

**California Department of Food and Agriculture  
Statewide Plant Pest Prevention and Management Program  
PEIR Addendum 6 Appendix 6A Part 2**

**Ecological Risk Assessment  
Residential Turf, Japanese Beetle  
Eradication Program**

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March 25, 2021

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**LIST OF ABBREVIATIONS**

For a list of abbreviations and glossary terms, see the Dashboard Database 4.0 – *Glossary and Abbreviations*.

# 1 Executive Summary

This Ecological Risk Assessment (ERA) is conducted as an addition to the ERA conducted as part of the California Department of Food and Agriculture's (CDFA) Statewide Plant Pest Prevention and Management Program Environmental Impact Report (PEIR) (CDFA, 2014a). One new alternative scenario for turf and groundcover treatments with Acelepryn® G and one new alternative scenario for turf and groundcover treatments with beetleGONE!® tlc for the eradication of Japanese Beetles were assessed. An alternative where Acelepryn G and beetleGONE! tlc are applied to adjacent areas within the treatment area was also assessed. The methods used in this risk assessment largely follow those methods used in the previous risk assessment in the Statewide PEIR and subsequent Japanese Beetle and Pierce's Disease Control Program Addenda (#1-3, and 5) (CDFA, 2016a, 2017a, 2020a, 2021a). Where methods differ, the new assumptions or receptors are discussed.

Applications for eradication of Japanese beetle can occur in residential/urban settings within a 200 meter radius around beetle detections encompassing a total contiguous area of up to 50 acres and includes ground application to turf (including lawns/golf courses), recreational areas, ground cover areas, also organic or inorganic mulch and bare soil. Residential/urban settings include: home lawns, commercial lawns, industrial facilities, residential dwellings, business and office complexes, shopping complexes, multi-family residential complexes, institutional buildings, airports, cemeteries, ornamental gardens, parks, wildlife plantings, playgrounds, schools, daycare facilities, golf courses, athletic fields, and other landscaped areas. Applications may be made during off hours in school settings or business areas. For Acelepryn G, granules are applied with spreaders with open and/or closed cab, and equipment may include rotary push-type, drop-spreader, belly-grinder, hand-applied, or tractor-drawn spreader. For beetleGONE! tlc, a mechanically pressurized sprayer, backpack sprayer or hand pump is typically used in residential settings; sports fields or other large areas may be treated using a boom sprayer.

Where applications of Acelepryn G are not permitted or are not advised (e.g., around sensitive habitats such as aquatic areas), a mechanically pressurized handgun, boom sprayer, or backpack sprayer may be used to apply beetleGONE! tlc. Applications of Acelepryn G and beetleGONE! tlc will be followed by "watering in" using ground spray equipment. No adjuvants were included in the application scenarios analyzed in this addendum.

CDFA and its risk assessment team determined the appropriate scenarios to assess, models to evaluate exposure, default data assumptions, and appropriate toxic effects based on scientific literature. Staff from the California Department of Pesticide Regulation (DPR) and the Office of Environmental Health Hazard Assessment (OEHHA) were briefed on the HHRA and provided review of project documents.

Similar methods were used to identify toxicity endpoints as were used for the Statewide PEIR and Addenda. Similar surrogate species were used as in the Statewide PEIR. Although new assessment methods have been developed for chronic effects on insects such as the honey bee, chronic effects were not added to this assessment because no chronic endpoints were available for the pesticides in this assessment. Updated USEPA models such as the Pesticide in Water Calculator (PWC) were used to employ the most current methods and models available.

The ERA relied upon the three-stage process for risk assessments: problem formulation, analysis, and risk characterization. In the problem formulation phase, CDFA and its risk assessment team determined the appropriate scenarios to assess, models to evaluate exposure, default data assumptions, and appropriate toxic effects based on scientific literature. The problem formulation stage concluded with Conceptual Site Models (CSM) that identified the complete exposure pathways carried forward in the analysis based on available information. During the analysis phase of the ERA, detailed exposure was estimated with models incorporating appropriate data and conservative assumptions. Also, in the analysis phase, effect values were developed that incorporated the toxicologic properties of the chemicals along with safety factors to address uncertainty.

The risk characterization phase provided conclusions on the potential for adverse effects to occur to ecological receptors. The risk characterization phase utilized both a quantitative and qualitative assessment for Acelepryn G but was limited to a qualitative assessment only for beetleGONE! tlc. If the estimated RQ for Acelepryn G was below the Level of Concern (LOC), then it was concluded that the potential for adverse effects is low. If the estimated Risk Quotient (RQ) was above the LOC, then a qualitative assessment was conducted to incorporate information that the quantitative models are not capable of considering appropriately. For beetleGONE! tlc, the analysis was limited to a qualitative assessment because environmental fate could not be quantitatively modeled for a microbial pesticide.

Where the quantitative assessment for Acelepryn G indicated the RQ was below the LOC, the potential for adverse effects was considered low, and no additional qualitative assessment to refine the risk conclusion was necessary. When the RQ was above the LOC, applying several qualitative considerations typically resulted in a refined conclusion that the potential for adverse effects would be low. The qualitative assessment includes incorporation of CDFA Best Management Practices (BMPs), the potential for species presence at an application site, incorporation of foraging range and diet, in addition to fate and transport processes such as dilution and degradation.

In the ERA, few groups of ecological receptors were found to have RQs that exceeded LOCs. These include terrestrial-phase amphibians and birds consuming large quantities of soil invertebrates; terrestrial insects, including pollinators; and aquatic invertebrates. The concentrations estimated for polybutene, an inert ingredient in Acelepryn G, in soil invertebrates are considered artificially high resulting in an overestimation of impacts to terrestrial-phase amphibians and birds. More realistic concentrations of polybutene are not anticipated to be harmful to birds and terrestrial-phase amphibians. CDFA's BMPs are designed to greatly reduce, if not eliminate, movement to surface water. Therefore, actual impacts to aquatic invertebrates are anticipated to be minimal. Because of the targeted nature of the application to turf and groundcover, direct contact with Acelepryn G is anticipated to be insufficient to cause adverse effects in terrestrial insects.

This ERA will be used to assist CDFA in assessing the potential to affect species and developing site-specific measures to protect these species.

## 2 Introduction

This Ecological Risk Assessment (ERA) evaluates three alternative application scenarios within the California Department of Food and Agriculture’s (CDFA) Pest Detection/Emergency Program (PD/EP) for the eradication of Japanese Beetles in urban/residential settings, herein referred to as the “Proposed Program.” This document is an addition to the CDFA Statewide Plant Pest Prevention and Management Program, Environmental Impact Report, Volume 2 - Appendix A, Ecological Risk Assessment, SCH # 2011062057 (Statewide PEIR) (CDFA, 2014a).

The primary objectives of the Pest Detection/Emergency Program (PD/EP) are the early detection and prompt eradication of serious agricultural pests from California including, but not limited to, Japanese beetle, exotic fruit flies, light brown apple moth, khapra beetle, gypsy moth, European corn borer, and European pine shoot moth. Eradication activities conducted under PD/EP are performed under the Pest Detection/Emergency Program – Eradication (PD/EP-E). Activities vary based on target pest and include pesticide application in a residential setting.

### 2.1 Purpose of the Ecological Risk Assessment

The ERA assesses potential future activities to be conducted under CDFA’s Proposed Program. Specifically, the ERA focuses on pesticide applications that would be available to eradicate Japanese beetle. The ERA evaluates the potential risk to terrestrial and aquatic species following such pesticide applications.

### 2.2 Approach

A detailed discussion of the approach for the ERA process is provided in the Statewide PEIR (CDFA, 2014a).

This ERA was conducted by using models and exposure data developed primarily by the United States Environmental Protection Agency (USEPA) in the context of typical pesticide application methods and settings in California. For the purpose of this ERA, the term “pesticide” refers to both active and inert ingredients in the formulated pesticide product and, if applicable, any adjuvant products used in conjunction. The ERA depends on these USEPA exposure models to estimate environmental concentrations (EECs) and risk estimates in lieu of measured EECs and observed adverse effects. Most of these models, described in detail in the applicable sections of the Statewide PEIR, (CDFA, 2014a) are Microsoft Excel-based user interface packages that allow for input of information specific to the Proposed Program, as well as default data when site-specific data are not available. Since multiple models were required for this ERA and some models require the output of other models as input, it was convenient to integrate several models into one Excel workbook so that information from all models could be combined into a single risk estimate as the final output for each pesticide application scenario. This Excel workbook is referred to as the Comprehensive Risk ANALysis Calculator (CRANK), providing a consolidated tool to estimate risk for the ERA as well as the associated Human Health Risk Assessment (HHRA).



To present information that serves as inputs for the various models used previously in the ERA in the Statewide PEIR (CDFA, 2014a) in an organized and efficient manner, a Microsoft Access database with a custom user interface was created. This Microsoft Access database is referred to as the Dashboard Database. Data used previously and used as part of this analysis can be found in the newest version of the Dashboard Database (4.0). It is a supplement to this report and no conclusions should be based solely on the Dashboard Database or ERA independently.

The Dashboard Database specifically contains the following information:

- Specific details of each chemical application scenario, including application rates, maximum number of applications per year, application intervals, method of application, application area, etc.
- Pesticide product information, including formulation and concentration of active and, to the extent information is available, inert and adjuvant ingredients
- Physical, chemical, and fate properties of the chemicals considered in the ERA, including degradation rate, vapor pressure, solubility, molecular weight, octanol-water coefficient ( $\text{Log } K_{ow}$ ) and soil adsorption coefficient ( $K_{oc}$ )
- Toxicological properties of the chemicals considered in the ERA, as well as toxicity reference values (TRVs)
- Summary of environmental effects based on published literature
- Model specific inputs and outputs
- Tissue concentrations based on dietary exposure model results
- Size of species home and foraging ranges
- Soil concentration estimation results
- Water concentration estimation results
- Individual RQs for all surrogate species for each chemical ingredient
- Total RQs for all surrogate species for combined chemical ingredients used in an application scenario

Staff from the California Environmental Protection Agency's Department of Pesticide Regulation (DPR) and Office of Environmental Health Hazard Assessment (OEHHA) reviewed and commented on the Proposed Program's ERA. The purpose of this involvement was to allow for peer review, facilitate the exchange of information, collaborate on methods to assess, and protect ecological health and the environment, and clearly communicate these methods and results to the public.

### 3 Problem Formulation

Problem formulation is the first step in the ERA process. Its purpose is to establish the goals, breadth, and focus of the assessment through a systematic process to identify the major factors to be considered in the assessment. As discussed in the Statewide PEIR (CDFA, 2014a), CDFA and the risk assessment team involved staff from DPR and OEHHA to facilitate the exchange of information such that this ERA meets both the public outreach and scientific goals desired by CDFA for the Proposed Program.

Problem Formulation integrates available information (sources, contaminants, effects, and environmental setting) and serves to provide focus to the ERA. Additional details regarding the Problem Formulation are available in the Statewide PEIR (CDFA, 2014a).

### 3.1 Application Scenarios

Details regarding the application of pesticides and adjuvants, when included in the application scenario, that impact the estimation of potential risk are:

- Type of chemical
- Concentration of chemical
- Application method (*e.g.*, soil injection, fumigation, spraying)
- Duration and frequency of applications
- Rate of application
- Area of application
- Setting in which activity would occur (*e.g.*, nursery, residential)

As part of the Statewide PEIR (CDFA, 2014a), seven application scenarios were analyzed in the PD/EP-Eradication-Treat portion of the Program. An additional seven scenarios were assessed in Addenda 1 and 2 (CDFA, 2016a, 2017a) to the PEIR. The scenarios analyzed in this ERA were compared to past work to determine if they could be considered a Substantially Similar Scenario (*i.e.*, one in which products and application details are identical or substantially similar to one or more previously analyzed scenario or differs only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment). None of the scenarios described were considered substantially similar to the scenarios analyzed in the Statewide PEIR (CDFA, 2014a) or subsequent Addenda (CDFA, 2016a, 2017a, 2020a, 2021a). Therefore, PD/EP-E-11, PD/EP-E-11b, PD/EP-E-11c, PD/EP-E-12a, PD/EP-E-12b, and PD/EP-E-12c that refer to distinctions necessary for the Human Health Risk Assessment. For the ERA, the scenarios are designated PD/EP-E-11 and PD/EP-E-12,

In this assessment, Acelepryn G (active ingredient- chlorantraniliprole, inerts- dolomite and butene, homopolymer) was analyzed as granular applications targeting turf and groundcovers in an urban/residential setting (PD/EP-E-11). No application scenarios in the 2014 Statewide PEIR or its addenda assessed pesticide products applied as granules. Additionally, although chlorantraniliprole was assessed in the Statewide PEIR and Addendum #2 (CDFA, 2014a, 2017a), neither homopolymer, butene (herein referred to as “polybutene”) nor dolomite were considered.

Application of beetleGONE!<sup>®</sup> tlc (active ingredient - *Bacillus thuringiensis* serovar *galleriae* strain SDS 502 (BtG), inerts- none identified) was analyzed as spray drench applications targeting turf and groundcovers in an urban/residential setting (PD/EP-E-12). beetleGONE! tlc is a liquid formulation applied as a spray drench targeting turf and groundcover. BtG was not previously analyzed in the Statewide PEIR or any addenda.

Consistent with the PEIR, CDFA defined the product application rate and other application details for each of the specific scenarios in the Program Material Data Sheet (PMDS) found in **Appendix Eco-A: PMDS**. The defined application rate for Acelepryn G is 125 lb/Ac or 0.25 lb.

chlorantraniliprole/Ac. PD/EP-E-11 consists of up to two applications per year of Acelepryn G to a 50-acre area within an urban/residential setting. The defined application rate for beetleGONE! tlc is up to 17.5 lb/Ac or 13.4 lb. BtG /Ac. PD/EP-E-12 consists of a single application per year of beetleGONE! tlc to a 50-acre area within an urban/residential setting. If Acelepryn G cannot be applied within portions of the treatment area, beetleGONE! tlc will be applied in adjacent areas to those treated with Acelepryn G (PD/EP-E-11-12). In this scenario, 45 to 47.5 acres may be treated with Acelepryn G and 2.5 to 5 acres treated with beetleGONE! tlc, with the total maximum treatment area size equaling 50 acres.

Under the Proposed Program, Acelepryn G and/or beetleGONE! tlc may be applied to turf and groundcover in urban/residential settings to up to a 50-acre area, representing the entire area of possibly multiple overlapping areas within the prescribed 200-m radius distance from Japanese beetle detections. Urban/residential settings include home lawns, commercial lawns, industrial facilities, residential dwellings, business and office complexes, shopping complexes, multi-family residential complexes, institutional buildings, airports, cemeteries, ornamental gardens, parks, wildlife plantings, playgrounds, schools, daycare facilities, golf courses, athletic/sports fields, and other landscaped areas. Applications in school settings and business areas may be made during off hours. A rotary push-type spreader, belly grinder, drop spreader, or open and/or closed cab tractor-drawn spreader may be used for applications of Acelepryn G. Alternatively, Acelepryn G granules may be applied by hand. Where applications of Acelepryn G are not appropriate (e.g., around sensitive habitats such as aquatic areas), a mechanically pressurized handgun, boom sprayer, or backpack sprayer may be used to apply beetleGONE! tlc. Applications of Acelepryn G and beetleGONE! tlc will be followed by “watering in” using ground spray equipment. Treatments will be applied to turf and groundcover or mulch. Within an application area, many features would not be treated, such as pavement, buildings, or other hardscapes. Following the approach used in PEIR Addenda 1, 2, 3 and 5 (CDFA, 2016a, 2017a, 2020a, 2021a), it was assumed approximately one-third of the entire urban/residential area was treated.

### 3.2 Active and Inert Ingredients

Product labels and Safety Data Sheets (SDSs) for Acelepryn G and beetleGONE! tlc were reviewed to determine active and inert ingredients relevant to the current analysis. No adjuvants were included in the application scenarios analyzed.

Acelepryn G contains the active ingredient chlorantraniliprole (0.2%) and two inert ingredients: dolomite ( $\geq 90\%$  to  $\leq 100\%$ ) and polybutene ( $\geq 1\%$  to  $< 5\%$ ). No other inert ingredients are known. Because of the potential variability of inert ingredient concentrations within each weight unit as indicated on the SDS, each inert ingredient was assumed to be present at the maximum plausible concentration with the minimum proportion of other ingredients (i.e., 98.9% dolomite and 4.99% polybutene). The ingredients were researched for chemical characteristics, including toxicity, as well as their environmental fate properties. Applicable environmental fate characteristics for the chemicals evaluated in this HHRA can found in the relevant sections of the Dashboard Database 4.0 associated with the Statewide PEIR and updated with data from this assessment.

Sufficient ecotoxicity data were identified for polybutene, but environmental fate characteristics and physical properties rely on estimated values based on the chemical structure. Polybutene

consists of polymers of differing chain lengths and the specific polymer(s) present in Acelepryn G is unspecified. Therefore, potential impacts from polybutene can be estimated, but the EECs contain considerable uncertainty. No ecotoxicity data were identified for dolomite, and insufficient chemical property data were available to model environmental fate for dolomite. Therefore, potential impacts from dolomite cannot be estimated.

A review of the beetleGONE! tlc label and SDS identified the only active ingredient consisting of 76.5% BtG fermentation solids, spores, and insecticidal toxins. The remainder of 23.5% is unknown. Because unknown ingredients are often considered confidential business information, their identity is not disclosed and as a result cannot always be assessed. No inert ingredients were identified in beetleGONE! Tlc, therefore potential impacts from inert ingredients cannot be estimated.

All identified ingredients were researched for chemical characteristics, toxicity, and environmental fate properties. Applicable environmental fate characteristics for the chemicals evaluated in this ERA can be found in the relevant sections of the Dashboard Database 4.0.

A brief description of the identified ingredients in Acelepryn G and beetleGONE! tlc is presented below. For additional information, including comprehensive chemical summaries, please see the *Chemical Details* section of the Dashboard Database 4.0.

### 3.2.1 Chlorantraniliprole (CAS #: 500008-45-7)

Chlorantraniliprole is a diamide insecticide that acts by binding to the lepidopteran ryanodine receptor. Chlorantraniliprole primarily controls insects by causing muscle contractions, which leads to paralysis and subsequent death (USEPA, 2008f). For additional information about chlorantraniliprole, including discussion about environmental fate and toxicity, see the *Chemical Summaries* section of the Dashboard Database 4.0.

### 3.2.2 Polybutene (CAS #: 9003-29-6)

Polybutene is a viscous chemical that is used in personal care products, agrochemicals (e.g., mammal and bird repellents), and sealants/coatings. The chain length of polybutene as contained in Acelepryn G is unknown, although in repellents/cosmetics it may be between 5 and 100 units (CIR, 1982a; USEPA, 2012q, 2013).

### 3.2.3 Dolomite (CAS #: 16389-88-1)

Dolomite ( $\text{CaMg}(\text{CO}_3)_2$ ) is a mineral component found in sedimentary rocks, used in construction, stone processing, and historically as a nutritional supplement. The term ‘dolomite’ or dolostone may also be used as a general term for aggregate compositions of crushed stone that contain dolomite as well as other materials.

### 3.2.4 *Bacillus thuringiensis*, subsp. *galleriae*

*Bacillus thuringiensis* (Bt) is a naturally occurring rod-shaped bacteria that has been isolated from soil, insects, and plant surfaces (NPIC, 2000a). The *Bacillus* genus is a gram-positive

aerobic and facultatively anaerobic bacterium that was first isolated in 1902 and has been widely used as a microbial pest control agent since the 1960's (USEPA, 1998c). The bacteria produce protein crystals that, upon ingestion, form endotoxins that bind to the insect gut leading to a fatal disruption in the osmotic balance (CDFA, 2009b). The mode of action of Bt is further described in Section 6.5.1.2: *Mode of Action*.

Bt is subclassified into different subspecies based on the serotype of antigens found on the flagella (USEPA, 1998c). While Bt-based pesticides are most commonly used to control lepidopteran insects, BtG is highly active against coleopteran insects, particularly scarab beetles such as the Japanese beetle (USEPA, 2013l). BtG was originally isolated from a soil sample in Japan (USEPA, 2013l). See Section 6.5 *Risk Analysis for the Pest Detection/Emergency Program's Turf Applications in an Urban/Residential Setting using beetleGONE! tlc (PD/EP-E-12)* for details regarding BtG.

### 3.2.5 Environmental and Ecological Settings

The application scenarios evaluated granular applications of Acelepryn G (PD/EP-E-11) and spray drench applications of beetleGONE! tlc (PD/EP-E-12) in an urban/residential setting includes applications to turf and groundcover and mulch. An alternative scenario where Acelepryn G and beetleGONE! tlc are applied to adjacent areas within the treatment area was also assessed (PD/EP-E-11-12). Applications to vegetables are not permitted under PD/EP-E-11, PD/EP-E-12, or PD/EP-E-11-12. Urban/residential settings areas are defined in Section 3.1: *Application Scenarios*.

To determine the types of species that could be exposed as a result of these scenarios, the range of locations where the scenario could occur, and the ecological characteristics of those locations were investigated. A more detailed discussion of the Environmental and Ecological Settings can be found in the Statewide PEIR (CDFA, 2014a).

## 3.3 Assessment Endpoints and Measures of Ecological Effect

An endpoint is the outcome of an effect on an ecological component, for instance, increased mortality of fish due to a pesticide application. An assessment endpoint is the specific statement of the environmental effect that is going to be protected, such as the prevention of fish mortality due to a pesticide application. Measurement endpoints are measurable attributes used to evaluate the risk hypotheses and are predictive of effects on the assessment endpoints (USEPA, 1998g). Since a specific individual of a species may have different mortality susceptibility compared to other individuals of the same species, it is common to use a statistical representation to define what is meant by the assessment endpoint. For instance, it is common to assess mortality by using the lethal dose at which 50 percent of the population in a study failed to survive (LD<sub>50</sub>).

Assessment endpoints are the ultimate focus in risk characterization and link the measurement endpoints with the risk decision making process. The ecological effects that the ERA intends to evaluate are determined by the assessment endpoint which is characterized by a specific measurement endpoint. The specific assessment and measurement endpoints that form the basis of this ERA are discussed in the following sections.

### 3.3.1 Assessment Endpoints

Three principal criteria are used to select ecological characteristics that may be appropriate for assessment endpoints: (1) ecological relevance, (2) susceptibility to known or potential stressors, and (3) relevance to management goals. Of these, ecological relevance and susceptibility are essential for selecting assessment endpoints that are scientifically defensible (USEPA, 1998g). Although stressors can consist of many different environmental factors, the stressors addressed in this ERA are those effects related to pesticides. This ERA's endpoints focus on organism-level outcomes. These include adverse effects such as mortality or reproductive effects (USEPA, 2003c).

The acute assessment endpoints selected in the ERA include the prevention of mortality in:

1. Soil-dwelling invertebrates, non-target insects, aquatic invertebrates including benthic invertebrates, aquatic-phase amphibians, and fish,
2. Terrestrial-phase amphibians, reptiles, birds, and mammals that eat insects (*i.e.*, insectivores) or invertebrates (*i.e.*, invertivores),
3. Herbivorous reptiles, birds, and mammals,
4. Reptiles, birds, and mammals that eat fish (*i.e.*, piscivores),
5. Terrestrial-phase amphibians, reptiles, birds, and mammals that eat both plants and animals (*i.e.*, omnivores),
6. Bird and mammals that eat seeds (*i.e.*, granivores), and
7. Carnivorous amphibians, reptiles, birds, and mammals.

The chronic assessment endpoints selected for the ERA include the protection of survival and reproduction of the same species groups.

Typically, reproduction is a more sensitive endpoint than survival. Thus, this endpoint has been used over survival when it is available to result in a more conservative analysis. Adverse reproductive effects generally do not materialize until chronic exposures have occurred.

### 3.3.2 Measurement Endpoints

In terms of measurement endpoints, measures of exposure have been used to evaluate levels at which exposure may occur whereas measures of effect have been used to evaluate the response of the assessment endpoints if exposed to stressors. Concentration of pesticides in water is a measure of exposure for an aquatic species, and daily intake of pesticides in dietary items, soil, and drinking water is a measure of exposure for terrestrial species. The concentration in water or the amount of daily ingestion of pesticides that causes adverse effects are measures of effects. The quantitative analysis assumed that a given species was present and did not address the likelihood that the species may actually occur in proximity to a specific pesticide application. The likelihood of presence at the application site is addressed qualitatively in the risk characterization.

In this ERA, toxicity is reported as TRVs, which are numerical representations of the measurement effects that are used in the risk assessment. A TRV is a toxicological index that, when compared with exposure, is used to quantify risk to an ecological receptor. The way in which TRVs are developed depends on available data on a pesticide's toxicological effects and commonly accepted assumptions that address uncertainty regarding the available data. TRVs are developed according to a highly structured and rigorous approach. This process often includes adjustments to observed laboratory values to account for uncertainty and application of safety factors to ensure that results of the risk assessment are conservative and ensure protection against adverse effects. TRVs are used to represent measurement endpoints of the environmental concentrations or daily doses (mg/kg bw-day) with uncertainty factors incorporated, such that exposure at levels above the TRV are likely to cause adverse effects for a species. If the EEC or the estimated daily dose (EDD) of a pesticide exceeds the TRV, concern is triggered regarding the potential for an adverse effect to an organism.

Complete details of the methods for developing TRVs for the pesticides and species evaluated in this ERA are described in Section 4: Effects Assessment of the ERA in the Statewide PEIR (CDFA, 2014a). Specific measurement endpoints used to develop the TRVs include no observable adverse effect levels (NOAELs), lowest observable adverse effects levels (LOAELs), and the median lethal (or effective) dose or concentration (*e.g.*, LD<sub>50</sub>, ED<sub>50</sub>, LC<sub>50</sub>, or EC<sub>50</sub>). Acute TRVs are based on results from acute toxicity tests. Chronic TRVs are based on chronic endpoints (*i.e.*, long term defined as greater than 10% of the animal's lifespan) when available. Subchronic endpoints (repetitive exposures during less than 10% of the animal's lifespan but greater than 14 days) (USEPA, 1999h) were used when no chronic endpoints are available. Acute endpoints were used only in cases where no chronic or subchronic endpoints were available. Appropriate safety factors are applied to convert acute or subchronic endpoint to chronic TRVs (U.S. Army, 2000; USEPA, 2004j). These TRVs were the measurement endpoint for the active/inert ingredient-species combination.

For many amphibians and reptiles, toxicity data from other taxonomic groups were used for TRV development. For the aquatic-phase for amphibians, fish, such as the rainbow trout, were often used to derive an appropriate TRV. For reptiles and terrestrial-phase amphibians, bird toxicity values act in place of specific toxicity values for reptile or terrestrial amphibian species (USEPA, 2004j).

### 3.4 Surrogate Species Selection

Numerous species occur in California. This ERA does not assess risk for every species, as such an assessment would be infeasible. The selection criteria and process by which surrogate species were selected, along with a complete list of species and their life history traits, can be found in the Statewide PEIR (CDFA, 2014a) as well as the relevant sections of the associated Dashboard Database.

### 3.5 Conceptual Site Models

Development of conceptual site models (CSMs) is a fundamental part of the risk assessment process, and their inclusion in the ERA is intended to allow the reader to understand the exposure pathways that were evaluated for the application scenario. The CSM is a written and

visual representation of predicted relationships among stressors (*e.g.*, a pesticide application), exposure pathways (*e.g.*, eating vegetation contaminated with the pesticide), and assessment endpoints (*e.g.*, mortality). It outlines the potential routes of exposure for each assessment endpoint and includes a description of the complete exposure pathways. An exposure pathway demonstrates how a pesticide would be expected to travel from a source (pesticide application) to a plant or animal that can be affected by that pesticide. An exposure pathway that is not complete means that it is unlikely for that organism to be exposed to the pesticide by that exposure route.

The ecological CSM covers the multiple pathways through which ecological receptors could be exposed to pesticides that may be applied under the Proposed Program. The starting point of each CSM is the application technique, which determines the characteristics of release of the pesticides into the environment. The possible pesticide application techniques addressed in this ERA for PD/EP-E-11 is a granular application to turf and ground cover in an urban/residential setting, and PD/EP-E-12 is a spray drench to turf and ground cover in an urban/residential setting.

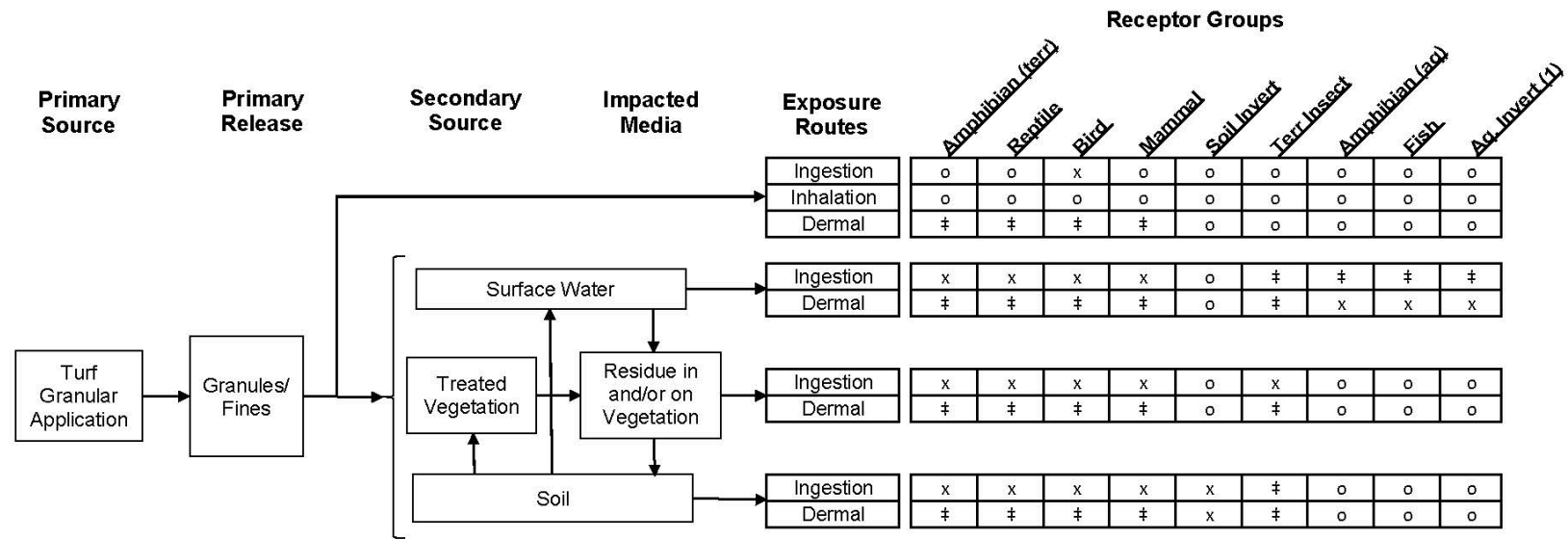
Additional details regarding the development and interpretation of CSMs can be found in Section 2.6: *Conceptual Site Models* of the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a).

### 3.5.1 Pest Detection/Emergency Program

**Figure Eco-1** provides details for granular applications to turf and groundcover that can occur in urban/residential settings (PD/EP-E-11). **Figure Eco-2** provides details for spray drench applications to turf and groundcover that can occur in urban/residential settings (PD/EP-E-12). Incomplete exposure pathways exist for inhalation for ecological receptors since the turf application is made with granules or a large droplet nozzle one to two feet above the ground, greatly reducing the amount of drift. Exposure pathways following granular and spray drench applications are generally similar with the exceptions indicated below. The exposure to terrestrial insects is complete for exposure via ingestion of foliage, pollen or nectar following uptake from treated soil or from deposition following turf or groundcover sprays. Other pathways for terrestrial insects lack sufficient toxicity data to assess. Dermal exposure to insects is considered *de minimis* following a granular application. Soil invertebrates have complete exposure pathways for soil ingestion and dermal exposure to soil. Exposure pathways for terrestrial vertebrates were complete for dermal contact and ingestion of surface water, vegetation, and soil. For birds, ingestion of intact granules is also assessed, based on the possibility they mistake the granules for grit. Adequate exposure and toxicity data exist only for the ingestion pathway for terrestrial vertebrates, so the dermal and inhalation routes, although potentially complete, have not been quantitatively evaluated. The exposure pathway for fish and aquatic invertebrates is complete via surface water following movement through or over soil beneath treated plants and from the possibility of limited drift to adjacent surface water. However, adequate toxicity data for ingestion of contaminated food items or ingestion of water was not identified, so only effects from immersion in surface water containing pesticide residues have been quantitatively analyzed.



**Conceptual Site Model (CSM) for PD/EP-Eradication - Residential Granular Turf Application  
Ecological Risk Assessment**



**Notes:**

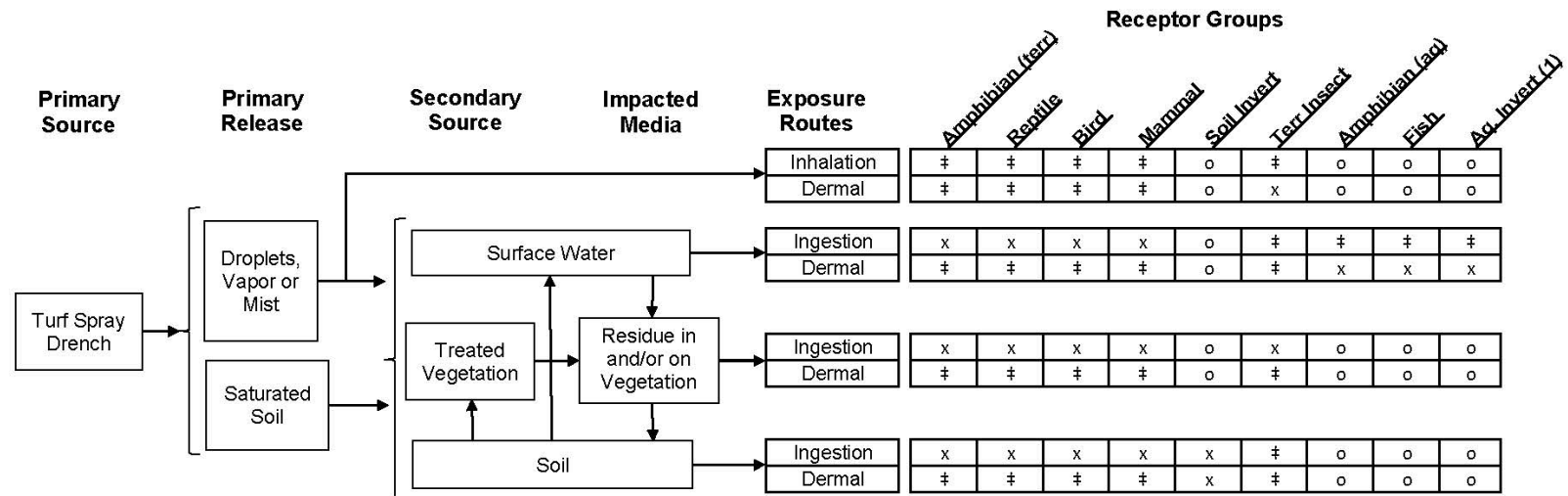
- x - Complete Exposure Pathway
- ‡ - Although complete, this pathway is not evaluated due to lack of toxicological or exposure data.
- o - Incomplete, Inconsequential, or De Minimus Exposure Pathway
- (1) Includes sediment-dwelling invertebrates.

**Abbreviations**

- Soil Invert: Soil Invertebrate
- Terr. Insect: Terrestrial Insect (incl. pollinators)
- Aq. Invert: Aquatic Invertebrate

**Figure Eco-1. Conceptual Site Model for residential granular applications to turf that may be made as part of CDFA’s Pest Detection/Emergency Programs.**

**Conceptual Site Model (CSM) for PD/EP-Eradication - Residential Turf Drench  
Ecological Risk Assessment**



**Notes:**

- x - Complete Exposure Pathway
- ‡ - Although complete, this pathway is not evaluated due to lack of toxicological or exposure data.
- o - Incomplete, Inconsequential, or De Minimus Exposure Pathway
- (1) Includes sediment-dwelling invertebrates.

**Abbreviations**

- Soil Invert: Soil Invertebrate
- Terr. Insect: Terrestrial Insect (incl. pollinators)
- Aq. Invert: Aquatic Invertebrate

**Figure Eco-2. Conceptual Site Model for residential spray drench applications to turf that may be made as part of CDFA’s Pest Detection/Emergency Programs.**

### 3.6 Analysis Plan

This ERA uses widely accepted models specific to ecological risk assessment to estimate the exposures outlined by the CSM. In addition, effects data for the measurement endpoints uses data available from the scientific literature. Since the applications adhering to scenarios analyzed in this ERA could occur in various locations in California, many of which would be unlikely to occur on a routine basis, it was not considered practical to collect and utilize field or site-specific data.

The analysis plan for the CSMs has been implemented in the next phase of the ecological risk assessment process: analysis. The analysis phase is subdivided into two sections: exposure assessment and effects assessment.

## 4 Exposure Assessment

The exposure assessment is part of the analysis phase of the risk assessment process that follows the problem formulation phase described in Section 3. The exposure assessment provides a description and quantification of the nature and magnitude of the interaction between pesticides in surface water, sediment, soil, or diet and the ecological receptors. This quantitative accounting of the amount of exposure is known as an EEC and is the main outcome of the exposure assessment. An EEC is defined as the predicted concentration of a pesticide within an environmental compartment (*i.e.*, within soil, water, plant tissue, or a specific organism) based on estimates of quantities released, discharge patterns and inherent disposition of the substance (*i.e.*, fate and distribution), as well as the nature of the specific receiving ecosystems. The results of the exposure assessment (*i.e.*, the EECs) are combined with the effects assessment to derive the risk characterization results in the final phase of the risk assessment process.

The exposure assessments are broken down between acute (short term) and chronic (long term) exposures, described in detail below. Several exposure models and assumptions are required to estimate the amount of pesticide that an organism is exposed to as the pesticide gets transported along the various exposure pathways. The exposure models and assumptions for acute and chronic exposures, for each receptor group in general, in aquatic and terrestrial environments, and under each application scenario were described in the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a) or subsequent Addenda (CDFA, 2016a, 2017a, 2020a, 2021a). Only those pathways or models new or unique to this assessment are included below.

Since it is not possible for this ERA to evaluate exact concentrations and exposures in the field, EECs are estimated using various conservative models that have been developed for use in risk assessments. These models are designed to use conservative assumptions and in many cases are not capable of modeling all the complex fate and transport processes that can occur once the pesticides are released into the environment (*e.g.*, dilution in estuarine/marine water bodies or flowing rivers or streams). Typical fate properties that tend to decrease the concentration of a pesticide include aerobic degradation, anaerobic degradation, photolysis, hydrolysis, absorption, solubilization, and volatilization. Key transport properties that may not be accounted for are dilution and partial transfer between media such as plants, soil, water, and air. Therefore, most of

the EECs will represent an upper-bound value since not all fate and transport properties have been modeled.

#### 4.1 Acute and Chronic Exposure

Please refer to the Statewide PEIR for an explanation of how acute and chronic exposures were determined (CDFA, 2014a).

#### 4.2 Assumptions for Exposure Following Granular and Turf Applications

Please refer to the Statewide PEIR for an explanation of how EECs were estimated following foliar applications (CDFA, 2014a). The exposure estimates for most environmental concentration procedures and models remained the same as were described in Section 3.2: Chronic Exposure of the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a). A brief discussion is presented here. For full details, please see the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a). Estimation methods for uptake of residues from soil into plants were updated. Concentrations in surface water were estimated using the USEPA's Pesticide in Water Calculator (PWC) rather than the outdated PE5 model.

##### 4.2.1 Concentration in/on Vegetation

###### 4.2.1.1 Concentration in/on Terrestrial Vegetation

Uptake by plants from soil was estimated in a similar manner as in the Ecological Risk Assessment of the PEIR (CDFA, 2014a). Plant surface residues following a foliar application were estimated using USEPA's T-REX model. USEPA (2012i) assumes 0.2% of the applied granular product adheres to turf following a granular application. Therefore, the estimated surface concentrations for Acelepryn G are assumed to be 0.2% of the modeled concentrations from T-REX. As discussed in Section 6: *Risk Characterization*, modeling concentrations of BtG on plant surfaces following applications for the qualitative assessment of beetleGONE! tlc was not necessary.

For beetleGONE! tlc, no uptake of a microbial insecticide from soil is assumed. For plant uptake from Acelepryn G ingredients from soil, a revised Briggs equation was used to estimate a Terrestrial Vegetation Uptake Factor (VUF) based on the updated version in USEPA (2014a). First, the  $K_{ow}$ -specific Transpiration Stream Concentration Factor (TSCF) was calculated to estimate the relative potential for the translocation of a chemical within a plant, based on the equation:

$$\text{TSCF} = [-0.0648 \times (\text{Log } K_{ow})^2 + 0.241 \times \text{Log } K_{ow} + 0.5822]$$

Where:

TSCF = Transpiration Stream Concentration Factor  
 $K_{ow}$  = Octanol/Water Partition Coefficient (unitless)

Using the TSCF and other inputs as described below, the Briggs equation (USEPA, 2014a) is utilized to yield the Terrestrial Vegetation Uptake Factor (VUF) in wet weight:

$$\text{Terrestrial VUF} = ([10^{(0.95 \times \text{Log } K_{ow} - 2.05)} + 0.82] \times \text{TSCF} \times \left[ \frac{\rho}{\theta + \rho \times K_{oc} \times f_{oc}} \right])$$

Where:

VUF = Vegetation uptake factor

$K_{ow}$  = Octanol/Water Partition Coefficient (unitless)

$\rho$  = soil bulk density (g/cm<sup>3</sup>)

$\theta$  = soil-water content by volume (cm<sup>3</sup>/cm<sup>3</sup>)

$K_{oc}$  = soil organic carbon-water partitioning coefficient (cm<sup>3</sup>/g-organic carbon or L/kg-organic carbon)

$f_{oc}$  = fraction of organic carbon in the soil

The values of  $\rho$ ,  $\theta$ , and  $f_{oc}$  are from Pesticide Root Zone Model (PRZM) data for California residential soil profiles for Tierra soils. See Section 4.2.2: *Surface Water Concentrations* for more details. Once the terrestrial VUF was estimated, it was multiplied by the concentration of pesticides in soil to get the EEC in terrestrial vegetation due to uptake from soil.

$$\text{EEC} = \text{VUF} \times \text{Soil Concentration}$$

Complete details regarding how the Briggs equation was used appear in the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a). In keeping with the guidance by USEPA (2014a), if the Log  $K_{ow}$  was greater than 5.0, no uptake was assumed. When the Log  $K_{ow}$  is negative, the TSCF is assumed to be 1.0 (Collins *et al.*, 2006). The EECs estimated and used in this assessment appear in the Dashboard Database.

#### 4.2.1.2 Concentration in Aquatic Vegetation

The Briggs equation was used to estimate concentrations in aquatic vegetation in a similar manner as was performed in the Statewide PEIR (CDFA, 2014a). However, no uptake of beetleGONE! tlc from water is assumed. The EECs estimated and used in this assessment appear in the Dashboard Database.

### 4.2.2 Surface Water Concentrations

The concentration of pesticides in surface water resulting from drift, runoff, or erosion during and after pesticide applications was estimated using USEPA's (2020c) PWC (Version 2), the successor to PE5 and the Surface Water Concentration Calculator (SWCC). The PWC, incorporates two distinct, but connected models to simulate transport from soil to water: the Pesticide Root Zone Model version 5.0+ (PRZM) and the Variable Volume Water Body Model (VVWM). PRZM is a one-dimensional, dynamic, compartmental model that can be used to simulate pesticide movement in unsaturated soil systems within and immediately below the plant root zone. VVWM contains a set of process modules that link fundamental chemical properties to the limnological parameters that estimate the kinetics of fate and transport in aquatic systems. The PWC estimates pesticide concentrations in the water as the upper 90th ranked annual peak,

1-day average, 4-day average, 21-day average, 60-day average, and 365-day average of the simulation as well as the mean value of all daily concentrations in the simulation. The PWC also estimates the upper 90th ranked annual and 21-day average sediment pore water peak concentrations as well as the annual and 21-day concentration in sediment.

The standard PRZM/VVWM runoff modeling scenario is based on site-specific conditions of fields draining into water bodies for drinking water and aquatic exposure assessments. Each PRZM simulation represents a unique combination of climatic conditions, crop-specific management practices, soil-specific properties, site-specific hydrology, and pesticide-specific application and dissipation processes. Daily edge-of-field loadings of pesticides dissolved in runoff waters and adsorbed to entrained particles, as predicted by PRZM, are discharged into a standard water body, and simulated by VVWM. VVWM accounts for volatilization, sorption, hydrolysis, biodegradation, and photolysis of the pesticide (USEPA, 2016e).

The PRZM standard scenario, referred to in the model documentation as the “farm pond scenario,” was used for pesticide exposure assessments because it focuses on exposure to ecological receptors (Wild and Jones, 1992). The default “farm pond” is defined as a one-hectare (2.47-acre) body of water, 2 meters (6.56 feet) deep equaling 20,000 cubic meters (706,293 cubic feet). In determining watershed dimensions, the USEPA farm pond scenario defaults were used with two exceptions: field area and hydraulic length. Within urban landscapes, roughly 1/3 of the total treatment area listed in the PMDS occupy potential treatment locations (e.g., beetle habitat such as turf or groundcover within the 200-meter radius around Japanese beetle detections). Thus, the field area modeled for urban/residential applications was 1/3 the field area listed in the PMDS. Scenario-specific PMDSs are provided in **Appendix Eco-A**. The hydraulic length was calculated as the square root of the selected field area to provide the depth of a field assumed to be a square. Limnetic or water column concentrations in a waterbody were used for drinking water for wildlife as well as exposure for fish and other aquatic species. Sediment and sediment pore-water concentrations were used for exposure to benthic invertebrates. The water volume in the water body was assumed to remain constant and no outflow was modeled.

It is possible that pesticide applications under the Proposed Program could be made in proximity to flowing water such as rivers or streams or other water bodies with inflow and outflow. These waterbodies will experience dilution of water concentrations from introduction of fresh water. Additionally, large streams or lakes or ponds larger than the modeled waterbody will not achieve the modeled concentrations due to the dilution in a larger volume of water. Similarly, marine/estuarine environments will not achieve the modeled concentrations due to larger volumes of water and flushing from tidal and wave action.

USEPA’s AgDRIFT model values for application efficiency and spray drift loading were used in previous analyses in the Statewide PEIR (CDFA, 2014a) and Addenda (CDFA, 2016a, 2017a, 2020a). Because of its granular formulation, the application efficiency and spray drift percentages used in the current analysis of Acelepryn G were 100% and 0%, respectively (Houbao Li, USEPA, personal communication, November 3, 2020).

PRZM Scenario Files have been selected based on similarities between application location and setting and the environment modeled by the scenario file. The CAresidentialRLF scenario was

selected to simulate urban/residential turf applications. The modeled soil parameters were left as the CAresidentialRLF defaults (Tierra soils), which are considered representative of urban residential areas. Additionally, to account for unintended applications to nearby impervious surfaces, such as pavement, sidewalks, and driveways, DPR recommends that a parallel run of PWC be performed with CAimperviousRLF and the area-weighted average of the two PWC-predicted EECs be reported as the final EEC (Luo, 2014). In estimating the area-weighted average, a weighting of 99.5% and 0.5% were applied to CAresidentialRLF and CAimperviousRLF runs, respectively, to account for the vast majority of applied pesticide reaching the target site with minimal application to impervious surfaces. The default soil parameters for the CAimperviousRLF scenario were used, representing a similar soil series as the in CAresidentialRLF scenario with the upper horizon adjusted to a non-soil nature (USEPA, 2020d).

The PWC uses USEPA (2020d) weather files containing weather data from 1961 through 1990. The default meteorological file for the CAresidentialRLF scenario, San Francisco (W23234.dvf), was used. The starting application date selected for urban/residential applications was March 1<sup>st</sup> and applications were assumed to take place over 10 consecutive years (Dean Kelch, CDFA, personal communication, December 8, 2020). All other application details are defined in the PMDS (**Appendix Eco-A**).

Scenarios were modeled as foliar (Above Crop) applications in which pesticide residues on treated foliage are subject to wash-off and degradation. PWC uses the selected weather files to simulate rainfall timing and amounts to determine the extent of surface residues washed off. Consistent with USEPA's (2012l) recommended values for post-application dermal exposure to granular pesticide residues on turf, 0.2% of the applied material was assumed to remain on foliage as residue following application of Acelepryn G.

The PWC determines a Henry's Law Constant based on the molecular weight, vapor pressure, and water solubility. Since the soil organic carbon/water partition coefficient ( $K_{oc}$ ) better predicts the mobility of organic contaminants in soil,  $K_{oc}$  values have been used in preference to the soil/water partition coefficient ( $K_d$ ). Neutral hydrolysis half-lives (pH 7) are used as inputs because water bodies modeled through PWC are fixed at pH 7 (USEPA, 2016e). A reference temperature of 25°C was selected for each degradation pathway and a value of 40°N was selected for the photolysis reference latitude. Chemical-specific physical and chemical properties are presented in the Dashboard Database.

The maximum surface water concentrations resulting from applications of beetleGONE! tlc were conservatively estimated by assuming that 100% of the product was applied directly to the default "farm pond" described above. The estimated maximum concentration of BtG in a "farm pond" is 0.75 mg/L. Although such an application would not occur, this concentration is the worst-case concentration theoretically possible. The EECs for Acelepryn G estimated and used in this assessment appear in the Dashboard Database.

### 4.2.3 Soil Concentrations

After application to turf and groundcover, these areas are ‘watered-in’ so the pesticide moves into the soil where the target Japanese beetle grubs exist. Although some pesticide residue might remain on the turf or groundcover, all the applied pesticide following a granular application is assumed to become incorporated into the soil. Bare ground areas beneath plants are assumed to have received 100% of the applied chemical.

Following a granular application, chronic soil concentrations are estimated as described for previous analyses in the Statewide PEIR (CDFA, 2014a) and Addenda (CDFA, 2016a, 2017a, 2020a, 2021a). However, exposure to soil concentrations for acute exposures are assumed to be distributed only in the upper 1 cm rather than the upper 15 cm as is assumed for chronic exposures. Concentrations in soils are assumed to remain closer to the surface following granular applications so modeled consumption of surface soils could also contain fully loaded granules. Consumption of intact granules is assumed to be inadvertent and cause no greater exposure to pesticides in soil than previously assessed, except for birds (see Section 4.2.4: *Consumption of Granules*). The EECs estimated and used in this assessment appear in the Dashboard Database.

For beetleGONE! tlc, soil concentrations of BtG were not modeled. The standard physical and fate parameters used to model movement and dissipation of a pesticide in soil are not available for microbial pesticides such as beetleGONE! tlc.

### 4.2.4 Consumption of Granules

Birds are known to intentionally ingest pesticide granules mistaking the granules for grit or possibly seeds (Best and Gionfriddo, 1991; Best and Fischer, 1992; Gionfriddo and Best, 1996). Since birds can intentionally ingest grit, granule consumption exposure for birds following a granular pesticide application is treated as a unique route of exposure. Gionfriddo and Best (1996) determined the number of grit particles consumed by many species of birds, focusing on those species that frequent agricultural fields. Seed eating species had more grit in their gizzards than insectivores or frugivores. More recently, Moore *et al.* (2010a, 2010b) used the data from Gionfriddo and Best (1996) to develop a refined risk assessment for granular pesticides. Upper 95% confidence limit estimates used for the bird surrogate species appear in **Table Eco-1**. Carnivorous and piscivorous species are assumed not to intentionally ingest grit and therefore not ingest granules.



Table Eco-1. Upper 95% Confidence Limit Estimates for Daily Grit Ingestion Rate for Avian Surrogate Species.

Surrogate Species	Upper 95% Confidence Limit	Source Species
tricolored blackbird	27	red-winged blackbird
mourning dove	5	mourning dove
Osprey	0	NA
California Brown Pelican	0	NA
California Condor	0	NA
White-tailed Kite	0	NA
Cooper's Hawk	0	NA
fulvous whistling-duck	10	killdeer
yellow-billed cuckoo	27	red-winged blackbird
purple martin	3	eastern kingbird
Yellow rail	10	killdeer

Data from Gionfriddo and Best, 1996 taken from Moore *et al.* 2010a

Moore *et al.* (2010a) assume 100% of granules are present on the soil surface following a broadcast application. Their assessment focused on corn field applications at planting, so the applications are made to bare soil. For a turf application, those granules that fall beneath the turf and into or beneath any thatch will be less available. Assuming 100% of the granules is considered likely to be an overestimate, but no reliable estimates for appropriately reducing availability following a turf application were found.

#### 4.2.4.1 Concentration in Granules

Estimates of the amount of pesticide within an individual granule could not be attained from regulators or the manufacturer. A commercially available sample of Acelepryn G was attained and used to estimate granule mass, from which the amount of pesticide per granule could be estimated from the percent content in the formulated product.

To estimate granule mass, 10 subsamples (with replacement) of Acelepryn G were weighed. The granules within each subsample were counted. After the granules were counted, the granules were weighed again. The difference between the masses of the initial measurement and the second, not containing the nongranular fine material was identified as the 'fines.' The mean sample mass without fines was 0.378 g, and the mean number of granules was 183.9. This results in an estimated mass of 0.00207 g/granule. The mean amount of fines was 0.73%.

To estimate the concentration within a granule, the content in the formulated product (*e.g.*, 0.2% chlorantraniliprole) can be used. Therefore, the mean content of chlorantraniliprole within granules is estimated to be 4.14 µg/granule.

#### 4.2.4.1 Size of Granules

In addition to weighing subsamples of granules, the size of granules was also measured. From each subsample, the largest, smallest, and typical granules were measured. Across all subsamples, the largest granule was 2.5 mm in diameter with the average large granule being 2.1 mm. The smallest granule across all subsamples was 0.64 mm with the average small granule

being 0.74 mm. Fines and granule fragments were not measured for size. The typical granule size was 1.3 mm. Gionfriddo and Best (1996) found birds used grit ranging from 0.3 to 3 mm. Therefore, the intact granules of Acelepryn G are within the size range that birds could collect as grit.

#### 4.2.5 Concentrations in Insects

The USEPA's T-REX model and the Briggs' equation were used to estimate concentrations in insect prey items in a similar manner as was performed in the Statewide PEIR with the following exception. Since most non-turf vegetation or other areas within the treatment area would not receive a direct application, only those insects in the turf or treated ornamental ground cover would be directly treated. Many if not most insects present in the treatment area and available as prey would contain little if any residues. Following granular applications of Acelepryn G, only 0.2% of the applied material is assumed to adhere to insects living in the turf or groundcover based on the amount assumed to adhere to turf (USEPA, 2012l). The Briggs equation was used to estimate concentrations in insect prey items in a similar manner as was performed in the Statewide PEIR (CDFA, 2014a) to estimate accumulation in insects from consumption of systemic plant residues. The EECs estimated following application of Acelepryn G and used in this assessment appear in the Dashboard Database.

For beetleGONE! tlc, concentrations of BtG in insects were not modeled. The standard physical and fate parameters used to model movement and dissipation of a pesticide in the environment are not available for microbial pesticides such as beetleGONE! tlc. As discussed in Section 6: Risk Characterization, modeling concentrations of BtG on or in insects following applications of beetleGONE! tlc was not necessary.

#### 4.2.6 Tissue Concentrations in Aquatic Organisms

As described Section 3.3.2: *Chronic Exposure in Aquatic Species* of the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a), tissue concentrations in aquatic organisms were estimated using the USEPA's (2009s) KABAM model ( $K_{ow}$  (based) Aquatic BioAccumulation Model). KABAM cannot be used to estimate accumulation of a microbial pesticide. Ingestion of any microbial pesticide residue by aquatic organisms is assumed to be *de minimis*, so no tissue concentrations are assumed for beetleGONE! tlc. The EECs estimated and used in this assessment appear in the Dashboard Database.

#### 4.2.7 Honey Bee and Non-target Insect Exposure

The USEPA (2014a) released guidance for assessing risk to honey bees that includes additional guidance on estimating acute and chronic exposure of larval and adult bees or non-target insects to pollen and nectar. Contact exposure is assessed only for acute exposure since the exposure is to a direct spray and would be a discrete, one-time event. The methods in the guidance document are otherwise essentially the same as those presented in the Statewide PEIR (CDFA, 2014a) based on the previous methods (USEPA, 2012g). For soil applications, including granular

applications, the only source for residues present in pollen or nectar is from systemic uptake from the soil.

### 4.3 Oral Ingestion Exposure Calculations

No changes were made to how dietary exposures for dietary items were estimated. Please see Section 3.4: *Terrestrial Exposure Assessment* of the Ecological Risk Assessment of the Statewide PEIR (CDFA, 2014a) for a full description of how oral ingestion exposure was estimated. See Section 4.2.3: *Soil Concentrations* for discussion of soil consumption following granular applications and Section 4.2.4: *Consumption of Granules* for exposure following consumption of granules.

#### 4.3.1 Area Use Factor

To acknowledge that some species' food could be acquired from outside the area receiving pesticide treatments, an Area Use Factor (AUF) was calculated for each species and each pesticide application scenario based on the species' foraging range and typical treatment areas. The treatment areas for the different scenarios have been described (see **Appendix Eco-A: Program Material Data Sheet (PMDS)**). In addition to the size of the treated area, the size of the species home range or foraging range was used to calculate the AUF as follows:

$$\text{AUF} = \frac{\text{Foraging Range}}{\text{Treated Area}}$$

For species with a home range or foraging area smaller than the size of the treated area, all their food was assumed to be gathered from the treated area. The consumption of granules by birds is addressed in a similar manner. For species with a home range larger than the size of the treated area, the proportion of diet containing pesticide residues or percentage of pesticide granules ingested in place of grit could be assumed to be comparable to the AUF. Long-term (chronic) exposures are reduced or diluted in such species because a portion of their diets or grit are likely acquired off the application area. The estimates used for each species foraging range can be found in the Dashboard Database.

In the assessment of acute risk, the AUF was always set to 1.0. An animal could potentially spend a short time within a treated area and become acutely exposed shortly after an application. Therefore, no reduction in the acute exposure estimate has been made based on the AUF. In the chronic assessment for terrestrial species, three exposure estimates were made. One exposure estimate used the calculated AUF based on the species' foraging or home range and the application area. A second estimate set the AUF to 1.0 to assess the potential situation where multiple adjacent applications might have been made to the entire home range. The third estimate used the midpoint between the estimated AUF and 1.0. For example, if the estimated AUF would have been 0.45, the Midpoint AUF would be 0.725. In the chronic assessment of aquatic species, the AUF was always 1.0 since aquatic species are restricted to their surface water bodies. By presenting a range of exposures estimated from different AUF (*i.e.*, no AUF, Midpoint AUF, and AUF), other species represented by the surrogate species that have similar diets, but a differing foraging range, were better included in the exposure estimates.

Given the large geographic scope of the Proposed Program, it was not possible to predict the number of treatment areas that might occur within a species home range. Assuming an AUF equal to 1.0 would likely be overly conservative but using the AUF based on the species' home range might not be sufficiently conservative. Inclusion of the Midpoint AUF was an attempt to capture this uncertainty. The Midpoint AUF also accounts for species with similar diets as a surrogate but that have a different foraging range. Therefore, both ends of this spectrum, as well as the midpoint, were developed and the full range of possibilities presented.

## 5 Effects Assessment

The effects assessment consists of an evaluation of available toxicity or other adverse effects information that can be used to relate the exposures to pesticides and adverse effects in ecological receptors. Toxicity is a property of a chemical, and the toxicity of a chemical alone does not indicate its potential to harm a given organism. A key to understanding the effects of a chemical on an organism is the dosage of the chemical that the organism receives or the concentration to which it is exposed. For example, certain substances are considered toxic (*e.g.*, caffeine), but are harmless in small dosages. Conversely, an ordinarily harmless substance (*e.g.*, water) can be lethal if over-consumed. This relationship between exposure and effect on an organism is called a dose-response effect and is discussed in Section 6: *Risk Characterization*. Data that can be used to define the toxicity of a chemical include literature-derived or site-specific single-chemical toxicity data, site-specific ambient-media toxicity tests, and site-specific field surveys (Suter, 2007). For this ERA, data were restricted to single-chemical toxicity data from literature sources because specific toxicity data for the mixtures of pesticides were not available.

In this ERA, numerical representation of the measurement effects for toxicity are reported as TRVs. TRVs are a toxicological index that, when compared with exposure, are used to quantify risk to ecological receptors. The way in which TRVs are developed depends on available data of the chemical's toxicological effects and commonly accepted assumptions that address uncertainty regarding the available data. TRVs were developed using the same methods as described in the Statewide PEIR (CDFA, 2014a). TRVs for chlorantraniliprole and polybutene can be found in the Dashboard Database. No relevant ecotoxicological data were available on which to base TRVs for dolomite, so no TRVs are included in the Dashboard Database for that inert ingredient. The assessment for BtG was qualitative, so development of TRVs for BtG was not performed. The results of the effects assessment (*i.e.*, the TRVs) are combined with the exposure assessment to derive the risk characterization results in the final phase of the risk assessment process.

The USEPA (2017f) has developed acute toxicity categories for pesticides ranging from the most toxic category of 'very highly toxic' to the least toxic category of 'practically nontoxic' (**Table Eco-2**). These are based solely on the results of laboratory acute toxicity tests and do not reflect the exposure or dose received by an organism that determines if there is an adverse effect following a pesticide application. This classification gives a description of the numerical toxicity of the chemical and provides a means of comparing the potency among chemicals. It is not until it is combined with an EEC or EDD that adverse effects following a specific exposure can be

addressed. The detailed description of the toxicity classification from **Table Eco-2** is provided for each active or inert ingredient below.

Table Eco-2. Acute Ecotoxicity Categories for Terrestrial and Aquatic Organisms.

Toxicity Category	Avian: Acute Oral LD <sub>50</sub> (mg/kg)	Aquatic Organisms: Acute LC <sub>50</sub> (ppm)	Wild Mammals: Acute Oral LD <sub>50</sub> (mg/kg)	Non-Target Insects: Acute LD <sub>50</sub> (µg/bee)
very highly toxic	<10	<0.1	<10	--
highly toxic	10-50	0.1 - 1	10 - 50	<2
moderately toxic	51-500	>1 - 10	51 - 500	2 - 11
slightly toxic	501-2000	>10 - 100	501 - 2000	--
practically nontoxic	>2000	>100	>2000	>11

Source: USEPA 2017f

## 5.1 Chlorantraniliprole

The active ingredient in Acelepryn G is chlorantraniliprole. Chlorantraniliprole is moderately toxic to aquatic-phase amphibians. Chlorantraniliprole ranges from very highly toxic to highly to freshwater and estuarine/marine aquatic invertebrates and is slightly to practically nontoxic to freshwater and estuarine/marine fish.

No toxicity information was available for terrestrial-phase amphibians, so the toxicity of chlorantraniliprole to terrestrial-phase amphibians was assumed to be similar to that in birds. Chlorantraniliprole is practically nontoxic to birds but slightly toxic to mammals. No toxicity data were available for reptiles, so chlorantraniliprole was assumed to show similar toxicity to reptiles as to birds. Chlorantraniliprole is moderately to highly toxic to bees.

## 5.2 Dolomite

The toxicology data for dolomite, an inert ingredient in Acelepryn G is limited. Only one study was identified. Lagarto *et al.* (2008) investigated developmental toxicity in rats and found no adverse effects at the highest oral dose of 1500 mg/kg-bw during days 6 – 15 of gestation. Since no adverse effects have been identified in this single study, and considering the lack of additional toxicology data, dolomite lacks sufficient endpoint to assess risk.

## 5.3 Polybutene

Sufficient toxicology data for polybutene, another inert ingredient in Acelepryn G, was available to include it in the risk assessment. Polybutene is classified as highly toxic to freshwater aquatic invertebrates and moderately toxic to freshwater fish. The toxicity for freshwater fish was used to assess risk for aquatic-phase amphibians. No toxicity data were available for marine/estuarine invertebrates or fish.

Polybutene is classified as practically nontoxic for birds and mammals. Although no toxicity data was available for terrestrial-phase amphibians or reptiles, toxicity data for birds was used in the

risk assessment for these taxonomic groups. No oral toxicity data was available for honey bees, but polybutene is classified as practically nontoxic to honey bees via contact exposure.

#### 5.4 *Bacillus thuringiensis* serovar *galleriae* strain SDS 502

USEPA (2013l) and Health Canada (2018a) summarize the ecotoxicology of BtG. No fish toxicity data are reported, but based on the results of fish toxicity tests with other strains of Bt, BtG is not considered toxic or pathogenic to fish. A study with the water flea (*Daphnia magna*) was reported to indicate BtG is practically nontoxic to aquatic invertebrates. No other aquatic toxicity data are reported.

For terrestrial species, BtG is classified as practically nontoxic for birds. The acute mammalian toxicity results are reported as colony forming units per animal (CFU/animal) so cannot be classified according to the categories in **Table Eco-2**. However, the results are interpreted as showing no toxicity. The results for honey bees are not definitive since the exposure is to the endotoxin from BtG, and it is unclear the amount of endotoxin present in the beetleGONE! tlc. However, the effects on larval honey bees were not considered highly harmful.

## 6 Risk Characterization

Risk characterization is the final phase in the risk assessment process. The purpose of the risk characterization phase is to integrate the two aspects of the analysis phase: exposure and effects assessments. In risk characterization, exposure and effects data are integrated to allow for conclusions concerning the presence, nature, and magnitude of effects that may exist under the application scenarios. This includes both quantitative and qualitative assessments for Acelepryn G to properly characterize the complete risk assessment outcome. The assessment for beetleGONE! tlc was entirely qualitative because environmental fate could not be properly modeled. The quantitative assessment for Acelepryn G is based on a comparison of the numerical value from combining exposure and effects – the RQ – against a target value – the LOC. For scenarios that have RQs below the LOC, a conclusion is appropriate for a low potential for adverse effects from implementation of the scenario. This conclusion is due to the conservative assumptions that were consistently used throughout the risk assessment process. For situations where the RQ for Acelepryn G exceeds the LOC, a qualitative analysis of the potential for adverse effects under the application scenario incorporates information that cannot be included in the quantitative analysis. The exceedance of an RQ alone is not sufficient to indicate a presumption that adverse effects are likely.

In ecological risk assessments for pesticides, EECs or EDDs determined in Section 4: *Exposure Assessment* are compared to TRVs developed in Section 5: *Effects Assessment* to calculate an RQ (USEPA, 2004j).

$$RQ = \frac{EEC \text{ or } EDD}{TRV}$$

Where:

RQ = Risk Quotient (unitless)

EEC = Estimated Environmental Concentration (mg dw/kg or µg/L)

EDD = Estimated Daily Dose (mg/kg bw-day)

TRV = Toxicity Reference Value (mg/kg bw-day or µg/L)

When the RQ is equal to or exceeds an LOC of 1.0, a potential risk has been presumed to exist for the non-threatened or non-endangered ecological receptor being assessed. For listed threatened or endangered (T&E) species, the LOC is reduced to 0.5, to represent the heightened concern for these species, and this LOC is referred to as the T&E LOC. It is important to remember that whenever an RQ exceeds the standard LOC of 1.0, suggesting exposures to non-T&E species might be harmful, the lower T&E LOC providing additional protection to special-status species is necessarily exceeded.

RQs for both acute and chronic risk have been calculated in the same manner using the appropriate acute or chronic EEC or EDD paired with appropriate acute or chronic TRV. When all pesticide active and inert ingredients were assessed individually, the RQs for all chemicals present were assumed to be additive and thus totaled together to determine the total RQ. The total RQ is then compared to the applicable LOC. The risk analysis focused on whether the total RQs from all ingredients in the Acelepryn G could exceed either the standard LOC of 1.0 or the T&E LOC of 0.5.

When RQs were above the applicable LOC, a qualitative assessment was conducted. Several common qualitative assessments were utilized, and the discussion below presents the rationale forming the basis of these qualitative assessments. It also includes specific measures that can be implemented to decrease the potential for adverse effects. This logic is referred to for specific application scenarios later in this section, but the full rationale presented here.

## 6.1 Potential for a Species to Be Present at the Application Site

One of the first qualitative attributes to consider is the likelihood of the specific species being present at a particular application site. This ERA was conducted assuming all species would be present at an application site. This is clearly not likely as species exist in particular habitats and not all habitats can occur at a single application site. For instance, if the application site does not contain suitable foraging habitat for a particular species, that species is relatively unlikely to come into the area and be exposed to pesticides by ingestion. Pollinating species are less likely to be present if no plants in bloom are present. Some locations are unlikely to have any species present, such as highly trafficked areas in an urban/residential setting. Marine/estuarine species would be absent if the application site is not near the coastline.

CDFA's standard practice prior to implementing any pesticide application scenario is to identify whether any special-status species habitat is nearby, and if so, identify appropriate measures to avoid adversely affecting the species. As part of this, CDFA obtains technical assistance from California Department of Fish and Wildlife (CDFW), National Marine Fisheries Service (NMFS), and/or United States Fish and Wildlife Service (USFWS). Examples of these measures include:

- Conduct application at times when the species is unlikely to be present.
- Ensure an adequate buffer distance is maintained to minimize the concentrations of pesticides that reach surrounding habitat by drift or run-off.
- Spray pots on impermeable surfaces to prevent leaching pesticides to native soil.
- Conduct BeeChecks and applicable notifications through the BeeWhere program (<https://beewherecalifornia.com>) to locate nearby honey bee colonies.

Advanced notice is **mandatory** under 3 CCR § 6654(a):

*“Each person intending to apply any pesticide toxic to bees to a blossoming plant shall, prior to the application, inquire of the commissioner, or of a notification service designated by the commissioner, whether any beekeeper with apiaries within one mile of the application site has requested notice of such application.”*

With implementation of this standard practice, the potential for adverse effects on species as a result of Proposed Program pesticides applications would be low.

## 6.2 Foraging Diet

The extent to which a particular species consumes food from the application area will greatly influence their exposure. Different species forage over vastly different areas. The analysis presented three different assumptions for the percentage of foraging range that would be within the application area. This was done to show the range of variabilities that may occur depending on the extent to which a particular species consumes vegetation or other organisms from within the application area. Species with large foraging areas are unlikely to consume all their diet from within an application area. Foraging range is typically related to availability of food resources, so most species with similar diets have similar foraging ranges. Long-term (chronic) exposures are reduced or diluted in such species because a portion of their diets are likely acquired off the application area. Refer to the discussion of AUFs in Section 4.3: *Oral Ingestion Exposure Calculations*.

## 6.3 Dilution and Degradation of Chemicals

Through time, concentration of pesticides generally decreases following an application. The models used in the quantitative risk assessment have limited capabilities to fully incorporate the numerous fate mechanisms which cause the pesticides to dissipate in the environment. Thus, in many instances, the concentrations that would likely occur would be less than the values modeled in the quantitative risk assessment. In the case of chronic exposures, the concentrations would be considerably lower than estimated. This applies in particular to soil and water concentrations as well as those estimated concentrations related to uptake from either soil or



water. In addition to overestimation of concentrations due to chemical breakdown, dilution (or reduction in concentration when mixed) will occur when the pesticide residues combine with environmental media that is not contaminated. For instance, during a rain event that assists in transporting pesticide residue from foliage and soil to a waterbody, additional, uncontaminated water will add to the volume of water in the waterbody itself. This also applies to water concentrations as the pesticides continue to move from various waterbodies, such as drainage ditches, streams, and rivers. Due to dilution and low probability of application scenarios being adjacent to a marine/estuarine waterbody, the potential for elevated concentrations in marine/estuarine waterbodies would be relatively low, and the potential for adverse effects to marine/estuarine species would be correspondingly low.

It is CDFA's practice to ensure measures are taken to prevent pesticide applications from directly reaching a waterbody. CDFA's protection measures for surface waters were presented in Section 2.11: *Program Management Practices* of the Main Body of the Statewide PEIR (CDFA, 2014a). Site-specific conditions cannot always be addressed by program BMPs, and it is possible that some areas cannot be treated or additional precautions will be necessary. Indirect pathways would likely have lower concentrations than predicted by the quantitative model. Therefore, the actual risk to aquatic organisms would be lower than predicted. Specific BMPs are required for specific applications conducted by CDFA under their Spray Applications National Pollutant Discharge Elimination System (NPDES) permit.

#### 6.4 Risk Analysis for the Pest Detection/Emergency Program's Turf Applications in an Urban/Residential Setting using Acelepryn G (PD/EP-E-11)

The risk analysis focused on whether the RQs resulting from turf and groundcover applications of Acelepryn G targeting Japanese beetle grubs in the soil in urban/residential settings exceed the LOCs, either the standard LOC of 1.0 or the T&E LOC of 0.5, which provide additional protection to special-status species. It is important to remember that whenever an RQ exceeds the standard LOC suggesting exposures to non-T&E species might be harmful, the T&E LOC is necessarily exceeded as well. The potential for risk from inert ingredients (for which sufficient data were available) in Acelepryn G is included in this analysis. Polybutene, but not dolomite was included in the assessment.

Considerable detail was included in the analysis of risk for eradication of Japanese beetles. This detail was provided to discuss specifics of exposures for various surrogate species and how such exposures could influence whether LOCs are exceeded. Granular turf and groundcover applications of Acelepryn G for the eradication of Japanese beetles would be made in urban/residential areas. Applications would be made up to twice per year to roughly a third of the 50-acre area surrounding where a Japanese beetle was found. Additionally, as described in Section 2.10.2: *Technical Assistance from the U.S. Fish and Wildlife Service, National Marine Fisheries Service, and California Department of Fish and Wildlife* of the Main Body of the Statewide PEIR (CDFA, 2014a), CDFA will consult as necessary with CDFW to ensure that there are no adverse effects on the special-status species by implementing buffers or other suitable measures.

In the PD/EP, Acelepryn G applied as a granular (PD/EP-E-11) treatment to turf and groundcover in an urban/residential setting up to twice per year was not already evaluated in the

Statewide PEIR (CDFA, 2014a). **Table Eco-3** presents the acute RQs and **Tables Eco-4** through **Eco-6** present chronic RQs associated with scenario PD/EP-E-11 when granular applications are made for the eradication of Japanese beetle. Chronic RQs for fully aquatic species appear only in **Table Eco-6** since no AUFs are considered for aquatic species. No acute TRVs are available for larval honey bees, so larval honey bees are not included in **Table Eco-3**. Chronic TRVs do not exist for terrestrial insects, so no terrestrial insects that appear in **Tables Eco-4** through **Eco-6**. Those RQs that exceed the standard LOC of 1.0 appear as bold text, whereas those RQs that exceed only the T&E LOC of 0.5 appear in bold italics.

#### 6.4.1 Risk to Amphibians

Granular applications of Acelepryn G in an urban/residential setting do not result in acute or chronic RQs that exceed LOCs for aquatic-phase amphibians. Therefore, the potential for adverse effects is thought to be low for aquatic-phase amphibians following applications of Acelepryn G in an urban/residential setting.

Chronic RQs for terrestrial-phase California red-legged frogs and western spadefoot and acute and chronic RQs for terrestrial-phase foothill yellow-legged frogs exceed LOCs. These exceedances result from consumption of terrestrial soil invertebrates such as earthworms. The exceedances result from residues of polybutene in soil invertebrates (see Dashboard Database for detailed risk results). Uptake from soil in soil invertebrates is based on Log  $K_{ow}$ . The unusually high Log  $K_{ow}$  for polybutene is based on estimated values derived from its assumed chemical structure, not laboratory-derived values and results in modeled concentrations of polybutene in earthworms that are extremely high (see Dashboard Database for detailed EEC values). There is considerable uncertainty regarding how well the uptake factors predict concentrations in earthworms at such high Log  $K_{ow}$  values, how bioavailable polybutene will be, and the extent to which earthworms might consume and subsequently accumulate polybutene. The  $K_{oc}$  value, which indicates how tightly polybutene will bind to organic content in soil is also high. The high  $K_{oc}$  for polybutene is also based on estimated values derived from its assumed chemical structure, not laboratory-derived values. A high  $K_{oc}$  value would indicate limited bioavailability.

If residues of polybutene concentrate sufficiently in earthworms, it is possible adverse effects could occur in terrestrial-phase amphibians that consume a high proportion of soil invertebrates. However, since polybutene is tightly bound to organic content, its bioavailability is likely low. Chlorantraniliprole contributes little to the overall RQ. Considering the limited bioavailability of polybutene, adverse effects for terrestrial-phase amphibians appears unlikely.

#### 6.4.2 Risk to Aquatic Invertebrates

The acute and chronic RQs following use of Acelepryn G as a granular treatment to turf and groundcover exceed LOCs for freshwater pool-dwelling species such as vernal pool fairy shrimp, and the chronic RQ exceeds the standard and T&E LOCs for the freshwater pool-dwelling Tomales isopod. The estuarine mimic tryonia and marine black abalone also have chronic RQs that exceed the standard and T&E LOCs. In locations where aquatic invertebrate species that exceed any LOCs or other special status species they represent may be present, CDFA will

consult with CDFW, USFWS and/or NMFS to ensure that there are no adverse effects on the species by implementing suitable buffers or other suitable measures. Implementation of the recommended measures by the agencies resulting in no residues moving to surface waters results in RQs that do not exceed LOCs, and the potential for adverse effects is low.

Implementation of the measures presented in Section 2.11: *Program Management Practices* of the Statewide PEIR (CDFA, 2014a) will greatly reduce the amount of chlorantraniliprole and polybutene that might move to surface waters. Wherever the nearby surface water is estuarine or marine, there will be tremendous dilution from wave action and the large volume of water present as compared to the size of the surface water body modeled in the PWC. Additionally, flowing water will represent a considerable dilution as compared the concentrations modeled by the PWC. Water concentrations in surface water following applications of Acelepryn G are anticipated to be much lower than the modeled concentrations because of model limitations and Program Management Practices in the Statewide PEIR (CDFA, 2014a). Therefore, the potential for adverse effects to aquatic invertebrates is low.

#### 6.4.3 Risk to Fish

No acute or chronic RQs for marine/estuarine or freshwater fish exceed LOCs. Therefore, use of Acelepryn G as a granular treatment to turf and groundcover in an urban/residential setting is unlikely to be harmful for fish.

#### 6.4.4 Risk to Reptiles

No acute or chronic RQs for reptiles exceed LOCs. Therefore, use of Acelepryn G as a granular treatment to turf and groundcover in an urban/residential setting is unlikely to be harmful for reptiles.

#### 6.4.5 Risk to Birds

No acute or chronic RQs for birds exceed LOCs except for tricolored blackbirds. Tricolored blackbirds have a diet consisting of a substantial proportion of terrestrial invertebrates. The discussion provided for terrestrial amphibians that consume soil invertebrates also applies to birds that consume soil invertebrates. For the same reasons as presented in Section 6.4.1: *Risk to Amphibians*, use of Acelepryn G as a granular treatment to turf and groundcover in an urban/residential setting is unlikely to be harmful for birds.

#### 6.4.6 Risk to Mammals

No acute or chronic RQs for mammals exceed LOCs. Therefore, use of Acelepryn G as a granular treatment to turf and groundcover in an urban/residential setting is unlikely to be harmful for mammals.

#### 6.4.7 Risk to Earthworms

The acute or chronic RQs for earthworms do not exceed any LOCs. Therefore, despite the high modeled concentration of polybutene in soil invertebrates, use of Acelepryn G as a granular treatment to turf and groundcover is unlikely to be harmful for soil-dwelling invertebrates.

#### 6.4.8 Risk to Terrestrial Insects

When Acelepryn G is applied to turf and groundcover in urban/residential settings under PD/EP-E-11, adult honey bees, *Blennosperma* vernal pool andrenid bees, and San Joaquin tiger beetles exposed via direct contact, but not via consumption of pollen or nectar or other food resources, have acute RQs that exceed LOCs. Sufficient direct contact with chlorantraniliprole in granular Acelepryn G that could lead to adverse effects in insects is unlikely. Therefore, adverse effects to insects from direct contact is not anticipated. Consumption of residues in plant tissues taken up from treated soil does not result in RQs that exceed LOCs. Similarly, adverse effects to insects from oral exposure is not anticipated.

Williams *et al.* (2020) determined that honey bees exposed orally to chlorantraniliprole exhibited reduced walking. The exposures were to a 50% (w/v) sucrose solution. Such an exposure greatly exceeds the modeled concentrations likely in any nectar possibly available to bees following an application of Acelepryn G to turf and groundcover. It is unlikely applications of Acelepryn G would result in a similar sublethal effect in honey bees.

Sublethal effects have been observed in pest species of moths such as cotton bollworm (*Helicoverpa armigera*) (Zhang *et al.*, 2013) and diamondback moths (*Plutella xylostella*) (Ribeiro *et al.*, 2013) following dietary exposure to chlorantraniliprole. It is not clear whether similar sublethal effects could occur in moth species that are not considered pest species.

Sublethal effects have also been observed in the beneficial greenbugs aphid parasitoid (*Lysiphlebus testaceipes*) (Moscardini *et al.*, 2014) following consumption of extrafloral nectar from sunflowers (*Helianthus annuus*) grown from seeds treated with chlorantraniliprole. It is unclear whether any of these sublethal effects seen in laboratory studies could occur following granular applications of Acelepryn G for eradication of Japanese beetles.

Table Eco-3. Potential risk associated with Application Scenario PD/EP-E-11 following acute exposure—Granular application to turf and groundcover of Acelepryn G (Chorantraniliprole) at 0.25 lb. a.i./acre: 2 applications per year in an urban/residential setting (50 Acres).

Table Eco-3a. PD/EP-E-11 Acute Freshwater Pool or Wetland Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
aquatic California tiger salamander	0.00	0.00
aquatic California red-legged frog	0.00	0.00
terrestrial California red-legged frog	0.28	0.28
aquatic western spadefoot	0.00	0.00
vernal pool fairy shrimp	<b>0.83</b>	0.00
Tomales isopod	0.23	0.00
Sacramento splittail	0.00	0.00
desert pupfish	0.00	0.00
giant garter snake	0.00	0.00
western pond turtle	0.00	0.00
tricolored blackbird	<b>3.48</b>	<b>3.47</b>
fulvous whistling-duck	0.00	0.00
yellow rail	0.00	0.00

Table Eco-3b. PD/EP-E-11 Acute Freshwater River Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
aquatic arroyo toad	0.00	0.00
aquatic southern torrent salamander	0.00	0.00
terrestrial southern torrent salamander	0.00	0.00
aquatic foothill yellow-legged frog	0.00	0.00
terrestrial foothill yellow-legged frog	<b>0.63</b>	<b>0.63</b>
California freshwater shrimp	0.00	0.00
Shasta crayfish	0.00	0.00
arroyo chub	0.00	0.00
coastal cutthroat trout	0.00	0.00
Chinook salmon	0.00	0.00
Osprey	0.00	0.00
southwestern river otter	0.02	0.02

Table Eco-3c. PD/EP-E-11 Acute Estuarine Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
mimic tryonia	0.20	0.00
tidewater goby	0.00	0.00
delta smelt	0.00	0.00

Table Eco-3d. PD/EP-E-11 Acute Marine Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
black abalone	0.20	0.00
East Pacific green sea turtle	0.00	0.00
California brown pelican	0.00	0.00
southern sea otter	0.00	0.00

Table Eco-3e. PD/EP-E-11 Acute Terrestrial Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial California tiger salamander	0.00	0.00
terrestrial arroyo toad	0.00	0.00
terrestrial western spadefoot	0.34	0.34
Alameda whipsnake	0.00	0.00
northern red diamond rattlesnake	0.00	0.00
desert tortoise	0.00	0.00
western fence lizard	0.00	0.00
blunt-nosed leopard lizard	0.00	0.00
mourning dove	0.00	0.00
California condor	0.00	0.00
white-tailed kite	0.00	0.00
Cooper's hawk	0.05	0.05
western yellow-billed cuckoo	0.00	0.00
purple martin	0.00	0.00
mule deer	0.00	0.00
riparian brush rabbit	0.00	0.00
American badger	0.00	0.00
northwestern San Diego pocket mouse	0.00	0.00
big free-tailed bat	0.00	0.00
southern grasshopper mouse	0.00	0.00
Nelson's antelope squirrel	0.00	0.00
Earthworm	0.06	0.06
honey bee-adult (contact)	<b>1.12</b>	<b>1.12</b>
honey bee-adult (oral)	0.22	0.22
Blennosperma vernal pool andrenid bee (contact)	<b>1.12</b>	<b>1.12</b>
Blennosperma vernal pool andrenid bee (oral)	0.22	0.22
San Joaquin tiger beetle (contact)	<b>1.12</b>	<b>1.12</b>

Table Eco-4. Potential risk associated with Application Scenario PD/EP-E-11 following chronic exposure with full AUF—Granular application to turf and groundcover of Acelepryn G (Chorantraniliprole) at 0.25 lb. a.i./acre: 2 applications per year in an urban/residential setting (50 Acres).

Table Eco-4a. PD/EP-E-11 Chronic Full AUF Freshwater Pool or Wetland Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial California red-legged frog	<b>8.47</b>	<b>8.47</b>
giant garter snake	0.02	0.01
western pond turtle	0.00	0.00
tricolored blackbird	0.26	0.26
fulvous whistling-duck	0.00	0.00
yellow rail	0.06	0.01

Table Eco-4b. PD/EP-E-11 Chronic Full AUF Freshwater River Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial southern torrent salamander	0.01	0.00
terrestrial foothill yellow-legged frog	<b>18.83</b>	<b>18.82</b>
Osprey	0.00	0.00
southwestern river otter	0.00	0.00

Table Eco-4c. PD/EP-E-11 Chronic Full AUF Marine Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
East Pacific green sea turtle	0.00	0.00
California brown pelican	0.00	0.00
southern sea otter	0.00	0.00

Table Eco-4d. PD/EP-E-11 Chronic Full AUF Terrestrial Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial California tiger salamander	0.00	0.00
terrestrial arroyo toad	0.00	0.00
terrestrial western spadefoot	<b>10.13</b>	<b>10.13</b>
Alameda whipsnake	0.02	0.02
northern red diamond rattlesnake	0.00	0.00
desert tortoise	0.00	0.00
western fence lizard	0.00	0.00
blunt-nosed leopard lizard	0.00	0.00
mourning dove	0.00	0.00
California condor	0.00	0.00
white-tailed kite	0.00	0.00
Cooper's hawk	0.00	0.00
western yellow-billed cuckoo	0.04	0.04
purple martin	0.05	0.01
mule deer	0.00	0.00
riparian brush rabbit	0.01	0.01
American badger	0.00	0.00
northwestern San Diego pocket mouse	0.00	0.00
big free-tailed bat	0.00	0.00
southern grasshopper mouse	0.01	0.01
Nelson's antelope squirrel	0.01	0.01
Earthworm	0.21	0.21

Table Eco-5. Potential risk associated with Application Scenario PD/EP-E-11 following chronic exposure with Midpoint AUF—Granular application to turf and groundcover of Acelepryn G (Chorantranilprole) at 0.25 lb. a.i./acre: 2 applications per year in an urban/residential setting (50 Acres).

Table Eco-5a. PD/EP-E-11 Chronic Midpoint AUF Freshwater Pool or Wetland Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial California red-legged frog	<b>8.47</b>	<b>8.47</b>
western pond turtle	0.06	0.06
tricolored blackbird	0.00	0.00
fulvous whistling-duck	<b>52.23</b>	<b>52.21</b>
yellow rail	0.00	0.00

Table Eco-5b. PD/EP-E-11 Chronic Midpoint AUF Freshwater River Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial southern torrent salamander	0.01	0.00
terrestrial foothill yellow-legged frog	<b>18.83</b>	<b>18.82</b>
Osprey	0.02	0.00
southwestern river otter	0.00	0.00

Table Eco-5c. PD/EP-E-11 Chronic Midpoint AUF Marine Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
East Pacific green sea turtle	0.00	0.00
California brown pelican	0.03	0.00
southern sea otter	0.00	0.00



Table Eco-5d. PD/EP-E-11 Chronic Midpoint AUF Terrestrial Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial California tiger salamander	0.00	0.00
terrestrial arroyo toad	0.00	0.00
terrestrial western spadefoot	<b>10.13</b>	<b>10.13</b>
Alameda whipsnake	0.02	0.02
northern red diamond rattlesnake	0.00	0.00
desert tortoise	0.00	0.00
western fence lizard	0.00	0.00
blunt-nosed leopard lizard	0.00	0.00
mourning dove	0.00	0.00
California condor	0.00	0.00
white-tailed kite	0.00	0.00
Cooper's hawk	0.08	0.08
western yellow-billed cuckoo	0.04	0.04
purple martin	0.07	0.02
mule deer	0.00	0.00
riparian brush rabbit	0.01	0.01
American badger	0.00	0.00
northwestern San Diego pocket mouse	0.00	0.00
big free-tailed bat	0.00	0.00
southern grasshopper mouse	0.01	0.01
Nelson's antelope squirrel	0.01	0.01
Earthworm	0.21	0.21

Table Eco-6. Potential risk associated with Application Scenario PD/EP-E-11 following chronic exposure with no AUF—Granular application to turf and groundcover of Acelepryn G (Chorantraniliprole) at 0.25 lb. a.i./acre: 2 applications per year in an urban/residential setting (50 Acres).

Table Eco-6a. PD/EP-E-11 Chronic No AUF Freshwater Pool or Wetland Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
aquatic California tiger salamander	0.01	0.00
aquatic California red-legged frog	0.01	0.00
terrestrial California red-legged frog	<b>8.47</b>	<b>8.47</b>
aquatic western spadefoot	0.01	0.00
vernal pool fairy shrimp	<b>0.70</b>	0.00
Tomales isopod	<b>1.95</b>	0.00
Sacramento splittail	0.00	0.00
desert pupfish	0.00	0.00
giant garter snake	0.10	0.10
western pond turtle	0.00	0.00
tricolored blackbird	<b>104.20</b>	<b>104.16</b>
fulvous whistling-duck	0.00	0.00
yellow rail	0.06	0.01

Table Eco-6b. PD/EP-E-11 Chronic No AUF Freshwater River Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
aquatic arroyo toad	0.01	0.00
aquatic southern torrent salamander	0.01	0.00
terrestrial southern torrent salamander	0.01	0.00
aquatic foothill yellow-legged frog	0.01	0.00
terrestrial foothill yellow-legged frog	<b>18.83</b>	<b>18.82</b>
California freshwater shrimp	0.04	0.00
Shasta crayfish	0.04	0.00
arroyo chub	0.00	0.00
coastal cutthroat trout	0.00	0.00
Chinook salmon	0.00	0.00
Osprey	0.04	0.00
southwestern river otter	0.01	0.01

Table Eco-6c. PD/EP-E-11 Chronic No AUF Estuarine Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
mimic tryonia	<b>1.71</b>	0.00
tidewater goby	0.01	0.00
delta smelt	0.01	0.00

Table Eco-6d. PD/EP-E-11 Chronic No AUF Marine Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
black abalone	<b>1.71</b>	0.00
East Pacific green sea turtle	0.00	0.00
California brown pelican	0.05	0.00
southern sea otter	0.00	0.00

Table Eco-6e. PD/EP-E-11 Chronic No AUF Terrestrial Species

Surrogate Species	Baseline- No Drift Buffer to Water or Habitat	Reduced Exp.- No Residue to Water
terrestrial California tiger salamander	0.00	0.00
terrestrial arroyo toad	0.00	0.00
terrestrial western spadefoot	<b>10.13</b>	<b>10.13</b>
Alameda whipsnake	0.02	0.02
northern red diamond rattlesnake	0.00	0.00
desert tortoise	0.00	0.00
western fence lizard	0.00	0.00
blunt-nosed leopard lizard	0.00	0.00
mourning dove	0.00	0.00
California condor	0.00	0.00
white-tailed kite	0.00	0.00
Cooper's hawk	0.15	0.15
western yellow-billed cuckoo	0.04	0.04
purple martin	0.09	0.02
mule deer	0.00	0.00
riparian brush rabbit	0.01	0.01
American badger	0.00	0.00
northwestern San Diego pocket mouse	0.00	0.00
big free-tailed bat	0.01	0.01
southern grasshopper mouse	0.01	0.01
Nelson's antelope squirrel	0.01	0.01
Earthworm	0.21	0.21

### 6.5 Risk Analysis for the Pest Detection/Emergency Program’s Turf Applications in an Urban/Residential Setting using beetleGONE! tlc (PD/EP-E-12)

The qualitative risk analysis focused on whether the potential for adverse effects (*i.e.*, risk) resulting from turf and groundcover spray drench applications of beetleGONE! tlc in urban/residential settings indicates a high likelihood for harm to nontarget species. Applications of beetleGONE! tlc for the eradication of Japanese beetles would be made to turf and groundcover in urban/residential areas. Deposition onto impervious surfaces such as sidewalks or driveways will be prevented with shielding. Since applications are directed to low growing plants to target pests in the soil, deposition onto shrubs or trees is not anticipated. Applications would be a maximum of once per year. Additionally, as described in Section 2.10.2: *Technical Assistance from the U.S. Fish and Wildlife Service, National Marine Fisheries Service, and California Department of Fish and Wildlife* of the Main Body of the Statewide PEIR (CDFA, 2014a), CDFA will consult as necessary with CDFW to ensure that there are no adverse effects on the species by implementing buffers or other suitable measures.

Considerable detail was included in the analysis of risk for eradication of Japanese beetles. This detail was provided to discuss specifics of exposures for various surrogate species. Turf and groundcover spray drench applications of beetleGONE! tlc for the eradication of Japanese beetles would be made in urban/residential areas. Applications would be made once per year to

roughly a third of the 50-acre treatment area surrounding where one or more Japanese beetles were detected.

In the PD/EP, beetleGONE! tlc applied as a spray drench (PD/EP-E-12) treatment to the turf and groundcover in an urban/residential setting once per year was not already evaluated in the Statewide PEIR (CDFA, 2014a). Since EECs could not be modeled for BtG, no RQs could be estimated.

### 6.5.1 *Bacillus thuringiensis* subsp. *galleriae* Risk Assessment

The risk assessment approach for all other chemicals used in CDFA pest control programs was based on standard toxicity studies in experimental animals. However, due to the lack of toxicity to most ecological receptors, the risk characterization for Bt in the Statewide PEIR (CDFA, 2014a) took a qualitative approach to evaluate the potential for risk from Bt to ecological receptors. EECs could not be modeled as could be done for all chemicals considered. Primarily for this reason, a quantitative risk assessment for BtG could not be performed. A literature review was conducted on each receptor to evaluate the potential for elevated levels of risk. The potential for elevated levels of risk was based on laboratory toxicity tests, field studies, and mode of action.

#### 6.5.1.1 Background

Bt is a naturally occurring rod-shaped bacteria that has been isolated from soil, insects, and plant surfaces (NPIC, 2000a). The *Bacillus* genus is a gram-positive aerobic and facultatively anaerobic bacterium that was first isolated in 1902 and has been widely used as a microbial pest-control agent since the 1960's (USEPA, 1998c). The bacteria produce protein crystals that, upon ingestion, form endotoxins that bind to the insect's gut leading to a fatal disruption in the osmotic balance (Bravo *et al.*, 2007; CDFA, 2009b; Castro *et al.*, 2019). Bt is classified into different subspecies based on the serotype of antigens found on the flagella (USEPA, 1998c). The subspecies used to eradicate the Japanese beetle is BtG.

#### 6.5.1.2 Mode of Action

The mode of action of Bt has been well characterized in insects, specifically in Lepidoptera. During sporulation, Bt produces insecticidal proteins as parasporal crystals, also known as delta-endotoxins (Bravo *et al.*, 2007). Upon ingestion by susceptible insect larvae (Castro *et al.*, 2019) or nymphs (Liu *et al.* 2018), the crystal inclusion, which are protoxins, are dissolved in the alkaline environment of the insect gut. The solubilized inactive protoxins are cleaved by midgut proteases to yield the active toxin, which then binds to specific receptors on the brush border membrane of the midgut epithelium columnar cells and subsequently inserts into the membrane. This leads to the formation of pores in the microvilli and subsequent cell lysis, disruption of epithelium and cell contents, sepsis, and insect death (Bravo *et al.*, 2007). It is important to note that lepidopteran (Casida and Quistad, 2004) and some coleopterans (Hosseininaveh *et al.*, 2007) insects have a basic pH in their gut (up to pH 11) in contrast to the acidic gut contents of mammals and others (USDA, 2004). Therefore, it is likely to not pose any health risk to non-insect ecological receptors.

### 6.5.2 Risk to Amphibians

There were no data concerning the toxicity of BtG to amphibians, however other strains of Bt had low toxicity to amphibians (USDA, 2004). Therefore, potential for adverse effects is low.

### 6.5.3 Risk to Aquatic Invertebrates

The toxicity data to aquatic invertebrates for BtG is limited with only a single toxicity test with the water flea (*Daphnia magna*) available (Health Canada, 2018a; USEPA, 2013l). Water flea were exposed to concentrations up to 100 mg/L for 21 days. There were no observed effects on survival. However, the mean neonate production per adult value in the highest test group was significantly lower than the control group. The 21-day EC<sub>50</sub> was greater than 100 mg/L. Although USEPA (2017f) bases toxicity categories on acute test results, the 21-day EC<sub>50</sub> of >100 mg/L places BtG in the practically nontoxic category. The no observed adverse effect concentration (NOAEC) value, based on neonate production, was 50 mg/L. The maximum concentration estimated for the standard USEPA “farm pond,” based on a direct overspray at an application rate of 17.5 lb/acre, is 0.75 mg/L. Such an application producing this maximum concentration would not occur in the program, but this maximum concentration is only 1.5% of the NOAEC for the water flea.

Other subspecies of Bt have been evaluated for impact to aquatic invertebrates in laboratory studies as well as field studies. A laboratory and corresponding stream channel study with formulated Bt *kurstaski* determined that it was unlikely to directly affect 12 species of aquatic insects at up to 100 times the expected environmental concentrations (Kreutzweiser *et al.*, 1992). Bt *israeliensis* is used for control of aquatic mosquito larvae, but other dipteran species such as midges (Diptera: Chironomidae) have not been shown to be susceptible at rates effective for mosquito larvae control. However, transient impacts to some non-target arthropods have been shown in field studies (UNEP, 1999).

The USEPA’s (1998c) Re-Registration Eligibility Decision (RED) for Bt concluded that there is no toxicity or infectivity risks to freshwater or marine/estuarine aquatic invertebrates at the label use rates. Most aquatic invertebrates tolerated Bt *kurstaski* in water at environmental concentrations up to 200,000 times higher than expected (USDA, 2004). No decreases in aquatic invertebrates surveyed in a field experiment coinciding with Bt *israeliensis* applications were observed (Gibbs *et al.*, 1986). A formulated product containing Bt *kurstaski* was considered moderately toxic to *Daphnia* sp., a freshwater invertebrate, with a 21-day LC<sub>50</sub> between 5 and 50 mg/L, however the toxicity was determined not due to the delta-endotoxin and was likely due to the formulation (USEPA, 1998c). Bt *kurstaski* was regarded as practically nontoxic to marine/estuarine species with an aqueous LC<sub>50</sub> > 4.9 uL/L for grass shrimp (*Palaemonetes* sp.) (USEPA, 1998c).

Based on the water flea study with BtG and information from other strains of Bt, the potential for adverse effects to most aquatic invertebrates is low. However, because transient impacts have been observed in field studies, drift to surface water must be avoided.

#### 6.5.4 Risk to Fish

The USEPA, in its RED for Bt, concluded that there is no toxicity or infectivity risks to freshwater or marine/estuarine fish at the label use rates (USEPA, 1998c). No toxicity tests for BtG with fish were available, but regulators in North America (USEPA, 2013l; Health Canada, 2018a) conclude adverse effects are unlikely based on testing with other strains of Bt. For example, Bt *kurstaski* was considered practically non-toxic to freshwater fish with an aqueous  $LC_{50} > 4.9 \mu\text{L/L}$  and oral  $LC_{50} > 2.5 \text{ nL/g}$  of food to trout (USEPA, 1998c). Bt *kurstaski* was regarded as practically nontoxic to marine/estuarine fish with an aqueous  $LC_{50} > 4.9 \mu\text{L/L}$  for sheepshead minnow (*Cyprinodon variegatus*) (USEPA, 1998c).

USEPA's conclusions were consistent with field and experimental studies on the effects of Bt on aquatic organisms. A laboratory study looking at the effects of Bt on fish found no mortality or visible adverse effects on zebrafish (*Danio rerio*) or Nile tilapia (*Oreochromis niloticus*) at any tested concentration which supports that the  $LC_{50}$  is greater than  $5 \times 10^6$  spores/mL of Bt *israeliensis* or Bt *kurstaski* for these species (Grisolia *et al.*, 2009). Additionally, in a necrosis-apoptosis study, Bt did not induce apoptosis in Nile tilapia indicating a lack of genotoxicity (Grisolia *et al.*, 2009).

In another study, groups of 10 freshwater mosquitofish (*Gambusia affinis*) were exposed at differing concentrations up to 1000 mg/L ( $2.5 \times 10^7$  spores/mg) of Bt *kenyae* for 96-hours. The fish showed no abnormal behavior and swimming pattern was comparable with control group. A  $LC_{50}$  was not determinable as no mortality was observed (Meher *et al.*, 2002).

No evidence was identified of harmful effects no fish resulting from exposure to any strain of Bt. Therefore, potential for adverse effects of BtG on fish is low.

#### 6.5.5 Risk to Reptiles

There were no data concerning the toxicity of BtG to reptiles.

#### 6.5.6 Risk to Birds

In the studies submitted to the USEPA required for registration of products containing BtG there was no toxicity or pathogenicity to any avian species (USEPA, 2013l). BtG is considered practically nontoxic to the mallard duck (*Anas platyrhynchos*) in a 34-day acute oral toxicity test with an  $LD_{50}$  of 3600 mg/kg (Heath Canada, 2018). Chronic testing and reproductive toxicity testing were not required due to the lack of toxicity seen in the acute tests.

Indirect effects may be seen in birds that prey on susceptible insects through a reduction in food source; however, these reductions in insect population are temporary. A study examined the reproductive success of hooded warblers (*Wilsonia citrina*) after treatment of plots with Bt *kurstaski* that resulted in an 85% reduction in lepidopteran larvae but found no differences in nesting success or number of eggs per nest. However, a difference in egg mass, typical of that seen when food is limited, was found but determined to not be biologically meaningful. The

study concluded that Bt application had little influence on reproductive parameters measured (Nagy and Smith, 1997).

Another study surveyed songbird populations before, during, and after Bt *kurstaski* spraying to examine relative abundance of the birds. No changes in relative abundance or productivity of song birds, with one possible exception, was found (Sopuck *et al.*, 2002). One species, the spotted towhee (*Pipilo maculatus*), had reduced abundance in one year of the study, but not the other, and this reduction did not coincide with reduced Lepidoptera larva abundance. The reduction may have resulted from factors other than Bt *kurstaski* treatment; however, the results were inconclusive (Sopuck *et al.*, 2002).

A study by Norton *et al.* (2001) found reduced growth rate in the chicks of spruce grouse (*Falci pennis canadensis*) in areas sprayed with Bt *kurstaski* compared to control areas. This was attributed to foraging on a protein-deficient diet of ants rather than protein-rich lepidopteran larvae (Norton *et al.*, 2001). However, these effects are transient as reduced lepidopteran populations recover and a possible solution to avoid indirect effects on birds is to spray 2 weeks after chicks hatch as the first two-weeks are the most lepidopteran dependent (Norton *et al.*, 2001).

Those studies that showed impact from food reductions were foliar applications to forested areas. The spray drench applications with beetleGONE! tlc will be made to much smaller areas and would not be expected to have population impact to available prey since few if any birds consume large amounts of beetle grubs from the soil. Laboratory toxicity tests suggest no direct adverse effects. Therefore, potential for adverse effects to birds from BtG is low.

#### 6.5.7 Risk to Mammals

Mammals do not have the alkaline gut environment that is needed for enzymes to activate the delta-endotoxin and instead digest the toxin into non-toxic fragments within an hour (Casida and Quistad, 2004). No known mammalian health effects have been demonstrated in any toxicity or pathogenicity study for various strains of Bt (USEPA, 1998c). Studies with laboratory rats exposed orally showed that BtG is not toxic, infective, or pathogenic when administered at maximum hazard doses (USEPA, 2013l). Bt is in USEPA's toxicity category IV (low toxicity) for acute oral, acute inhalation, and acute dermal toxicity (USEPA, 1998c). Slight to moderate skin irritation has been observed in product tests, which could be attributed to the formulation, and eye irritation has been seen in primary eye irritation tests for BtG (USEPA, 2013l). This is most often associated with the dry forms of the product, indicating that it is likely physical irritation effects rather than traditional toxicity (USEPA, 1998c).

The acute toxicity studies on rodents indicate that there are not likely to be any adverse effects on wild mammals. USEPA only requires wild mammal studies when data is insufficient to assess the hazard to wild animals (USEPA, 1998c). Therefore, potential for adverse effects to mammals exposed to BtG is low.

### 6.5.8 Risk to Earthworms

No toxicity data for BtG with earthworms was identified. However, a study with a water-based formulation and an oil-based formulation of Bt *kurstaski* tested the formulations at 1,000 times the expected environmental concentration on earthworms. The water-based formulation showed no effects in the earthworm populations over a 10-week period, while the oil-based formulation showed 50% mortality in the worms indicating that the toxicity was related to the oil used in the formulation and not Bt *kurstaski* (Addison and Holmes, 1996). Bt *kurstaski* showed little to no toxicity or pathogenicity in annelid indicator species in studies submitted for its reregistration (USEPA, 1998c).

No toxicity data were available to indicate BtG or other strains of Bt were toxic to earthworms. Therefore, potential for adverse effects to earthworms from exposure to BtG is low.

### 6.5.9 Risk to Terrestrial Insects

Terrestrial insects are the receptor most likely to be adversely affected by BtG. The protein toxins produced and released by BtG are specific to beetles (Coleoptera) (Health Canada, 2018a). No toxicity from the endotoxin Cry8Da was demonstrated for the Oriental silkworm moth (*Bombyx mori*), Oriental leafworm moth (*Spodoptera litura*), Colorado potato beetle (*Leptinotarsa decemlineata*), or four species of adult parasitic wasps (Hymenoptera) (USEPA, 2013I). No sustained adverse effects are anticipated for populations of adult ladybird beetles (*Hippodamia convergens*) (USEPA, 2013I). BtG is weakly toxic to diamondback moths (*Plutella xylostella*), and highly toxic to the emerald ash borer (*Agrilus planipennis* or *Agrilus marcopoli*) and oriental beetle (*Anomala cuprea*) (USEPA, 2013I).

BtG is specifically targeted for coleopteran larvae and must be eaten in order to be effective as an insecticide (Health Canada, 2018a), however, some lepidopterans are also susceptible (USEPA, 2013I). Redmond *et al.* (2020) demonstrated that monarch butterfly larvae (*Danaus plexippus*) were highly susceptible after feeding on milkweed sprayed with liquid formulations containing BtG. For other strains of Bt, some Lepidoptera exhibit sensitivity to Bt *kurstaski* dependent on developmental stage. For example, the cinnabar moth (*Tyria jacobaeae*) late instar larvae are very sensitive to Bt *kurstaski* while early instar larvae are tolerant to it (USDA, 2004). Additionally, the response of non-target Lepidoptera varies widely amongst different species. A field study by Rastall *et al.*, (2003) studied 19 lepidopteran species during 2 years of aerial Bt *kurstaski* application. Only three of the 19 species studied, spring hemlock looper (*Lambdina fervedaria*), saddled prominent moth (*Heterocampa guttivitta*), and distinct Quaker (*Achatia distincta*), showed significantly lower amounts of larvae in treatment plots versus control plots (Rastall *et al.*, 2003).

The limited information available demonstrates that effects on terrestrial insects other than coleopteran and lepidopteran species would be minor (USEPA, 2013I). Impacts to adult honey bees (*Apis mellifera*) are not expected based on a study where an unnamed strain of BtG was sprayed on or impregnated into wax in a hive for control of wax moths (*Galleriae* spp.) and caused no adverse effects on the adult bees. Honey bee larvae were not harmed when exposed to 500 ng SDS-502 Cry8Da protein/honey bee larval cell. SDS-502 Cry8Da protein is the toxin



produced by BtG. Although no harm occurred to the honey bee larvae, the dose amount might not reflect the amount fed to larvae following a field application. Therefore, it is not clear whether adverse effects could occur to honey bee larvae at realistic exposure levels (USEPA, 20131). However, in another study reported by Health Canada (2018a), honey bee larvae were not impacted, and Health Canada used that study to conclude no adverse effects are likely.

Impacts to terrestrial insects, particularly nontarget beetle, moth, and butterfly larvae, are possible following applications of beetleGONE! tlc. Impacts to moth and butterfly larvae can be minimized by avoiding spraying host plants for nontarget species. Limited residues would be expected on foliage since applications are “watered-in” which would wash off residues to the soil. Additionally, a spray drench application targets only low growing plants such as turf or groundcover, mulch or bare soil. No residues would be expected in floral nectar available to pollinators such as honey bees. As long as host plants of nontarget coleopteran and lepidopteran species are avoided, the potential for adverse effects to terrestrial insects is low following spray drench application of beetleGONE! tlc to turf and groundcover for eradication of Japanese beetles.

## 6.6 Risk Analysis for the Pest Detection/Emergency Program’s Turf Applications in an Urban/Residential Setting using Acelepryn G and beetleGONE! tlc (PD/EP-E-11-12)

The risk analysis focused on the potential for adverse effects (*i.e.*, risk) resulting when turf and groundcover applications of Acelepryn G occurs for a treatment area of up to 47.5 acres and beetleGONE! tlc occurs for an adjacent treatment area of up to 5 acres in urban/residential settings. Applications of Acelepryn G and beetleGONE! tlc for the eradication of Japanese beetles would be made to turf and groundcover in urban/residential areas. Deposition onto impervious surfaces such as sidewalks or driveways will be prevented with shielding. Since applications are directed to low growing plants to target pests in the soil, deposition onto shrubs or trees is not anticipated. Applications with both products on adjacent areas would be made a maximum of once per year. Although Acelepryn G can be applied twice per year, beetleGONE! tlc can be applied only once. Additional details specific to Acelepryn G and beetleGONE! tlc have been presented sections 6.4: *Risk Analysis for the Pest Detection/Emergency Program’s Turf Applications in an Urban/Residential Setting using Acelepryn G (PD/EP-E-11)* and 6.5: *Risk Analysis for the Pest Detection/Emergency Program’s Turf Applications in an Urban/Residential Setting using beetleGONE! tlc (PD/EP-E-12)*. Since the risk assessment for beetleGONE! tlc was qualitative, the analysis combining the two products will be qualitative also.

### 6.6.1 Risk to Amphibians

Possible adverse effects resulting from exposure to earthworms with polybutene, an inert ingredient in Acelepryn G, were identified following applications of Acelepryn G. No adverse effects were identified for amphibians following spray drench applications of beetleGONE! tlc. As described in Section 6.4.1: *Risk to Amphibians*, polybutene is considered unlikely to be

bioavailable to the extent the modeled concentrations in earthworms indicate, based on a high Log  $K_{ow}$ . A similar low potential for adverse effects for amphibians exists when Acelepryn G and beetleGONE! tlc are applied to adjacent areas as determined for when Acelepryn G is applied to the entire 50 acres.

#### 6.6.2 Risk to Aquatic Invertebrates

Toxicity data for aquatic invertebrates is limited for BtG. However, other strains of Bt have shown possible adverse effects to aquatic invertebrates, particularly larval stages of insects. Acute and chronic RQs exceed LOCs for some freshwater and marine/estuarine invertebrate species following applications of Acelepryn G. Since each product could cause adverse effects to aquatic invertebrates, applying the products to adjacent areas might also produce adverse effects to aquatic invertebrates. Therefore, similar BMPs and consultations with natural resource agencies as described in Section 6.4.2 *Risk to Aquatic Invertebrates* will be necessary when both products are applied to adjacent areas individually.

#### 6.6.3 Risk to Fish

The potential for adverse effects when Acelepryn G or beetleGONE! tlc are applied individually was low. Therefore, use of Acelepryn G as a granular treatment to turf and groundcover and spray drench applications of beetleGONE! tlc to adjacent areas individually in an urban/residential setting is unlikely to be harmful for fish.

#### 6.6.4 Risk to Reptiles

No adverse effects to reptiles were identified when Acelepryn G or beetleGONE! tlc were applied to separate treatment areas, so no adverse effects are anticipated if the two products are applied individually to adjacent areas.

#### 6.6.5 Risk to Birds

Acute or chronic RQs for birds exceed LOCs for birds that consume a high proportion of soil invertebrates following applications of Acelepryn G caused by exposure to polybutene. No adverse effects are anticipated for birds following applications of beetleGONE! tlc. As discussed in Section 6.6.1: *Risk to Amphibians*, concentrations of polybutene, the ingredient causing RQs to exceed LOCs, are likely overestimated. Therefore, no adverse effects to birds are anticipated with Acelepryn G and beetleGONE! tlc applied to adjacent areas.

#### 6.6.6 Risk to Mammals

No adverse effects to mammals were identified when Acelepryn G or beetleGONE! tlc were applied to separate treatment areas, so no adverse effects are anticipated if the products are applied individually to adjacent areas.

### 6.6.7 Risk to Earthworms

No adverse effects to soil invertebrates were identified when Acelepryn G or beetleGONE! tlc were applied to separate treatment areas, so no adverse effects are anticipated if the two products are applied individually to adjacent areas.

### 6.6.8 Risk to Terrestrial Insects

When Acelepryn G is applied to turf and groundcover in urban/residential settings some insects exposed via direct contact have RQs that exceed LOCs, but since the granular application is made to turf and groundcover, and then watered in, direct contact exposure to anticipated to be minimal. BtG does not exhibit contact toxicity for insects. Some classes of insects such as coleopterans, dipterans, and lepidopterans can be harmed by various strains of Bt. As long as host plants of nontarget coleopteran and lepidopteran species are avoided, the potential for adverse effects to terrestrial insects is low following spray drench applications of beetleGONE! tlc to turf and groundcover for eradication of Japanese beetles.

## 7 Uncertainties

Uncertainty in ecological risk assessment derives partly from biological variability. The response of ecological receptors following exposure to contaminants will vary among individuals within a species as well as across species. Also, literature values from various species are used to predict the response of the surrogate species of interest in this ERA. Differences among species always introduces unavoidable uncertainty to an ERA. Uncertainty regarding predictions in a risk assessment may be due to inherent randomness, limited knowledge, or lack of knowledge (Suter, 2007: p. 69).

A common practice in ERAs is to apply uncertainty factors to various values used in calculations to estimate potential risk. In this ERA, we applied uncertainty factors to toxicity endpoints in the development of TRVs when the ideal value (*e.g.*, acute or chronic NOAELs) was not available. In the development of TRVs (Section 4: *Effects Assessment* of the of the Ecological Risk Assessment of the Statewide PEIR [CDFA, 2014a]), the uncertainty factors suggested by the U.S. Army (2000) and USEPA (2004j) were used. Uncertainty factors were also applied when using the biomagnification factor (BMF) to estimate tissue concentration in predatory terrestrial vertebrates. In this instance, using the BMF from shrews developed by Armitage and Gobas (2007) and applying that BMF to terrestrial vertebrates is novel and no published references were available for determining appropriate uncertainty factors. Professional judgment is used in assigning uncertainty factors to the shrew BMF.

### 7.1 Exposure Assessment Uncertainties

In this ERA, exposure of ecological receptors could not be measured directly. Models were used to estimate exposure following applications of Acelepryn G. The use of models to estimate exposure necessarily introduces uncertainty regarding how well those models will predict the exposure that actually occurs following applications. Reliance on exposure models developed by

the USEPA was intended to standardize the approach here and to reduce the potential of underestimating exposure.

### 7.1.1 Application Scenarios

Acelepryn G and beetleGONE! tlc application scenarios were based on descriptions provided by CDFA staff. Where a range of conditions were possible, such as the area of an application site, CDFA staff were requested to provide conditions that were ‘reasonably foreseeable’ and tending toward worse case. The most common conditions under which applications were likely to be made were analyzed, but some uncommon conditions that could lead to greater or lesser exposure than the scenarios represented in the risk assessment were not analyzed. For example, to produce a quantitative estimate of risk, the area of application needed to be defined. It is certainly possible that smaller or larger application areas than used in this ERA could occur in the future.

For urban/residential application scenarios, the application area was defined as a 50-acre area representing the entire area within the prescribed 200-m distance from possibly multiple Japanese beetle detections. Treatments will target turf and groundcover. Within an application area, many features would not be treated such as pavement, buildings, vegetable gardens, and areas deemed not to be beetle habitat. Following the approach used in previous PEIR Addenda, it was assumed approximately one-third of the entire urban/residential area was treated. Since it is not possible to know how much lawn and groundcover would exist within the 50-acre application area, assuming one-third of the area is treated adds uncertainty.

### 7.1.2 Aquatic Exposure Assessment

Water concentrations used to estimate exposure for drinking water of terrestrial species or for uptake into aquatic prey were based on outputs from USEPA’s (2020c) PWC model. PWC did not provide a means to appropriately estimate water concentrations in surface water that was not immediately adjacent to the application site. The inability to accurately model concentrations in water bodies not immediately adjacent to application sites tended to produce an overestimate for water concentrations. The resulting risk estimates would therefore be exaggerated.

Water concentrations in PWC are based on what would occur in a 1-ha (2.471-acre) waterbody. A wide variety of water bodies could be adjacent to application sites. Estimated concentrations from PWC would underestimate concentrations for vernal pools or other water bodies that are smaller and shallower than the modeled waterbody. However, where water bodies were larger, the estimates were likely greatly exaggerated. PWC did not allow for estimated water concentrations in a flowing water body. Any flow that would dilute the concentration would lead to an overestimation of water concentrations by PWC.

Uptake from water into aquatic prey was estimated using KABAM (USEPA, 2009s). KABAM had a limitation in the range of chemicals for which it provided appropriate tissue concentrations. Chemicals with Log  $K_{ow}$  outside the ideal range of 4 to 8 such as polybutene are not appropriate for use with KABAM. However, KABAM is a model developed by USEPA for estimating tissue

concentrations and no other USEPA model exists for chemicals outside the range of Log  $K_{ow}$  of 4 to 8. It is not known whether use of KABAM on chemicals with Log  $K_{ow}$  outside the ideal range would produce under or overestimates of tissue concentrations because the model was not validated with chemicals outside of this range.

No attempt was made to eliminate food items, such as aquatic invertebrates that might have died from exposure to the pesticide prior to being available for consumption. Since it is unlikely that dead prey would be consumed, failure to eliminate dead prey would have produced an overestimation of exposure.

### 7.1.3 Marine/Estuarine Exposure Assessment

No models were available for estimating water concentrations in marine/estuarine environments. Many of the same uncertainties existed for marine/estuarine environments as for freshwater environments. It is not known how a more saline environment might affect the outputs from the models. PWC was expected to greatly exaggerate the water concentrations in marine/estuarine habitats because of the much larger volume of water present in the marine/estuarine environments and the routine flushing of the areas from tides and wave action.

### 7.1.4 Terrestrial Exposure Assessment

Whenever EECs are based on modeled residues, uncertainty exists regarding the representativeness of the model outputs. T-REX, the model used for many of the EECs in terrestrial food items was developed from empirical data for vegetation (Hoerger and Kenaga, 1972; Fletcher *et al.*, 1994), but also estimates residues on food items such as fruits, seeds, and insects. The model has been updated to better estimate residues on insects (USEPA, 2012i), but residues on seeds were not based on empirical data. Without empirical data to evaluate seed residues, the accuracy of the estimated concentrations is not known. However, by using models developed by the USEPA, significant effort was made to reduce the chances that exposure was underestimated. Also, the husks of many seeds or fruits might be discarded when wildlife eat them, which would cause the EEC used in the ERA to be greater than actual exposure and risks overestimated.

Systemic residues taken up by plants tissues or terrestrial invertebrates were estimated using the modified Briggs equation, and primarily influenced by the  $K_{ow}$  of the pesticides and assumed to be instantaneous. Uptake from an environmental media such as soil or water would occur over an extended time period making any acute EECs selected shortly after an application an overestimation of what was actually present within the plant or animal tissue. Many factors can influence the rate of uptake in plants. Water soluble chemicals are taken up more quickly when plants are actively transpiring and water is available for uptake (*i.e.*, they are not under drought conditions). Other pesticides will be taken up more quickly when plants are actively metabolizing and absorbing nutrients. The actual rate will depend on chemical characteristics and the conditions at the time of and following an application, but the uptake will not be instantaneous.

Acute concentrations of pesticides in soil following a granular application were based on the amount concentrated in the upper 1 cm. This assumption differs from the assumed concentration in the upper 15 cm of soil following spray drench applications. Intact granules and smaller particles containing pesticides would be available at or near the soil surface for consumption by wildlife immediately after an application. Chronic concentrations of pesticides in soil following spray drench or granular applications were based on the amount concentrated in the upper 15 cm. Residues were assumed to instantaneously be distributed throughout the soil column. For an acute exposure to soil in the diet, such an assumption of instantaneous distribution would lead to an underestimation of exposure to concentrations in surface soils immediately following an application as the pesticides may not have had time to migrate through the 1-cm or 1- cm depth. Since many pesticides are known to penetrate deeper than 15 cm (*e.g.*, Ramanand *et al.*, 1988; Zhang *et al.*, 2000), limiting the penetration zone to only 15 cm leads to an overestimation of chronic exposures.

Tissue concentrations in terrestrial vertebrate prey were assumed to be equivalent to the daily intake of a pesticide. Initially, these residues would necessarily be concentrated in the gastrointestinal tract and not uniformly distributed throughout the body. Over the longer term, the concentration in other body tissues will depend on the degree to which pesticides are absorbed from the gastrointestinal tract, the rate at which they are metabolized, and the rate at which they are excreted. The amounts of pesticide present in the gastrointestinal tract are generally higher than in other tissues because it will contain residues from the diet that might pass through unabsorbed. If the gastrointestinal tract is preferentially selected or avoided in larger prey, exposure estimates could be systematically over or underestimated.

The only terrestrial vertebrate model for calculating a BMF for chronic exposures of predators is for the simple food chain of soil → earthworm → shrew (Armitage and Gobas, 2007). The applicability of using the shrew BMF to other mammals and other terrestrial vertebrate groups is not known. Whether use of this model produces a systematic over or underestimation of exposure is not known.

No attempt was made to eliminate food items, particularly insect prey that might have died from exposure to the pesticide prior to being available for consumption. Since it was unlikely that dead prey would be consumed by predators or insectivores, failure to eliminate dead or moribund prey would have produced an overestimation of exposure.

Since this ERA is attempting to address potential future applications of pesticides, the proximity of application sites to each other is not known. For species with large foraging areas, an AUF was used to account for the difference between the area where pesticide applications occur and the full area where a terrestrial species could forage. Should more than one application site occur within a species' foraging range, use of an AUF would underestimate potential exposure. In addition to presenting RQs based on an AUF, RQs estimated from exposure based on no AUF and a Midpoint AUF were also presented. Without knowing the distribution of application sites across a species foraging range, the appropriateness of any of these estimates of exposure cannot be known. By including the full range of possibilities from using an AUF to assuming the full foraging range could be treated, the complete range of exposures and the resulting RQs were presented.

### 7.1.5 Exposure of Birds and Mammals to Aquatic Prey

Osprey or southwestern river otter that typically forage in freshwater habitats larger than the farm pond modeled in PWC or the California brown pelican and southern sea otter that forage in marine/estuarine environments are among species likely to be exposed to prey from waters with lower concentrations than estimated by PWC.

## 7.2 Effects Assessment Uncertainties

### 7.2.1 Use of Surrogate Species Effects Data

Toxicity data were rarely available for the surrogate species considered in the risk assessment. Use of effects data from species other than the species of concern inherently added uncertainty to the assessment. When toxicity data for more than one species was available, the more sensitive species was selected. Data from species as closely related as possible were used. For example, when toxicity data from a passerine species was available, it was used for the passerine birds in the assessment.

Toxicity data were not always available for all taxonomic groups. This lack of data was most common for amphibians and reptiles. Bird or fish toxicity data were used when no data were available for terrestrial-phase amphibians and reptiles or aquatic-phase amphibians, respectively. It was not known when this approach might lead to an over or underestimation of risk.

### 7.2.2 Sublethal Effects

Sublethal effects were not specifically addressed, but when ecologically relevant sublethal toxicity endpoints were available on which to base TRVs, those results were preferentially selected. The only sublethal effects identified in the literature were for insect species exposed to chlorantraniliprole in laboratory studies (Section 6.4.8: Risk to Terrestrial Insects).

### 7.2.3 Dermal or Inhalation Effects

In ERAs, it is standard practice to only address effects from oral exposure for terrestrial vertebrates. In general, focusing on effects from oral exposures is adequate (Suter, 2007: pp. 258-259). However, for terrestrial-phase amphibians, it is possible that dermal exposure to pesticide on surface soils might be readily absorbed and contribute to adverse effects in these species. Effects data for this pathway do not exist, so any effects from contact of terrestrial-phase amphibians to pesticides in soils are unknown. Also, inhalation exposure to airborne concentrations of pesticides can occur. Effects data from inhalation exposure are also lacking for wildlife species. The inability to include any potential risk derived from dermal or inhalation exposure will necessarily underestimate total risk, but since these routes are thought to generally be negligible, exclusion of exposure from these routes did not seriously affect the assessment of risk.

#### 7.2.4 Synergism

Synergism is the effect caused when exposure to two or more chemicals concurrently or consecutively results in health effects that are greater than the sum of the effects of the individual chemicals (Health Canada, 2016c). Uncertainty exists as to whether any of the chemicals analyzed in this ERA produce synergistic effects. No available endpoints were available in the literature to evaluate synergistic relationships for active and inert ingredients analyzed in this ERA. Therefore, synergistic effects could not be evaluated in this risk assessment.

## 8 Conclusions

This ERA was conducted to determine the potential harm to ecological receptors from turf and groundcover applications of Acelepryn G or beetleGONE! tlc for eradication of Japanese beetles. The ERA was conducted using procedures and methodologies commonly used by government agencies such as USEPA as well as the risk assessment profession. The ERA relied upon the three-stage process for risk assessments: problem formulation, analysis, and risk characterization. CDFA and its risk assessment team consulted with DPR and OEHHA to determine the appropriate scenarios to assess, models to evaluate exposure, default data assumptions, and appropriate toxicity effects based on scientific literature. DPR and OEHHA assisted to facilitate the exchange of information such that this ERA meets both the public outreach and scientific goals desired by CDFA for the Proposed Program. The problem formulation stage concluded with a CSM that identified the complete exposure pathways carried forward in the analysis based on information that was available to evaluate the potential exposure pathways. During the analysis phase of the ERA, detailed exposure was estimated with models incorporating appropriate data and conservative assumptions. Also, in the analysis phase, effect values were developed which incorporated the toxicologic properties of the pesticides along with safety factors to address uncertainty. The risk characterization phase provided conclusions on the potential for adverse effects to occur to ecological receptors. The risk characterization phase utilized both a quantitative and qualitative assessment for Acelepryn G but was limited to a qualitative assessment only for beetleGONE! tlc. If the estimated RQ for Acelepryn G was below the LOC, then it was concluded that the potential for adverse effects is low. If the estimated RQ was above the LOC, then a qualitative assessment was conducted to incorporate information that the quantitative models are not capable of considering appropriately. For beetleGONE! tlc, the analysis was limited to a qualitative assessment because environmental fate could not be quantitatively modeled for a microbial pesticide.

Section 6: *Risk Characterization* lists the detailed results of the risk characterization phase for every species class. In some situations where the quantitative assessment indicated the RQ was below the LOC, it was easily concluded that the potential for adverse effects was low. When the RQ was above the LOC, several qualitative considerations typically resulted in a conclusion that the potential for adverse effects would be low. As described in Section 6: *Risk Characterization*, the qualitative assessment considered the potential for species presence at an application site, incorporation of foraging range and diet, and fate and transport processes such as dilution and degradation.



In this ERA, few groups of ecological receptors were found to have RQs that exceed LOCs. These include terrestrial-phase amphibians and birds consuming large quantities of soil invertebrates, terrestrial insects, including pollinators, and aquatic invertebrates. The concentrations estimated for polybutene in soil invertebrates are considered artificially high resulting in an overestimation of impacts to terrestrial-phase amphibians and birds. More realistic concentrations of polybutene are not anticipated to be harmful to birds and terrestrial-phase amphibians. CDFA's BMPs are designed to greatly reduce, if not eliminate, movement to surface water. Therefore, actual impacts to aquatic invertebrates are anticipated to be minimal. Because of the targeted nature of the application to turf and groundcover, direct contact with Acelepryn G is anticipated to be insufficient to cause adverse effects in terrestrial insects.

This ERA, along with the Statewide PEIR, will be used to assist CDFA in assessing the potential effects on particular species and developing site-specific measures to protect these species. This ERA did not identify new significant environmental effects or substantial increases in the severity of the significant effects identified in the PEIR accruing to the use of these scenarios in addition to previously analyzed treatment scenarios. No alterations to any of the scenarios assessed in this ERA that were not already indicated for other scenarios in the PEIR are recommended for the protection of biological resources.

## 9 Literature

*References for this report may be found in the Dashboard Database 4.0.*

*NOTE: References match those previously listed in the Statewide PEIR (CDFA, 2014a). Therefore, lettering order following publication years may not always be in sequence in this report. Links to webpages were active as of the listed access date. Access to those web resources and information presented therein are subject to change.*

