Purity: 99.1%, Cheminova Batch No. 20522-00
5	**Were the effects endpoints ecologically relevant?**	Y	LC50, NOEL Mortality, body weight, feed consumption, necropsy
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Exposed to test substance in feed for 5 consecutive days, followed by at least 3 d of observation.
7	**Were appropriate controls included, reported and the results adequate?**	Y	Untreated control, no control mortality
8	**Were statistical procedures reported and appropriate?**	Y	Body weight – one-way ANOVA followed by Dunnett's test.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0, 36, 75, 150, 300 and 600 mg active ingredient/kg diet
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	Y	The concentration of the test substance in the diet was verified at the beginning and end of the exposure period.
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	Y	Birds were acclimated to test cages for 3 d. Supplier: test animals were bred in the testing facility Sex: not determined Age: 10 d old at study start
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	Y*	Temperature: 21°C ± 2 in the test room; heaters were used to allow chicks to find their optimum conditions (the temperature in the centre was 37.6°C – 41.2°C) Humidity: 50-75% (deviations were ≤ 2 h) Photoperiod: 16 h light: 8 h dark Density: 30 chicks/cage
13	**Were individual body weights measured during testing and observation periods?**	Y	Reported on days 0, 5 and 8
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	Y	Ad libitum. Mean feed consumption was measured.
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for mortality, clinical signs, mean feed consumption, body weight. Dose-response for mortality demonstrated.

* Parameters generally within acceptable ranges

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Zok, S. 2001a. Acute Toxicity in the Northern Bobwhite Quail (*Colinus virginianus*) After Single Oral Administration (LD50). BASF Aktiengesellschaft. Project ID 11W0466/99128. October 30, 2001. Unpublished report. CHA Doc. No. 470 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Northern Bobwhite Quail (*Colinus virginianus*)

Endpoint(s): 1 dose (14 d) LD50 (male and female survival) 10.5 mg/kg bw
1 dose (14 d) LD50 (male survival) 10.8 mg/kg bw
1 dose (14 d) LD50 (female survival) 10.2 mg/kg bw
1 dose (14 d) NOEL (survival) 5 mg/kg bw

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	Test design followed the requirements of US EPA protocols: EPA/9-82-024 (Avian single-dose oral LD50 test), EPA-540/9-85-007 (Standard Evaluation Procedure), and EPA 712-C-96-139, OPPTS 850.2100 (Avian Acute Oral Toxicity Test).
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5) Purity: 99.1%, Cheminova Batch No. 20522-00
5	**Were the effects endpoints ecologically relevant?**	Y	LD50 (and LD0 and LD100 if possible), NOEL, LOEL Mortality, body weight, feed consumption, necropsy
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Single dose, by gavage followed by 14 d observation period
7	**Were appropriate controls included, reported and the results adequate?**	Y	Carrier control, no control mortality.

	GENERIC CRITERIA	Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	**Y**	LD50 – probit analysis according to Finney, 1971. Body weight – parametric one-way ANOVA via F-test. If p-value was ≤ 0.05, comparisons were done via Dunnett's test.

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	**Y**	0, 5, 10, 20, 40, 80 and 160 mg a.i./kg bw [0, 5.0, 10.1, 20.2, 40.4, 80.7 and 161.5 mg a.i./kg bw) Test substance was suspended in 0.5% aqueous CMC (carboxy methyl cellulose) The concentration of the test substance in the test substance preparations was checked analytically.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	**n/a**	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	**Y**	Birds were acclimated to housing conditions for 7 d after arrival at the laboratory, followed by an acclimation period of an additional 9 days to test cages. Supplier: H&E Kuberich, Geesdorf/Wiesentheid, Germany Sex: Male and female Age: Approx. 6 mo at study start, before their first egg-laying season
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y***	Temperature: 21°C ± 2°C Humidity: 45-70% (deviations were generally ≤ 2 h, with 2 exceptions) Photoperiod: 8 h light: 16 h dark Density: 5 birds/cage; males and females caged separately
13	**Were individual body weights measured during testing and observation periods?**	**Y**	Reported on days 0, 7 and 14
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	**n/a**	

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for mortality, clinical signs, mean feed consumption, body weight. Dose-response for mortality demonstrated. Decreased feed consumption was observed in 10 mg/kg dose group; no effect in 5 mg/kg dose group. No effect could be measured in other dose groups due to mortality. No statistically signficant effect on body weight in 5 or 10 mg/kg dose groups; no effect could be observed in other dose groups due to mortality.

* Parameters generally within acceptable ranges

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments: This study is considered acceptable although humidity fell outside the acceptable range, generally for short periods of time.

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Zok, S. 2001b. Acute Toxicity in the Ring-necked Pheasant (*Phasianus colchicus*) After Single Oral Administration (LD50). BASF Aktiengesellschaft. Project ID 12W0466/99126. October 30, 2001. Unpublished report. CHA Doc. No. 471 DMT.

Secondary reference: n/a

Is the primary reference study a GLP study?: Yes

Species tested: Ring-necked Pheasant (*Phasianus colchicus*)

Endpoint(s): 1 dose (14 d) LD50 (male and female survival) 14.1 mg/kg bw
1 dose (14 d) NOEL (male survival) 5 mg/kg bw
1 dose (14 d) NOEL (female survival) 10 mg/kg bw

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	Y	Test design followed the requirements of US EPA protocols: EPA/9-82-024 (Avian single-dose oral LD50 test), EPA-540/9-85-007 (Standard Evaluation Procedure), and EPA 712-C-96-139, OPPTS 850.2100 (Avian Acute Oral Toxicity Test).
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	n/a	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y	Dimethoate (CAS 60-51-5), Purity: 99.1%, Cheminova Batch No. 20522-00
5	**Were the effects endpoints ecologically relevant?**	Y	LD50 (and LD0 and LD100 if possible), NOEL, LOEL Mortality, body weight, feed consumption, necropsy
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Single dose, by gavage, followed by 14 d observation period
7	**Were appropriate controls included, reported and the results adequate?**	Y	Carrier control, no control mortality

GENERIC CRITERIA		Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	**Y**	LD50 – probit analysis according to Finney, 1971. Body weight – parametric one-way ANOVA via F-test. If p-value was ≤ 0.05, comparisons were done via Dunnett's test.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	**Y**	0, 5.0, 10.1, 20.2, 40.4, and 80.7 mg technical test substance/kg bw, 0, 5, 10, 20, 40, and 80 mg a.i./kg bw corrected for content of active ingredient. The concentration of the test substance in the test substance preparations was verified analytically.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	**n/a**	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	**Y**	Birds were acclimated to housing conditions for 7 d after arrival at the laboratory, followed by an acclimation period of an additional 7 days to test cages. Supplier: Gibis SARL, Chatte, France Sex: Male and female Age: Approx. 11 mo at study start; before their first egg-laying season
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y**	Temperature: 18°C ± 2°C Humidity: 35-70% (deviations were generally ≤ 2 h, with 2 exceptions) Photoperiod: 6 h light: 18 h dark Density: 5 birds/cage; males and females caged separately
13	**Were individual body weights measured during testing and observation periods?**	**Y***	Reported on days 0 and 14 only. Body weight was not recorded on Day 7, which deviates from OPPTS-Guideline 850.2100.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	**n/a**	

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	Y	Raw data reported for mortality, clinical signs, mean feed consumption, body weight. Dose-response for mortality demonstrated. No definitive conclusions on feed consumption. No statistically significant effect on body weight surviving birds.

*See comments below

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: (X) ACCEPTABLE ( ) SUPPLEMENTAL ( ) UNACCEPTABLE

Comments:. The Study Director states that, although body weights were erroneously not determined on Day 7, the NOEL can still be determined with sufficient certainty despite lack of these data.

Unacceptable studies

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Bakre, P., and M. Rajasekaran. 1989. Acute toxicity of certain pesticides to house sparrow, *Passer domesticus*. Geobios; 16(6): 249-251

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species tested: House sparrow (*Passer domesticus*)

Endpoint(s): 1 dose LD50 18.75 mg/kg bw

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate (30EC)
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	N	No supporting documentation was referenced for study design.
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	N	Minimal information was provided regarding laboratory practice. Birds (n=10/dose group; 5 dose groups) were exposed to dimethoate and malathion as emulsions in water given orally (a.i. mg/kg bw) with a syringe.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	% a.i., sources of a.i. and purity of a.i. not provided.
5	**Were the effects endpoints ecologically relevant?**	Y	LD50
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Single dose administred; toxic symptoms observed within 15 or 20 min (i.e., reduced activity, ataxia, heavy breathing, leg paralysis, huddling, wing beat convulsions). Mortalities observed within 6 or 8 h of exposure; at higher doses (not identified) mortality was observed within 20 min of exposure.
7	**Were appropriate controls included, reported and the results adequate?**	N	No control birds appear to have been incorporated into study design.

GENERIC CRITERIA		Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	**N**	LD50 determined graphically based on Ipsen and Feigl method (1970).

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	**Y**	Dimethoate: 200, 400, 600, 800, 1000 mg/kg bw
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	**n/a**	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	**Y/N**	Adult wild-caught birds were laboratory acclimated for one week; sex and mass not specified.
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**N**	Not specified
13	**Were individual body weights measured during testing and observation periods?**	**N**	Not specified
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	**n/a**	
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	**n/a**	Not applicable
16	**Was a concentration- or dose-response relationship demonstrated?**	**N**	Numeric data not presented and dose-response curve was estimated graphically; LD50 dimethoate=18.75 mg/kg bw

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Brunet, R., C. Girard, and A. Cyr. 1997. Comparative study of the signs of intoxication and changes in activity level of red-winged blackbirds (*Agelaius phoeniceus*) exposed to dimethoate. Agr Ecosyst Environ 64:201-209.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species tested: Red-winged blackbird (*Agelaius phoeniceus*)

Endpoint(s): 1 dose (24 h) 9.9 mg/kg bw

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate (Cygon 2E)
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	N	
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	N	
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Dimethoate (Cygon 2E), purity not reported (24.9g dimethoate per 100 mL Cyclo-Sol 63 (American Cyanamid Co.).
5	**Were the effects endpoints ecologically relevant?**	Y	LD50 Symptoms of intoxication (mortality, ataraxia, hyperexcitability, tremors, vomiting, etc.)
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	24 h after one gavage dose
7	**Were appropriate controls included, reported and the results adequate?**	Y	Water control, no mortality in controls
8	**Were statistical procedures reported and appropriate?**	Y	LD50 - probit analysis Intoxication symptoms significance of linear relationships was tested by an analysis of variance.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	**Y/N**	For LD50 calculation, the doses ranged from 0-30 mg/kg bw. They were "force-fed" by gavage using a cannula inserted into the crop.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	**n/a**	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	**Y/N**	Adult birds were captured from the wild, acclimated for at least 1 mo, sex or weight were not reported.
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**Y**	Humidity: 47±5%, temperature 23±0.5°C, phototperiod 12 h light:12 h dark under natural intensity. Birds held in individual cages.
13	**Were individual body weights measured during testing and observation periods?**	**N**	Body weights were not reported.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	**n/a**	
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	**n/a**	
16	**Was a concentration- or dose-response relationship demonstrated?**	**N**	Figures provided but raw data were not provided for mortality (LD50 study).

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: () ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments:.

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Hill, E.F., R.G. Heath, J.W. Span, and J.D. Williams. 1975. Lethal Dietary Toxicities of Environmental Pollutants to Birds. U.S. Fish and Wildlife Service Special Scientific Report—Wildlife No. 191. Washington, D.C. CHA Doc. No. DMT-LIT 1.

Secondary reference: n/a

Is the primary reference study a GLP study?: No

Species tested: Japanese quail (*Coturnix c. japonica*), ring-necked pheasants (*Phasianus colchicus*) and mallards (*Anas platyrhynchos*)

Endpoint(s): 5 d (3 d observation) LC50 346 mg/kg diet (Cortunix cortunix)
5 d (3 d observation) LC50 1011 mg/kg diet (*Anas platyrhynchos*)
5 d (3 d observation) NOEL (survival) 375 mg/kg diet (*Anas platyrhynchos*)
5 d (3 d observation) NOEL (body weight) 94 mg/kg diet (*Anas platyrhynchos*)
5 d (3 d observation) LD50 332 mg/kg diet (*Phasianus colchicus*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Technical" dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	N	Not specified.
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	N	Test methods not provided.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Dimethoate (Purity: 99%) Source not provided.
5	**Were the effects endpoints ecologically relevant?**	Y	Mortality, growth
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Exposed to test substance in feed for 5 consecutive days, followed by 3 d of observation.
7	**Were appropriate controls included, reported and the results adequate?**	Y/N	Feed treeted with corn oil was the control. Propylene glycol was the carrier; no control for propylene glycol was tested. Results not reported

	GENERIC CRITERIA	Y/N	COMMENTS
8	**Were statistical procedures reported and appropriate?**	Y	LC50 – probit analysis described by Finney (1952).

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	N	Not specified
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	N	Not specified
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	N	No information provided regarding acclimation. Supplier: All test birds were incubator-hatched progeny of outbred Patuxent colonies. Colony origins were noted. Sex: not specified (may be too young to determine) Age: 10 d old for pheasants and mallards; 14 d old for quail
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	Test conditions not reported
13	**Were individual body weights measured during testing and observation periods?**	N	Not reported
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	N	Ad libitum. Feed consumption was measured at 24 h intervals; no data reported.
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	N	No raw data reported

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Hudson, R.H., Tucker, R.K. and M.A. Haegele. 1984. Handbook of Toxicity of Pesticides to Wildlife. Second Edition. Dimethoate. Page 32. United States Department of the Interior. Fish and Wildlife Service, Resource Publication 153. Washington, D.C.

Secondary reference: not specified

Is the primary reference study a GLP study?: No

Species tested: Mallard (*Anas platyrhynchos*) and Pheasant (*Phasianus colchicus*)

Endpoint(s): 1 dose (14 d) LD50 41.7 mg/kg bw (*Anas platyrhynchos*) (purity 97%)
1 dose (14 d) LD50 63.5 mg/kg bw (*Anas platyrhynchos*) (purity 99.8%)
1 dose (14 d) LD50 20 mg/kg bw (*Phasianus colchicus*)

	GENERIC CRITERIA	Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate (CAS 60-51-5)
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	N	No details provided
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	N	No details provided
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	Y/N	Dimethoate (Purity: 97%) Received from manufacturer
5	**Were the effects endpoints ecologically relevant?**	Y	Mortality
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Single oral dose; 14 d observation period.
7	**Were appropriate controls included, reported and the results adequate?**	N	Details not provided
8	**Were statistical procedures reported and appropriate?**	N	Details not provided

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	**N**	Details not provided; usually 4 dose levels.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	**n/a**	Oral administration via gelatin capsule into the crop, proventriculus or stomach (no carrier).
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	**N**	Source: Pen-reared from stock lines
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	**N**	Details not provided
13	**Were individual body weights measured during testing and observation periods?**	**N**	Animals were weighed on the morning of the test.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	**n/a**	
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	**n/a**	
16	**Was a concentration- or dose-response relationship demonstrated?**	**N**	Details not provided.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments: Few study details provided; this is a handbook compilation of studies conducted at Patuxent.

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Levinskas, G.J. 1965. Dimethoate: Demyelination Studies in White Leghorn Hens. American Cyanamid Company. Report number 65-56. Unpublished study.

Secondary reference:

Is the primary reference study a GLP study?: No

Species tested: Leghorn hens (*Gallus Gallus domesticus*)

Endpoint(s): 1 dose LD50 50 mg/kg bw

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	**N**	Dimethoate
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	**N**	
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	**N**	This is a single dose and 1 mo repeated feeding study. Details about study design are lacking.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	**Y**	98.1% dimethoate, lot number W-40403-1, supplied by Research and Development Department, Agricultural Division, Princeton.
5	**Were the effects endpoints ecologically relevant?**	**Y**	Mortality (LD50) and weight changes.
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	**Y**	Single dose: 7 d acute study Repeat feeding: 4 wk exposure followed by sacrifice and some birds given basal diet for 4 more weeks and then sacrificed.
7	**Were appropriate controls included, reported and the results adequate?**	**Y/N**	1 control bird died 26 d after start of testing.
8	**Were statistical procedures reported and appropriate?**	**N**	Statistical approach for deriving LD50 not discussed.

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	Single dose study: 17.5, 35, 70 ppm (n=4/group) Repeat feeding study: controls (n=12), 65, 130, 260 ppm (n=6/group)
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	n/a	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	N	Adult hens (at least 1-2 yr of age if not older) from Kerr Chickeries, New Jersey.
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	Room temperature: 75°F ± 3 °F Relative humidity: 40-60% Photoperiod not reported
13	**Were individual body weights measured during testing and observation periods?**	Y	At initiation of repeat study, at week 2 and 4.
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	N	
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	n/a	
16	**Was a concentration- or dose-response relationship demonstrated?**	N	Single dose study: LD50 of 50 mg/kg bw Repeat study: one mortality at 65 ppm and 130 ppm (9 and 4 d after return to basal diet, respectively) Dose-response not demonstrated.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

Study Quality and Acceptability Evaluation

Compound: Dimethoate

Study reference (Primary): Schafer, E.W. 1972. The Acute Oral Toxicity of 369 Pesticidal, Pharmaceutical and Other Chemicals to Wild Birds. Toxicology and Applied Pharmacology 21: 315-330. [this paper is simply reporting the results as per Schafer, 1982.] CHA Doc. No. DMT-LIT 2.

Secondary reference: Schafer, E.W. Jr. 1982. Letter with attached bird toxicity test results. Unpublished. USFWS, Denver WRC, Denver, CO.

Is the primary reference study a GLP study?: No

Species tested: Red-winged blackbird (*Agelaius phoeniceus*); European starling (*Sturnus vulgaris*)

Endpoint(s): 1 dose LD50 32 mg/kg bw (*Strunus vulgaris*)
1 dose LD50 17.8 mg/kg bw, 8.8 mg/kg bw, 5.4 mg/kg bw (*Agelaius phoeniceus*)

GENERIC CRITERIA		Y/N	COMMENTS
1	**Single chemical exposure?**	Y	Dimethoate technical grade
2	**Was the study conducted according to a recognized international standard (OPPTS, OECD, ASTM, ISO, etc.)?**	N	Test methods roughly consistent with guidelines (7/10/78), with many discrepancies (different type of species, concurrent controls not cited, fast period was shorter than specified, most environmental conditions not reported, number of birds tested below number specified). The reviewer (James Felkel) stated no individual test could be considered to fully meet the intent of the proposed guidelines).
3	**If NO to 2, was a complete description given of the physical test system and methods? Were the methods used considered acceptable laboratory practices?**	N	No information on the test was provided except nominal test concentrations.
4	**Were the identification, purity and source of test substance given and comparable to the current technical material and formulation?**	N	Dimethoate (% a.i. not cited) Source not provided.
5	**Were the effects endpoints ecologically relevant?**	Y	Mortality

	GENERIC CRITERIA	Y/N	COMMENTS
6	**Were an appropriate exposure duration and post-exposure observation period used and reported?**	Y	Single dose, by gavage. Time to each death was recorded.
7	**Were appropriate controls included, reported and the results adequate?**	N	No controls
8	**Were statistical procedures reported and appropriate?**	N	No stats done; LD50 was ball-parked by looking at test data. The reviewer (James Felkel) did probit analysis on the LD50 data; he could only confirm the red-winged blackbird test dated 5/11/62 with an LD50 = 5.4 mg/kg)

	CRITERIA FOR AN ACCEPTABLE STUDY	Y/N	COMMENTS
9	**Were test diet concentrations or doses provided?**	Y	0.88, 1.56, 2.8, 5.0, 8.8, 15.0, and 25.0 mg/kg bw (red-winged blackbird) 18, 25, 32, 40 and 50 mg/kg bw (starling) Test substance was suspended in propylene glycol. The concentration of the test substance was not checked analytically.
10	**Were test diet concentrations or doses measured (acute and chronic) / maintained (chronic)?**	n/a	
11	**Were the test species acclimated and characteristics of the test species reported (e.g., source, sex, age, weight)?**	N	Birds were preconditioned to captivity. Supplier: wild-trapped birds Sex: Male and female (starlings) Only male red-winged blackbirds Age: not specified
12	**Were appropriate test conditions (e.g., temperature, light intensity, humidity, photoperiod, loading density, etc.) measured, reported and within acceptable ranges?**	N	Test conditions not reported
13	**Were individual body weights measured during testing and observation periods?**	N	Not reported
14	**For dietary studies, was feeding consumption measured, or at least estimated, during the study?**	n/a	

CRITERIA FOR AN ACCEPTABLE STUDY		Y/N	COMMENTS
15	**For reproduction tests, were the number of eggs laid, egg shell thickness, development of the eggs, viability of the embryos, percent hatchability and offspring survival and growth measured and evaluated?**	**n/a**	
16	**Was a concentration- or dose-response relationship demonstrated?**	**Y**	Raw data reported for mortality. Dose-response only confirmed with statistical analysis for red-winged blackbird study.

CRITERIA FOR A SUPPLEMENTAL STUDY

Studies that meet the generic criteria only.

UNACCEPTABLE STUDY

Studies that do not meet the generic criteria.

EVALUATION: ( ) ACCEPTABLE ( ) SUPPLEMENTAL (X) UNACCEPTABLE

Comments:

APPENDIX E
BENCHMARK DOSE ANALYSIS

The effects metric used in this effects determination for determining chronic risk to terrestrial-phase CRLF and birds was a NOEL of 10.1 mg/kg diet, as reported by Gallagher et al. (1996a [MRID 44049001]). EPA used the same study in their ERA to assess chronic risk to birds. However, they calculated and used a NOEL of 4 mg/kg diet.

Cheminova re-analyzed the study data of Gallagher et al. (1996a) using the Benchmark Dose (BMD) methodology (Crump et al., 1995; EPA, 2000) and available EPA BMD analysis software (EPA, 2008d) to derived a more scientifically defensible effects metric for birds.

The BMD analysis of the data from the northern bobwhite reproduction study (Gallagher et al., 1996a) was submitted to the Agency (Reiss, 2009c). The results of this analysis are summarized in Table E-1 below. The lowest BMD_{σ} was for the number of eggs laid and the resulting $BMDL_{\sigma}$ (lowest BMD_{σ}) for this endpoint was 12.4 mg/kg diet. The lowest $BMDL_{\sigma}$ is similar to the 10.1 mg/kg NOEL reported by Gallagher et al. (1996a).

Table E-1 Summary of BMD analysis for northern bobwhite reproduction study

Endpoint	***BMD_{σ} (mg/kg diet)***	***$BMDL_{\sigma}$ (mg/kg diet)***
Body weight, males at 6 wk	26.4	15.1
Body weight, females at 2 wk	38.8	24.2
Number of eggs laid	16.1	12.4
Weekly eggs laid	23.2	15.9
Number of hatchlings	19.7	14.6
Hatchling survival at day 14	18.7	14.0
14 d survivor body weight	21.9-63.4	14.5-30.0

APPENDIX F
JUSTIFICATION FOR NOT ASSESSING DIMETHOATE METABOLITES

Justification for Not Assessing Metabolites of Dimethoate

Data on the occurrence and toxicity of dimethoate metabolites suggest that risks associated with metabolites are likely negligible for both direct and indirect effects to CRLF. Therefore, risk of metabolites to CRLF, their prey and habitat was not investigated in this refined effects determination.

Aquatic Assessment

Three main degradation products of dimethoate have been observed after field application, namely omethoate, O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid.

O-desmethyl dimethoate and O,O-dimethyl thiophosphoric acid are not toxic to aquatic species (Hertl, 2001a,b,c; 2002a,b). Hertl (2001a,b,c) estimated that the 96h-LC50, 72h-EC50 and a 48h-LC50 to be >100 mg/L for rainbow trout (*Oncorhynchus mykiss*), algae (*Scenedesmus subspicatus*) and *Daphnia magna* exposed to O-desmethyl dimethoate, respectively. Similarly, O,O-dimethyl thiophosphoric acid was found to have low toxicity to rainbow trout (*Oncorhynchus mykiss*) and *Daphnia magna* with a 96h-LC50 of >1000 mg/L and 48h-EC50 of 70.5 mg/L, respectively (Hertl, 2002a,b).

Omethoate has not been reported as a metabolite in laboratory fate and behaviour studies in various media. In a study examining dimethoate elimination in natural river and pond water/sediment systems, the only major metabolite was characterized as desmethyldimethoate, with unidentified minor metabolites occurring at less than 3.7% (Völkl, 1993 [MRID 47784101]). In a photodegradation study with 14-C dimethoate in water, omethoate was not detected after 15 d exposure to artificial sunlight (Hawkins et al., 1986b [MRID 00159762]). In sandy loam soil exposed to natural sunlight, omethoate was not detected after 30 days, and the major metabolites were dimethylthiophosphoric acid and dimethylphosphoric acid (Skinner and Shelper, 1994 [MRID 43276401]). In an anaerobic soil metabolism study, the metabolites of 14-C dimethoate were found to be O-desmethyldimethoate, dimethylphosphorothioic acid, as well as unknown compounds, while omethoate was not detected (Hawkins et al., 1986d). Similarly, in another anaerobic soil study, omethoate was not detected as a degradation product of dimethoate applied to sandy loam soil for 60 d (Hawkins et al., 1990 [MRID 42884402]).

In 2011, the PDP released their annual report for the 2009 calendar year (USDA, 2011). Monitoring data were contributed by 12 states (i.e., CA, CO, FL, MD, MI, MN, MO, NY, OH, TX, WA, and WI). Media sampled included finished and raw water for drinking and potable groundwater from domestic wells (agricultural/farm wells, school or childcare facility wells, and private domestic wells). For potable groundwater a total of 278 groundwater samples were collected with 19 pesticides represented. Dimethoate was not detected in any of the 278 groundwater samples collected. In 2009, PDP analyzed 612 drinking water samples, 306 finished drinking water samples and 306 untreated (raw) drinking water samples. Omethoate was detected in three finished water samples. Detections ranged from 0.0005 µg/L to 0.004

µg/L. The detection limit for omethoate was 0.0003 µg/L (USDA, 2011). Omethoate is not expected to be a major degradate in water except as a result of chlorination for drinking water treatment (EPA, 2008c). In addition, the new restrictions identified in the RED are expected to reduce the magnitude and frequency of detections of dimethoate and omethoate in drinking and surface water (EPA, 2008c).

Since there is strong evidence that omethoate is not produced in the aquatic environment, and because other metabolites are practically non-toxic to aquatic organisms tested, no metabolites of dimethoate were considered in the aquatic effects determination.

Terrestrial Assessment

Omethoate has been observed to form on avian and mammalian food items (e.g., insects and plants) after dimethoate products are applied (Corden, 2000, 2001, 2005; Goodband, 2003; Knäbe, 2004a, Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001 a-l; 2002a-f, 2003a,b). In these studies, omethoate only occured at low concentrations on feed items relative to the concentrations of dimethoate measured. In addition, peak concentrations of omethoate occured after much of the dimethoate had degraded (Corden, 2000, 2001, 2005; Goodband, 2003; Knäbe, 2004a, Pollman, 2006; Raufer, 2009a-d; Wilson, 2000, 2001 a-l; 2002a-f, 2003a,b). Both omethoate and dimethoate have the same mode of action.

Birds were selected as a surrogate taxon for CRLF, in absence of terrestrial-phase amphibian toxicity data. A large data set of avian toxicity studies on dimethoate and omethoate was provided to the Agency (Table F-1). These studies indicate that dimethoate and omethoate are similarly toxic to birds. In the acute oral toxicity studies, the toxicity ratios for dimethoate and omethoate range from 0.49 (dimethoate more toxic) to 1.1 (omethoate more toxic). In the dietary toxicity studies, the range spans from 0.5 (dimethoate more toxic) to 1.7 (omethoate slightly more toxic). The results of a recent comparative chronic toxicity study with northern bobwhite quail reported a common NOEL of 12 mg/kg diet (1.1 mg a.i./kg bw/d) for reproductive effects of both omethoate and dimethoate (Temple et al., 2010). Given the natural variability in the test systems and expected inter- and intra-laboratory variability in experimental procedures, we believe that the two substances have similar toxicity. The expanded data set of available avian toxicity studies on dimethoate and omethoate clearly supports the Agency's earlier conclusion, based on fewer data, that the toxicity of dimethoate and omethoate to birds is essentially the same (EPA, 2008a).

Table F-1 Comparison of toxicities of technical dimethoate and omethoate to birds.

Family	*Species*	*Test Substance*	*Endpoint*[a]	*Reference [MRID]*	*Study Rating*	*Ratio Parent/Oxon*
Anatidae	Mallard duck (*Anas platyrhynchos*)	Dimethoate	Acute oral LD50 = 41.7 mg/kg bw (97% a.i.) LD50 = 63.5 mg/kg bw (99.8% a.i.)	Hudson et al., 1984 [00160000]	Unacceptable	—
		Dimethoate	5 d dietary LC50 = 1066 mg/kg diet	Hubbard et al., 2009c [47744401]	Acceptable	0.78
		Dimethoate	5 d dietary LC50 = 1011 mg/kg diet	Hill et al., 1975 [00022923]	Unacceptable	
		Omethoate	5 d dietary LC50 = 1374 mg/kg diet	Hubbard et al., 2009b [47709502]	Acceptable	—
		Dimethoate	22 wk[b] NOEL = 35.4 mg/kg diet 22 wk[b] LOEL = 152 mg/kg diet (Reduction in adult body weight and feed consumption, egg production and embryo viability)	Gallagher et al., 1996b [43967101]	Acceptable	—
Icteridae	Red-winged blackbird (*Agelaius phoeniceus*)	Dimethoate	Acute oral LD50 = 5.4 mg/kg bw	Schafer 1972 [0020560]	Unacceptable	—
		Dimethoate	Acute oral LD50 = 9.9 mg/kg bw	Brunet et al., 1997	Unacceptable	—
Odontophoridae	Northern bobwhite quail (*Colinus virginianus*)	Dimethoate	Acute oral LD50 = 10.5 mg/kg bw	Zok 2001a [47769701]	Acceptable	1.1
		Omethoate	Acute Oral LD50 = 9.9 mg/kg bw	Gallagher et al., 2003a [47769703]	Acceptable	—
		Dimethoate	5 d dietary LC50 = 154 mg/kg diet	Zok 2001c [47769705]	Acceptable	1.7
		Omethoate	5 d dietary LC50 = 90 mg/kg diet	Hubbard et al., 2009a [47709501]	Acceptable	—
Odontophoridae	Northern bobwhite quail (*Colinus virginianus*)	Dimethoate	22 wk[b] NOEL = 10.1 mg/kg diet 22 wk[b] LOEL = 35.4 mg/kg diet (Reduction in adult body weight and feed consumption, egg production and hatchling survivorship)	Gallagher et al., 1996a [44049001]	Acceptable	0.84

Table F-1 Comparison of toxicities of technical dimethoate and omethoate to birds.

Family	*Species*	*Test Substance*	*Endpoint*[a]	*Reference [MRID]*	*Study Rating*	*Ratio Parent/Oxon*
Odontophoridae	Northern bobwhite quail (*Colinus virginianus*)	Dimethoate	10 wk[b] NOEL (weight gain, reproduction) = 12 mg/kg diet (1.1 mg a.i./kg/day) 10 wk[b] NOEL (mortality) = 30 mg/kg diet 10 wk[b] LOEL (weight gain, reproduction) = 30 mg/kg diet 10 wk[b] LOEL (mortality) = 75 mg/kg diet	Temple et al., 2010	Acceptable	2.5 (mortality) 1 (growth and reproduction)
		Omethoate	10 wk[b] NOEL (mortality, weight gain[c], reproduction[c]) = 12 mg/kg diet (1.1 mg a.i./kg/day) 10 wk[b] LOEL (mortality, weight gain[c], reproduction[c]) = 30 mg/kg diet	Temple et al., 2010	Acceptable	
Phasianidae	Ring-necked pheasant (*Phasianus colchicus*)	Dimethoate	Acute oral LD50 = 20 mg/kg bw	Hudson et al., 1984 [00160000]	Unacceptable	—
		Dimethoate	Acute oral LD50 = 14.1 mg/kg bw	Zok 2001b [47769702]	Acceptable	0.49
		Omethoate	Acute oral LD50 = 29 mg/kg bw	Gallagher et al., 2003b [47768704]	Acceptable	—
		Dimethoate	5 d dietary LC50 = 332 mg/kg diet	Hill et al., 1975 [0022923]	Unacceptable	—
		Dimethoate	5 d dietary LC50 = 396 mg/kg diet	Zok 2001d [47769706]	Acceptable	—
	Japanese quail (*Coturnix coturnix*)	Dimethoate	5 d dietary LC50 = 346 ppm	Hill et al., 1975 [00022923]	Unacceptable	—
		Dimethoate	6 wk[b] NOEL (Body Weight) = 10 mg/kg diet 6 wk[b] LOEL (Body Weight) = 35 mg/kg diet	Solecki et al., 2001	Acceptable	—
Sturnidae	European starling (*Sturnus vulgaris*)	Dimethoate	Acute oral LD50 = 32 mg/kg bw (99.8% purity)	Schafer, 1972 [00020560/FEODIM04]	Unacceptable	—

[a] New acute gavage studies with the mallard duck (*Anas platyrhynchos*) and canary (*Serinus canaria*) to be conducted in early 2012.
[b] One-generation reproduction study.
[c] The authors reported that statistical analyses were not performed on the LOEL group to confirm significant effects to weight gain and reproduction because of significant mortality at this dosing level. The measured data suggest that these effects were likely significant despite low sample size due to mortality.

Given that omethoate is only produced on terrestrial feed items in small amounts, which peak after much of the dimethoate has already degraded, and given that omethoate and dimethoate appear to be equivalently toxic to birds tested, it seems that any risk associated with omethoate exposure is likely negligible for terrestrial-phase CRLF. For these reasons omethoate was not considered in the terrestrial effects determination.

Small mammals are not a common prey item of CRLF. However, a study by Hayes and Tennant (1985) suggests that adult CRLF may on occasion consume mice (Hayes and Tennant, 1985). Radiolabelled omethoate, was rapidly excreted in rats within 48 h (88-98% of radioactivity) following single and 14-day exposures to dimethoate (Hoshino, 1989). Given the low concentrations of omethoate expected on the feed items of small mammals, and this observed rapid omethoate excretion in mammals, it is expected that omethoate in mammalian prey does not pose a significant risk to CRLF. For these reasons omethoate was not considered in the terrestrial effects determination.

APPENDIX G
RISK CURVES FOR THE REFINED TERRESTRIAL EFFECTS DETERMINATION

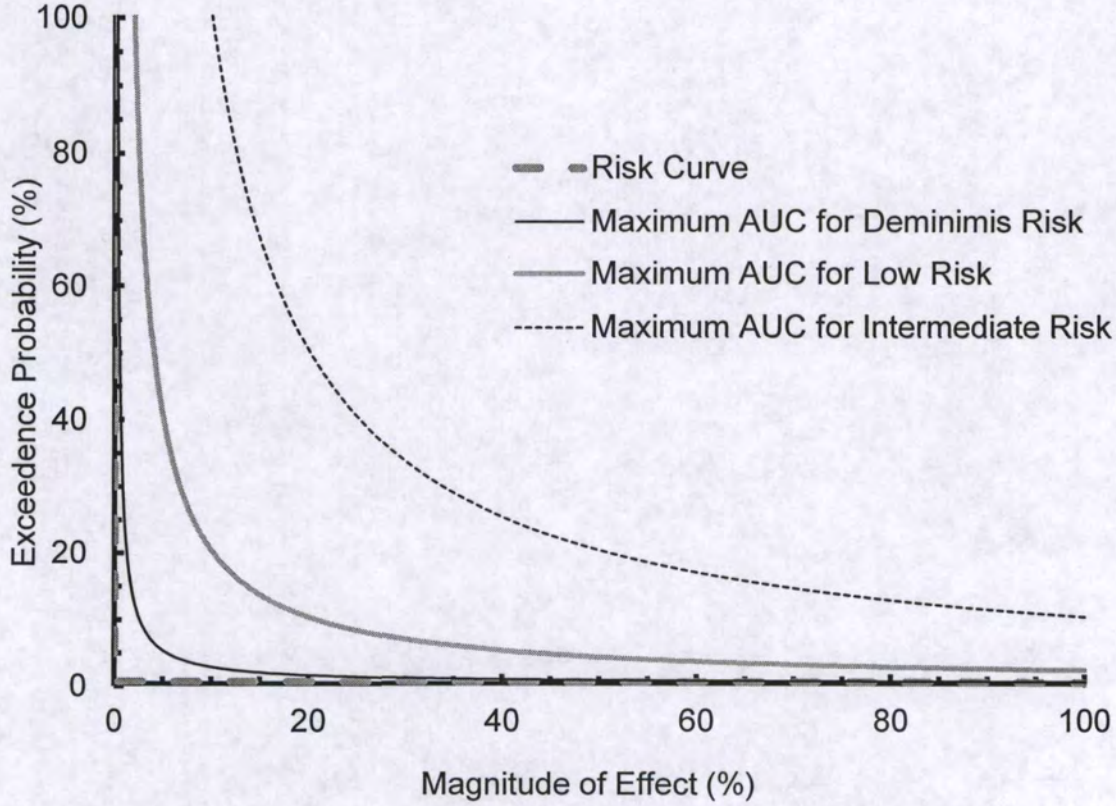

Figure G-1 **Risk curve for acute exposure of juvenile CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to ground application of dimethoate to Christmas tree nurseries (1 lb a.i./A, three times per year, with a 14-day retreatment interval).**

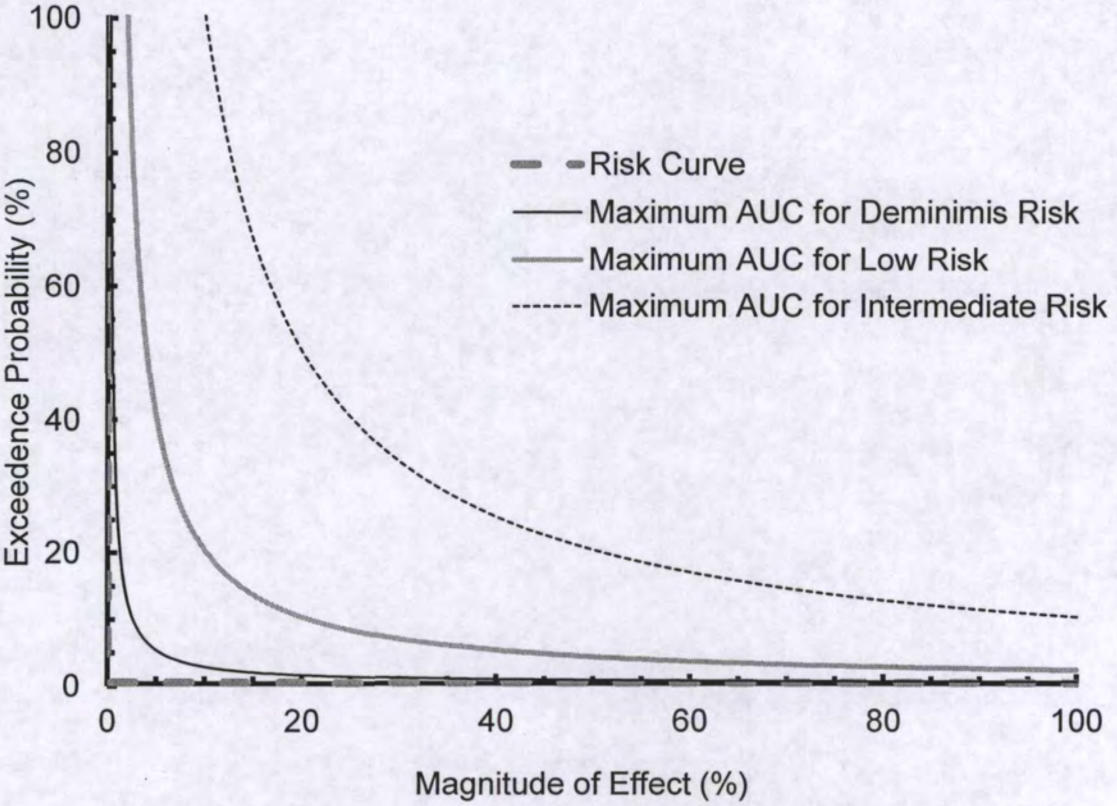

Figure G-2 Risk curve for acute exposure of juvenile CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to airblast application of dimethoate to Christmas tree nurseries (1 lb a.i./A, three times per year, with a 14-day retreatment interval).

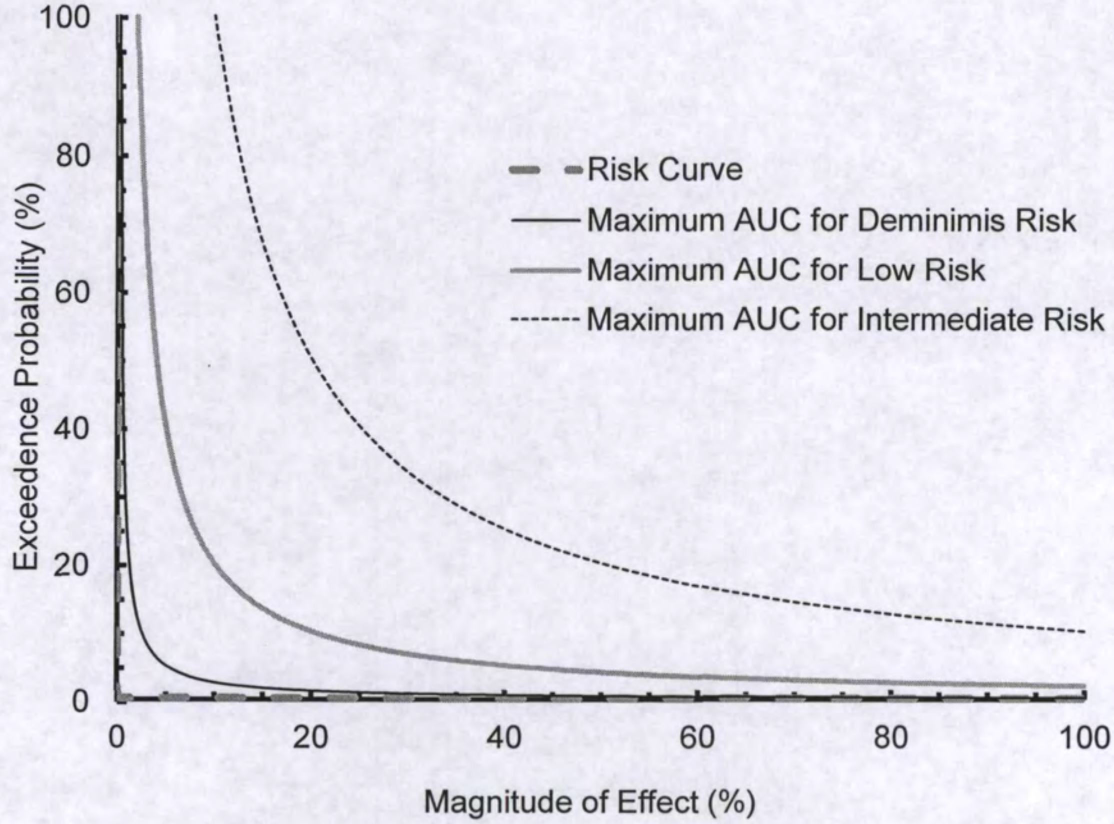

Figure G-3 **Risk curve for acute exposure of adult CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to ground application of dimethoate to Christmas tree nurseries (1 lb a.i./A, three times per year, with a 14-day retreatment interval).**

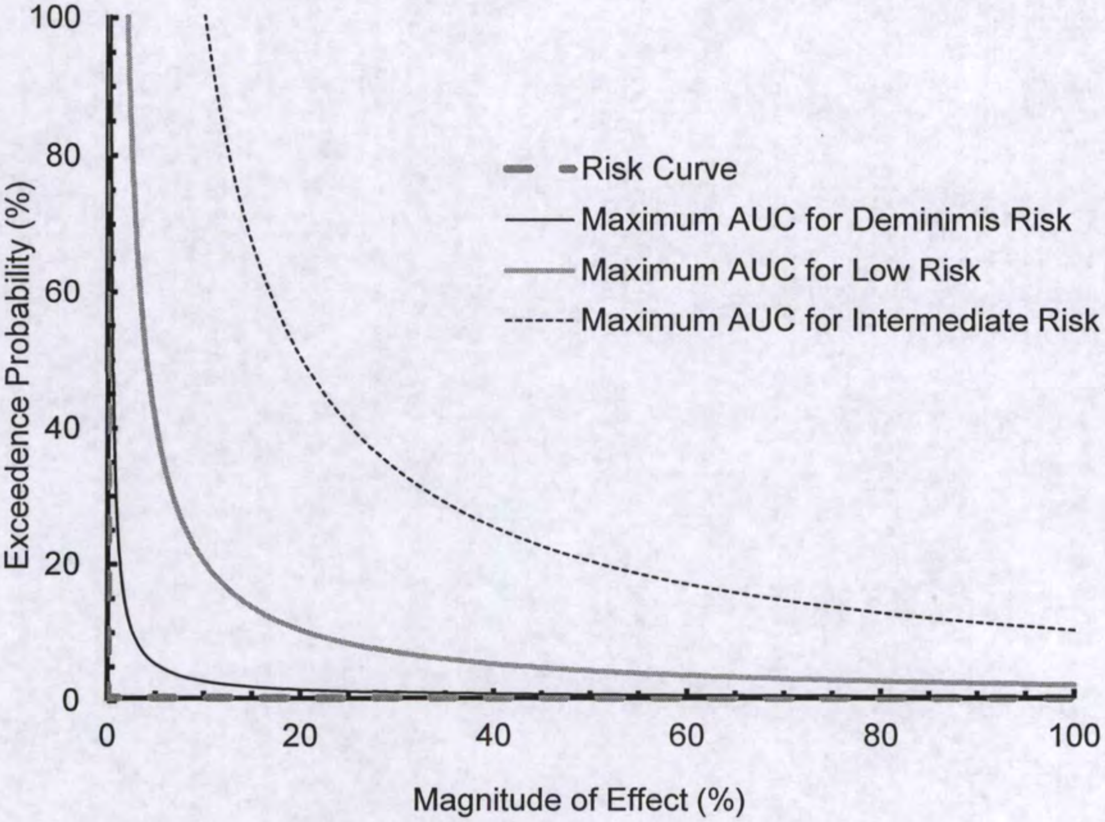

Figure G-4 **Risk curve for acute exposure of adult CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to airblast application of dimethoate to Christmas tree nurseries (1 lb a.i./A, three times per year, with a 14-day retreatment interval).**

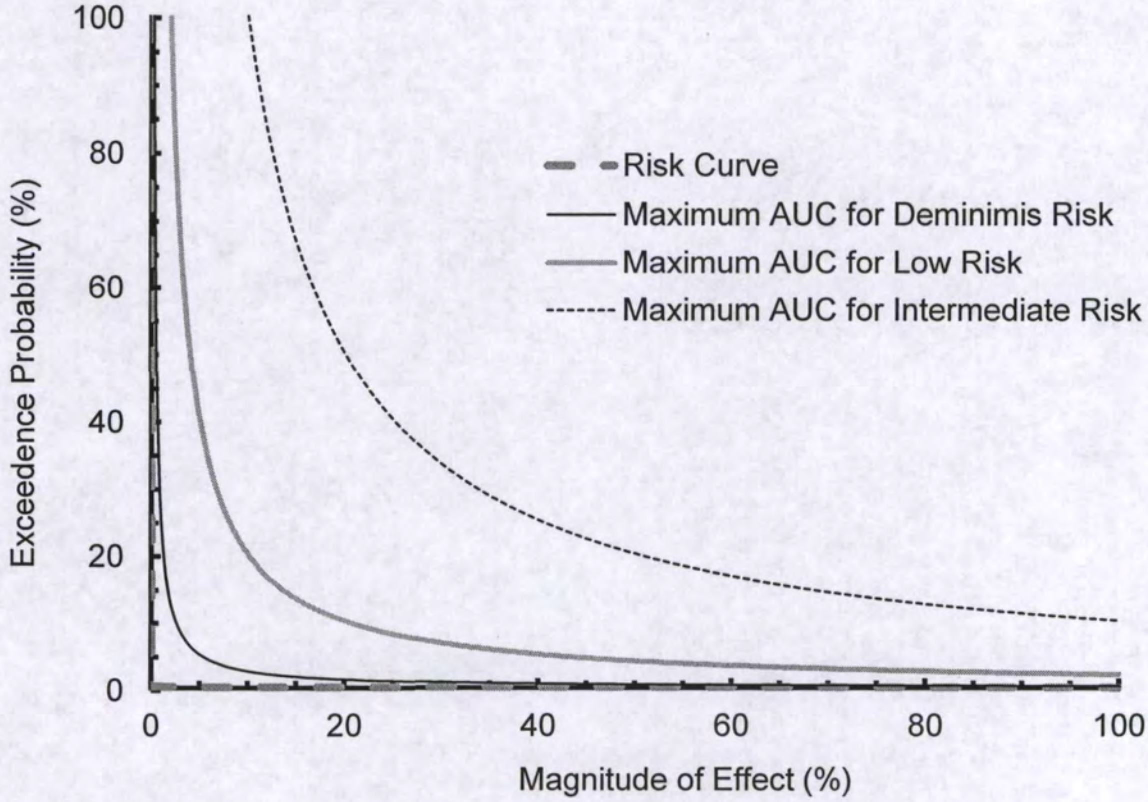

Figure G-5 **Risk curve for acute exposure of adult CRLF due to consumption of a whole mouse that has been exposed to a diet containing residues from ground/airblast application of dimethoate to Christmas tree nurseries (1 lb a.i./A, three times per year, with a 14-day retreatment interval).**

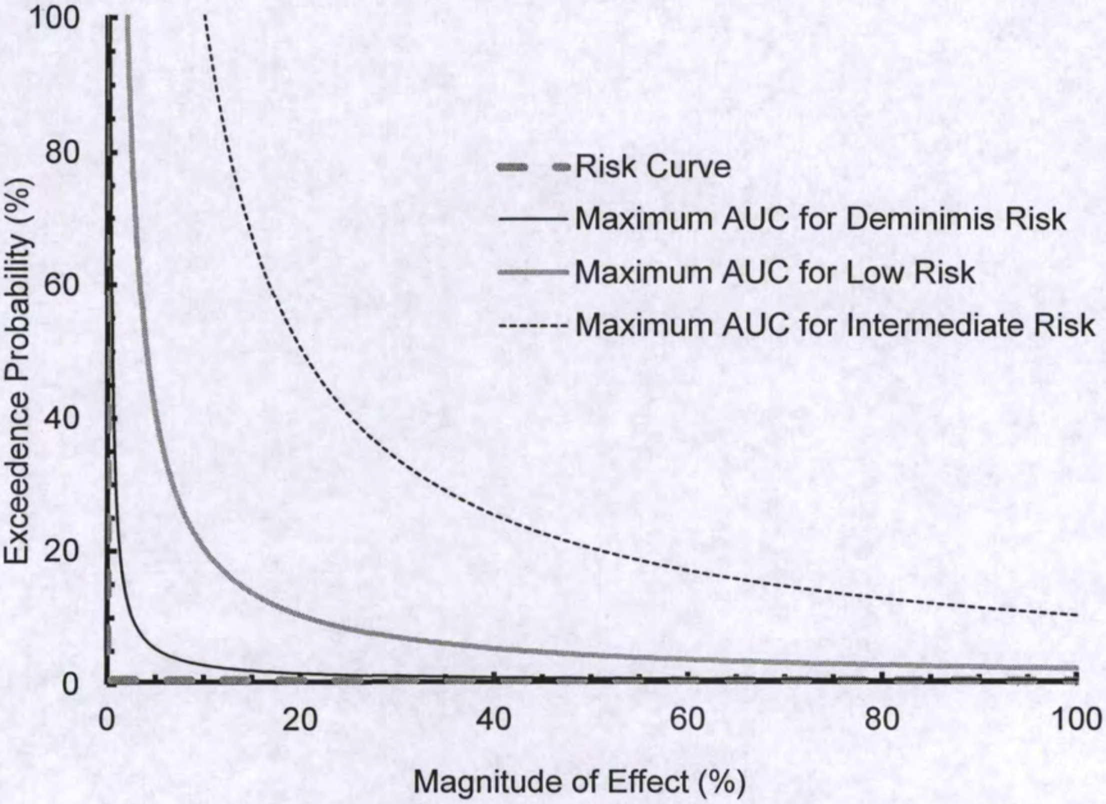

Figure G-6 **Risk curve for acute exposure of adult CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to aerial or chemigation application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).**

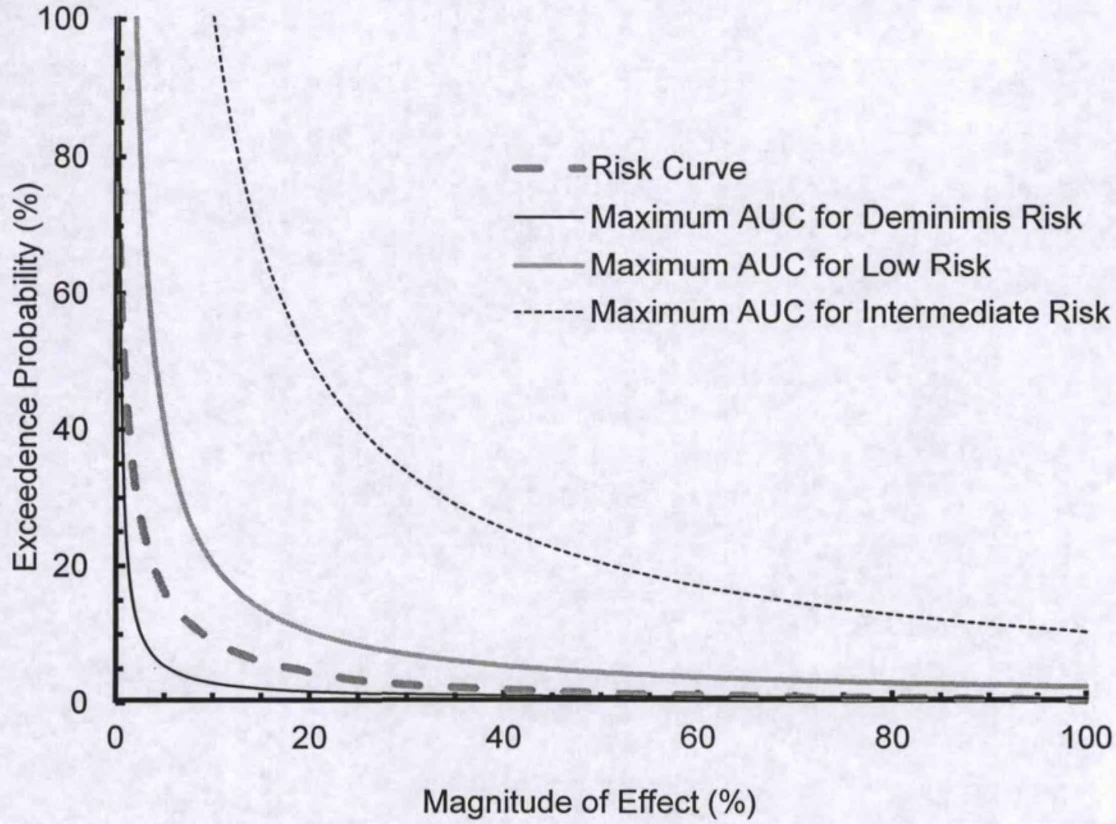

Figure G-7 **Risk curve for chronic exposure of adult CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to aerial or chemigation application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).**

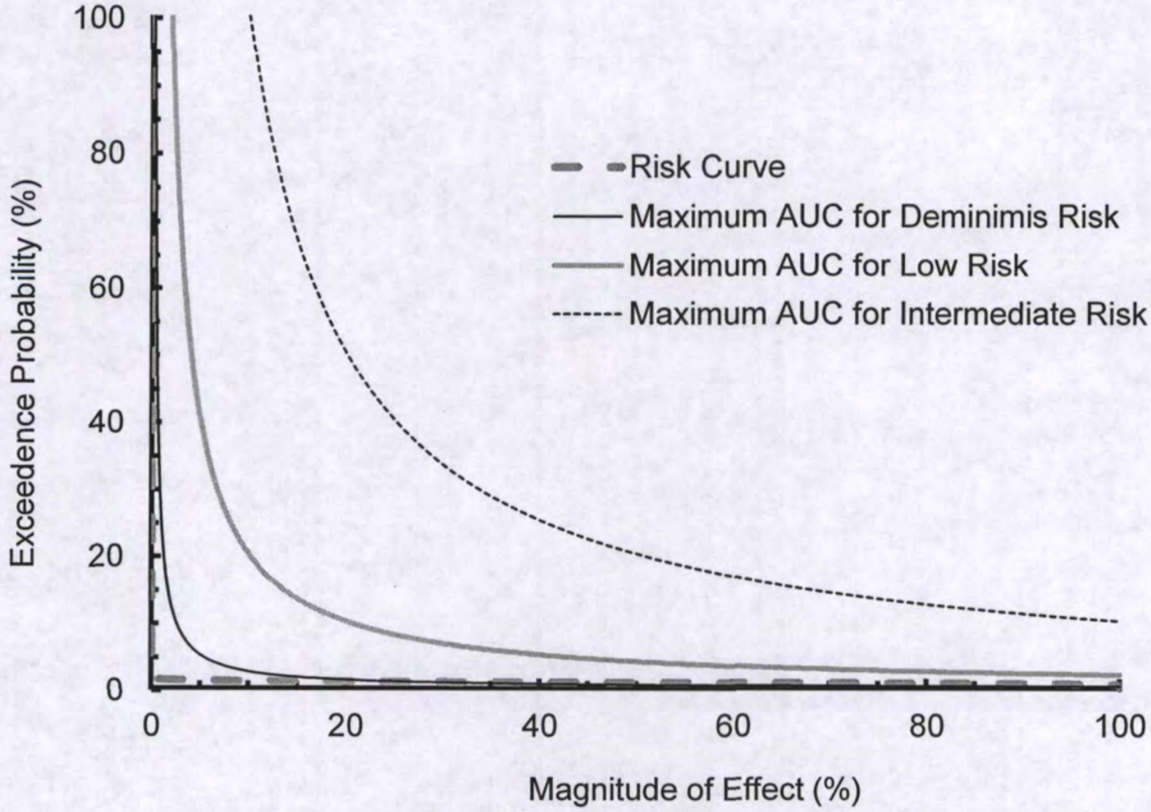

Figure G-8 **Risk curve for acute exposure of adult CRLF due to consumption of a whole mouse that has been exposed to a diet containing residues from aerial/chemigation application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).**

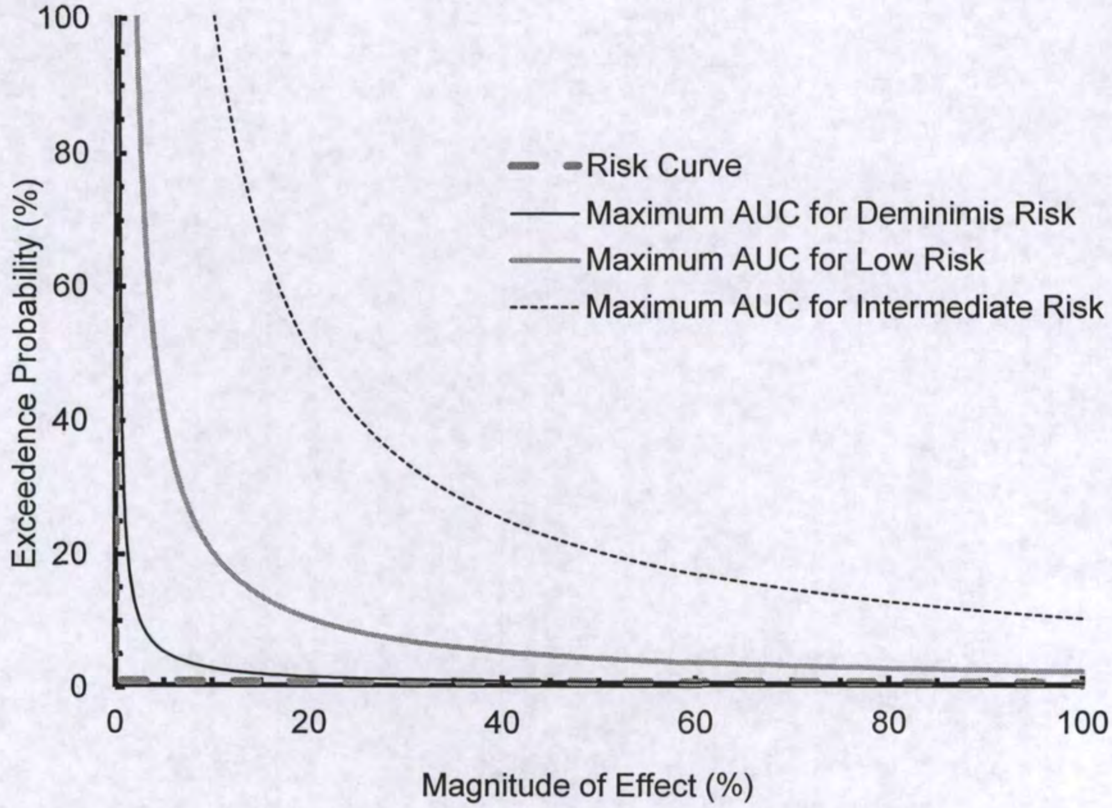

Figure G-9 Risk curve for acute exposure of juvenile CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to aerial or chemigation application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).

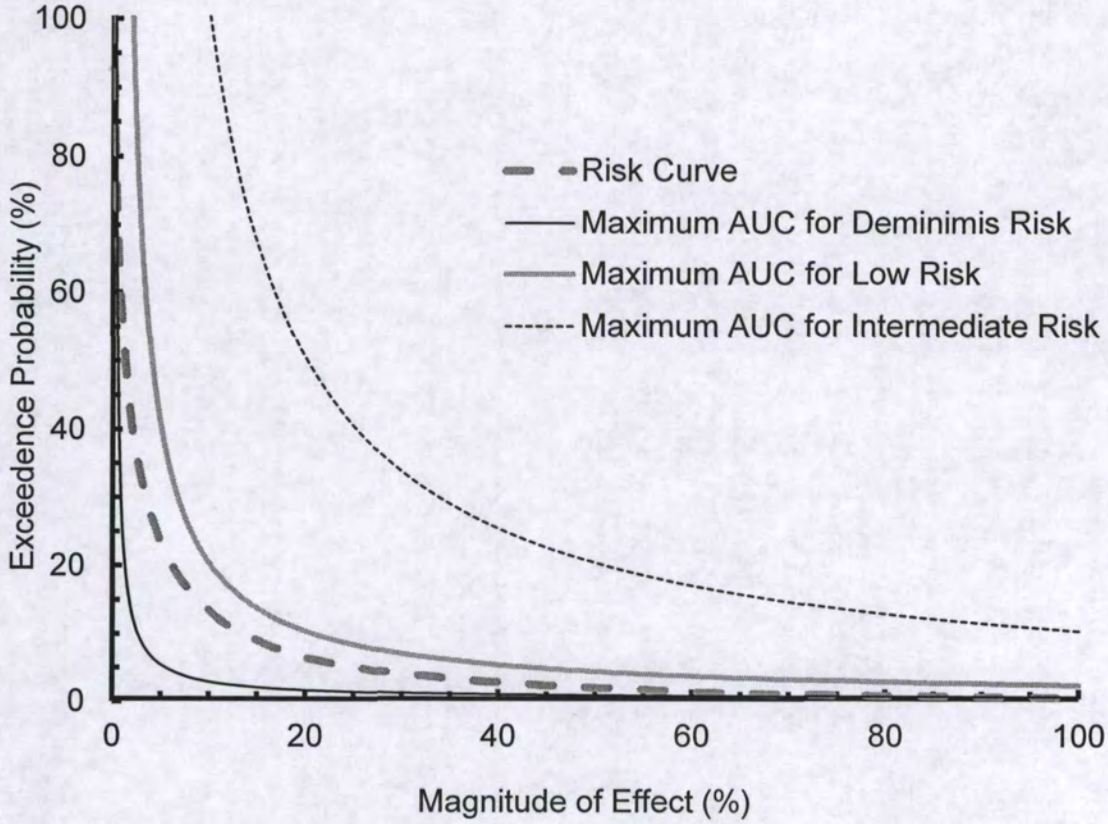

Figure G-10 Risk curve for chronic exposure of juvenile CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to aerial or chemigation application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).

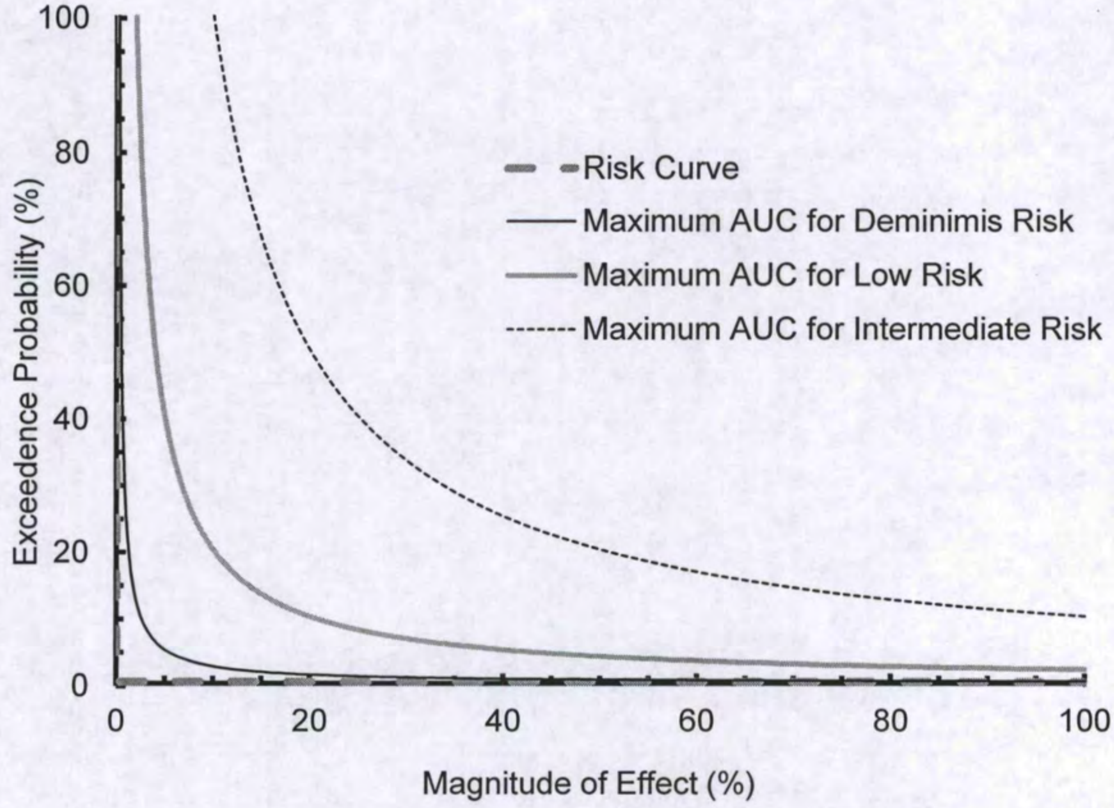

Figure G-11 Risk curve for acute exposure of juvenile CRLF to an intermediate-case diet consisting of 50% terrestrial invertebrates and 50% aquatic invertebrates that have been exposed to chemigation or aerial application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).

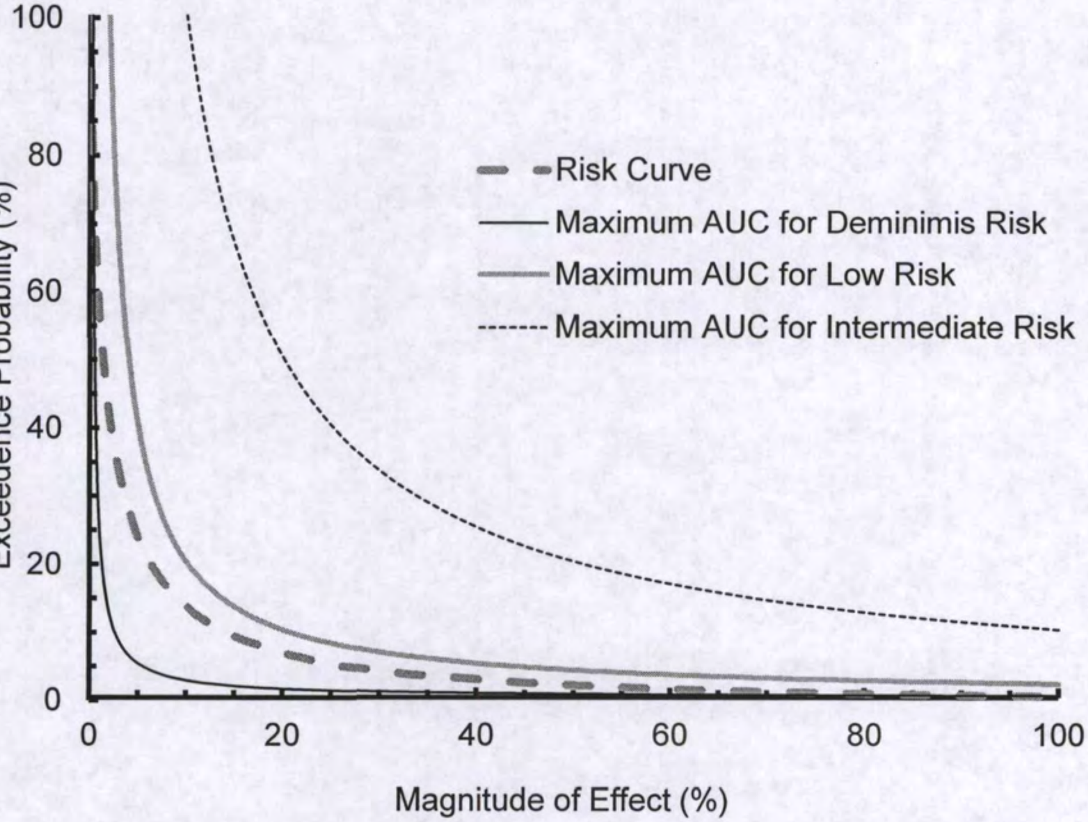

Figure G-12 **Risk curve for chronic exposure of Pacific tree frog to a diet consisting of 81% terrestrial invertebrates and 19% aquatic invertebrates that have been exposed to chemigation or aerial application of dimethoate to cottonwood grown for pulp (2 lb a.i./A, three times per year, with a 10-day retreatment interval).**

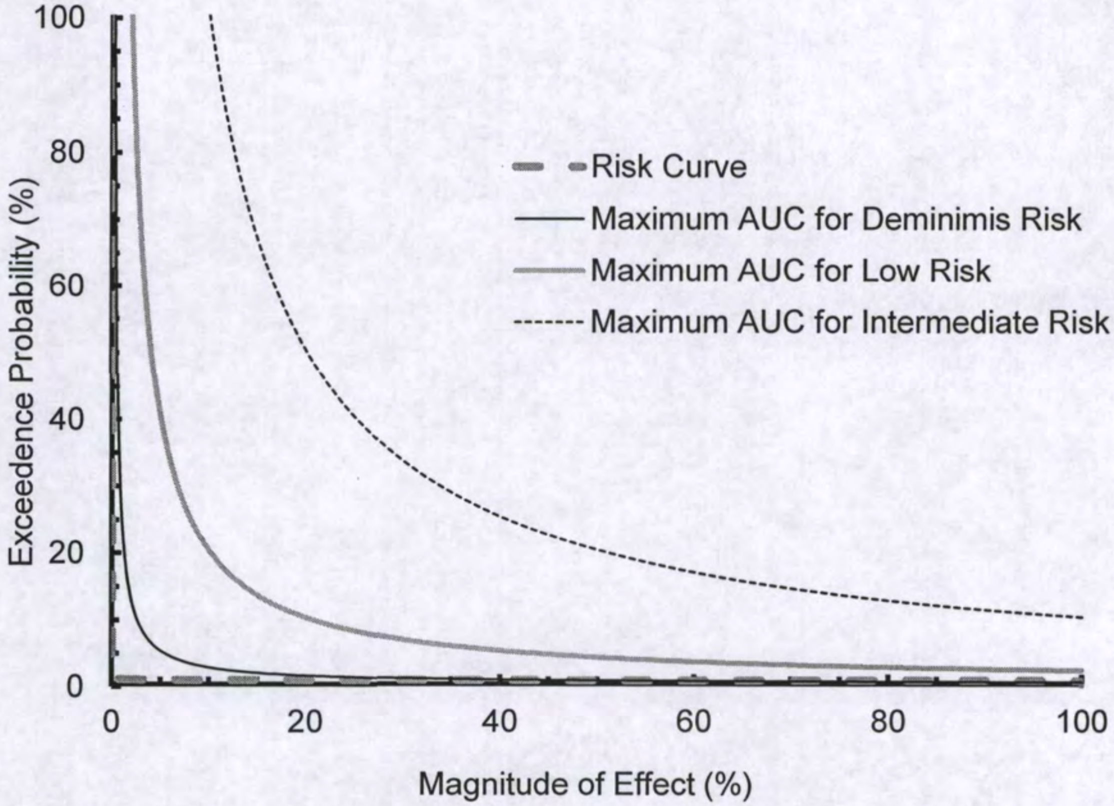

Figure G-13 Risk curve for acute exposure of adult CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

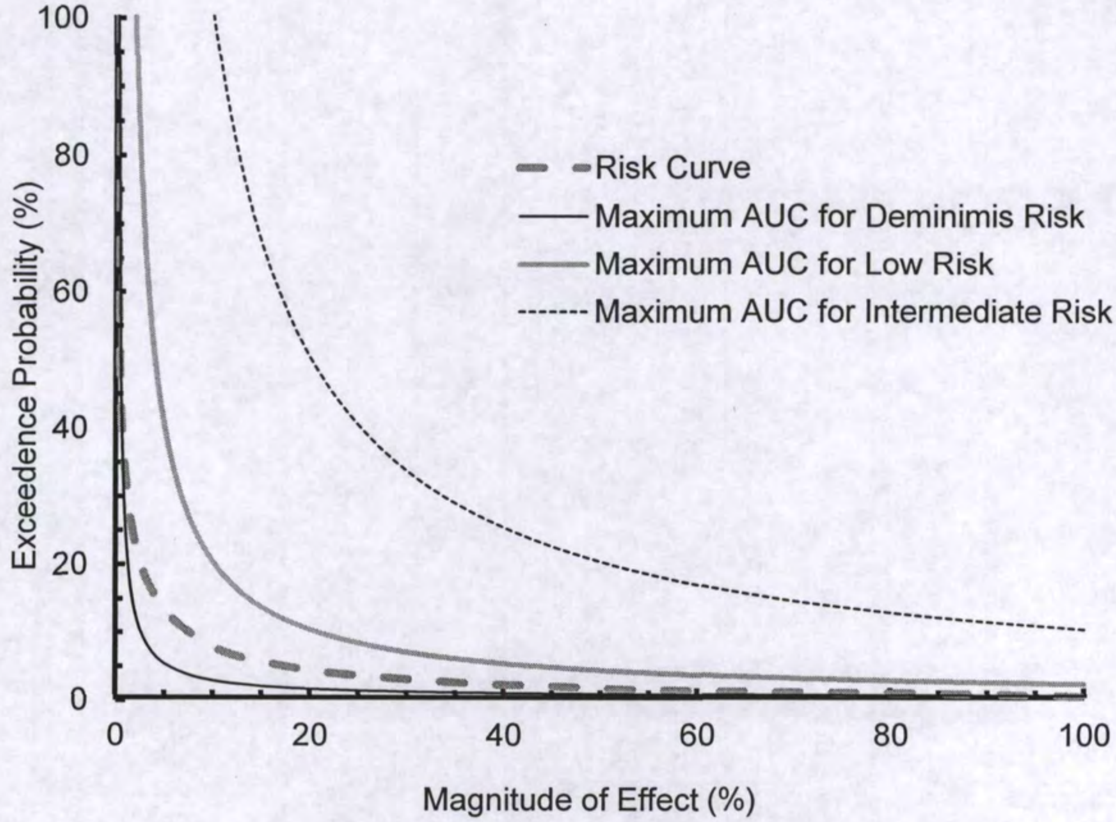

Figure G-14 Risk curve for chronic exposure of adult CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

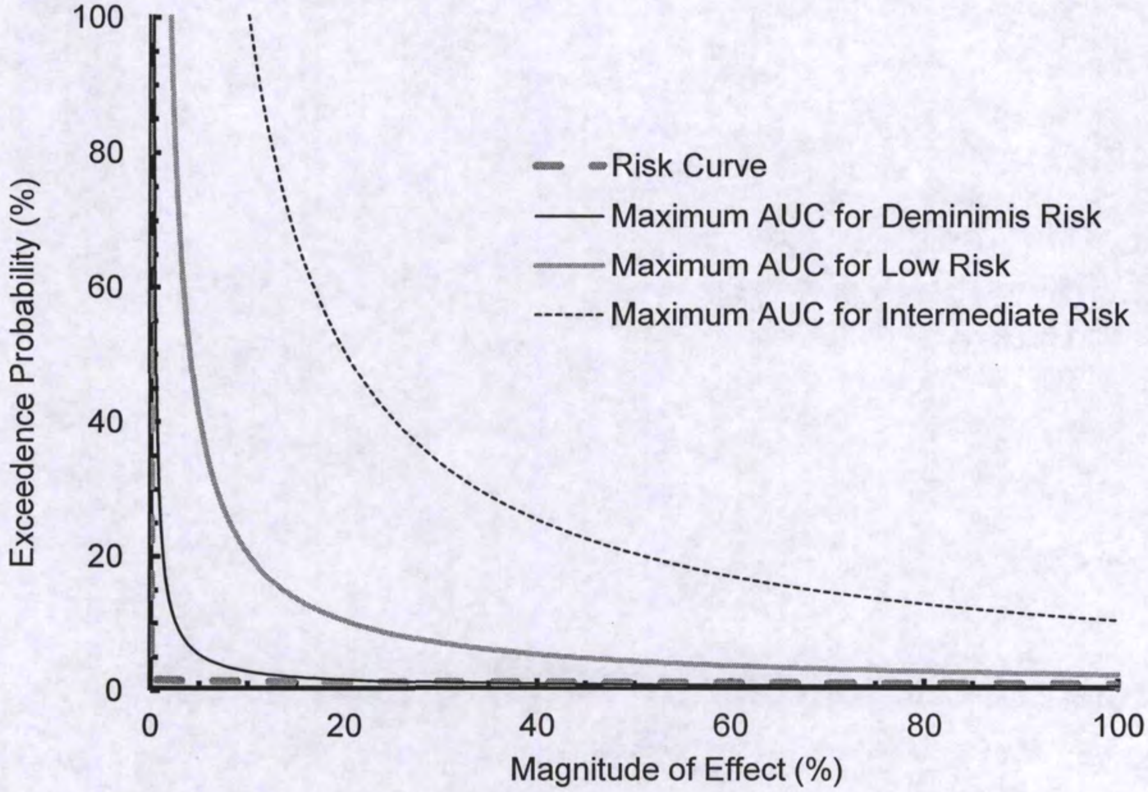

Figure G-15 Risk curve for acute exposure of adult CRLF due to consumption of a whole mouse that has been exposed to a diet containing residues from ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

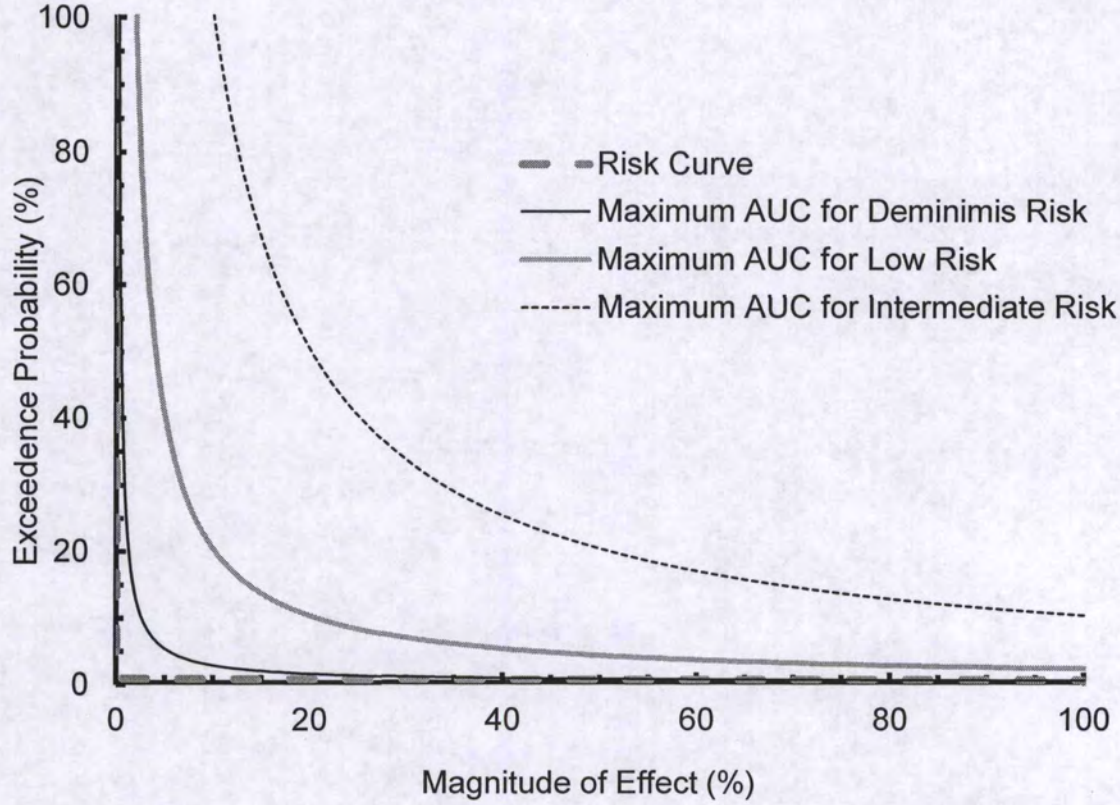

Figure G-16 Risk curve for acute exposure of juvenile CRLF to an intermediate-case diet consisting of 50% terrestrial invertebrates and 50% aquatic invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

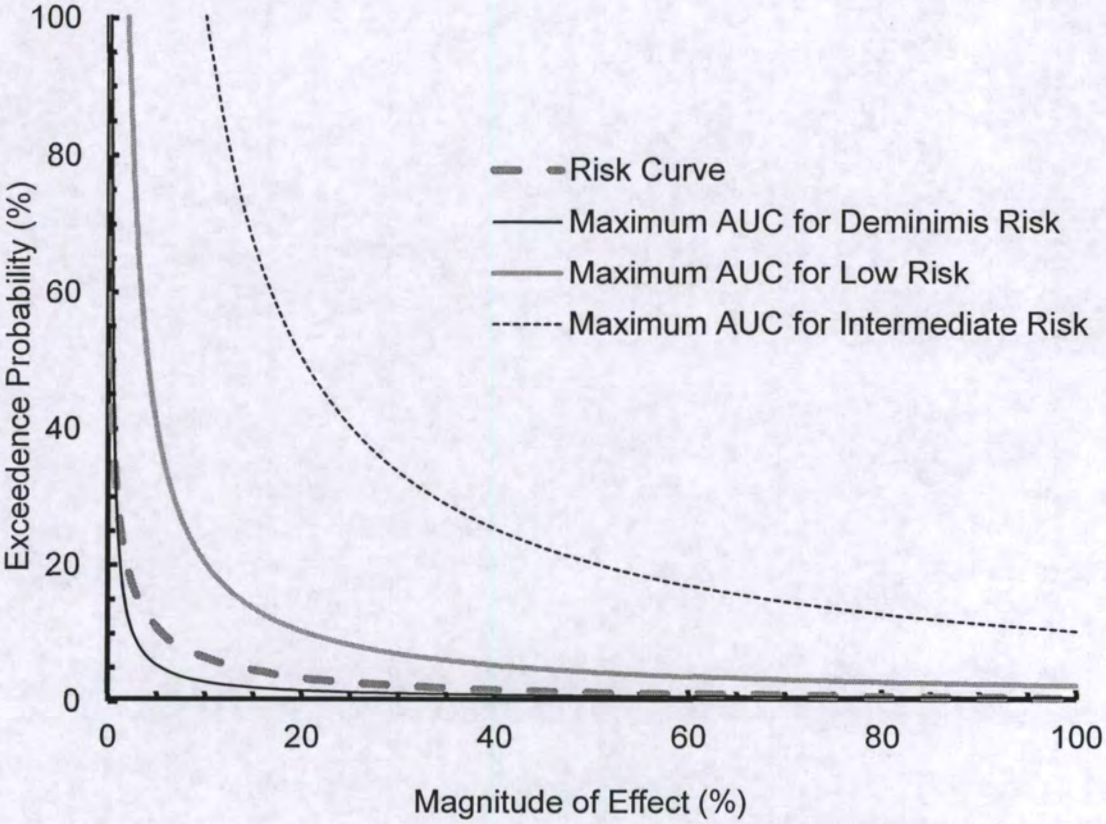

Figure G-17 Risk curve for chronic exposure of juvenile CRLF to an intermediate-case diet consisting of 50% terrestrial invertebrates and 50% aquatic invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

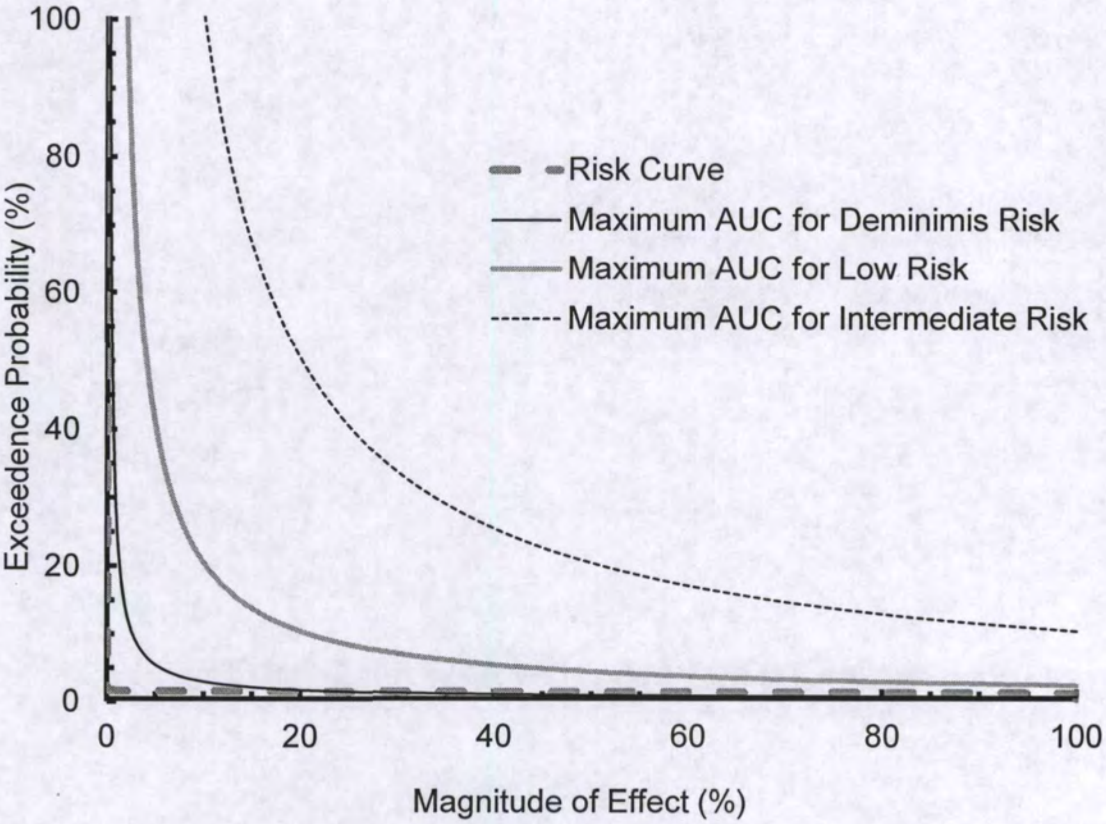

Figure G-18 Risk curve for acute exposure of juvenile CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

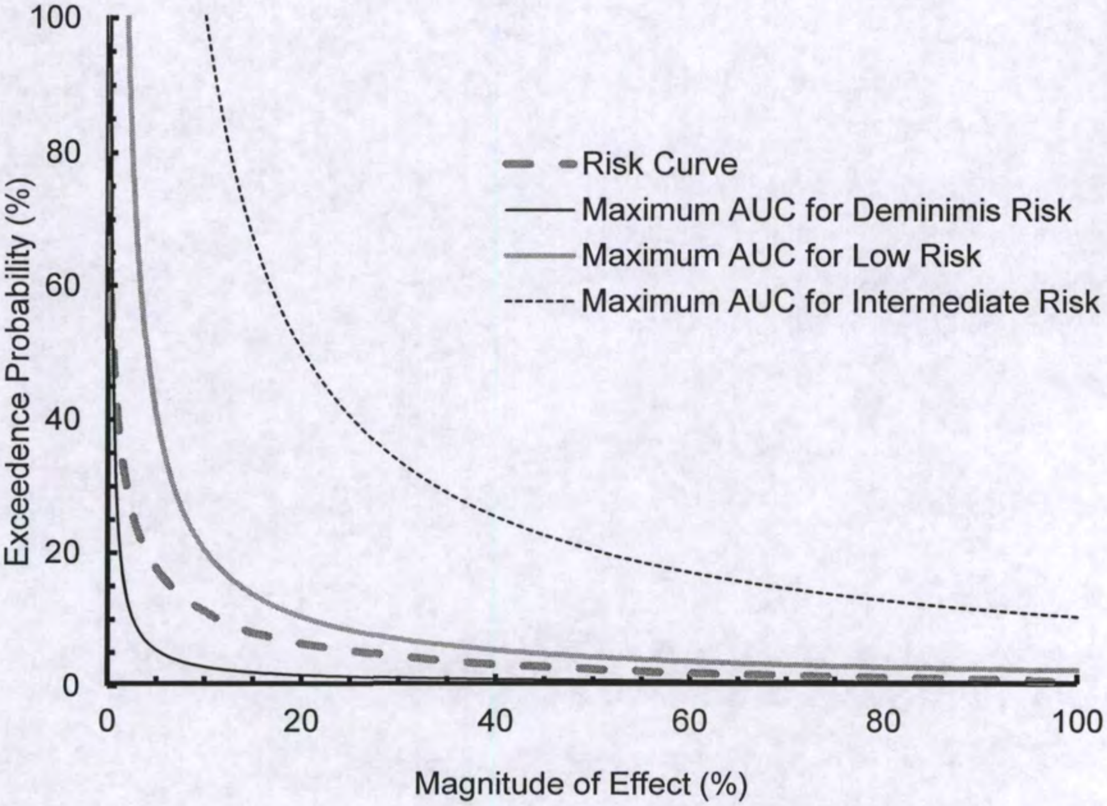

Figure G-19 Risk curve for chronic exposure of juvenile CRLF to a worst-case diet consisting of 100% terrestrial invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

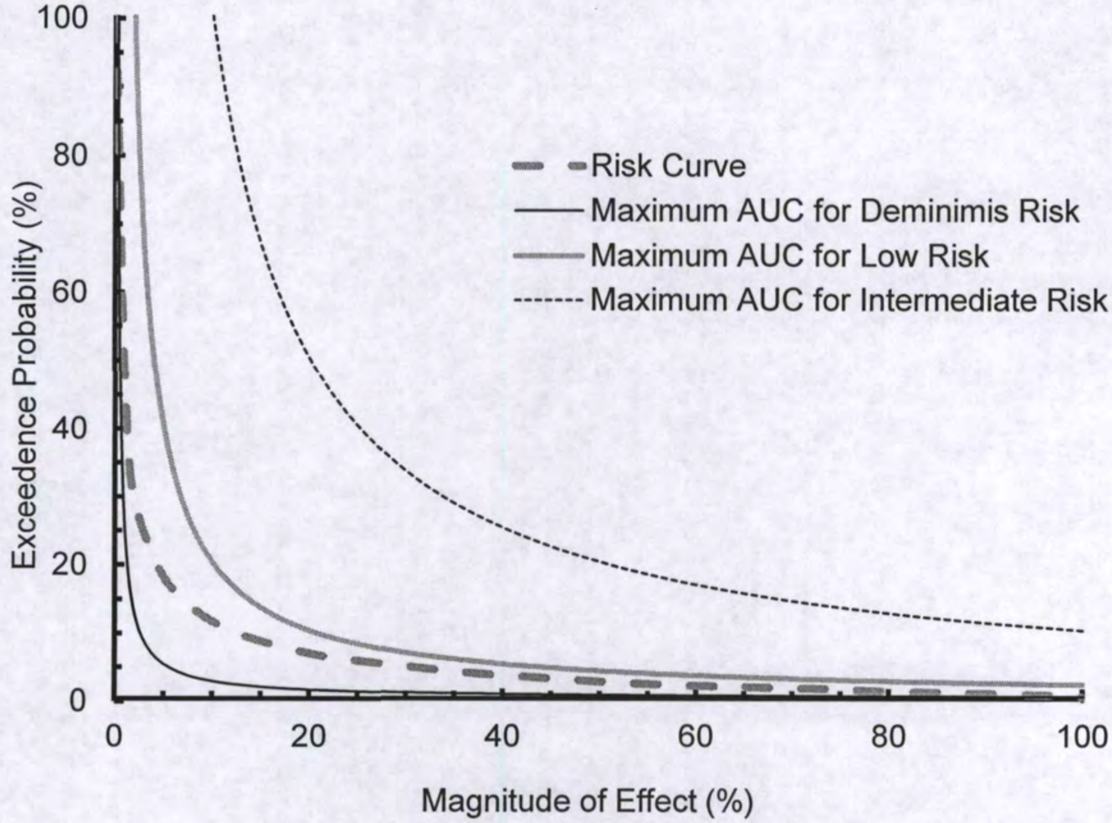

Figure G-20 Risk curve for chronic exposure of Pacific tree frog to a diet consisting of 81% terrestrial invertebrates and 19% aquatic invertebrates that have been exposed to ground application of dimethoate to non-cropland areas adjacent to vineyards (2 lb a.i./A, twice per year, with a retreatment interval of 14 days).

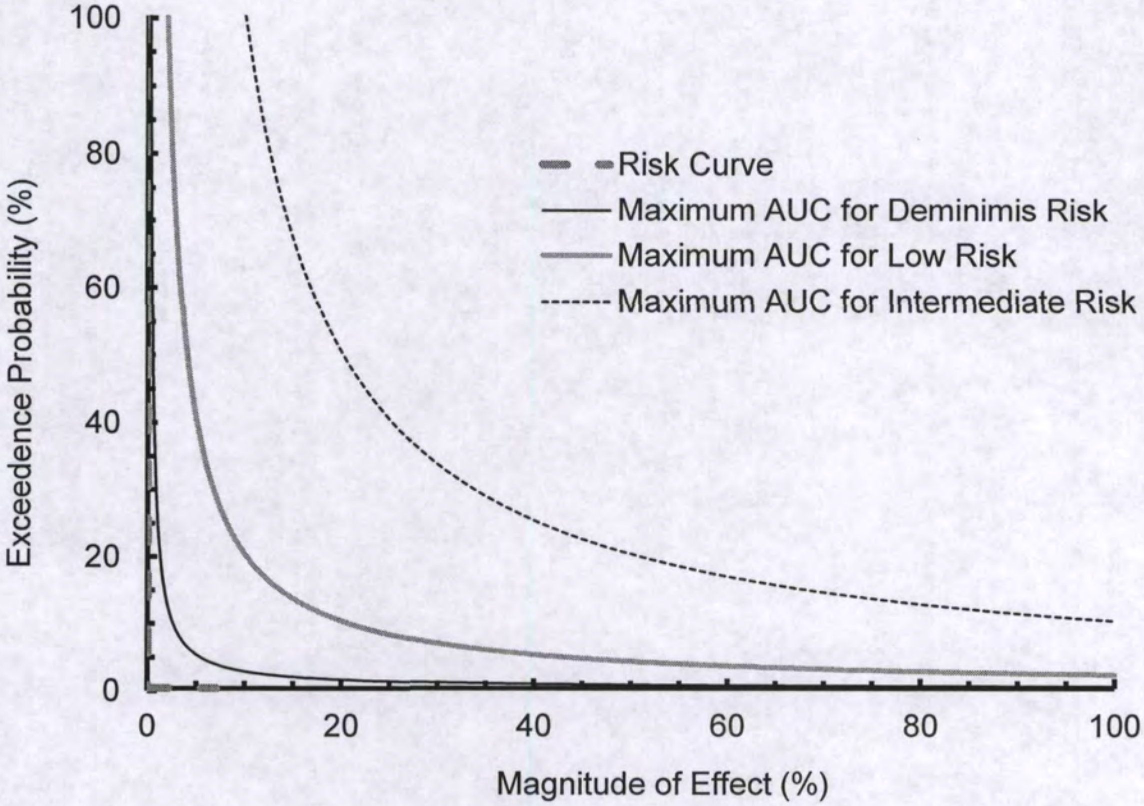

Figure G-21 Risk curve for acute exposure of adult CRLF due to consumption of a whole mouse that has been exposed to a diet containing residues from aerial/ground application of dimethoate to broccoli (0.5 lb a.i./A, three times per year, with a retreatment interval of 7 days).

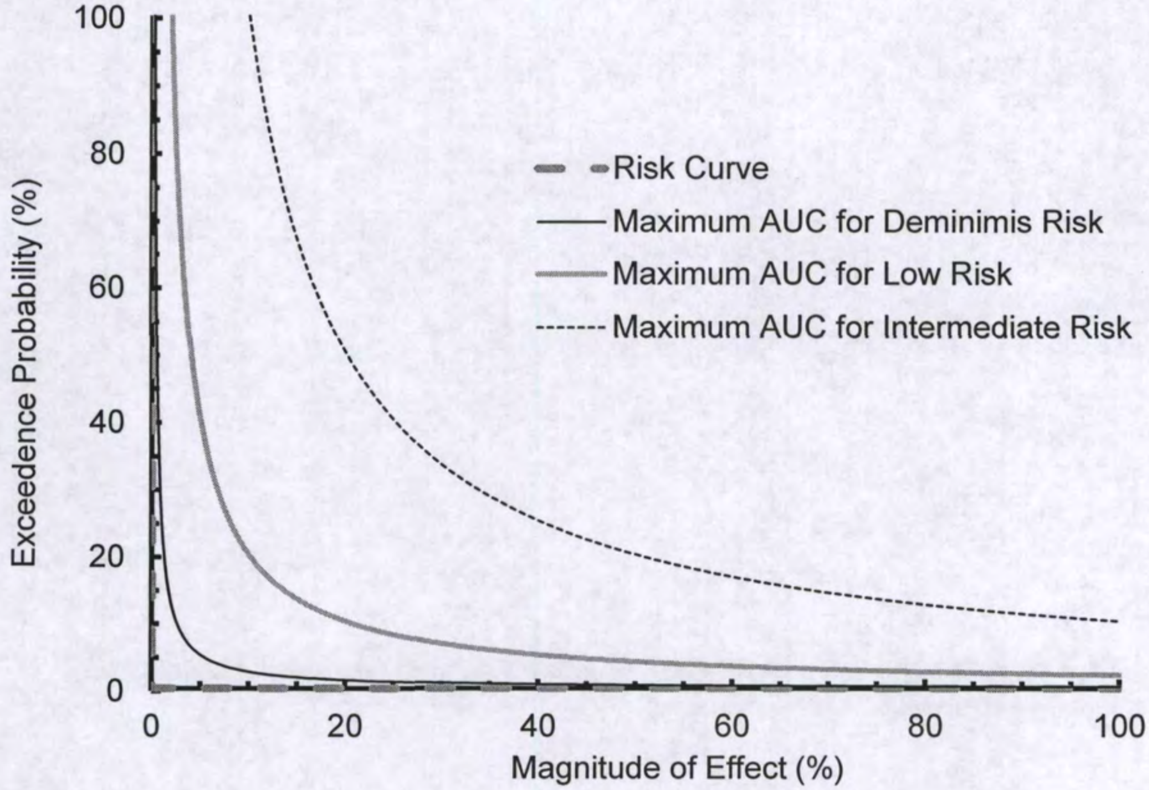

Figure G-22 Risk curve for acute exposure of adult CRLF due to consumption of a whole mouse that has been exposed to a diet containing residues from aerial/ground application of dimethoate to wheat (0.67 lb a.i./A, twice per year, with a retreatment interval of 7 days).