California Department of Food and Agriculture
Statewide Plant Pest Prevention and Management Program
PEIR Addendum 6

Prepared for:

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1. Introduction

This document is Addendum No. 6 (Addendum) to the Statewide Plant Pest Prevention and Management Program Environmental Impact Report (PEIR) prepared by the California Department of Food and Agriculture (CDFA). The PEIR is intended to provide the public, responsible agencies, and trustee agencies with information about the potential environmental effects of implementation of the Statewide Plant Pest Prevention and Management Program (Statewide Program). The PEIR was prepared in compliance with the California Environmental Quality Act (CEQA) (Pub. Resources Code, § 21000 et seq.) and the State CEQA Guidelines (Cal. Code Regs., tit. 14 § 15000 et. seq.) (CEQA Guidelines). The PEIR was certified on December 24th, 2014 by CDFA Secretary Karen Ross. CDFA was the Lead Agency. A Notice of Determination was filed with the Office of Planning and Research.

CDFA is proposing changes to the PEIR and Statewide Program to include turf/groundcover applications of granular Acelypryn G (Chlorantraniliprole) and spray drench of liquid beetleGONE! Tlc (active ingredient: *Bacteria thuringiensis*, an organic bacterial product product, Bt), individually or in combination, in urban/residential settings as alternatives to the Japanese Beetle Program treatments previously analyzed in the PEIR. Under CEQA, an addendum may be prepared when minor modifications are proposed for a project that has already been approved and when no additional significant environmental impacts would result. (CEQA Guidelines, §§, 15162, 15163, 15164.) Addendum No. 6 evaluates whether any new significant impacts or a substantial increase in the severity of previously identified significant impacts would result from implementation of the proposed modification.

2. Purpose of Addendum

The purpose of this addendum is to include the additional turf/groundcover application scenarios in the PEIR as part of the Japanese Beetle Program. Under CEQA, the lead agency or a responsible agency shall prepare an addendum to a previously-certified EIR if some changes or additions are necessary to the prior EIR, but none of the conditions calling for preparation of a subsequent or supplemental EIR have occurred. (CEQA Guidelines, § 15164.) Once an EIR has been certified, several approaches can be used to achieve CEQA compliance for specific activities. A subsequent EIR is only required when the lead agency or responsible agency determines that one of the following conditions has been met:

(1) Substantial changes are proposed in the project, or substantial changes occur with respect to the circumstances under which the project is

undertaken, which require major revisions of the previous EIR due to the involvement of new significant environmental effects or a substantial increase in the severity of previously identified significant effects (CEQA Guidelines, § 15162 (a)(1),(2));

(2) New Information of substantial importance, which was not known and could not have been known with the exercise of reasonable diligence at the time the previous EIR was certified as complete, shows any of the following:

a. The Project will have one or more significant effects not discussed in the previous EIR;

b. Significant effects previously examined will be substantially more severe than shown in the previous EIR;

c. Mitigation measures or alternatives previously found not to be feasible would in fact be feasible and would substantially reduce one or more significant effects of the project, but the project proponents decline to adopt the mitigation measure or alternative; or

d. Mitigation measures or alternatives which are considerably different from those analyzed in the previous EIR would substantially reduce one or more significant effects on the environment, but the project proponents decline to adopt the mitigation measures or alternatives (CEQA Guidelines, §15162(a)(3)).

A CEQA Addendum is the appropriate CEQA compliance document when changes or additions are necessary to an EIR, but none of the conditions described in Section 15162 calling for preparation of a subsequent EIR have occurred. (CEQA Guidelines, § 15164(a).) The CEQA Guidelines recommend that a brief explanation of the decision to prepare an addendum rather than a subsequent or supplemental EIR be included in the record. (CEQA Guidelines, §15164(e).)

This Addendum has been prepared because the proposed modifications to the PEIR do not meet the conditions for a subsequent or supplemental EIR. This Addendum explains why the proposed modifications would not result in new significant environmental effects or result in a substantial increase in the severity of previously-identified significant effects. There is no new information demonstrating that the proposed modifications would have new effects or substantially increase the severity of previously identified significant effects on the environment or that modifications would change the conclusions of the previously certified PEIR. An addendum does not need to be circulated for public review, but rather can be attached to the final EIR. (CEQA Guidelines, §15164(c

3. Statewide Program Environmental Impact Report Overview

CDFA is mandated to prevent the introduction and spread of injurious insect or animal pests, plant diseases and noxious weeds in California. (Cal. Food & Ag. Code § 403.) To accomplish this, CDFA implements the Statewide Program, an ongoing effort to protect California's agriculture and the environment from the damage caused by invasive plant pests.

The Statewide Program encompasses a range of phytosanitary measures (such as compliance protocols, conditions, inspections, and/or certifications) whose purpose is preventing the introduction and spread of quarantine pests or limiting the economic impact of regulated non-quarantine pests. The activities include prevention, exclusion, management, and control carried out or overseen by CDFA against specific injurious pests and their vectors, throughout California.

Program activities may occur anywhere that a pest may be found in agricultural, nursery, or residential settings. They may also occur at California Border Protection Stations and sometimes outside of California in response to restrictions on importation of potentially infested commodities and equipment. The location, area and extent of specific activities under the Statewide Program are ultimately evaluated based on the site-specific situation and dictated by the target pest, as well as by the regulatory requirements and management approaches available for response.

Activities that would be conducted under the Statewide Program include pest risk analysis (evaluation of the pest's environmental, agricultural, and biological significance), identification, detection and delimitation of new pest populations, and pest management required responses that may include rapid eradication, suppression or containment including prevention of the movement of plant pests into and within California.

The Statewide Program is administered by CDFA's Plant Health and Pest Prevention Division, Citrus Program, and Pierce's Disease Control Program. The Division is divided into four branches. All phytosanitary measures related to pest management activities are carried out or overseen by one of the branches under the oversight of the Division Director. The four branches are:

- **Plant Pest Diagnostics Branch**, provides scientific information on pests and making all official identifications and diagnoses for suspect pests and diseases;
- **Pest Detection/Emergency Projects Branch**, initiates and operates programs which carry out phytosanitary procedures of control including suppression, containment or eradication and treatments of priority pests to prevent establishment;
- **Pest Exclusion**, initiates prevention and exclusion to keep priority pests out of the state of California and to prevent or limit the spread of newly discovered pests in the role of quarantine regulatory compliance and service to the agricultural industry and the public; and

- **Integrated Pest Control Branch,** conducts a wide range of pest management and eradication programs in cooperation with growers, county agricultural commissioners and federal and state agencies and non-governmental organizations.

The Statewide Program is ongoing. This Addendum adds turf/groundcover applications of granular Acelypryn G (Chlorantraniliprole) and spray drench of beetleGONE! Tlc (Bt), individually or in combination, in residential/urban settings as alternatives to the Japanese Beetle Program treatments previously analyzed in the PEIR. The aforementioned activities are referred to herein as the "Proposed Program." The PEIR serves as both a program and project-level document. The PEIR was intended to be a flexible and efficient foundation to facilitate implementation of the Statewide Program activities within its scope, and, if needed, preparation of a tiered, project-level CEQA analysis for activities not covered in the PEIR.

As part of the PEIR, application use scenarios were analyzed in the Pest Detection/Emergency Projects Program (PD/EP) Activities. These application use scenarios describe type of chemical, concentration of chemical, application method, rate of application, area of application settings, and duration/frequency of application. The application use scenarios were uniquely identified by program name, chemical and identifying number. An example would be PD/EP-E-01. For further information please refer to the PEIR (Volume 1, Main Body, Volume 3, Appendix B, and Addenda 1 and 2). The treatment equipment and the setting (urban/residential) for Acelepryn applications were previously analyzed in the PEIR. The chemical Acelepryn in its liquid form, and its foliar and turf/groundcover application were previously analyzed in PEIR Addendum 2. The product BeetleGone!, and its active ingredient Bt, were not analyzed in the PEIR.

4. Proposed Modification to Statewide Program Scenario

As identified in the PEIR, to prevent the entrance of Japanese Beetle (JB) in California, CDFA currently enforces the Japanese Beetle Exterior Quarantine, Title 3 of the California Code of Regulations Section 3280, restricting movement of host commodities and possible carriers. CDFA also enforces the Japanese Beetle Federal Domestic Quarantine, Title 7 of the Code of Federal Regulations, Section 301.48. CDFA has an active eradication program in place for any incipient populations of JB per the requirements of the U.S. Domestic Japanese Beetle Harmonization Plan.

CDFA conducts statewide detection trapping to intercept JB, and a single beetle find in a trap may trigger a delimitation survey to further identify the significance of the find. If further detection and trapping indicates that JB may be present in numbers or life stages above a specific threshold, and eradication is determined to be feasible, an eradication project may be initiated. The PEIR's JB Program description and analysis included foliar and soil applications using Merit® 2F Insecticide with respect to JB urban/residential treatments. Currently, the PEIR describes the PD/EP-E-04 scenario using Merit® 2F Insecticide that can be applied as a soil drench using a backpack sprayer or mechanically pressurized system.

Based on the biological life stages of JB and recommendations by the CDFA's JB Science Advisory Panel (JBSAP), CDFA is proposing to add alternative application use scenarios to the JB treatment scenarios that were previously analyzed in the PEIR. The additional scenarios consist of turf/groundcover applications using granular Acelepryn G (Chlorantraniliprole) and spray drench of BeetleGONE! Tlc (Bt)), individually or in combination, in urban/residential settings. to. The JB is a destructive plant pest, both grubs (larvae) and adults. Adults feed on the foliage and fruits of several hundred species of fruit trees, ornamental trees, shrubs, vines and field and vegetable crops. Adults leave behind skeletonized leaves and large irregular holes in leaves. The grubs develop in the soil, feeding on the roots of various plants and grasses and often destroying turf in lawns, parks, golf courses, and pastures. Today, the Japanese Beetle is the most widespread turf-grass pest in the United States. Efforts to control the larval and adult stages are estimated to cost more than $460 million a year. Losses attributable to the larval stage alone have been estimated at $234 million per year - $78 million for control costs and additional $156 million for replacement of damaged turf. This includes losses to non-nursery crop production, but as JB spreads in corn and soybean growing regions of the Midwest, losses involving row crop production are expected to increase.

The $78 million for control costs represents increased pesticide use in areas east of the Rocky Mountains where JB is established and there is no attempt to eradicate it, as it is not feasible. These are the pest control management costs that come with having to "live with" the JB. The management of JB and its associated costs and impacts are expected to continue in perpetuity where the pest is fully established. Because of the severe impacts JB has on the urban/residential environment affecting homeowners, it is critical to be able to address all life stages of the JB.

Application of Acelepryn G is slightly different from application of the liquid form, as it is applied via spreaders and then watered in rather than applied by a sprayer. Application of BeetleGONE! Tlc is applied in a manner similar to the foliar and soil applications already analyzed in the PEIR because it requires use of the same backpack sprayer, boom sprayer, or mechanically pressurizedsprayer. The application of BeetleGONE! Tlc would occur in urban/residential settings with drench applications made to turf (lawns/golf courses) and ornamental ground cover (including flowers and containerized plants), recreational areas, and commercial settings using a mechanically pressurized sprayer or backpack sprayer. Additionally, larger areas such as school athletic fields or cemeteries could receive applications made with a small low-pressure boom sprayer, although in general the use of BeetleGONE! Tlc will be restricted to a small portion of the treatment area that is not appropriate for use of Acelepryn®.

CDFA will follow existing management practices (MPs) and mitigation measures for activities conducted under the PEIR including general MPs such as conducting a site assessment, following appropriate treatment procedures, training personnel in proper use of pesticides, and enforcing runoff and drift prevention. (See Statewide PEIR, Volume 1_Main Body, Section 2.11 Program Management Practices.)

The addition of the alternative JB treatments with granular Acelepryn G (Chlorantraniliprole) and BeetleGONE! Tlc will be added as PDEP-EP-E-11, PDEP-EP-E-12, and PDEP-EP-E-11-12, which are scenarios of treatments to turf and/or groundcover in urban/residential settings... The Human Health (HHRA) and Ecological Risk Assessments' (ERA) (Appendix 6A) analyzes PDEP-EP-E-11, PDEP-EP-E-12, and PDEP-EP-E-11-12 and provides substantial evidence that the proposed modification would not have any new significant impacts nor substantially increase the severity of the significant impacts identified in the PEIR and would not change the PEIR's conclusions.. (See Appendix 6A, Executive Summary HHRA and ERA, Problem Statement HHRA and ERA and Conclusions.)

5. Analysis of Potential Environmental Impacts Associated with the Proposed Modifications

Appendix 6A includes an HHRA and an ERA. The ERA and HHRA were conducted to determine if the alternative JB treatments with granular Acelepryn G (Chlorantraniliprole) and BeetleGONE! Tlc scenarios would result in any additional or more severe environmental impacts other than those addressed in the PEIR. The scenarios were analyzed as spreader dispersion followed by watering in of granular Acelypryn G for the eradication of JB and a turf/groundcover drench application of beetleGONE! TLC using a sprayer with low pressure.. The methods used in the ERA and HHRA largely follow those methods used in the previous risk assessments in the PEIR. Where methods differ, the new assumptions or receptors are discussed.

The ERA (Appendix 6A) along with the PEIR was used to assist CDFA in assessing the potential to affect particular species and develop site-specific measures to protect these species. This ERA did not identify new significant effects beyond those identified in the PEIR, or any substantial increase in the severity of impacts described in the PEIR. No alterations or mitigation measures to PD/EP-E-12 scenario that were not already indicated for other scenarios in the PEIR are recommended for the protection of biological resources. (See Appendix 6A ERA.)

The HHRA (Appendix 6A) along with the PEIR was used to assist CDFA in assessing potential impacts to human health. The HHRA did not identify any new significant human health impacts or any substantial increase in the severity of the significant effects identified in the PEIR. No alterations to PD/EP-E-11 or PD/EP-E-11-12 that were not already indicated for other scenarios in the PEIR are recommended. (See Appendix 6A HHRA).

CDFA staff considered the findings and conclusions of the ERA and HHRA in the context of CEQA Appendix G environmental factors that may be potentially affected by the three application scenarios (PD/EP-E-11, PD/EP-E-12, and PD/EP-E-11-12) that comprise this Addendum. These findings are discussed below in further detail.

Aesthetics were considered in the PEIR, and the Proposed Program would be consistent with typical agricultural or urban pest management practices. As with the Statewide Program, any

visual changes resulting from the Proposed Program would be short term and temporary for sensitive viewer groups. Therefore, for locations where the three additional scenarios may occur, the Proposed Program would have no new significant impacts on aesthetics, nor substantially increase the severity of significant impacts identified in the PEIR.

Agricultural resources were analyzed in the PEIR. As with the Statewide Program, the additional three scenarios in the Proposed Program would have beneficial impacts to agricultural resources due to the reduction or elimination of pests that are injurious to agricultural resources. Therefore, for locations where the addition of the three scenarios may occur, the Proposed Program would have no new significant impacts on agriculture resources, nor substantially increase the severity of significant impacts identified in the PEIR.

The PEIR analyzed potential effects of air quality by conducting an emissions inventory of Statewide Program activities for each basin in the state. The PEIR also noted that while air pollutants could possibly increase over time in a particular air basin to a level that would be significant, no additional feasible measures exist beyond those outlined by CDFA to further reduce criteria air pollutant emissions below the threshold (Volume 1; Main Body of the Statewide PEIR). CDFA currently implements all feasible measures to minimize criteria air pollutant emissions. The health risk associated with the exposure to toxic air from the activities carried out under the Statewide Program was not determined to be significant, and because of the short-term nature of the activities, such exposure would not be substantial (Volume 1; Main Body of the Statewide PEIR, Appendix 5A, HHRA). The Proposed Program utilizes the same methods and equipment as scenarios previously evaluated in the PEIR (Volume 3; Appendix B of the Statewide PEIR), and, therefore, the three new scenarios would have no new significant impacts on air quality, nor substantially increase the severity of significant impacts identified in the PEIR.

The evaluation of biological resources in the PEIR considered the potential for Statewide Program activities to result in substantial adverse effects on special-status species and sensitive natural communities. Physical and biological management activities were evaluated qualitatively and determined to have either no impact or a less than significant impact on biological resources. For chemical management activities, the analysis incorporated the results of the ERA completed with the PEIR (See Volume 2; Appendix A of the Statewide PEIR), which considered a variety of chemicals and their effects on special-status species. The ERA for the PEIR used surrogate species that were selected to represent the range of special-status species that may be found in proximity to the sites where chemical management activities could occur. A number of scenarios were found to have no potential to exceed a level of concern for any or a subset of surrogate species, and therefore such impacts would be less than significant. Where the modeling suggested risk to special-status species, CDFA evaluates potential site-specific effects before the management activity, then identifies and implements appropriate mitigation measures. As part of this process, CDFA obtains technical assistance from the California Department of Fish & Wildlife, United States Fish & Wildlife Service, and National Marine Fisheries Service regarding the mitigation measures.

Proposed Program activities would utilize management practices, mitigation measures, protocols, and equipment as the scenarios previously evaluated (Volume 2; Appendix A, and Volume 3; Appendix B of the Statewide PEIR). However, the Proposed Program could utilize a

new active agent (*Bacteria thuringiensis*) and different application methods as an alternative to the scenarios previously evaluated. The Proposed Program ERA (Appendix 6A) indicated that the three new scenarios in the Proposed Program would have no new significant impacts on biological resources, nor substantially increase the severity of significant impacts identified in the PEIR.

Cultural resources were considered in the PEIR, and no information was found to suggest that there has been, or could be in the future, loss or degradation of significant historic resources as a result of the Statewide Program. As in the Statewide Program, the Proposed Program would not include any activities which could physically modify historic structures or excavate into native soils potentially containing archeological resources, paleontological resources, or human remains. Therefore, the three new scenarios in the Proposed Program would have no new significant impacts on cultural resources, nor substantially increase the severity of significant impacts identified in the PEIR.

Geology and soils were considered in the PEIR as part of the Statewide Program. The Proposed Program would not include construction of structures that could be subject to earthquake-related hazards, unstable soils, expansive soils, or other geotechnical hazards, and it would not entail construction of septic or other wastewater disposal systems. The extent to which the Proposed Program could disturb soils would be limited to host plant removal, and such activities would be consistent with current agricultural crop practices under existing conditions (e.g. tilling of soil, crop rotation). Thus, the Proposed Program would not expose individuals to increased geologic or seismic hazards, would not result in erosion or loss of topsoil, would not construct structures on unstable soil, and would not create wastewaters systems in unsuitable soils. Therefore, the three new scenarios in the Proposed Program would have no new significant impacts on geology and soils, nor substantially increase the severity of significant impacts identified in the PEIR.

Global climate change was considered in the PEIR and included quantifying greenhouse gas emissions from Statewide Program activities. Over the past twenty years, statewide PDCP activities that contribute to global climate change have remained the same or decreased, depending on location and scenario. The Proposed Program will not lead to new or increased activities; rather the new scenarios will replace existing scenarios. The analysis in the PEIR concluded that emissions would decrease due to several factors, including federal and state regulations targeted at reducing emissions. However, the PEIR also explained that if the level of activity increases in the Statewide or Proposed Program, emissions could possibly increase to a level that would be significant and unavoidable. As discussed in the PEIR, if the level of activity increases under the Statewide Program or Proposed Program, no feasible mitigation measures would reduce the impact to a less-than-significant level. Therefore, the three new scenarios in the Proposed Program would have no new significant impacts on global climate change, nor substantially increase the severity of significant impacts identified in the PEIR.

Hazards and hazardous materials were considered and addressed in the PEIR, including hazards associated with use of equipment and related hazardous materials (e.g., fuels), the risk to human health associated with pesticide applications, the potential to encounter site contamination during pest management activities, the impacts of activities conducted at or near schools and airports, and the potential for pest management activities to generate wildfires. The

PEIR determined that Statewide Program impacts would be less than significant through following regulatory requirements, management practices for transport, storage, and use of hazardous substances, and implementation of mitigation measures (Volume 1; Main Body of the Statewide PEIR).

In the PEIR HHRA (Volume 3; Appendix B), various groups with the potential to be exposed to a number of different pesticide application scenarios were evaluated. The PEIR HHRA concluded that the Statewide Program's impacts due to hazards and hazardous materials could be potentially significant. However, the PEIR included mitigation measures that would reduce hazards and hazardous materials impacts to less than significant. These mitigation measures are also applicable to the Proposed Program. The Proposed Program HHRA did not identify any new significant human health impacts or any substantial increase in the severity of the significant impacts as a result of the Proposed Program activities. Therefore, the three new scenarios in the Proposed Program would have no new significant impacts on hazards and hazardous materials, nor substantially increase the severity of significant impacts identified in the PEIR, which determined that impacts would be less than significant with mitigation.

Hydrology was considered in the PEIR. As in the Statewide Program, the Proposed Program would not require the use of ground or surface water and would not result in the obstruction or diversion of any waterbody. It would not require the construction of structures that could be subject to flooding or other hydrologic hazards either. Therefore, the three new scenarios in the Proposed Program would have no new significant impacts on hydrology, nor substantially increase the severity of significant impacts identified in the PEIR.

Water quality was also considered in the PEIR. This water quality analysis considered the extent that Statewide Program activities could result in violations of water quality standards, impairment of beneficial uses, or water quality conditions that could be harmful to aquatic life or human health. It also considered applicable permits and relevant management practices designed to reduce the potential for drift, runoff, or erosion. As in the Statewide Program, chemical management activities in the Proposed Program are subject to a number of regulatory requirements, and the chemicals would have fate and transport properties that would make them unlikely to be found in water at concentrations that could exceed relevant standards or impair beneficial uses. While identifying that potential significant impacts would be possible in cases where affected parties implement certain activities in response to quarantines, in these cases, protective mitigation measures would be implemented by CDFA. Though the Proposed Program activities would utilize a new active ingredient and means of application, they would utilize the same management methods, protocols, and equipment as the scenarios previously evaluated (Volume 2; Appendix A and Volume 3; Appendix B of the Statewide PEIR). Therefore, the three new scenarios would have no new significant impacts on water quality, nor substantially increase the severity of significant impacts identified in the PEIR.

Land use and planning was considered in the PEIR. As in the Statewide Program, the Proposed Program would not result in the creation of any structures or barriers that could divide an established community, nor result in any permanent land use changes or regulations. All activities conducted under the Proposed Program would be required to obtain the necessary authorizations from the relevant land use authority or property owners and comply with applicable laws or policies of the area. Therefore, the three new scenarios would have no new

significant impacts on land use and planning, nor substantially increase the severity of significant impacts identified in the PEIR.

Mineral resources were considered in the PEIR. The PEIR concluded that none of the activities analyzed would have the potential to affect mineral production sites. Because the three scenarios comprising the Proposed Program would use methods previously evaluated, the Proposed Program would have no new significant impacts on mineral resources, nor substantially increase the severity of significant impacts identified in the PEIR.

Noise was considered in the PEIR. For the noise analysis, typical noise-generating equipment that may be used for the various types of pest management activities were identified, and noise generation estimates were developed for each activity. The analysis then identified the distance from sensitive receptors at which noise thresholds would be exceeded. The analysis concluded that daytime noise generation would not have the potential to result in significant impacts. Although such activities generally would not be conducted at night, nighttime activities were considered. In cases where nighttime noise thresholds could be exceeded, mitigation measures were included that would require such activity be conducted during daytime. The Proposed Program utilizes the same methods and equipment as scenarios previously evaluated in the PEIR (Volume 3; Appendix B of the Statewide PEIR); therefore, the three new scenarios would have no new significant impacts on noise, nor substantially increase the severity of significant impacts identified in the PEIR.

Population and housing were considered in the PEIR. As with the Statewide Program, the Proposed Program would not require additional staff for implementation, nor would it involve construction or movement of housing. It would also not result in the construction of infrastructure or involve activities that could indirectly alter population growth. Therefore, the three new scenarios would have no new significant impacts on population and housing, nor substantially increase the severity of significant impacts identified in the PEIR.

Public services were considered in the PEIR. As with the Statewide Program, the Proposed Program would have no effect on the demand for public facilities because it would not increase housing or involve activities that could cause a greater demand for public services. (See Hazards section for hazardous material spill response in Volume 1; Main Body of the Statewide PEIR). It would also not include any activities that could interfere with provisions of public services. Therefore, the three new scenarios would have no new significant impacts on public services, nor substantially increase the severity of significant impacts identified in the PEIR.

Recreation was considered in the PEIR. As concluded in the PEIR, although certain Proposed Program activities may be conducted on recreational sites, the Proposed Program does not include any activities that would permanently affect the use or availability of recreation sites. Because the Proposed Program would include minimal, if any, temporary closures to recreational sites because of Proposed Program activities, effects of the availability or the use of recreational facilities would be negligible. Therefore, the three new scenarios would have no new significant impacts on recreation, nor substantially increase the severity of significant impacts identified in the PEIR.

Transportation was considered in the PEIR. As in the Statewide Program, anticipated on-road vehicle use under the Proposed Program would be associated with personnel and equipment transport to and from work sites. Such trips would be limited to the duration and needs of the management activity at any given site. The effects on increased traffic would be intermittent and widespread and are not expected to have a substantial effect on regional or local roadways or the overall transportation system. In addition, many of these vehicle trips are already occurring as part of Statewide Program activities. Proposed Program activities would not exceed a level of service standard for congestion management, nor would they result in increased hazards due to design features, incompatible uses, or inadequate emergency access. Therefore, the three new scenarios would have no new significant impacts on transportation and traffic, nor substantially increase the severity of significant impacts identified in the PEIR.

Utilities and service systems were considered in the PEIR. Although host removal activities would be rare in the Proposed Program, should any vegetation require landfill disposal, all materials would be handled according to proper containment and treatment regulations associated with disposal as described in the PEIR. Because of the low volume of materials expected to be generated under Proposed Program activities, any effects on landfill facilities would be temporary and not include any long-term waste generation at any given location throughout the state. Thus, the effects on landfill facilities would be minimal. Additionally, as in the Statewide Program, the Proposed Program would not include the disturbance, creation, or need for utility systems, including water, sewage, wastewater, or storm water. Therefore, the three new scenarios would have no new significant impacts on utilities or service systems, nor substantially increase the severity of significant impacts identified in the PEIR.

The ERA and HHRA (Appendix 6A), along with the PEIR, were used to assist CDFA in assessing potential impacts to the environment and human health. Neither the ERA nor HHRA identified any new significant environmental or human health impacts or any substantial increase in the severity of significant effects identified in the PEIR due to the use of these scenarios in addition to previously analyzed treatment scenarios.

6. Conclusions

The CDFA Plant Health and Pest Prevention Division staff, with the assistance of the ERA and HHRA, did not identify any new significant environmental effects or a substantial increase in the severity of the significant effects identified in the PEIR. In addition, Division staff determined that no new information of substantial importance exists, which was not known and could not have been known with the exercise of reasonable diligence at the time the previous EIR was certified as complete, that would require the preparation of a subsequent EIR.(See Appendix 6A).

7. References

"Action Plan for Japanese Beetle, *Popillia japonica* (Newman)", May 2000, California Department of Food and Agriculture, Plant Health and Pest Prevention Services.

California Department of Food and Agriculture. 2021. Japanese Beetle (JB). (Accessed February 23, 2021): https://www.cdfa.ca.gov/plant/pdep/target_pest_disease_profiles/japanese_beetle_profile.htmlhttps://www.cdfa.ca.gov/plant/pdep/target_pest_disease_profiles/japanese_beetle_profile.html

Ecological Risk Assessment, February 2021, Blankinship and Associatess

Human Health Risk Assessment, February 2021, Blankinship and Associates

Japanese Beetle California Exterior Quarantine, Section 3280, Title 3, California Code of Regulations.

Japanese Beetle Federal Domestic Quarantine, Section 301.48, Title 7, Code of Federal Regulations.

Shanovich, Hailey N., Ashley N Dean, Robert L Koch, Erin W Hodgson 2019. Biology and Management of Japanese Beetle (Coleoptera: Scarabaeidae) in Corn and Soybean, Journal of Integrated Pest Management, Volume 10: https://doi.org/10.1093/jipm/pmz009

"Statewide Plant Prevention and Management Program Environmental Impact Report", certified
December 24, 2014. Accessed June 28, 2016:
http://www.cdfa.ca.gov/plant/peir/.

U.S. Domestic Japanese Beetle Harmonization Plan", Revised March 4, 2016. National Plant Board. Accessed June 28, 2016:
http://nationalplantboard.org/japanese-beetle-harmonization-plan/.

California Department of Food and Agriculture
Statewide Plant Pest Prevention and Management Program
PEIR Addendum 6 Appendix 6-A Part 1

Human Health Risk Assessment

Residential Treatments, Japanese Beetle Eradication Program

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

1 Executive Summary

This Human Health Risk Assessment (HHRA) is conducted as an addition to the HHRA conducted as part of the California Department of Food and Agriculture (CDFA) Statewide Plant Pest Prevention and Management Program Environmental Impact Report (PEIR) (CDFA, 2014a). Three new alternative scenarios were assessed for granular and turf/ground cover spray drench applications of Acelepryn® G and/or beetleGONE!® tlc insecticides, respectively, for the control of the Japanese beetle. The methods used in this risk assessment largely follow those methods used in the previous risk assessment in the Statewide PEIR (CDFA, 2014a) 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.

The application of Acelepryn G and/or beetleGONE! tlc could occur in urban/residential settings within a 200-meter radius around beetle detections and includes ground application to turf (includes lawns/golf courses), recreational areas, ornamental plants (includes flowers and ground cover areas). 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 fields, and other landscaped areas. Applications may be made during off hours in school settings or business areas. An open or closed cab rotary push-type spreader, belly grinder, drop spreader, or tractor-drawn spreader may be used for applications of Acelepryn G. Alternatively, Acelepryn G granules may be applied by hand to a smaller application area. 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.

Acute, subchronic, and chronic dermal, inhalation, and ingestion exposures were considered for residents present after pesticide application (i.e., Post Application Resident, or PAR) and those present downwind during an application (i.e., Downwind Bystander, or DWB). The lifestages considered included the <2 year-old, 2-<16 year-old, and 16< year-old. In addition to resident receptors, the personnel responsible for handling and applying pesticides were evaluated (i.e., the Mixer-Loader-Applicator, or MLA). Environmental media considered to contain pesticide residue included inedible vegetation, edible vegetation, drinking water, turf, soil, and air. For the purpose of this HHRA, the term "pesticide" refers to both active and inert ingredients.

Risk was quantitatively assessed using the Margin of Exposure (MOE) technique. For this HHRA, the level of concern value, also referred to as the level of concern (LOC), that indicates an unlikely adverse impact to human health was 300. MOE values less than the LOC indicate the potential for adverse impacts to human health; MOE values greater than the LOC indicate that adverse health impacts are unlikely. MOE values calculated for this HHRA ranged from approximately 7,130 to greater than $>10^{10}$. This indicates that exposure to pesticides during the Proposed Program is not expected to result in adverse impacts to human health.

The magnitude of an MOE is indicative of the general safety of exposure, with larger MOEs generally indicating smaller potential health risk. Comparatively large MOEs should not, however, be interpreted as encouraging unnecessary contact with environmental media containing pesticides.

2 Introduction

This Human Health Risk Assessment (HHRA) evaluates three alternative pesticide application scenarios within the California Department of Food and Agriculture's (CDFA) Pest Detection/Emergency Program (PD/EP) for the eradication of Japanese beetle in an urban/residential setting, herein referred to as the "Proposed Program." This document is a supplement to the CDFA Statewide Plant Pest Prevention and Management Program Environmental Impact Report 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 Human Health Risk Assessment (HHRA)

The HHRA assesses potential future activities to be conducted under CDFA's Proposed Program. Specifically, the HHRA focuses on pesticide applications that would be available for use to control the Japanese beetle and evaluates the potential risk to human receptors following such pesticide applications.

2.2 Approach

A detailed discussion of the approach for the HHRA process is provided in the Statewide PEIR, Volume 3, Appendix B, Human Health Risk Assessment (CDFA, 2014a).

This HHRA 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 HHRA, 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 HHRA depends on these USEPA exposure models to estimate chemical environmental concentrations and associated risk. The majority 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 HHRA and some models require the output of previous models as their 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 application scenario. This Excel workbook, developed by Blankinship & Associates and Ardea Consulting under contract with CDFA, is referred to as the Comprehensive Risk ANalysis Kalculator (CRANK) and provided a consolidated tool to estimate risk for the HHRA as well as the associated Ecological Risk Assessment (ERA).

To present information that serves as inputs for the various models used previously in the HHRA 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 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 HHRA 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 and applicable, inert and adjuvant ingredients
- Physical, chemical, and fate properties of the chemicals considered in the HHRA, including degradation rate, vapor pressure, solubility, molecular weight, octanol-water coefficient (Log K_{OW}), and soil adsorption coefficient (K_{OC})
- Toxicological properties of the chemicals considered in the HHRA
- Summary of environmental effects based on published literature
- Model-specific inputs and outputs
- Soil concentration estimation results
- Water concentration estimation results

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 HHRA. The purpose of this involvement was to allow for peer review, facilitate the exchange of information, collaborate on methods to assess and protect human health and the environment, and clearly communicate these methods and results to the public.

3 Hazard Identification

The first step in conducting the HHRA is a planning process called Hazard Identification (OEHHA, 2001a). This included identification of the ingredients of the pesticide products and adjuvants and the use scenarios that are anticipated under the Proposed Program. Pesticide and adjuvant ingredients were determined from the product label and Safety Data Sheet (SDS) provided by the pesticide manufacturer.

3.1 Application Scenarios

Details regarding the application of pesticide active and inert ingredients 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)
- Restricted Entry Interval (REI) requirements

As part of the Statewide PEIR (CDFA, 2014a), seven application scenarios were analyzed under 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 HHRA 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-12, and PD/EP-E-11-12 were directly analyzed in this HHRA.

In this assessment, Acelepryn® G (active ingredient- chlorantraniliprole, inerts- dolomite and homopolymer, butene) was analyzed as granular applications targeting turf and groundcovers in an urban/residential setting (PD/EP-E-11). No application scenarios in the Statewide PEIR or its previous 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 beetleGONE!® tlc (active ingredient - *Bacillus thuringiensis* serovar *galleriae* strain SDS 502 fermentation solids, spores, and insecticidal toxins (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 A: PMDS**. The defined application rate for Acelepryn G is 125 lb/Ac. Corresponding application rates for specific active and inert ingredients are provided in Section 1.4 below. 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. Refer to Section 1.4 for information on the corresponding application rate for Btg. PD/EP-E-12 consists of one 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.

To evaluate the different ways in which Acelepryn G may be applied to turf and groundcover in the Proposed Program, one use scenario (PD/EP-E-11) was developed for the HHRA and subsequently divided into three subscenarios (PD/EP-E-11a, PD/EP-E-11b, and PD/EP-E-11c). The subscenarios consisted of granule application through rotary push-type spreaders, drop spreaders, or belly grinders (PD/EP-E-11a), tractor-drawn spreaders (PE/EP-E-11b), or by hand (PD/EP-E-11c). Similarly, PD/EP-E-12 was divided into three subscenarios (PD/EP-E-12a, b, and c for the backpack sprayer, mechanically pressurized handsprayer, and boom sprayer, respectively).

Details as specified in the PMDS were used to characterize these scenarios to allow for exposure estimates to be made in the HHRA and are summarized in **Table 1**. Note that quantitative risk analysis of BtG was not performed, due to a lack of human toxicity and limitations in environmental fate modeling of biopesticides. Consistent with the Statewide PEIR evaluation of *Bacillus thuringiensis* subsp. *kurstaki* (CDFA, 2014a), the assessment of BtG was qualitatively assessed.

Table 1: Turf Drench Applications of Acelepryn G and beetleGONE! for Japanese Beetle

PD/EP-E-Treat	Product	App Technique	Max Apps/ Year	App Interval	Area Treated/Worker/ Day (ac)	Total App Area (ac)
11a	Acelepryn G	Belly grinder, rotary push-type or drop spreader	1-2	2-5 mo	5	50
11b		Tractor-Drawn Spreader			10	
11c		Hand Application			0.22	
12	beetleGONE! tlc	Backpack sprayer handsprayer, mechanically pressurized handsprayer,	1	Yr	5	50
		Boom sprayer			10	
11a-12	Acelepryn G	Belly grinder, rotary push-type or drop spreader	1-2	2-5 mo	5	47.5
	beetleGONE! tlc	Backpack sprayer handsprayer, mechanically pressurized handsprayer, boom sprayer	1	Yr	5	5
11b-12	Acelepryn G	Tractor-Drawn Spreader	1-2	2-5 mo	10	47.5
	beetleGONE! tlc	Backpack sprayer handsprayer, mechanically pressurized handsprayer, boom sprayer	1	Yr	5	5
11c-12	Acelepryn G	Hand Application	1-2	2-5 mo	0.22	47.5
	beetleGONE! tlc	Backpack sprayer handsprayer, mechanically pressurized handsprayer, boom sprayer	1	Yr	5	5

*When multiple application equipment are permitted for use under an application scenario, the ground equipment with the greatest unit exposure (UE) was selected as a health protective representative for exposure assessment. For PD/EP-E-11b, the belly grinder yielded the greatest UE for both dermal and inhalation exposure. In some cases, scenarios required subdivision (i.e., assigned letters “a”, “b”, or “c”) to accommodate differences in equipment that favored greater inhalation or dermal exposure, or when the area treated/worker/day varied by equipment.

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 (≥90% to ≤100%) and polybutene (≥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). Refer to **Table 2** for a summary of the composition and application rate for Acelepryn G. 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.

Table 2: Acelepryn G Composition by Chemical

Product Application Rate (lb/ac)	Ingredient	% Ingredient Composition of Product	Ingregient Application Rate (lb/ac)
125	Chlorantraniliprole	>= 0.1 - < 1	0.25
	Butene, homopolymer	>= 1 - < 5	Up to 6.2375
	Dolomite (CaMg(CO3)2)	>= 90 - <= 100	Up to 123.625

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.

Refer to Table 3 for a summary of the composition and application rate for beetleGONE! tlc.

Table 3: beetleGONE! tlc Composition by Chemical

Product Application Rate (lb/ac)	Ingredient	% Ingredient Composition of Product	Ingredient Application Rate (lb/ac)
17.5	*Bacteria thuringiensis* subsp. *galleriae*, Strain SDS-502	76.5% w/w Concentration 0.85×10^{10} CFU/g	13.3875

All identified ingredients were researched for chemical characteristics, toxicity, and environmental fate properties. Applicable environmental fate characteristics for the chemicals evaluated in this HHRA 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 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, see the *Chemical Summary* 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 ($CaMg(CO_3)_2$ 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 of the ERA.

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).

3.2.5 Environmental 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*.

4 Toxicity Dose-Response Assessment

The second step in the HHRA process is the assessment of toxicity (OEHHA, 2001a). All chemicals have some degree of toxicity and no substances are completely non-toxic. This fundamental concept of toxicology is expressed by Philippus Von Hohenheim (also known as Paracelsus), a 16th century physician and scientist (Pachter, 1951), in his famous maxim: "All things are poison, and nothing is without poison: only the dose permits something not to be poisonous." Accordingly, understanding the toxicity of pesticide active and inert ingredients and adjuvants, and the potential dose that human receptors might receive as part of the Proposed Program, is critical. Two fundamentally different toxicological responses may transpire following exposure depending on the end response: cancerous and non-cancerous health effects. Toxicity values are quantitative values that describe the relationship between an estimated dose and the probability of developing cancer or the likelihood of producing non-cancerous health effects.

Non-cancerous health effects (e.g., difficulty breathing, neurological effects) were evaluated using no observable adverse effect levels (NOAELs). A NOAEL is the highest exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its control (USEPA, 1993q).

When multiple, suitable NOAELs were available in the literature, the most sensitive effect level was selected. All NOAELs used in this assessment are reported in units of milligrams of chemical per kilogram body weight (BW) per day (mg/kg-day). Extrapolations were made and uncertainty factors applied to NOAELs selected from the literature for use in estimating risk. Extrapolation and uncertainty include using animal studies and/or surrogate chemicals. Use of the most sensitive effect level along with conservative extrapolation and uncertainty factors is generally considered health-protective of a representative cross section of the general population.

Consistent with the methods described in the Statewide PEIR, NOAELs were obtained for each assessed chemical for the available and relevant routes of exposure. Refer to Section 1.7 for a description of critical NOAELs selected for risk assessment.

Cancer risk was not characterized in this risk assessment because none of the active or inert ingredients are suspected to be carcinogenic (USEPA, 2019d).

Data sources reviewed in the toxicity assessment are presented in Section 1.6 below.

4.1 Mechanism of Action and Target Organs and Systems

Toxicity studies are often conducted using single chemicals rather than a combination of chemicals that may be found in a specific pesticide formulation. An HHRA typically evaluates each chemical individually, and then combines the risks from multiple chemicals with the same effects to get a final, combined representation of risk.

As a health-protective and conservative approach, the cumulative risk of pesticide active and inert ingredients was estimated regardless of their mechanism of action (e.g., acetylcholinesterase inhibition), target organ (e.g., liver), or target system (e.g., nervous system).

The most sensitive effect considered to be relevant for each chemical by the USEPA or other authoritative agency was used as the basis for risk characterization. By assuming exposure to each chemical contributes toward cumulative adverse health effects, the potential risk to human health was likely overestimated, and, as a result, health protective and conservative in nature. This methodology is consistent with the approaches described in the USEPA (2004i) *Risk Assessment Guide to Superfund (RAGS)* and USEPA (2001e) *General Principles for Performing Aggregate Exposure and Risk Assessment* which provides guidance on assessing aggregate chemical risk and aggregate exposure pathway risk.

4.2 Data Sources

The toxicity assessment reviewed the following data sources. In the event that no conflicting or suspect data were found, other sources were used to corroborate the initial data found. The most conservative and health-protective data were used when two or more suitable data points existed. Any sources utilized during previous Statewide PEIR analyses were also considered.

- USEPA Pesticide Chemical Search: Reregistration Eligibility Decision (RED) and Human Health Risk Assessment (HHRA) documents (USEPA, 2020b)
- DPR Risk Characterization Documents (RCD) (DPR, 2020a)
- Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles (ATSDR, 2020a)
- OEHHA Toxicity Criteria Database (OEHHA, 2020a)
- United Nations Environmental Programme (UNEP) Screening Information Dataset System (SIDS) Initial Assessment Profiles (UNEP, 2020a)
- United States Department of Agriculture (USDA) Human Health Risk Assessments (USDA, 2020a)
- National Center for Biotechnology Information, National Library of Medicine PubChem (NCBI, 2020a)

4.3 Toxicity Endpoints Selected for Risk Characterization

Critical NOAELs used for risk characterization were identified and selected from the literature in a manner consistent with the methods described in the Statewide PEIR. When determining critical NOAEL, it is important to acknowledge that treatment-related effects may be either adverse in nature, an adaptive response, or otherwise non-adverse (e.g., an effect that lacks biological significance). An adverse effect is a change in morphology, physiology, growth, development, reproduction, or life span of a cell or organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences (Keller et al., 2012). In contrast, an adaptive response, in the context of toxicology, is the process whereby a cell or organism responds to a xenobiotic so that the cell or organism will survive in the new environment that contains the xenobiotic without impairment of function (Keller et al., 2012). Critical NOAELs used in the current assessment were selected based on evidence of adversity as reported in the literature. Where specific effects may be interpreted as either adverse or non-

adverse (e.g., an adaptive response), a discussion of the determination of the adversity, or lack thereof, of such effects is presented in the subsections below.

Each pesticide or adjuvant ingredient was categorized into one of three categories for each evaluated exposure route (oral, inhalation, dermal) depending on the toxicity information available. These categories of classification include: Not of Concern (NOC), Potential Toxicological Concern (PTC), and No Data Available (NDA). Chemicals evaluated as NOC are not of toxicological concern for an exposure route based on the criteria described previously in the Statewide PEIR. Chemicals evaluated to be of potential toxicological concern for specific exposure routes were deemed PTC and available NOAELs were used to characterize risk quantitatively using the methods described in Section 0. A chemical was designated as NDA when endpoint data suitable for assessing risk was not available for this chemical and endpoint category. The risk for chemicals designated NDA could not be evaluated.

4.3.1 Chlorantraniliprole

The literature investigating the toxicity of chlorantraniliprole is robust, and has been evaluated by DPR (2008c), OEHHA (2020b), USEPA (2008f, 2008h, 2010h), U.S. Department of Agriculture (USDA, 2019a), Joint Food and Agriculture Organization of the United Nations/World Health Organization Meeting on Pesticide Residues (JMPR) (JMPR, 2008a), European Food and Safety Authority (EFSA, 2013), and the New York State Department of Environmental Conservation (NYSDEC, 2009b).

Subchronic and chronic oral toxicity studies indicate that the two primary target organs of chlorantraniliprole include the adrenal gland and the liver. In this section, specific effects observed during these studies are described. A summary table of studies reviewed for endpoint selection is presented in **Table 4**.

Table 4. Summary of Chlorantraniliprole Subchronic and Chronic Toxicity Studies

Study[1]	Doses (mg/kg d)	NO(A)EL (mg/kg d)	LO(A)EL (mg/kg d)	Effects
14-d Oral (gavage)/ Rats	0, 25, 100, 1000	1000	Not established	Increased cytochrome P450 3A activity in females at the highest dose tested.
28-d Oral (feeding)/ Rats	Male: 0, 20.7,106, 584; Female: 0, 24.0, 128, 675	Male: 584; Female: 675	Not established	Increased total protein, globulin, and serum calcium levels in females at the highest dose tested. Increased UDP-glucuronyl transferase activity and relative liver weight in females at the highest and second highest doses tested. Other effects noted but not of statistical significance: centrilobular hypertrophy and eosinophilic appearance of hepatocytes in females and adrenal cortical microvesiculation in males at the highest dose tested.

Study[1]	Doses (mg/kg d)	NO(A)EL (mg/kg d)	LO(A)EL (mg/kg d)	Effects
28-d Oral (feeding)/ Mice	Male: 0, 52.1, 181.6, 538.3, 1443; Female: 0, 64.4, 206.1, 657.6, 1524	Male: 1443; Female: 1524	Not established	Reduced bodyweight gain and food efficiency in males at the highest dose tested. No noted reduction in absolute bodyweight. Increased absolute and relative liver weight in females at the 657.6 mg/kg-d dose level. Increased absolute liver weight in both sexes at the highest dose tested. Other effects noted but not of statistical significance: increased relative weight of and focal necrosis in liver of males noted at the highest dose tested; increased cytochrome P450 activity in the liver of both sexes at the highest and second highest dose levels.
28-d Dermal/ Rats	0, 100, 300, 1000	1000	Not established	Reduced bodyweight gain and food efficiency in males at the highest dose tested. Increased absolute, but not relative, spleen weight at the highest and second highest dose levels and kidney weight at the highest dose level in males. Other effects noted but not of statistical significance: reduced bodyweight gain and food efficiency in females at the highest dose tested; adrenal cortical microvesiculation in males noted at the 100 mg/kg-d dose level and above.
90-d Oral (feeding)/ Rats	Male: 0, 36.9, 119.7,358.9, 1188; Female: 0, 47.0, 156.7, 459.8, 1526	Male: 1188; Female: 1526	Not established	Increased absolute and relative liver weight of both sexes at the highest dose tested. Other effects noted but not of statistical significance: increased adrenal cortical microvesiculation in males at the highest dose tested; decreased bilirubin in females at the 156.7 mg/kg-d dose level and above.
90-d Oral (feeding)/ Mice	Male: 0, 32.6, 115.2, 345.0,1135; Female: 0, 40.7, 158.4, 422.4, 1539	Male: 1135; Female: 1529	Not established	Reduced bodyweight gain and/or absolute bodyweight in both sexes at the highest dose tested and in males at the second highest dose tested during the first week (not noted for the remainder of the study). Increased relative liver weight in males at the highest dose tested.
90-d Oral (feeding)/ Dogs	Male: 0, 32.2, 118.5, 303.2, 1163; Female: 0, 36.5, 133.1, 317.8, 1220	Male: 1163; Female: 1220	Not established	Increased absolute and relative liver weight in males at the highest dose tested.
1-yr Oral (feeding)/ Dogs	Male: 0, 32.0, 111.5, 316.6, 1164; Female: 0, 34.0, 113.2, 277.8, 1233	Male: 1164; Female: 1233	Not established	Increased serum alkaline phosphatase activity and relative liver weight in both sexes at the highest dose tested.
18-mo Oral (feeding)/ Mice	Male: 0, 2.60, 9.20, 26.1, 157.6, 935.1; Female: 0, 3.34,11.6,	158	Male: 935; Female: not established	Reduced bodyweight gain in males at the highest dose tested during the first 13 weeks (not noted for the remainder of the study). Increased absolute and relative liver weight of both sexes at the highest and second highest dose levels. Decreased mean and absolute kidney weight in females at the

Study[1]	Doses (mg/kg d)	NO(A)EL (mg/kg d)	LO(A)EL (mg/kg d)	Effects
	32.9, 195.6, 1155			highest dose tested. Eosinophilic foci in liver of males at the highest dose tested. Other effects noted but not of statistical significance: centrilobular hepatocellular hypertrophy in males at the highest and second highest dose levels.
2-yr Oral (feeding)/ Rats	Male: 0, 7.71, 39, 156.2, 805.3; Female: 0, 10.9, 51, 211.5, 1076	Male: 805.3; Female: 1076	Not established	Increased adrenal cortical microvesiculation in males at the 39 mg/kg-d dose level and above. Microvesicles noted to contain lipid. Increased relative liver weight of 211.5 and 1076 mg/kg-d females after 12 months (not apparent at the end of the study). Other effects noted but not of statistical significance: decreased bilirubin in females at the 51 mg/kg-d dose level and above.

[1] Study details obtained from DPR (2008c), OEHHA (2020b), and USEPA (2008f, 2008h, 2010h)

4.3.1.1 Adrenal Cortical Microvesiculation

In subchronic oral and dermal studies in rats, a slightly increased incidence of adrenal cortical microvesiculation was observed in males (DPR, 2008c; OEHHA, 2020b; USEPA, 2008h). These effects, however, were not considered adverse in the current assessment based on the lack of evidence of adrenal cellular degeneration or toxicity as well as data indicating that the increased microvesiculation did not impact the capacity of the adrenal gland to produce corticosterone under basal (i.e., non-stressed) or following adrenal corticotropic hormone stimulation (i.e., under physiological stress).

The conclusion of non-adversity is consistent with findings from a chronic oral toxicity study in rats which resulted in a statistically significant increase of adrenal cortical microvesiculation in males (DPR, 2008c; OEHHA, 2020b; USEPA, 2008h). No evidence indicating notable alterations to cellular morphology compared to untreated rats, cytotoxicity, or other signs of structural or functional impairment of the adrenal gland was observed. Furthermore, the microvesicles observed during the chronic study were reported to contain lipid. As noted by OEHHA (2020b), the accumulation of lipid inclusions in the adrenal cortex has been reported as an age-related occurrence in rodents, and not a chemical one.

The conclusion drawn in this HHRA is that microvesiculation of the adrenal cortex is better characterized as a general effect, rather than an adverse one. This determination is in agreement with the evaluations performed by DPR (2008c), USEPA (2008f), OEHHA (2020b), USDA (2019a), JMPR (2008a), and EFSA (2013).

4.3.1.2 Increased Liver Weight

The most consistent effect observed in subchronic and chronic oral studies was increased relative liver weight (DPR, 2008c; OEHHA, 2020; USEPA, 2008h). Although in some cases this effect may appear to be associated with later development of toxicity (e.g., fibrosis, necrosis, vacuolization, fatty degeneration, neoplasia), it may also be a non-adverse, adaptive response associated with hepatic enzyme induction, as discussed below (Hall et al., 2012a).

Observations indicative of hepatic enzyme induction following chlorantraniliprole exposure have been reported in multiple subchronic and chronic studies. In a 28-day rat feeding study described by DPR (2008c) and USEPA (2008h), increased relative liver weight in females was associated with increased uridine 5'-diphospho-glucuronyl transferase (UDP-glucuronyl transferase) activity and slightly increased incidence of hepatocellular hypertrophy. Note that exposure to hepatic enzyme inducers results in increases in liver weight by way of hepatocellular hypertrophy (Sherlock, 1970a) and that, in general, an increase in liver weight of at least 20% is required to histologically detect hypertrophy (Hall et al., 2012a).

In a 90-day mouse feeding study and a 2-year rat feeding study described by DPR (2008c) and OEHHA (2020b), increased relative liver weight and slightly decreased bilirubin values were reported in females. While not a liver enzyme in itself and usually an insensitive measure of hepatotoxicity in laboratory animals (Plaa, 2010a), Hall et al. (2012a) points out that total bilirubin can be reduced by hepatic enzyme inducers as a result of higher conjugation rates and excretion via bile, whereas increased bilirubin, when accompanied by increased serum bile acids, is indicative of hepatic and bile duct toxicity and loss of function. Within the liver, bilirubin is conjugated by the microsomal enzyme UDP-glucuronyl transferase (Sherlock, 1970a). In support of this assessment, it is reported that serum bilirubin concentrations reflect the ability of hepatocytes to take up, conjugate, and secrete bilirubin, so it is a functional marker rather than a marker of cellular integrity (Gwaltney-Brant, 2016a).

In a one-year dog feeding study described by DPR (2008c), increased relative liver weight was associated with increased serum alkaline phosphatase (ALP) activity in both sexes. Previous studies in dogs, however, correlated increased serum ALP activity with increased microsomal enzyme activity and demonstrated that the ALP increase was of hepatic origin without histologically detectable hepatobiliary injury (Hall et al., 2012a). The elevated serum ALP observed in these studies was noted to return to normal levels 8 days after cessation of treatment in concordance with a reduction in hepatic microsomal enzyme activity. Furthermore, it should be acknowledged that the hepatic isoform is the main contribution to total circulating ALP activity in the dog compared to other species, further supporting the conclusion this marker is not indicative of toxicity (Hall et al., 2012a).

In the absence of degenerative or necrotic evidence and without significant changes in hepatic-derived plasma enzymes, an increase in relative liver weight and associated hepatocellular hypertrophy through hepatic enzyme induction was, therefore, considered to be an adaptive effect in the current assessment. This conclusion is consistent with that of DPR (2008c), USEPA (2008h; 2010h), USDA (2019a), and JMPR (2008a).

4.3.1.3 Eosinophilic Foci Accompanied by Increased Liver Weight and Hepatocellular Hypertrophy

In an 18-month mouse feeding study described by DPR (2008c) and JMPR (2008a), increase in absolute and relative liver weight, hepatocellular hypertrophy, and the presence of eosinophilic foci of cellular alteration were observed in the liver of males at the highest dose tested of 935 mg/kg-d. While the eosinophilic appearance of hepatocytes is associated with exposure to hepatic enzyme inducers and is itself not considered to be adverse (Hall et al., 2012a), altered hepatic foci may be associated with the subsequent development of toxicity such as necrosis or

neoplasms. Specifically, USEPA (2008f) asserts that eosinophilic foci are preneoplastic lesions. In rodents, for example, the development of altered hepatic foci and subsequent appearance of adenomas and carcinomas is well reported (Hall et al., 2012a). It should be noted, however, that treatment-related tumor development was not reported in either the 18-month mouse feeding study or the 2-year rat feeding study following exposure to chlorantraniliprole (USEPA, 2008f).

Although it has been suggested that this response in rodents may have little relevance in the context of estimating the risk of human hepatocarcinogenesis (Hall et al., 2012a; JMPR, 2008a), USEPA (2008f) notes that eosinophilic foci are not considered adaptive since they are neither reversible nor commonly associated with a normal liver response to high dose xenobiotics. Therefore, the development of eosinophilic foci accompanied by increased liver weight and hepatocellular hypertrophy as reported in the chronic mouse study was considered to be an adverse endpoint in the current assessment.

The adversity of the combination of increased liver weight, hepatocellular hypertrophy, and increased eosinophilic foci assumed in the current assessment is consistent with assessments performed by DPR (2008c), OEHHA (2020b), USEPA (2008h; 2010h), USDA (2019a), JMPR (2008a), and EFSA (2013).

4.3.1.4 Reduced Bodyweight Gain

Several studies investigating subchronic and chronic toxicity of chlorantraniliprole reported reduced bodyweight gain and food efficiency in rats and mice (DPR, 2008c; USEPA, 2008h). In a 28-day mouse feeding study, for example, reduced bodyweight gain and food efficiency was observed in males at the highest dose tested. This effect, however, was not considered adverse in the current assessment based on USEPA's (2008h) indication that there was no reduction in absolute bodyweight. In addition, reduced bodyweight gain and food efficiency was reported during the first week of a 90-day mouse feeding study and during the first 13 weeks of an 18-month mouse feeding study; however, this effect was not apparent at the end of the studies. Reduced bodyweight gain and food efficiency in males was also reported in a 28-day rat dermal study. Although recovery was not observed in this study, this effect was considered non-adverse in the current assessment due to its mild and transient nature as indicated in other studies. Furthermore, chlorantraniliprole is not known to be associated with any adverse developmental or neurotoxic effects (USEPA, 2008f).

For the purposes of this HHRA, reduction in bodyweight gain was similarly considered to be a non-adverse effect by DPR (2008c), USEPA (2008f; 2010h), USDA (2019a), JMPR (2008a), and EFSA (2013).

The critical NOAELs selected for risk characterization of chlorantraniliprole are presented in **Table 5**. Additional notes about selected endpoints may be found in the *Chemical Details (Human Endpoints)* section of the Dashboard Database 4.0.

Table 5: NOAELs Selected for Risk Characterization of Chlorantraniliprole

Exposure Duration	Exposure Route	NOAEL (mg/kg-d)	Adverse Effect	Source
Acute	Oral	NOC	None	OEHHA, 2020b
	Dermal	NOC	None	OEHHA, 2020b
	Inhalation	NOC	None	OEHHA, 2020b
Subchronic	Oral	1,443	None	DPR, 2008c
	Dermal	1000	None	DPR, 2008c
	Inhalation	1,443	None	DPR, 2008c
Chronic	Oral	158	Eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight in male mice	DPR, 2008c
	Dermal	158	Adapted from chronic oral endpoint, applying dermal absorption factor at exposure assessment	DPR, 2008c
	Inhalation	158	Adapted from chronic oral endpoint	DPR, 2008c

4.3.2 Polybutene

Acute toxicity to polybutene is reported to be low for the oral, dermal, and inhalation route, with an LD50 > 25.9 g/kg and >7.68 g/kg through the oral and dermal route, respectively, and an LC50 > 17.3 mg/L (CIR, 1982a). One subacute inhalation study reported lethality in male Wistar rats exposed to polybutene aerosols 7 hours/day, 5 days/week for two weeks at a concentration of 700 mg/m^3; this study was not considered appropriate for this HHRA because: (1) the granular formulation and chemical viscosity are not anticipated to result in prolonged aerosol exposure; (2) no intermediate doses were evaluated, preventing a dose-response relationship from being established; (3) not all animals received full doses or were replaced during the study; and (4) effects were expected to be local based on viscosity of chemical coating alveoli/clogging airways and expected to be more pronounced in rats due to their smaller airways (Skyberg et al., 1990a; USEPA, 2012q). The USEPA (2012q) was in agreement that this study was not appropriate for use in evaluating polybutene in pesticide formulations.

Several longer-term studies investigating polybutene suggest its overall oral toxicity is low. One 90-day dietary study in rats reported no adverse effects in male or female rats, including body weight changes, hematological and limited clinical chemistry parameters, organ weights and histopathology, at doses up to 2,500 mg/kg-d (CIR, 1982a; USEPA, 2012q). Two chronic dietary

studies were located, investigating oral exposure to polybutene up to 20,000 ppm polybutene. In the first, 240 albino rats (30 sex/treatment group) were fed 0, 800, 4,000, and 20,000 ppm polybutene and sacrificed one year into the study; no gross or microscopic pathological changes were reported. Throughout the entirety of the test, no body weight, mortality, reactions, tumors, or hematologic, urologic, nor pathologic changes were discovered (CIR, 1982a). In the second, deaths were reported in 6/30 rats at the highest dose tested during weeks 17-24 in males only. It is unclear, however, if this effect were treatment-related and it was subsequently dismissed by the USEPA (2012q). Lastly, a two-year chronic oral study in beagles up to 1,000 mg/kg-d of H-100 (75% polybutene concentrate) reported no abnormalities in body weight, food consumption, survival, behavioral patterns, hematology, blood chemistry, urinalysis, liver function, gross and histopathological examinations, or organ weights/ratio (CIR, 1982a). However, this study was also deemed unacceptable by the USEPA because the integrity of the data could not be validated (USEPA, 2012q).

No dermal and inhalation subchronic and chronic NOAELs for polybutene were located.

Despite limited subchronic and/or chronic studies, oral and dermal toxicity is thought to be minimal, and as such, it is exempt from residue tolerance as an inert in pesticide formulations pursuant to 40 CFR 180.960 (2011) and for residues in or on raw agricultural commodity cotton to disrupt pink bollworm mating or when used as a sticker agent in or on commodity artichoke to disrupt mating of the artichoke plume moth (40 CFR 180.1037, 2009). Its use in lipsticks and sunscreens supports its minimally anticipated toxicity through the oral and dermal route. Further in support of polybutene's minimal toxicity, no incident reports were returned from a query of the DPR California Pesticide Illness Query (CalPIQ) between 1992-2017 for agricultural use of polybutene as the only contributing chemical (DPR, 2020b). Additionally, USEPA (2012q) concluded dermal toxicity from exposure to polybutene is not anticipated based on the general low oral toxicity and its anticipated low dermal absorption due to an average molecular weight of >300. Polybutene is also on the USEPA Safer Chemical List, a list of chemical ingredients evaluated and determined to be safer than traditional chemical ingredients to assist manufacturers in finder safer chemical alternatives (USEPA, 2021a, b).

The critical NOAELs selected for risk characterization of polybutene are presented in **Table 6**. Additional notes about endpoint selection may be found in the *Chemical Details (Human Endpoints)* section of the Dashboard Database 4.0.

Table 6: NOAELs Selected for Risk Characterization of Polybutene

Acute	Oral	NOC	None	CIR, 1982a; USEPA, 2012q
	Dermal	NOC	None	CIR, 1982a; USEPA, 2012q
	Inhalation	NOC	None	CIR, 1982a; USEPA, 2012q
Subchronic	Oral	NOC	None	CIR, 1982a; USEPA, 2012q
	Dermal	NOC	None	CIR, 1982a; USEPA, 2012q
	Inhalation	No Data Available		
Chronic	Oral	NOC	None	USEPA, 2012q
	Dermal	NOC	None	USEPA, 2012q
	Inhalation	No Data Available		

4.3.3 Dolomite

Little toxicity information is available for mineral dolomite, with only one development study reporting no adverse effects in Wistar rats from oral administration of 1,500 mg/kg-d of dolomite during organogenesis (Lagarto et al., 2008). Dolomite is categorized as Generally Recognized as Safe (GRAS) for use as a substitute for calcium and magnesium salts to enhance the mineral content of purified bottle water beverages and is exempt for pesticides of a character not requiring FIFRA regulation (FDA, 2019a; 40 CFR § 152.25, 2015). Because no NOAELs were found for dolomite, all endpoints were listed as having No Data Available.

4.3.4 Bacillus thuringiensis, subsp. galleriae (BtG)

Acute toxicity studies described by USEPA (2013l) and Health Canada (2018a) indicate that BtG is practically non-toxic through the oral, dermal, and inhalation routes. In a 21-day acute oral (gavage) study of 9-week-old rats exposed to a single dose of Phyllom SDS-502 Technical (containing BtG at $1.13x10^{10}$ CFU/g) in phosphate buffered saline at $2.2x10^{8}$ CFU/animal, no treatment-related deaths, clinical signs, necropsy findings, or changes in body weight or body weight gain were reported (Health Canada, 2018a). Similarly, no adverse effects were reported in a 14-day acute inhalation (nose only) study of 5-week-old rats exposed to Phyllom SDS-502 Technical (containing BtG at 6.17×10^{10} CFU/g) for 4 hours at 4.3 mg/L (Health Canada, 2018a).

Very slight erythema was observed on some rabbits on Day 1 or 4 following exposure of 14-week-old New Zealand White albino rabbits to 2,020 mg/kg grubGONE!® G (containing BtG at $1x10^9$ CFU/g) for 24 hours (Maximum Irritation Score 1.9/8); however, all signs of irritation had resolved by Day 7 (Health Canada, 2018a). Due to the mild and transient nature of this effect, it was not selected as a critical endpoint for risk characterization of BtG.

Although minimal data on the subchronic and chronic toxicity of BtG is available, prolonged exposure to BtG is not expected to result in the development of adverse effects due to the lack of acute toxicity through all exposure routes. USEPA (2013l) and Health Canada (2018a) were in agreement with this judgement and waived the requirement for subchronic toxicity, reproductive toxicity, carcinogenicity, immunotoxicity, and infectivity/pathogenicity study submittal for the registration of products containing BtG.

The critical NOAELs selected for risk characterization of BtG are presented in **Table 7**. Additional notes about endpoint selection may be found in the *Chemical Details (Human Endpoints)* section of the Dashboard Database 4.0.

Table 7: NOAELs Selected for Risk Characterization of BtG

Exposure Duration	Exposure Route	NOAEL (mg/kg-d)	Adverse Effect	Source
Acute	Oral	NOC	None	Health Canada, 2018a
	Dermal	NOC	None	Health Canada, 2018a
	Inhalation	NOC	None	Health Canada, 2018a
Subchronic	Oral	NOC	None	Health Canada, 2018a; USEPA, 2013l
	Dermal	NOC	None	Health Canada, 2018a; USEPA, 2013l
	Inhalation	NOC	None	Health Canada, 2018a; USEPA, 2013l
Chronic	Oral	NOC	None	Health Canada, 2018a; USEPA, 2013l
	Dermal	NOC	None	Health Canada, 2018a; USEPA, 2013l
	Inhalation	NOC	None	Health Canada, 2018a; USEPA, 2013l

5 Exposure Assessment

The third step in the HHRA is to estimate how much pesticide or adjuvant exposure an individual (herein referred to as a "receptor") would receive (OEHHA, 2001a). Exposure is commonly defined as contact of visible external physical boundaries (i.e., external boundaries such as the mouth, nostrils, and skin) with a chemical. In an exposure assessment, factors related to human behavior and characteristics that affect their exposure are often utilized for both qualitative and quantitative purposes. These parameters that influence the extent to which a receptor is exposed to a chemical are referred to as exposure factors (USEPA, 2011p). Exposure is dependent upon the intensity, frequency, and duration of contact. The intensity of contact is typically expressed in terms of the concentration of chemical per unit mass or volume (i.e., µg/g, µg/L, mg/m^3, ppm, etc.) in the media (i.e., soil, air, water, etc.) to which the receptor is exposed. Dose refers to the amount of chemical to which receptors are exposed that crosses the external boundary. Dose is dependent upon chemical concentration and the rate of intake (i.e., inhalation or ingestion) or uptake (e.g., dermal absorption) and may be normalized to receptor body weight as a function of time (i.e., mg/kg-day). The receptor average daily dose (ADD) rate is estimated in the generalized equation shown below:

$$ADD = \frac{C * CR * ED * EF * DAF}{BW * AT}$$

Where:

ADD = average daily dose (mg/kg-day);
C = chemical concentration (mg/L, mg/m^3; mg/cm^2, mg-medium/day);
CR = contact rate (L/day; m^3/day; cm^2/day, mg/day);
ED = exposure duration (years);
EF = frequency of exposure events (days/year);
DAF = dermal absorption factor (unitless)
*only applied for dermal exposure when endpoint was derived from an oral or inhalation study
BW = body weight (kg); and
AT = averaging time (days).

The chemical concentration (C), also expressed as an estimated environmental concentration (EEC), refers to the amount of pesticide residue in the media of interest, and contact rate (CR) refers to the rate of ingestion, inhalation, or dermal deposition per day. Exposure duration (ED) refers to the length of time that contact occurs and is affected by activity patterns. Exposure frequency (EF) is the number of exposure events over a specified time period. Absorbed doses may be estimated by applying an absorption factor. Body weight (BW) and averaging time (AT) are specific to the receptor and exposure scenarios being evaluated. For the average daily dose (ADD), a single-day exposure to a receptor was calculated using an acute exposure duration and averaging time of 1 day. The averaging time represents the number of days over which the exposure is averaged. For subchronic exposure, the subchronic average daily dose (SADD) was calculated using an averaging time of 30 days, which is consistent with the exposure duration. For chronic exposure, the annual average daily dose (AADD) is calculated using an averaging time which is receptor-specific and consistent with methods used in the Statewide PEIR, unless otherwise specified.

The exposure assessment portion of the HHRA was divided into two parts. The first part was to estimate the concentration of pesticides in the environment through fate and transport processes. This included estimating the concentration of pesticide residues that may be found in the air, water, soil, and contained in/on the plant. This methodology takes into account the total amount of pesticide applied, along with chemical-specific mechanisms of dispersal or degradation that may occur during or shortly after application. The next part in determining human exposure (i.e., ADD, SADD, and AADD) was to estimate how much of the EEC would be absorbed by the receptor. The three main uptake pathways addressed in the HHRA were inhalation, ingestion, and dermal absorption. Receptor exposure and EECs are each discussed in further detail below.

5.1 Conceptual Site Model

A conceptual site model (CSM) is a written and graphical presentation of predicted exposure pathways (i.e., inhalation, dermal contact, or ingestion) between the pesticide application and receptor. It includes a description of the complete exposure pathways and outlines the primary release mediums, impacted media, and potential routes of exposure for each receptor. A complete exposure pathway exists when pesticide or adjuvant can be traced (i.e., is expected to travel) from the point of application to plants, soil, or air and eventually to a receptor. An exposure pathway that is not complete means that it is unlikely for that receptor to be exposed to a pesticide or adjuvant through that exposure pathway. The CSM identifies multiple pathways through which receptors can be exposed to pesticides as part of the Proposed Program.

Receptors that were considered to have the potential for exposure included the Mixer, Loader, and/or Applicator (MLA), Downwind Bystander (DWB), Post-Application Resident (PAR), and the During and Post-Application Resident (DPAR). The MLA is a worker who is occupationally exposed to pesticides and, where relevant, adjuvants while preparing pesticide solutions and applying them. The DWB is any human receptor 25 feet away from an application in a residential or nursey setting who may be exposed to off-site drift. The PAR is an individual living in an urban/residential area who has the potential to come into contact with active or inert residues following residential treatments. The DPAR is a person present 25 feet downwind of a residential application and also has the potential to be exposed to pesticide or adjuvant residues after the treatment (i.e., a combination of the DWB and PAR). The receptors considered will be discussed in greater detail in Section 1.11.

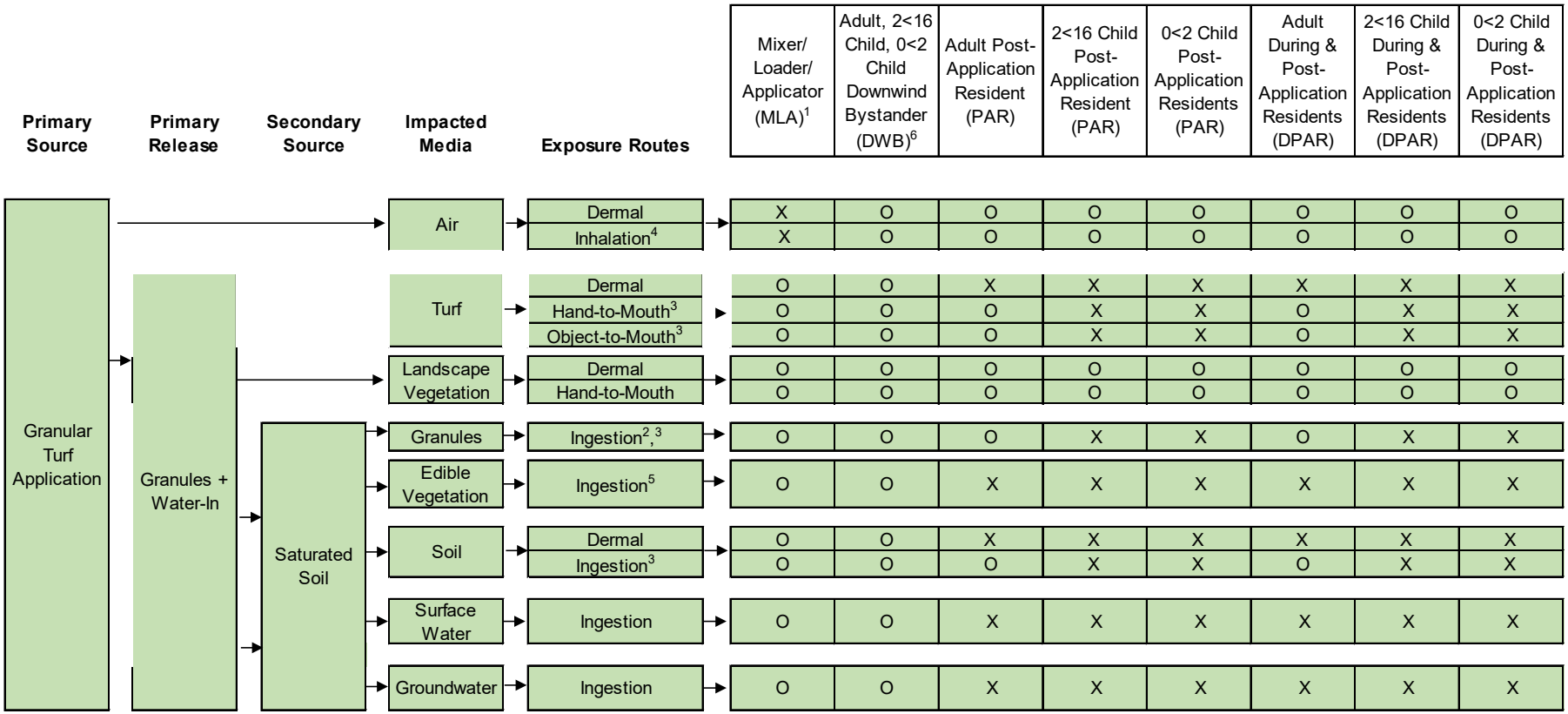
The starting point of the CSM is the application technique which considers the release of pesticide and/or adjuvant ingredients into the environment. The next exposure step following an application depends on the environmental media that the applied material reaches after application. Pesticide and/or adjuvant residues may be present on or in the soil, air, water, turf, and vegetation, and receptors present at the time of the application. Turf or other plants present within the treated area may be exposed to pesticide via direct application, overspray, and uptake from the soil.

Following an application, the potential for off-site movement via aerial drift (hereinafter referred to as “drift”), runoff, and leaching such that pesticide residues may be present in surface water, groundwater, and/or adjacent untreated areas are considered.

Once a pesticide is present in an environmental media, three routes of exposure exist for a receptor to become exposed: ingestion, dermal, and inhalation.

The CSMs for applications in residential settings in the Proposed Program are presented in **Figure 1** and **Figure 2.**

Figure 1: Japanese Beetle Residential CSM for Granule (Acelepryn G) Application



Exposure Routes	Mixer/ Loader/ Applicator (MLA)[1]	Adult, 2<16 Child, 0<2 Child Downwind Bystander (DWB)[6]	Adult Post-Application Resident (PAR)	2<16 Child Post-Application Resident (PAR)	0<2 Child Post-Application Residents (PAR)	Adult During & Post-Application Residents (DPAR)	2<16 Child During & Post-Application Residents (DPAR)	0<2 Child During & Post-Application Residents (DPAR)
Air – Dermal	X	O	O	O	O	O	O	O
Air – Inhalation[4]	X	O	O	O	O	O	O	O
Turf – Dermal	O	O	X	X	X	X	X	X
Turf – Hand-to-Mouth[3]	O	O	O	X	X	O	X	X
Turf – Object-to-Mouth[3]	O	O	O	X	X	O	X	X
Landscape Vegetation – Dermal	O	O	O	O	O	O	O	O
Landscape Vegetation – Hand-to-Mouth	O	O	O	O	O	O	O	O
Granules – Ingestion[2,3]	O	O	O	X	X	O	X	X
Edible Vegetation – Ingestion[5]	O	O	X	X	X	X	X	X
Soil – Dermal	O	O	X	X	X	X	X	X
Soil – Ingestion[3]	O	O	O	X	X	O	X	X
Surface Water – Ingestion	O	O	X	X	X	X	X	X
Groundwater – Ingestion	O	O	X	X	X	X	X	X

General Notes:

CSM is for PD/EP-Eradication applications to turf that takes place in residential environments, as defined in the report.

X - Complete Exposure Pathway

O - Incomplete, Inconsequential, or De Minimis Exposure Pathway

[1] Worker exposure scenarios assume that all appropriate personal protective equipment (PPE) is worn according to the product label.

[2] Granule ingestion is assumed to be episodic and only evaluated for the acute duration.

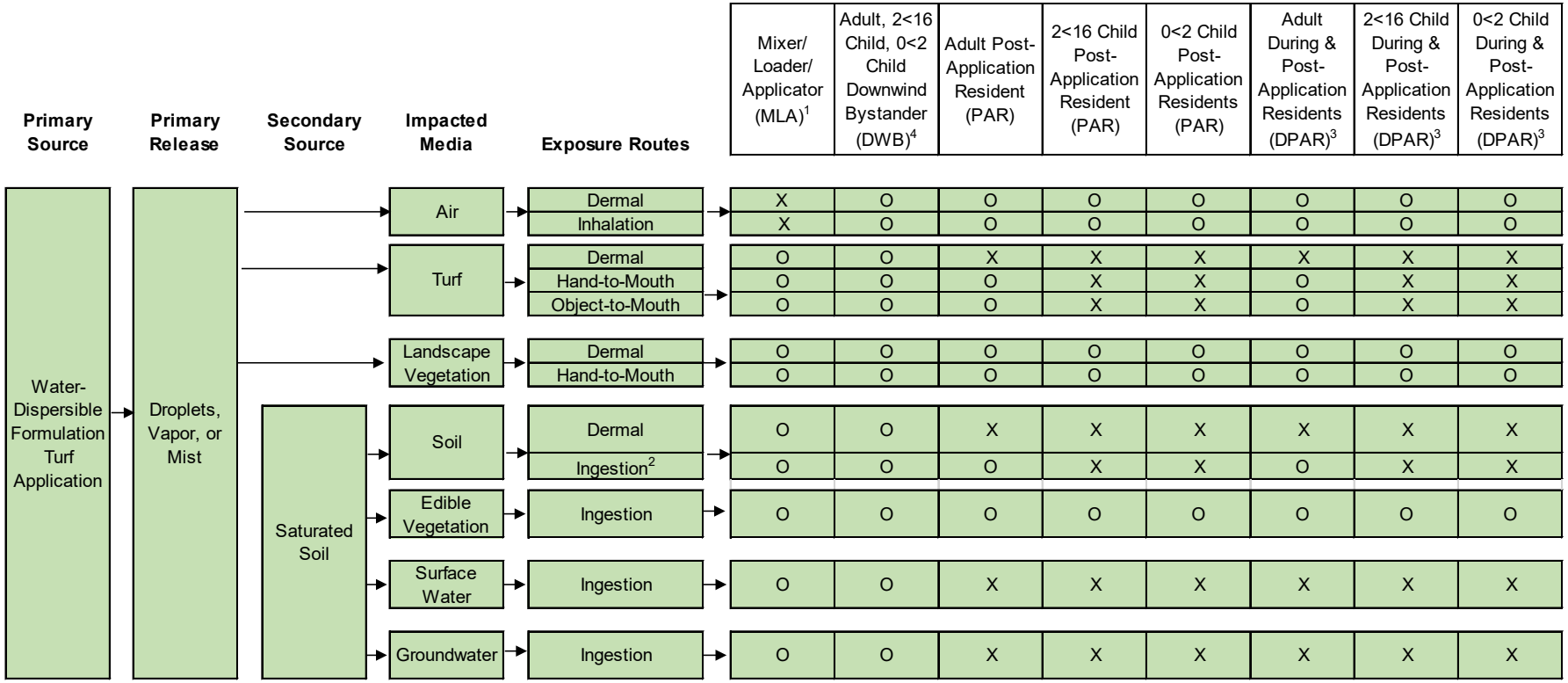
[3] Unintentional ingestion of pesticide from hand-to-mouth and object-to-mouth activities and soil and granule ingestion by the child resident is considered health protective of the adult.

[4] Post-application residents are not anticipated to have inhalation exposure due to product formulation and low vapor pressure of ingredients

[5] Exposure from the consumption of treated fruit was estimated through uptake of soil, despite BMPs in place that avoid contact of pesticide residues with human edibles.

[6] Exposure to the downwind bystander is considered de minimis due to the proximity of application to the ground and the physical properties of solid granules.

Figure 2: Japanese Beetle Residential CSM for Water Dispersible Formulation (beetleGONE! tlc) Application



General Notes:

CSM is for PD/EP-Eradication applications to turf that takes place in residential environments, as defined in the report.

X - Complete Exposure Pathway

O - Incomplete, Inconsequential, or De Minimis Exposure Pathway

1. Worker exposure scenarios assume that all appropriate personal protective equipment (PPE) is worn according to the product label.

2. Unintentional ingestion of pesticide from hand-to-mouth and object-to-mouth activities and soil and granule ingestion by the child resident is considered health protective of the adult.

3. Application through ground-directed, handheld sprayers is assumed to result in de minimis drift. However, exposure from off-target drift from boom sprayer applications was estimated for the DWB and DPAR.

5.2 Physical, Chemical, and Environmental Fate Properties

Data on physical, chemical, and environmental fate (PCF) properties were reviewed from the sources below. Any sources utilized during previous Statewide PEIR analyses were also considered:

- USEPA Reregistration Eligibility Decision (RED) documents (USEPA, 2020b)
- DPR Risk Characterization Documents (RCD) (DPR, 2020a)
- ATSDR Toxicological Profiles (ATSDR, 2020a)
- National Center for Biotechnology Information (NCBI) PubChem Database (PubChem, 2020a)
- United Nations Environmental Programme (UNEP) Screening Information Dataset System (SIDS) Initial Assessment Profiles (UNEP, 2017a)

When multiple suitable values were available, final PCF values utilized in the risk analysis were calculated consistent with the methods described in the Statewide PEIR. The PCF data selected and estimated final values selected for risk assessment are available in the *Chemical Details* section of the Dashboard Database 4.0. If PCF data were not available for a given chemical, a suitable surrogate was selected, when possible, based on its similarity in chemical structure and physical properties.

5.2.1 Chlorantraniliprole

Chlorantraniliprole is persistent in soil and relatively persistent in water via aerobic metabolism. It is stable to hydrolysis but breaks down rapidly through aqueous photolysis. Chlorantraniliprole is non-volatile and has a reported foliar half-life of 1.5 to 30 days (USEPA, 2008f).

For specific PCF values used in exposure assessment, see the Dashboard Database 4.0.

5.2.2 Polybutene

Based on its structure, polybutene is generally characterized as immobile in soil and insoluble in water due to its high estimated lipophilicity (log Kow = 17.14 (USEPA, 2012r; 2017h; USEPA, 2013k)). It is resistant to breakdown through aqueous photolysis and hydrolysis, probably in part due to its propensity to stay afloat rather than dissolve in water (USEPA, 2013k). Polybutene is resistant to microbial breakdown and has negligible volatility (USEPA, 2013k).

For specific PCF values used in exposure assessment, see the Dashboard Database 4.0.

5.2.3 Dolomite

No environmental fate information was located for mineral dolomite. Personal observation suggests dolomite has negligible vapor pressure and water solubility, and is likely resistant to most environmental breakdown processes. Due to the lack of available PCF for dolomite, a quantitative exposure assessment could not be completed for this chemical.

5.2.4 Bacillus thuringiensis, subsp. *galleriae*

Limited environmental fate data is available for microbial BtG. After application of a Bt species, vegetative cells and spores may persist at gradually decreasing concentrations for weeks to years as a component of natural microflora, while crystal proteins may be rendered biologically inactive within hours or days (WHO, 1999b). Under normal sunlit conditions, Bt degrades within 48 hours with a half-life of 3.8 hours (USEPA, 2013l).

Because of Bt is commonly found in soil and on plants, exposure to BtG residues on edible vegetation are expected to be negligible compared to likely background exposure levels (USEPA, 2013l). USEPA (2013l) notes that non-occupational dermal and inhalation exposures to BtG are almost certainly already occurring and that Bt is often detected in drinking water even after going through acceptable water treatment processes.

Application of beetleGONE! tlc is expected to temporarily increase natural populations of Bt in terrestrial and aquatic environments; however, BtG levels are expected to return to naturally sustainable levels (Health Canada, 2018a). Because Bt species are capable of self-sustaining, the use or estimation of PCF values for BtG was deemed inappropriate for modeling and estimating EECs. Therefore, a qualitative risk assessment was performed in lieu of a quantitative assessment.

5.3 Estimating Pesticide Environmental Concentrations

The EEC is defined as the predicted concentration of pesticide within an environmental compartment (i.e., soil, water, plant tissue, or a specific organism) based on estimates of quantities applied, application methods, chemical-specific fate and transport properties, and the nature and characteristics of the application and surrounding area.

Because no empirical data were available for the scenarios analyzed in this HHRA, EECs were estimated for relevant chemicals (i.e., chlorantraniliprole and polybutene) using various 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 of the complex fate and transport processes that can occur once a pesticide and/or adjuvant is released into the environment. Typical fate properties that tend to decrease the concentration of pesticide chemicals include aerobic degradation, anaerobic degradation, photodegradation, 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 represent an upper-bound, conservatively high value since not all fate and transport properties have been modeled.

Procedures for estimating EECs for the Proposed Program are often consistent with those used in the Statewide PEIR (CDFA, 2014a). The assumptions that differ between the Proposed Program and the Statewide PEIR are presented below.

See Section 1.3 for specific details about the Program scenarios assessed. Estimated environmental concentrations are presented in the *Pest Programs* and *Risk Results* sections of Dashboard Database 4.0.

5.3.1 Occupational Exposure Values

For occupation exposure assessments (e.g., MLA), unit exposures (UEs) from USEPA's (2020a) OPHED were selected in accordance with methods described in USEPA's (2007k) *Review of Worker Exposure Assessment Methods*. Selection of unit exposures was generally completed in a similar manner as presented in the Statewide PEIR (CDFA, 2014a). Refer to Section 4.2.1.6.1 Mixer-Loader-Applicator of the Statewide PEIR (CDFA, 2014a) for additional details.

Occupational unit exposures selected are presented in the *Pest Programs* and *Risk Results* sections of the Dashboard Database 4.0.

5.3.2 Pesticide Off-target Drift

Off-target drift of pesticide residues was estimated in a similar manner as presented in the Statewide PEIR (CDFA, 2014a). Methods for assessing ground applications in AgDRIFT (USEPA, 2017d) were followed, and in accordance with USEPA's (1999f) *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment*, a "Flagger" UE from USEPA's (2020a) *Occupational Pesticide Handler Exposure Database* (OPHED) was used to assess exposure to off-target drift to the DWB. Refer to Section 4.2.1.4.3 Pesticide Off-target Drift and Section 4.2.1.6.5 Downwind-Bystander of the Statewide PEIR (CDFA, 2014a) for additional details.

Flagger unit exposures and AgDRIFT estimated percent deposition are presented in the *Pest Programs* or *Risk Results* section of the Dashboard Database 4.0.

5.3.3 Soil

Concentrations in soil below garden plants or in bare spots of lawns were used to estimate exposure from dermal contact and ingestion of soil and edible vegetation. The soil was assumed to receive 100% of the applied Acelepryn G despite any residue retention that may occur on turf surface.

Soil concentrations for acute exposure in residential settings are represented by the peak residue concentrations immediately following an application. Soil concentrations for subchronic exposure represent the maximum 30-day daily average concentration that could occur over one year. Soil concentrations for chronic exposure represent the daily concentration averaged over a 365-day period. Despite signage posted at the treatment area instructing residents not to enter until the spray has dried, environmental concentrations were modeled assuming no Restricted Entry Interval (REI).

5.3.4 Granules

Concentrations of active and inert ingredients in granules were used to estimate exposure from non-dietary ingestion of Acelepryn G applied to lawns. The amount of chemical available for

ingestion of post-application granules was expressed as a fraction of the pesticide or inert in the dry formulation (unitless).

Because consumption of vestigial granules is considered episodic (i.e., would not occur as routine behavior), only acute exposure was assessed. It was assumed the proportions of pesticide and inert chemical in the dry product did not change with any environmental exposure following application and contact with a receptor. Additionally, homogenous dissolution was assumed following in the water-in process.

5.3.5 Edible Vegetation Residue

Uptake by plants from soil in residential settings was estimated in a similar manner to that used in the ERA of the Statewide PEIR (CDFA, 2014a) with the exception that a revised Briggs equation was used based on the updated version in USEPA's (2014a) *Guidance for Assessing Pesticide Risk to Bees*. Complete details regarding how the Briggs equation is used appear in the Statewide PEIR (CDFA, 2014a).

First, the octanol/water partition coefficient- (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:

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

Where:

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

Consistent with guidance provided by USEPA (2014a), if the Log K_{ow} was greater than 5.0, no uptake was assumed. When the Log K_{ow} was negative, the TSCF was assumed to be 1.0 (Collins *et al*., 2006).

Because polybutene has an estimated log K_{ow} of 17.14 (USEPA, 2010u, 2012r, 2013k, 2017h) it is not expected to migrate into plants.

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:

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

Where:

VUF = Vegetation uptake factor
K_{ow} = Octanol/Water Partition Coefficient (unitless)
ρ = soil bulk density (g/cm^3)
θ = soil-water content by volume (cm^3/cm^3)
K_{oc} = soil organic carbon-water partitioning coefficient (cm^3/g-organic carbon or L/kg-organic carbon)
f_{oc} = fraction of organic carbon in the soil

The values of ρ, θ, and f_{oc} were obtained from USEPA (2006y) data associated with its Pesticide Root Zone Model (PRZM) inputs for Tierra loam soil. Please see Section 4.4.2 of the ERA for more details. The total concentration of residues in plant tissue was estimated by multiplying the Terrestrial VUF, where applicable, and the concentration of pesticide available in the soil, as shown in the equation below.

$$EEC_{Briggs} = VUF * Soil\ Concentration$$

The exposure factors used in estimating chlorantraniliprole and polybutene concentrations in edible vegetation are summarized in **Table 8**.

Table 8: Exposure Factors Used in Estimating Edible Vegetation Residues

Chemical	Log K_{ow}	ρ (g/cm3)	θ (cm^3/cm^3)	K_{oc} (cm3/g)	f_{oc}	Soil EEC (mg/kg)
Chlorantraniliprole	2.86	1.5	0.309	335.43	0.0174	See the Dashboard Database 4.0
Polybutene	17.1	1.5	0.309	2.50E+09	0.0174	

Due to the proximity of applications to the ground, turf drench applications are not assumed to result in surface residues to human edibles. In this risk assessment, it is assumed that consumption of edible vegetation will occur without external precautionary measures such as buffers and shielding. However, due to chlorantraniliprole's persistence in soil, pesticide uptake into fruit and vegetables was estimated based on the possibility that a human edible plant could be planted in the same plot in the future.

For estimating residue concentrations for acute exposures, the internal plant EEC is represented by peak concentration.

For subchronic exposures, ingestion of treated edible vegetation was assumed to occur every day over 30 days. The subchronic EEC is represented by the maximum 30-day average concentration in foliage that could occur over a 365-day period.

For chronic exposures, ingestion of treated edible vegetation was assumed to occur every day for 365 days, so the estimated EEC in plants was averaged over a 365-day period. The chronic EEC

value represents the 365-day average concentration in edible plants assessed over the course of a year.

Edible vegetation residue concentration results are presented in the *Pest Programs* and *Risk Results* sections of the Dashboard Database 4.0.

5.3.6 Transferable Turf Residue

In turf drench application scenarios, 100% of the pesticide applied to turf was assumed to deposit onto turf surface (DtT), conservatively ignoring any subsequent watering-in. Chlorantraniliprole and polybutene EECs on turf surfaces were used to estimate exposure from dermal contact with turf and incidental hand-to-mouth ingestion of pesticide residues.

Post-application chloratraniliprole and polybutene on turf surfaces that are available for dermal transfer to a receptor's skin and hand-to-mouth ingestion are referred to as transferable turf residues (TTRs). The method for estimating the TTR_t was selected from USEPA's (2012l) SOP. The following equation was used to estimate the TTR_t:

$$TTR_t = AR * F_{AR} * (1 - F_D)^t * CF_1 * CF_2 * DtT$$

Where:

TTR_t = Transferable turf residue (t) days after application (µg/cm^2)
AR = Application rate (lb a.i./acre)
F_{AR} = Fraction of transferable a.i.
F_D = Fraction of residue that dissipates per day
t = Time after application (days)
CF_1 = Weight conversion factor (µg/lb)
CF_2 = Area unit conversion factor (acre/cm^2)
DtT = Deposition to Turf (%)

The F_{AR} was left unchanged from the default USEPA (2012l) SOP value of 0.002 for granules, and the F_D was modified to reflect the rate at which chlorantraniliprole or polybutene dissipates per day. The F_D was calculated by determining the percent of chlorantraniliprole or polybutene remaining 1 day after application, using a foliar half-life of 16.136 days for chlorantraniliprole and stable for polybutene, and the equation for first-order rate kinetics (Juraske et al., 2008; USEPA, 2012l, 2014e). Using this method, the residue concentration remaining after 1 day for chlorantraniliprole was estimated to be 95.8%; therefore, the percent of chlorantraniliprole residue that dissipated per day is 4.2%. The equation of first-order rate kinetics is given below:

$$C_t = C_0 e^{-kt}$$

Where:

C_t = Concentration on Day t following the application
C_0 = Concentration on Day 0 (immediately following application)
e = 2.718
k = 0.693/half life
t = time (days)

For polybutene, the literature reports that it is resistant to breakdown through most pathways (e.g., microbial degradation, aqueous photolysis, and hydrolysis). In the absence of chemical-specific information, it was conservatively assumed polybutene stable to foliar degradation. A summary of the exposure factors used in estimating TTR_t is given in **Table 9**.

Table 9: Exposure Factors Used in Estimating TTR_t

Chemical	F_{AR}	F_D	t (days)	DtT (unitless)	Foliar Half Life (days)
Chlorantraniliprole	0.002	4.2%	0-365	1	16.136
Polybutene		0.0%			Stable

For estimating chlorantraniliprole and polybutene concentrations for acute exposures, dermal contact with turf was assumed to occur immediately after an application. The acute TTR_t value represents the peak concentration on turf over the course of a year.

For estimating chlorantraniliprole and polybutene concentrations in subchronic exposures, dermal contact was assumed to occur every day for 30 days. The subchronic TTR_t value represents the maximum 30-day average on turf over the course of a year.

For chronic exposures, dermal contact was assumed to occur every day for 365 days, so the estimated daily TTR_t was averaged over a 365-day period. The chronic TTR_t value represents the 365-day average concentration on turf assessed over the course of a year.

For all exposure durations, the TTR_t takes into account the possibility of chlorantraniliprole and polybutene accumulation when multiple applications are done under the Proposed Program.

TTR_t concentration results are presented in the *Pest Programs* and *Risk Results* section of the Dashboard Database 4.0.

5.3.7 Surface water

The concentration of pesticides in surface water was estimated using the Pesticides in Water Calculator (PWC) Version 2 for the active and inert ingredients utilized in the Proposed Program when sufficient PCF data was available. The PWC is a model designed by the USEPA (2020c) to estimate the concentration of pesticide ingredients in surface waters resulting from drift, runoff, and/or erosion during and after pesticide applications. Model details and run parameters were the same as those discussed and presented in the Ecological Risk Assessment except as noted below.

The Pesticide Root Zone Model version 5.0+ (PRZM) standard scenario used for surface water assessment is a 172.8-hectare (427-acre) watershed, releasing pesticide-containing runoff into a 5.26-hectare (13-acre) drinking water reservoir, 2.74 meters (9 feet) deep equaling 144,124 cubic meters. The water volume in the reservoir was assumed to remain constant and no outflow was modeled.

The PWC estimates multiple EECs, including the peak concentration and the 1-day, 4-day, 21-day, 60-day, 90-day, and 365-day average. Upper 90th ranked peak concentrations were used to assess acute and subchronic exposure to surface water potentially used as drinking water, while upper 90th ranked 90-day average concentrations were used to assess chronic exposure.

5.3.8 Groundwater

Groundwater simulations were conducted consistent with surface water simulations, described in Section 1.10.7 above and in the Ecological Risk Assessment, except as noted below.

Although previous analyses (CDFA, 2020a) relied on empirical groundwater monitoring data to draw conclusions on potential human health risks associated with groundwater contamination, scenario-specific groundwater EECs in the current assessment were estimated using PWC. The estimation of pesticide concentrations in groundwater was based on an aquifer with a recommended vertical thickness of 1 meter (3.3 feet) (D. F. Young, USEPA, personal communication, June 11, 2020).

As described in the ERA, primary PRZM Scenario Files were selected based on similarities between application location and setting and the environment modeled by the scenario file. For the current groundwater assessment, however, the depth to groundwater was adjusted to better reflect California conditions and soil profiles were conservatively assumed to be more porous than scenario file defaults. While the default depth to groundwater was 182 cm (<6 feet), the adjusted depth to groundwater was estimated for scenarios that may take place throughout the state. CDFA's (2020c) Japanese Beetle webpage was used to identify California counties in which Japanese Beetle has been detected from 2016 to 2019. A total of ten (10) counties were identified: Alameda, Los Angeles, Monterey, Orange, Riverside, Sacramento, San Bernardino, San Diego, San Joaquin, and Santa Clara.

The California Department of Water Resources' (DWR's) California Statewide Groundwater Elevation Monitoring (CASGEM) database was used to characterize the depth to groundwater in the fifteen selected counties from 2015 to 2019 (DWR, 2020a). Drinkable groundwater was conservatively assumed to occur at a minimum depth of 0.01 feet. The depth to groundwater was estimated for each county by calculating the arithmetic mean of groundwater depth data obtained from each groundwater monitoring station, then calculating the geometric mean of the average monitoring station groundwater depths. A depth to groundwater of 65.8 feet was used in the current assessment by calculating the arithmetic mean of the county-specific groundwater depths.

Through collaboration with Dirk F. Young, senior scientist at the USEPA and developer of the PWC, soil profiles were modified to be more amenable to modified groundwater depths (D. F. Young, USEPA, personal communication, June 11, 2020). Soil parameters for Tifton loamy sand were obtained from the USEPA-developed Pesticide Root Zone Model for Groundwater (PRZM-GW) scenario GACOASTAL_STD. This scenario was one of six available groundwater scenarios and selected based on relative similarity of the associated soil profile to those associated with the PRZM Scenario Files used for surface water assessment. According to the *Georgia Southern Coastal Plain (Peanuts) Ground Water* description file provided by USEPA (2020e): "Tifton is a very deep, well drained soil on uplands. The subsoil is loamy and extends to a depth greater than 5 feet. Plinthite occurs below a depth of 30 to 50 inches and ironstone

nodules are present throughout the soil. Permeability is moderate in the upper part of the subsoil and moderately slow in the lower part. Available water capacity is moderate. This soil falls into the Hydrologic Group B." Note that soils in Hydrologic Group B, including Tifton loamy sand, typically contain 10-20% clay and 50-90% sand, while soils in Hydrologic Group D, including the Tierra loam soil used for surface water assessment, typically contain more than 40% clay and less than 50% sand (NRCS, 2009a). Because of their coarse texture and porous nature, sandier soils have greater infiltration capacity than finer, more compacted soils and may therefore render local groundwater aquifers more vulnerable to contamination.

The default simulation duration of PWC is 30 years. To increase the likelihood that peak groundwater concentrations would be observed during the simulation, the 100-year peak groundwater concentration was used assess acute, subchronic, and chronic exposure to groundwater potentially used as drinking water.

5.4 Estimating Human Receptor Exposure

The exposure assessment estimates the dose, or amount of pesticide/inert, that different receptors may be exposed to, under different application scenarios that would be a part of the Proposed Program. The exposure to pesticide or adjuvant ingredients varies for different receptors, depending on the activities of a particular receptor and proximity to the application site. The following four receptors were assessed in this HHRA:

- Mixer, Loader, and/or Applicator (MLA): Pesticide handlers
- Downwind Bystander (DWB): Bystanders 25 feet from the application site during application
- Post-Application Resident (PAR): Residents in contact with pesticide residues after an application
- During and Post-Application Residents (DPAR): Residents near the application site during application and in contact with residues after application (i.e., the DWB + PAR)

The potential health impacts, if any, to receptors can be estimated by comparing exposure doses with the measures of toxicity. Descriptions of the methodology used to characterize risk are described in Section 0.

5.4.1 Exposure Routes

Depending on the activities and location of a particular receptor, twelve exposure routes could potentially occur under application scenarios. The pathways considered in this HHRA are the following:

- Inhalation: Aerosols and vapors to pesticide applicators
- Dermal Exposure to Airborne Residues: Deposition onto skin to pesticide applicators
- Ingestion of Edible Vegetation Residues: Eating home-grown edible vegetation (e.g., fruit)
- Dermal Exposure to Residues on Turf: Contact to skin due to activities in treated areas

- Hand-to-Mouth Ingestion of Turf Residues: Unintentional ingestion of residue from activities on turf through hand-to-mouth transfer
- Object-to-Mouth Ingestion of Turf Residues: Unintentional ingestion of residue from activities on turf through object-to-mouth transfer
- Ingestion of Soil Residues: Deliberate and unintentional soil consumption
- Ingestion of Granules: Incidental consumption of pesticide pellets and granules
- Dermal Exposure to Residues in Soil: Skin contact due to working or playing in treated areas
- Ingestion of Surface Water: Consumption of residues potentially in surface water
- Ingestion of Groundwater: Consumption of residues potentially in groundwater

A description of the four receptors identified in Section 1.11 is provided below. These receptor groups represent the groups with reasonable potential for exposure during the Proposed Program.

5.4.1.1 Mixer-Loader-Applicator

The mixer-loader-applicator (MLA) represents the combination exposure of a worker who may be occupationally exposed to pesticide active and inert ingredients while mixing, loading, and/or applying pesticides. The MLA is assumed to be exposed through dermal and inhalation routes. Ingestion was not evaluated for this receptor because the MLA is properly trained to minimize any hand-to-mouth transfers.

For the application of granular products, some equipment does not require a mixing process (e.g., belly grinders). In these cases, while the worker may still potentially be referred to as an MLA, exposure is only anticipated through the loading and/or applying process.

5.4.1.2 Acute Exposure Assessment

Acute exposure for the MLA was evaluated in the same manner as in the Statewide PEIR (CDFA, 2014a). Refer to the Statewide PEIR Appendix B Section 2.3 for more details about exposure assessment methodology for the MLA. USEPA's (2020a) Occupational Pesticide Handler Exposure Database (OPHED) was most recently updated in March 2020, and unit exposure values were derived from the updated version.

The following equation was used to estimate the ADD:

$$ADD = \frac{AR * ATPD * UE * DAF}{BW * CF_1}$$

Where:

ADD = Average daily dose (mg/kg-day)
AR =Application rate (lb/ac)
ATPD = Acres treated per day (ac/day)
UE = Unit exposure (µg/lb)
DAF = Dermal absorption factor*
*Only applied for dermal exposure when acute endpoint was derived from an oral or inhalation NO(A)EL
BW = Body weight (kg)
CF_1 = Conversion factor (µg/mg)

A summary of the exposure factors used in estimating acute exposure to residues through dermal contact and inhalation to the MLA are given in **Table 10**.

Table 10: Exposure Factors Used in Estimating Acute Exposures to Residues to the MLA

Receptor	DAF	Body Weight[1] (kg)
MLA	See the Dashboard Database 4.0 for Chemical-Specific DAFs	80

1. USEPA, 2011p

Refer to the Dashboard Database 4.0, *Pest Programs* or *Risk Results* sections for the OPHED unit exposures used for estimating exposure to the MLA.

5.4.1.2.1 Subchronic Exposure Assessment

Subchronic exposure for the MLA was evaluated in a similar manner as the chronic in the Statewide PEIR (CDFA, 2014a), except the exposure frequency was limited to the number of applications that could occur over 30 days and a DAF was only applied in the dermal exposure assessment if the subchronic NOAEL was extrapolated from an oral or inhalation endpoint. Additionally, the averaging time reflected the intermediate period of 30 days instead of the chronic exposure duration. The USEPA's (2020a) OPHED was most recently updated in March 2020, and unit exposure values were derived from the updated version.

The following equation was used to estimate the SADD:

$$SADD = \frac{AR * ATPD * UE * DAF * EF * ED}{BW * AT * CF_1 * CF_2}$$

Where:

SADD = Subchronic average daily dose (mg/kg-day)
AR =Application rate (lb/ac)
ATPD = Acres treated per day (ac/day)
UE = Unit exposure (µg/lb)
DAF = Dermal absorption factor*
*Only applied for dermal exposure when subchronic endpoint was derived from an oral or inhalation study
EF = Exposure frequency (days/year)
ED = Exposure duration (days)
BW = Body weight (kg)
AT = Averaging time (days)
CF_1 = Conversion factor (µg/mg)
CF_2 = Conversion factor (days/years)

A summary of the exposure factors used in estimating subchronic exposure to residues through dermal contact and inhalation to the MLA are given in **Table 11**.

Table 11: Exposure Factors Used in Estimating Subchronic Exposures to Residues to the MLA

Receptor	DAF	Exposure Duration (days)	Averaging Time (days)	Body Weight[1] (kg)
MLA	See the Dashboard Database 4.0 Chemical-Specific DAFs	30	30	80

a. EFH (USEPA, 2011p)

Refer to the *Pest Programs* section of the Dashboard Database 4.0 for the OPHED unit exposures used for estimating exposure to the MLA.

5.4.1.2.2 Chronic Non-Cancer Exposure Assessment

Chronic exposure for the MLA was evaluated in the same manner as in the Statewide PEIR (CDFA, 2014a), except unit exposure values were selected from an updated version of the USEPA's (2020a) OPHED. Refer to the Statewide PEIR Appendix B Section 2.3 for exposure assessment methodology.

The following equation was used to estimate the AADD:

$$AADD = \frac{AR * ATPD * UE * DAF * ED * EF}{BW * AT * CF_1 * CF_2}$$

Where:

AADD = Annual average daily dose (mg/kg-day)
AR =Application rate (lb/ac)
ATPD = Acres treated per day (ac/day)
UE = Unit exposure (µg/lb)
DAF = Dermal absorption factor*
*Only applied for dermal exposure when chronic endpoint was derived from an oral or inhalation study
ED = Exposure duration (years)
EF = Exposure frequency (days/year)
BW = Body weight (kg)
AT = Averaging time (years)
CF_1 = Conversion factor (µg/mg)
CF_2 = Conversion factor (days/year)

A summary of the exposure factors used in estimating chronic exposure to residues through dermal contact and inhalation to the MLA are given in **Table 12**.

Table 12: Exposure Factors Used in Estimating Chronic Exposures to Residues to the MLA

Receptor	DAF	Exposure Duration (years)	Averaging Time (years)	Body Weight[1] (kg)
MLA	See the Dashboard Database 4.0 Chemical-Specific DAFs	20	20	80

1. EFH (USEPA, 2011p)

Refer to the *Pest Programs* or *Risk Results* section of the Dashboard Database 4.0 for the OPHED unit exposures used for estimating exposure to the MLA.

5.4.1.2.3 Cancer Exposure Assessment

Cancer exposure was not characterized in this risk assessment because none of the active or inert ingredients are suspected carcinogens (USEPA, 2019d).

5.4.1.3 Downwind-Bystander

The downwind bystander (DWB) represents any adult or child that is downwind from a residential application site and has the potential to be exposed to off-site drift. In accordance with USEPA's (1999f) *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment*, the DWB was assumed to be 25 feet away from the application site.

The DWB was subcategorized into a <2 year-old child, a 2-<16 year-old child, and a 16< year-old (i.e., adult). The DWB was assumed to be exposed to pesticide residue through dermal and inhalation off-target drift for liquid applications using a groundboom; handheld equipment drift is assumed to be *de minimis*.

For this HHRA, drift from turf drench application of solid granules is anticipated to be negligible, consistent with the USEPA (2013i) *Residential Exposure Assessment Standard Operating Procedures Addenda 1: Consideration of Spray Drift*.

5.4.1.3.1 Acute Exposure Assessment

Acute exposure for the DWB was evaluated in the same manner as in the Statewide PEIR (CDFA, 2014a), except as described here. Refer to the Statewide PEIR Appendix B Section 2.3 for exposure assessment methodology. USEPA's Occupational Pesticide Handler Exposure Database (OPHED) was most recently updated in March 2020, and unit exposure values were selected from the updated version (USEPA, 2020a). DWB exposure was estimated identically for the three age-groups, except the body weights selected were 11.4 kg for the <2 year-old child DWB (data for 1<2 year-olds), 13.8 kg for the 2-<16 year-old child DWB (data for 2<3 year-olds), and 80 kg for the adult DWB (USEPA, 2011p).

The following equation was used to estimate the ADD:

$$ADD = \frac{AR * OSD * ATPD * UE * DAF}{BW * CF_1}$$

Where:

ADD = Average daily dose (mg/kg-day)
AR =Application rate (lb/ac)
OSD = Off-site drift (%)
ATPD = Acres treated per day (ac/day)
UE = Unit exposure (µg/lb)
DAF = Dermal absorption factor*
*Only applied for dermal exposure when acute endpoint was derived from an oral or inhalation NO(A)EL
BW = Body weight (kg)
CF_1 = Conversion factor (µg/mg)

A summary of the exposure factors used in estimating acute exposure to residues through dermal contact and inhalation to the DWB are given in **Table** .

Table 13: Exposure Factors Used in Estimating Acute Exposures to Residues to the DWB

Receptor	Index Lifestage	DAF	Body Weight[1] (kg)
0<2 DWB	1-<2 years	See the Dashboard Database 4.0 for Chemical-Specific DAFs	11.4
2-<16 DWB	2-<3 years		13.8
Adult DWB	Adult		80

1. EFH (USEPA, 2011p)

Refer to the Dashboard Database 4.0 *Pest Programs* or *Risk Results* section for the OPHED "Flagger" unit exposures and off-site drift used for estimating exposure to the DWB.

5.4.1.3.2 Subchronic Exposure Assessment

Subchronic exposure for the DWB to active and inert ingredients was evaluated in the same manner as the chronic exposure in the Statewide PEIR (CDFA, 2014a), except the number of applications per year (exposure frequency) was limited to the number of applications that could occur over 30 days. USEPA's (2020a) Occupational Pesticide Handler Exposure Database (OPHED) was most recently updated in March 2020 and unit exposure values were selected from the updated version.

The following equation was used to estimate the SADD:

$$SADD = \frac{AR * OSD * ATPD * UE * EF * ED * DAF}{BW * AT * CF_1 * CF_2}$$

Where:

SADD = Subchronic average daily dose (mg/kg-day)
AR =Application rate (lb/ac)
OSD = Off-site drift (%)
ATPD = Acres treated per day (ac/day)
UE = Unit exposure (µg/lb)
EF = Exposure frequency (days/year)
ED = Exposure duration (days)
DAF = Dermal absorption factor*
*Only applied for dermal exposure when subchronic endpoint was derived from an oral or inhalation NO(A)EL
BW = Body weight (kg)
AT = Averaging time (days)
CF_1 = Conversion factor (µg/mg)
CF_2 = Conversion factor (days/year)

A summary of the exposure factors used in estimating subchronic exposure to residues through dermal contact and inhalation to the DWB are given in .

Table 14: Exposure Factors Used in Estimating Subchronic Exposures to Residues to the DWB

Receptor	Index Lifestage	ED (days)	AT (days)	DAF	Body Weight[a] (kg)
<2 DWB	1-<2 years	30	30	See the Dashboard Database 4.0 for Chemical-Specific DAFs	11.4
2-<16 DWB	2-<3 years				13.8
Adult DWB	Adult				80

a. EFH (USEPA, 2011p)

Refer to the Dashboard Database 4.0 *Pest Programs* or *Risk Results* section for the OPHED "Flagger" unit exposures and off-site drift used for estimating exposure to the DWB.

5.4.1.3.3 Chronic Exposure Assessment

Chronic exposure for the DWB was evaluated in the same manner as in the Statewide PEIR (CDFA, 2014a), with exception to changes described in this subsection. Refer to the Statewide PEIR Appendix B Section 2.3 for exposure assessment methodology.

For applications in residential and urban settings, the maximum number of consecutive years the program was anticipated to occur at a single residence was 10 years. Therefore, the exposure duration for the adult and 2-<16 year-old DWB was assumed to be 10 years for applications in residential and urban settings. The exposure duration for the 0-<2 year-old DWB was assumed to be the entirety of that lifestage (i.e., 2 years).

Unit exposure values for the DWB were selected from an updated version of the USEPA's (2020a) Occupational Pesticide Handler Exposure Database (OPHED).

The following equation was used to estimate the AADD:

$$AADD = \frac{AR * OSD * ATPD * UE * EF * ED * DAF}{BW * AT * CF_1 * CF_2}$$

Where:

AADD = Average daily dose (mg/kg-day)
AR =Application rate (lb/ac)
OSD = Off-site Drift (%)
ATPD = Acres treated per day (ac/day)
UE = Unit exposure (µg/lb)
DAF = Dermal absorption factor*
*Only applied for dermal exposure when chronic endpoint was derived from an oral or inhalation NO(A)EL
EF = Exposure Frequency (days/year)
ED = Exposure Duration (years)
BW = Body weight (kg)
AT = Averaging Time (years)
CF_1 = Conversion factor (µg/mg)
CF_2 = Conversion factor (days/year)

A summary of the exposure factors used in estimating chronic exposure to residues through dermal contact and inhalation to the DWB are given in .

Table 15: Exposure Factors Used in Estimating Chronic Exposures to Residues to the DWB

Receptor	Index Lifestage	Exposure Duration (years)	Averaging Time (years)	Dermal Absorption Factor	Body Weight[1] (kg)
<2 DWB	1-<2 years	2	2	See the Dashboard Database 4.0 for Chemical-Specific DAFs	11.4
2-<16 DWB	2-<3 years	10	10		13.8
Adult DWB	Adult	10	10		80

1. EFH (USEPA, 2011p)

Refer to the Dashboard Database 4.0 *Pest Programs* or *Risk Results* section for the OPHED "Flagger" unit exposures and off-site drift used for estimating exposure to the DWB.

5.4.1.3.4 Cancer Exposure Assessment

Cancer exposure was not characterized in this risk assessment because none of the active or inert ingredients are suspected carcinogens (USEPA, 2019d).

5.4.1.4 Post-Application Resident

The post-application resident (PAR) represents a typical receptor living in an urban or residential environment who has the potential to be exposed after treatments have been conducted under the Proposed Program. The PAR was conservatively assumed to be active on his/her lawn and to consume home-grown edible vegetation (e.g., fruits). An adult resident was assumed to be exposed to residues on turf and soil through dermal contact and through ingestion of home-grown edible vegetation and drinking of surface water and groundwater. Child residents were assumed to be exposed to residues on turf and soil through dermal contact, incidental ingestion of residues on turf from hand-to-mouth and object-to-mouth activity, ingestion of soil, home-grown edible vegetation, and the drinking of groundwater and surface water. Post-application inhalation exposure to chlorantraniliprole and polybutene was not considered because of their low vapor pressure (1.58E-13 mmHg and 1.37E-06, respectively) (USEPA, 2008q, 2012q).

For the purposes of this risk assessment, the resident was analyzed over three lifestages: <2 year-old child, 2-<16 year-old child, and adults 16 years of age and older. To estimate potential exposure for these three age-groups, guidance and exposure factors from sources including, but not limited to, USEPA's (2012l) *Standard Operating Procedures for Residential Pesticide Exposure Assessment* (SOP), USEPA's (1989e, 2004i, 2014d) *Risk Assessment Guidance for Superfund* (RAGS), and USEPA's (2011p) *Exposure Factors Handbook* (EFH) and subsequent chapter releases were selected. If exposure factors from multiple age-ranges (e.g., 3-<6 year-old, 6-<11 year-old, etc.) within each lifestage (e.g., 2-<16 year-old child) were available, the exposure factor from the age-range that resulted in the highest exposure was selected for each lifestage. The SOP designates "index lifestages" for specific exposure assessments. An index lifestage (ILS) represents "the lifestage of highest concern due to unique behavioral characteristics that may lead to higher levels of exposure." The USEPA (2012l) determined these index lifestages through both "quantitative (e.g., exposure assessments) and qualitative (e.g., exposure and activity data) considerations," and assessment of the ILS is expected to "protect for the exposures and risks for all potentially exposed lifestages."

Unless otherwise specified, exposure factors for the adult drawn from the EFH (USEPA, 2011p) were based on data from a 21-<80+ year-old. Similarly, exposure factors from the SOP (USEPA, 2012l) were based on data from a 16-<80 year-old.

5.4.1.4.1 Acute Exposure Assessment

Dermal Exposure to Residues in Soil

The <2 year-old child PAR, 2-<16 year-old child PAR, and the adult PAR were assumed to be dermally exposed to chlorantraniliprole and polybutene residues on bare spots on lawns. Methods and exposure factors from the USEPA's (2004i, 2014d) RAGS, USEPA's (2011p) EFH, and USEPA's (2012l) SOP were used in this assessment. Exposure factors for a 1-<2 year-old and a 2-<3 year-old were selected to represent the <2 year-old child and 2-<16 year-old child PARs, respectively. For certain exposure factors, data were not available for the 2-<3 year-old lifestage index. In those instances, values from other lifestages were selected as surrogates as described below.

To calculate the ADD, the peak chlorantraniliprole and polybutene residue estimated to be in soil, as described in Section 1.10.2, was multiplied by the resident's skin surface area that typically contacts soil, a soil-to-skin adherence factor, the number of times the resident is expected to come into contact with treated soil per hour, the number of hours per day the receptor was anticipated to spend in a treated area, a dermal absorption factor, and divided by the resident's body weight. A surface area of 6,032 cm^2/event was selected for an adult PAR, based on the mean surface area of an adult (USEPA, 2014d). A surface area of 2,373 cm^2/event was selected for a 2-<16 year-old child PAR based on the weighted average of a 0-<6 year-old (USEPA, 2014d). A surface area of 610 cm^2/event was used for a <2 year-old child PAR, based on the 95th percentile for total body surface area of a 1-<2 year-old child (USEPA, 2011p). The soil adherence factor (AF) used for an adult was 0.07 mg/cm^2, based on the 50th percentile of a gardener in a high activity setting (DTSC, 2019a; USEPA, 2004i, 2014d). A soil adherence factor of 0.2 mg/cm^2 was used for both child PARs, based on the 95th percentile of a 1-<6 year-old child (USEPA, 2004i, 2014d). The adult PAR was assumed to spend 2.2 hours per day outside in treated areas and the two child PARs were assumed to spend 1.1 hours per day outside in treated areas, based on the arithmetic mean of adults and for 6-<11 year-old activity in gardens, respectively (USEPA, 2012l). The adult and both child PARs were assumed to contact soil 71 times per hour, based on the 90th percentile soil contact rate of both hands of a 1 to 5-year-old child (USEPA, 2011p). The mean body weights for a 1-<2 year-old, 2-<3 year-old, and adult were used for the <2 year-old PAR, 2-<16 year-old PAR, and adult PAR, respectively (USEPA, 2011p).

The following equation was used to estimate the ADD:

$$ADD = \frac{EEC * CF * SA * AF * ET * CR * DAF}{BW}$$

Where:

ADD = Average daily dose (mg/kg-day)
EEC = Estimated environmental concentration (mg/kg)
CF = Conversion factor (kg/mg)
SA = Surface area exposed per event (cm^2/event)
AF = Soil adherence factor (mg/cm^2)
ET = Exposure time (hours/day)
CR = Contact rate (events/hour)
DAF = Dermal absorption factor
*Only applied for dermal exposure when acute endpoint was derived from an oral or inhalation NO(A)EL
BW = Body weight (kg)

A summary of the exposure factors used in estimating acute dermal exposure to residues in soil is given in **Table 16**.

Table 16: Exposure Factors Used in Estimating Acute Dermal Exposure to the PAR in Soil

Receptor	EEC (mg/kg)	SA (cm^2/event)	AF[b,d] (mg/cm^2)	ET[c] (hours/day)	CR[a] (events/hour)	DAF	BW (kg)[a]
<2 PAR	Refer to Dashboard Database 4.0	610[a]	0.2	1.1	71	See Dashboard Database 4.0 for chemical-specific DAFs	11.4
2-<16 PAR	Refer to Dashboard Database 4.0	2,373[b]	0.2	1.1	71	See Dashboard Database 4.0 for chemical-specific DAFs	13.8
Adult PAR	Refer to Dashboard Database 4.0	6,032[b]	0.07	2.2	71	See Dashboard Database 4.0 for chemical-specific DAFs	80

a. USEPA, 201lp
b. USEPA, 2014d
c. USEPA, 2012l
d. USEPA, 2004i

Pica and Incidental Ingestion of Soil

Both the <2 year-old and 2-<16 year-old child PARs were assumed to be exposed to chlorantraniliprole and polybutene through ingestion of treated soils underneath garden plants or bare spots on lawns. The two child PARs were assumed to exhibit soil pica behavior, which is the recurrent ingestion of unusually high amounts of soil of between 1,000 – 5,000 mg/day (USEPA, 2017g). USEPA's (2011p) EFH states, "soil-pica should not be limited to intentional soil ingestion, primarily because children can consume large amounts of soil from their typical behaviors and because differentiating intentional and unintentional behavior in young children is difficult." Therefore, the soil ingestion rate is based on a total mg soil per day, and accounts for both intentional and incidental soil ingestion (OEHHA, 2012d). Due to the higher likelihood of children to consume soil, exposure from soil ingestion by the two child PARs was considered health protective of the adult PAR.

Methods and exposure factors from the USEPA's (1989e) RAGS, USEPA's (2011p, 2017g) EFH, and ATSDR's (2001a) Soil-Pica Workshop were used in this assessment. The ILSs for the <2 year-old child PAR and 2-<16 year-old child PAR were the 1-<2 year-old and 2-<3 year-old, respectively.

To calculate the ADD, the peak chlorantraniliprole and polybutene concentration estimated to be in soil was multiplied by a soil ingestion rate, the fraction of soil ingested that had been treated, and then divided by the child's body weight. A soil ingestion rate of 1,000 mg soil/day was selected based on suggested value from the ATSDR (2001a) Soil-Pica Workshop Summary Report. The fraction of soil ingested from a treated site was assumed to be 100%.

The following equation was used to estimate the ADD:

$$ADD = \frac{EEC * CF * IR_s * FI}{BW}$$

Where:

ADD = Average daily dose (mg/kg-day)
EEC = Estimated environmental concentration (mg/kg)
CF = Conversion factor (kg/mg)
IR_s = Soil ingestion rate (mg/day)
FI = Fraction ingested from Contaminated Source (unitless)
BW = Body weight (kg)

A summary of the exposure factors used in estimating acute pica and incidental soil ingestion is given in **Table 17**.

Table 17: Exposure Factors Used in Estimating Acute Pica and Incidental Soil Ingestion

Receptor	Index Lifestage	EEC (mg/kg)	IR_s[a] (mg/day)	FI[b]	BW[c] (kg)
<2 PAR	1-<2 years	Refer to the Dashboard Database 4.0	1,000	1	11.4
2-<16 PAR	2-<3 years	Refer to the Dashboard Database 4.0	1,000	1	13.8

a. USEPA, 2017g; ATSDR, 2001a
b. Professional judgment
c. USEPA, 2011p

Episodic Ingestion of Granules

To account for the possibility of young children consuming leftover granules from Acelepryn G application, the ingestion of granules was estimated using methods and exposure factors from the USEPA (2012l) SOP. The SOP indicates that exposure to non-dietary ingestion of granules and pellets should be considered episodic, meaning, it would not occur as a result of routine behavior and more readily related to a poisoning event. Therefore, these events should be addressed as a

single scenario and not combined with any other sources of exposure to the pesticide (USEPA, 2012l).

The 1-<2 year-old and 2-<3 year-old were considered the ILS for the 0-<2 and 2-<16 year old child receptors, respectively, based on SOP guidance and professional judgment. Because children are more likely to eat random objects (including solid pesticide) off the ground, exposure to the child PARs was considered health protective of the adult PAR.

To estimate exposure, the ingestion rate is multiplied by the fraction of ingredient in the dry formulation product, a conversion factor, and divided by the body weight, as shown in the following equation:

$$ADD = (IR_g * FD * CF)/BW$$

Where:

IR_g = ingestion rate of dry pesticide formulation (g/day)
FD = fraction of ai in dry formulation (unitless)
CF = weight unit conversion factor (1,000 mg/g)
BW = body weight (kg)

Although the SOP recommends an IRg of 300 mg/d, independent of child mobility or density of granules per unit area, the soil ingestion rate of 1,000 mg/d was selected to account for the size and color of Acelepryn G granules (ATSDR, 2001a; USEPA, 2017g). Exposure factors for estimating episodic granule ingestion are depicted in **Table 18**.

Table 18: Exposure Factors Used in Estimating Non-Dietary Granule Ingestion

Receptor	Index Lifestage	FD (unitless)	IR_s[a] (mg/day)	BW[c] (kg)
<2 PAR	1-<2 years	See Dashboard Database 4.0	1,000	11.4
2-<16 PAR	2-<3 years[b]	See Dashboard Database 4.0	1,000	13.8

a. USEPA, 2017g; ATSDR, 2001a
b. Professional judgment
c. USEPA, 2011p

Ingestion of Edible Vegetation Residues

The <2 year-old child, 2-<16 year-old child, and the adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues through consumption of edible vegetation (i.e., home-grown fruit). Methods for estimating pesticide residue concentrations in plants are described in Section 1.10.5. When evaluating turf drench applications, it was assumed plant surfaces were not directly treated and 100% of the applied material was available for uptake, despite best management practices implemented to avoid treatment of human edible plants.

Methods and exposure factors from the USEPA's (1989e) RAGS and USEPA's (2011p) EFH were used in this assessment. Exposure factors for a 1-<2 years old and a 3-<5 years old were selected to represent the ILSs for the <2 year-old child and 2-<16 year-old child PARs, respectively. Exposure factors for a 40-<69 year-old were selected to represent the adult PAR (USEPA, 2018d).

To calculate the ADD, the maximum EEC of chlorantraniliprole and polybutene in edible vegetation, found in the Dashboard Database 4.0, was multiplied by the amount of vegetation a resident was expected to consume per day relative to his/her body weight. For the <2 year-old child PAR assessment, a vegetation ingestion rate of 8.7 g/kg-day, based on mean intake of home-produced fruits for a 1-2 years old. For the 2-<16 year-old child PAR assessment, a vegetation ingestion rate of 4.1 g/kg-day, based on mean intake of home-produced fruits for a 3-5 years old. For the adult PAR assessment, a vegetation ingestion rate of 2.7 g/kg-day, based on mean intake of home-produced fruits for a 40-69 year-old. Each of the aforementioned ingestion rates was selected from USEPA's (2018d) EFH.

The following equation was used to estimate the ADD:

$$ADD = EEC * CF * IR_v$$

Where:

ADD = Average daily dose (mg/kg-day)
EEC = Estimated environmental concentration (mg/kg)
CF = Conversion factor (kg/g)
IR_v = Vegetation ingestion rate (g/kg-day)

A summary of the exposure factors used in estimating acute exposure to residues through ingestion of edible vegetation is given in **Table 19**.

Table 19: Exposure Factors Used in Estimating Acute Exposures to Residues through Ingestion of Edible Vegetation

Receptor	Index Lifestage	EEC (mg/kg)	IR_v[a] (g/kg day)
<2 PAR	1-<2 years	Refer to the Dashboard Database 4.0 *Pest Programs* Section	8.7
2-<16 PAR	3-<5 years	Refer to the Dashboard Database 4.0 *Pest Programs* Section	4.1
Adult PAR	40-<69 years	Refer to the Dashboard Database 4.0 *Pest Programs* Section	2.7

a. USEPA, 2018d

Dermal Exposure to Residues on Turf

The <2 year-old child, 2-<16 year-old child, and adult PARs dermal exposure to chlorantraniliprole and polybutene residues on turf were assessed using USEPA's (2012l) SOP guidance for "Lawns/Turf - High Contact Lawn Activities." In accordance with the SOP, the 1-<2 year-old PAR served as the ILS for the <2 year-old. The 2-<3 year-old child represented the 2-<16 year-old PAR. The first step of the Lawns/Turf SOP equation was to estimate the Transferable Turf Residue (TTR_t) of chlorantraniliprole and polybutene. Refer to Section 1.10.5 for the TTR_t equation and additional details.

The SOP-recommended TCs were used to estimate the transfer of residue from turf-surface to skin. The recommended TCs for granules were 54,000 cm^2/hour for a 1-<2 years old, 110,000 cm^2/hour for a 2-<3 year-old, and 200,000 cm^2/hour for an adult (USEPA, 2012l). For the definition of TCs, refer to the *Glossary and Abbreviations* section of the Dashboard Database 4.0. It was assumed the adult, 1-<2 year-old child, and 3-<6 year-old child PARs spent 1.5 hours in turf settings. The default exposure factors used in the SOP for a child 1-<2 years old, a child 2-<3 years old, and an adult were left unchanged for the assessment of the <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR, respectively.

To estimate the Turf Dermal Exposure (TDE), the TTR_t was multiplied by the TC, and the number of hours per day the resident was expected to be exposed (ET).

The following equation was used to estimate the TDE:

$$TDE = TTR_t * CF * TC * ET$$

Where:

TDE = Turf Dermal Exposure (mg/d)
TTR_t = Transferable turf residue (t) days after application (μg/cm^2)
CF= Weight unit conversion factor (mg/μg)
TC = Transfer coefficient (cm^2/hour)
ET = Exposure time (hours/day)

To estimate the PAR's Average Daily Dose (ADD), the TDE was multiplied by the DAF and then divided by the resident's body weight.

$$ADD = \frac{TDE * DAF}{BW}$$

Where:

ADD = Average daily dose (mg/kg-day)
TDE = Turf Dermal Exposure (mg/d)
DAF = Dermal absorption factor
*Only applied for dermal exposure when acute endpoint was derived from an oral or inhalation NO(A)EL
BW = Body weight (kg)

A summary of the exposure factors used in estimating acute dermal exposure to turf is given in **Table 20**.

Table 20: Exposure Factors Used in Estimating Acute Dermal Exposure to Turf

Receptor	Index Lifestage	TC[a] (cm^2/hour)	ET[a] (hours/d)	DAF	BW[b] (kg)
<2 PAR	1-<2 years	54,000	1.5	See the Dashboard Database 4.0 for chemical-specific DAFs	11.4
2-<16 PAR	2-<3 years	110,000	1.5	See the Dashboard Database 4.0 for chemical-specific DAFs	13.8
Adult PAR	Adult	200,000	1.5	See the Dashboard Database 4.0 for chemical-specific DAFs	80

a. USEPA, 2012l
b. USEPA, 2011p

Hand-to-Mouth Ingestion of Turf Residues

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to come into contact with chlorantraniliprole and polybutene by contacting residues on turf and then transferring that residue from his/her hand to mouth. Due to the higher likelihood of children placing their hands in their mouths, exposure from hand-to-mouth ingestion for the two child PARs was considered health protective of the adult PAR. The USEPA's (2012l) SOP guidance for Lawns/Turf was used as a source of exposure factors and methods. Exposure factors for the ILS of 1-<2 year-old and a 3-<6 year-old were selected to represent the <2 year-old child PAR and the 2-<16 year-old child PAR, respectively.

In accordance with the SOP, the TDE, which was estimated in the Dermal Exposure to Residues on Turf Section, was multiplied by the fraction of total residue on the child's hands. The result was then divided by the surface area of the child's hands to estimate the potential amount of residue available on the PAR child's hands. The following equation was used to estimate the HR:

$$HR = \frac{Fai_{hands} * TDE}{SA_H * 2}$$

Where:

HR = Residue available on hand (mg/cm^2)
Fai_{hands} = Fraction of total residue on hands
TDE = Turf dermal exposure (mg)
SA_H = Hand surface area (cm^2)

To estimate the ADD, the SOP accounts for the residue available on the receptor's hands, the fraction of hand surface area mouthed each event, the typical surface area of one hand, the

number of hours per day the child may be exposed, the number of times the child contacts treated turf per hour, the fraction of residue removed from saliva, the frequency of hand-to-mouth contacts per hour, and the child PAR's body weight (USEPA, 2012l). The following equation was used to estimate the ADD:

$$ADD = \frac{HR * F_M * SA_H * ET * N_{Rep} * (1 - (1 - SE)^{EV_{HtM} / N_{Rep}})}{BW}$$

Where:

ADD = Average daily dose (mg/kg-day)
HR = Residue available on hand (mg/cm^2)
F_M = Fraction of hand surface area mouthed per event (unitless/event)
SA_H = Hand surface area (cm^2)
ET = Exposure time (hours/day)
N_{Rep} = Number of replenishment intervals per hour (intervals/hour)
SE = Extraction by saliva
EV_{HtM} = Frequency of hand-to-mouth (events/hour)
BW = Body weight (kg)

A summary of the exposure factors used in estimating acute hand-to-mouth ingestion of turf residues is given in **Table 21**.

Table 21: Exposure Factors Used in Estimating Acute Hand-to-Mouth Ingestion of Turf Residues

Receptor	Index Lifestage	Fai_{hands}[a]	SA_H (cm^2)	F_M[a]	ET [a] (hours /day)	N_{Rep}[a] (intervals/ hr)	SE[a]	EV_{HtM} (events/ hour)[a]	BW (kg)[b]
<2 PAR	1-<2 years	0.06	150[b]	0.127	1.5	4	0.48	13.9	11.4
2-<16 PAR	3-<6 years	0.06	225[a]	0.127	1.5	4	0.48	8.5	18.6

a. USEPA, 2012l
b. USEPA, 2011p

Object-to-Mouth Ingestion of Turf Residues

Both the <2 year-old and 2-<16 year-old child PARs were assumed to come into contact with chlorantraniliprole and polybutene through turf-to-object contact that subsequently transferred to his/her mouth from the object. Due to the higher likelihood of children placing objects in their mouth, exposure from incidental ingestion to the two child PARs was considered health protective of the adult PAR. The USEPA's (2012l) SOP guidance for Lawns/Turf was used as a source of exposure factors and methods. Exposure factors for a 1-<2 year-old and a 2-<3 year-old were selected to represent the <2 year-old child and 2-<16 year-old child PARs, respectively.

To estimate the potential amount of residue available on an object (OR_t), a variation of the equation found in the USEPA SOP was used. Consistent with a personal communication with Jeff Dawson of the USEPA on July 20th, 2016, the application rate was multiplied by the fraction of total residue on the object and the dissipation rate (J. Dawson, USEPA, personal communication, July 20, 2016). For acute exposure, the OR_t was the peak value possible considering environmental degradation. It was assumed the dissipation of pesticide residue on an object was comparable to the degradation on foliage. As such, the foliar half-life of 16.136 days was used to estimate the concentration of chlorantraniliprole on the object over time. It was assumed polybutene experienced no environmental degradation. See Section 1.10 for more details on the use of first-order rate kinetics to estimate environmental degradation. For turf drench applications, despite BMPs implemented to avoid contact of pesticide residues with lawn objects, it was conservatively assumed objects received direct application.

The following equation was used to estimate the OR_t:

$$OR_t = AR * F_O * (1 - FD)^t * CF_1 * CF_2 * DtO$$

Where:

OR_t = Residue available on object (µg/cm^2)
AR = Application rate (lb a.i./acre)
F_O = Fraction of total residue on object
F_D = Fraction of residue that dissipates per day
t = Time after application (days)
CF_1 = Weight unit conversion factor (µg/lb)
CF_2 = Area unit conversion factor (acre/cm^2)
DtO = Drift to Object

To estimate the ADD due to object-to-mouth (OtM) exposure, the SOP accounts for the residue available on the object, the object surface area mouthed for each event, the number of hours per day the child is assumed to be exposed (i.e., exposure time), the number of times the object contacts treated turf per hour, the fraction of residue removed by saliva, the frequency of object-to-mouth contacts per hour, and the child PAR's body weight (USEPA, 2012l).

The following equation was used to estimate the ADD:

$$ADD = \frac{OR_t * CF_3 * SAM_O * ET * N_{Rep} * (1 - (1 - SE)^{(EV_{OtM} / N_{Rep})})}{BW}$$

Where:

ADD = Average daily dose (mg/kg-day)
OR_t = Residue available on object (µg/cm^2)
CF_3 = Weight unit conversion factor (mg/ug)
SAM_O = Object surface area mouthed per event (cm^2/event)
ET = Exposure time (hours/day)
N_{Rep} = Number of replenishment intervals per hour (intervals/hour)
SE = Extraction by saliva
EV_{OtM} = Frequency of OtM events per hour (events/hour)
BW = Body weight (kg)

A summary of the exposure factors used in estimating acute object-to-mouth ingestion of turf residues is given in **Table 22**.

Table 22: Exposure Factors Used in Estimating Acute Object-to-Mouth Ingestion of Turf Residue

Receptor	Index Lifestage	t (days)	EV_{OtM}[a] (events /hr)	BW[b] (kg)	F_O[a]	DtO	SAM_O[a] (cm^2/ event)	ET[a] (hrs/ day)	N_{Rep}[a] (intervals/ hr)	SE[a]
0<2 PAR	1-<2 years	0-365	8.8	11.4	0.002	1	10	1.5	4	0.48
2-<16 PAR	2-<3 years	0-365	8.1	13.8	0.002	1	10	1.5	4	0.48

a. USEPA, 2012l
b. USEPA, 2011p

Ingestion of Surface Water Residues

The <2 year-old child, 2-<16 year-old child, and the adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues through drinking water sourced from surface water. Methods for estimating pesticide residue concentrations in surface water are described in Section 1.10.7.

In addition to PWC estimated EECs, exposure factors and guidance from the USEPA's (1989e) *Risk Assessment Guidance for Superfund* (RAGS) and OEHHA's (2012e) *2012 Technical Support Document for Exposure Assessment and Stochastic Analysis* were used to estimate exposure. Exposure factors for a 16-70 year-old were selected to represent the adult PAR (USEPA, 2011p). Exposure factors for a 0<2 years old and a 2<9 years old were selected to represent the ILSs for the <2 year-old child and 2-<16 year-old child PARs, respectively. To estimate the ADD, the peak EEC of chlorantraniliprole and polybutene in surface water was multiplied by the amount of water a resident was expected to consume per day relative to their body weight. The water ingestion rates for these receptors, as seen in **Table 23**, represent the 95th percentile recommended point estimate and was used for both surface and groundwater ingestion

(i.e., it is assumed a person drinks twice as much as the 95th percentile water ingestion rate). It was assumed residents consumed drinking water only from contaminated sources (i.e., there was no reduction in water consumption based on other potential sources).

The following equation was used to estimate the Drinking Water Exposure (DWE):

$$DWE = IRw * EEC * CF1$$

Where:

DWE = Drinking water exposure (mg/kg-day)
IR_w =Water intake rate (L/kg-d)
EEC = Estimated environmental concentration (µg/L)
BW = Body weight (kg)
CF1 = Conversion factor (mg/µg)

A summary of the exposure factors used in estimating DWE are presented in **Table 23**.

Table 23: Exposure Factors Used to Estimate Drinking Water Exposure from Surfacewater

Receptor	Index Lifestage	IR_w (L/kg-d)[1]	EEC (ug/L)
0-<2 year old	0-<2	0.196	See Dashboard Database 4.0 Section *Pest Programs*
2-<16 year old	2<9	0.066	
Adult	16-70	0.045	

1. OEHHA, 2012e

Ingestion of Groundwater Residues

Methods and exposure factors for estimating exposure to residues from drinking groundwater are the same as those described in the Ingestion of Surface Water Residues, except the peak groundwater EEC was used. See 1.10.8 for discussion of groundwater EEC calculations.

5.4.1.4.2 Subchronic Exposure Assessment

The subchronic duration is defined as repeated daily exposure over multiple days up to 10 percent of a life span in humans or 30 to 90 days in laboratory animal species (USEPA, 1996g). For this assessment, the subchronic exposure was assumed to be 30 days, based on the USEPA (2011w) Integrated Risk Information System (IRIS) Glossary definition of 'subchronic exposure.'

To assess subchronic exposure to the PAR, an average daily dose (ADD_{SC}) was estimated using a similar method and equation as the acute exposure, except a subchronic EEC was used instead of the peak EEC. See Section 1.10 for more details about the methods used to calculate subchronic EECs.

To estimate the Subchronic Average Daily Dose (SADD), the ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year, and the time frame the resident was expected to be exposed. A chemical-specific dermal absorption factor (DAF) was also included when evaluating dermal exposure if the associated subchronic endpoint was derived from an oral NOAEL. This value was then divided by the total duration of time assessed (i.e., averaging time). The exposure frequency, exposure duration, and averaging time reflected the assumed 30-day exposure.

The general equation for calculating the SADD was as follows:

$$SADD = \frac{ADD_{SC} * EF * ED * DAF}{CF * AT}$$

Where:

SADD = Subchronic average daily dose (mg/kg-day)
ADD_{SC} = Average daily dose (mg/kg-day)
EF = Exposure frequency (days/year)
ED = Exposure duration (days)
DAF = Dermal absorption factor (unitless)
*Only applied for dermal exposure when subchronic endpoint was derived from an oral or inhalation NO(A)EL
CF = Conversion factor (days/year)
AT = Averaging time (days)

Dermal Exposure to Residues in Soil

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from dermal contact with treated soil daily for 30 days. An adjusted ADD (ADD_{SC}) was estimated by the same process as the acute ADD, except a subchronic soil EEC was used, considering first-order environmental degradation. See Section 1.10 for more details about how subchronic EECs were estimated.

To calculate the SADD, the ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), and a chemical-specific DAF when appropriate, then divided by the total duration of time assessed (AT).

Pica and Incidental Soil Ingestion

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from ingestion of treated soil daily for 30 days. An adjusted ADD (ADD_{SC}) was estimated through the same process as the acute ADD, except a subchronic soil EEC was used, considering first-order environmental degradation over 30 days. See Section 1.10 for more details about how subchronic EECs were estimated.

To calculate the SADD, the ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Ingestion of Edible Vegetation

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues in edible vegetation daily for 30 days. An adjusted ADD (ADD_{SC}) was estimated through the same process as the acute ADD, except a subchronic EEC was used, considering first-order environmental degradation over 30 days.

To calculate the SADD, the acute ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT). Refer to Section 1.10 for additional details regarding the estimation of edible vegetation EECs.

Dermal Exposure to Residues on Turf

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from dermal contact with turf for 30 days. An adjusted ADD (ADD_{SC}) was estimated through the same process as the acute ADD, except a subchronic TTR_t was used, considering first-order environmental degradation over 30 days. See Section 1.10 for more details about how subchronic EECs were estimated.

To calculate the SADD, the ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), a chemical-specific dermal absorption factor (DAF) when appropriate, and then divided by the total duration of time assessed (AT).

Hand-to-Mouth Ingestion of Turf Residues

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from hand-to-mouth activity daily for 30 days. An adjusted ADD (ADD_{SC}) was estimated through the same process as the acute ADD, except a subchronic TTR_t was used, considering first-order environmental degradation and the possibility of accumulation from multiple applications over 30 days. Refer to Section 1.10 for more details about how subchronic EECs were estimated.

To calculate the SADD, the ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Object-to-Mouth Ingestion of Turf Residues

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from object-to-mouth contact daily for 30 days. An adjusted ADD (ADD_{SC}) was estimated through the same process as the acute ADD, except a subchronic OR_t was used, considering first-order environmental over 30 days. Refer to the acute object-to-mouth exposure section Object-to-Mouth Ingestion of Turf Residues for details about how OR_t s were estimated.

To calculate the SADD, the ADD_{SC} was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Ingestion of Surface Water Residues

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from ingestion of surface water for 30 days. The ADD was estimated through the same process as the acute ADD. See Section 1.10 for more details about how EECs were estimated.

To calculate the SADD, the ADD was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), and then divided by the total duration of time assessed (AT).

Ingestion of Groundwater Residues

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from ingestion of groundwater for 30 days. The ADD was estimated through the same process as the acute ADD. See Section 1.10 for more details about how EECs were estimated.

To calculate the SADD, the acute ADD was multiplied by the number of days the resident had the potential to be exposed per year (EF), the duration the resident was expected to be exposed (ED), and then divided by the total duration of time assessed (AT).

5.4.1.4.3 Chronic Exposure Assessment

To assess the chronic exposure to the PAR, an average daily dose (ADD_C) was estimated using a similar method and equation as the acute exposure, except a chronic EEC was used instead of the peak EEC. See Section 1.10 for more details about how chronic EECs were estimated.

To estimate the Annual Average Daily Dose (AADD), the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year, the time frame the resident was expected to be exposed, and a chemical-specific dermal absorption factor (DAF) when the chronic endpoint was derived from an oral or inhalation NOAEL. This value was then divided by the total duration of time assessed. The duration of Proposed Program treatments at a single residence was assumed to be 10 years. Because the <2 year-old child PAR lifestage is limited to two years, a two year exposure duration was assumed for this subgroup.

The following equation was used to calculate the AADD:

$$AADD = \frac{ADD_c * EF * ED * DAF}{AT * CF}$$

Where:

AADD = Annual average daily dose (mg/kg-day)
ADD_c = Average daily dose (mg/kg-day)
EF = Exposure frequency (days/year)
ED = Exposure duration (years)
DAF = Dermal Absorption Factor (unitless)
*Only applied for dermal exposure when chronic endpoint was derived from an oral or inhalation NO(A)EL
AT = Averaging time (years)
CF = Conversion factor (days/year)

A summary of the exposure factors used in estimating the AADD is given in **Table 24**.

Table 24: Exposure Factors Used in Estimating the AADD

PAR Lifestage	EF (days/year)	ED (years)	AT (years)
<2 year-old	365	2	2
2-<16 year-old	365	10	10
Adult	365	10	10

Dermal Exposure to Residues in Soil

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues in soil daily for the entire year. An adjusted ADD (ADD_C) was estimated through the same process as the acute ADD, except a chronic soil EEC was used, considering first-order rate environmental degradation over 365 days. See Section 1.10 for more details about how chronic EECs were estimated.

To calculate the AADD, the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), a chemical-specific DAF when appropriate, then divided by the total duration of time assessed (AT).

Pica and Incidental Soil Ingestion

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from ingestion of treated soil every day of the year. An adjusted ADD (ADD_C) was estimated through the same process as the acute ADD, except a chronic soil EEC was used, considering first-order rate environmental degradation over 365 days. See Section 1.10 for more details about how chronic EECs were estimated.

To calculate the AADD, the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Ingestion of Edible Vegetation

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues in edible vegetation daily for the entire year. Because fruits have seasonal limits of availability, consumption of residues on treated fruit over an entire year is not anticipated. However, to complete this extrapolation, the ADD_c was multiplied by the number of potential exposure days and the number of years the resident was expected to be exposed, and then divided by the total duration of time assessed. The AADD was then compared to the chronic NOAEL. Refer to Section 1.10 for additional details regarding estimating edible vegetation residue concentrations.

Dermal Exposure to Residues on Turf

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from dermal contact with turf every day of the year. An adjusted ADD (ADD_C) was estimated using the same process as the acute ADD, except a chronic TTR_t was used, considering first-order environmental degradation over 365 days. See Section 1.10 for more details on how chronic EECs were estimated.

To calculate the AADD, the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), and a chemical-specific DAF when appropriate, then divided by the total duration of time assessed (AT).

Hand-to-Mouth Ingestion of Turf Residues

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from hand-to-mouth activity every day of the year. An adjusted ADD (ADD_C) was estimated through the same process as the acute ADD, except a chronic TTR_t was used, considering first-order rate environmental degradation and the possibility of accumulation from multiple applications over 365 days. See Section 1.10 for more details about how chronic EECs were estimated.

To calculate the AADD, the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Object-to-Mouth Ingestion of Turf Residues

The <2 year-old child PAR and 2-<16 year-old child PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from object-to-mouth activity daily for the entire year. An adjusted ADD (ADD_C) was estimated through the same process as the acute ADD, except a chronic OR_t was used, considering first-order rate environmental degradation and the possibility of accumulation from multiple applications over 365 days. Refer to the acute object-to-mouth exposure (Section 1.11.1.1.1) for details about how OR_t s were estimated.

To calculate the AADD, the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Ingestion of Surface Water Residues

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from ingestion of surface water every day of the year. An adjusted ADD (ADD_C) was estimated using the same process as the acute ADD, except a 90-day average EEC was used. See Section 1.10 for more details on how chronic EECs were estimated.

To calculate the AADD, the ADD_C was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

Ingestion of Groundwater Residues

The <2 year-old child PAR, 2-<16 year-old child PAR, and adult PAR were assumed to be exposed to chlorantraniliprole and polybutene residues from ingestion of groundwater every day of the year. The ADD, estimated using the 100-year peak groundwater EEC, was used for chronic ingestion. See Section 1.10 for more details on how chronic EECs were estimated.

To calculate the AADD, the ADD was multiplied by the number of days the resident had the potential to be exposed per year (EF), the number of years the resident was expected to be exposed (ED), then divided by the total duration of time assessed (AT).

5.4.1.4.4 Cancer Exposure Assessment

Cancer exposure was not characterized in this risk assessment because no chemicals evaluated in this HHRA are suspected carcinogens (USEPA, 2019d).

5.4.1.5 During and Post-Application Resident

The during and post-application resident (DPAR) represents a combination exposure of a resident who is downwind at the time his/her property is being treated, and who has the potential to be exposed to chlorantraniliprole and polybutene residues on the treated vegetation, turf, and soil after the application. A <2 year-old child, a 2-<16 year-old child, and a ≥16 year-old adult were analyzed in the DPAR exposure assessment.

To estimate the DPAR's exposure, the DWB's and the PAR's risk values were summed. For additional details about the DWB and PAR individual exposures, refer to Sections 1.11.1.2 and 1.11.1.3, respectively. Further details of methods and equations to combine risk values can be found in Section 1.12.

6 Risk Characterization

The risk characterization phase compared estimates of pesticide active or inert ingredient and adjuvant receptor exposure (i.e., ADD, SADD, AADD) to relevant toxicity endpoints (i.e., NOAELs) to characterize the potential risk for each receptor (OEHHA, 2001a).

6.1 Non-Cancer Effects

The method used to quantify non-cancer risk due to estimated pesticide exposure is the Margin of Exposure (MOE) approach. The MOE represents how close the receptor's daily intake is to the NOAEL (i.e., how close a pesticide active or inert ingredient or adjuvant exposure is to the level of exposure that is expected to result in adverse health impacts, if any). The MOE is then compared to the level of concern (LOC), which accounts for uncertainty in inter-species extrapolation and intra-species variation through the use of two 10x uncertainty factors and an additional uncertainty factor of 3 is applied to account for individual who may be more sensitive to adverse effects (OEHHA, 2001c, 2008a, 2016a, 2020a; USEPA, 2005q). Calculated MOEs for the receptor's exposures greater than the LOC are typically not considered to be of concern (USEPA, 2007k). It should be noted that MOEs estimated in this analysis are not probabilistic statements of risk, but instead represent a threshold model.

The generic formula for estimating an MOE is:

MOE = Toxicity (mg/kg-day) / ADD (mg/kg-day)*

Where:

MOE = Margin of Exposure (unitless)

ADD = Average Daily Dose

* For subchronic or chronic assessments, the ADD is replaced by the SADD or AADD, respectively

In situations where multiple pathways are present, multiple exposures occur. An MOE was estimated for each active or inert ingredient individually for each individual exposure route, except episodic consumption of granules, and the MOEs were summed regardless of mode of action or target organs and systems to conservatively estimate the risk that may be associated with the combined exposure. This methodology is consistent with the approaches described in the USEPA (1989e) *Risk Assessment Guide to Superfunds (RAGS*) and USEPA (2001e) *General Principles for Performing Aggregate Exposure and Risk Assessment* which provides guidance on assessing aggregate chemical risk and aggregate exposure pathway risk. Consistent with the evaluation of individual MOEs in this HHRA, summed MOEs greater than 300 are not considered to be of concern (OEHHA, 2016a, 2020a; USEPA, 2007k).

The generic formula for summing MOEs is:

$$MOE_{total} = 1 / ((1/MOE_1) + (1/MOE_2) + \ldots + (1/MOE_n))$$

Where:

MOE = Margin of Exposure (unitless)

6.2 Cancer Effects

Cancer risk is not estimated in this HHRA because there is no evidence suggesting any of the pesticide active or inert ingredients analyzed are carcinogenic (USEPA, 2019d).

6.3 Numeric Data Presentation

Some numeric data presented in the risk characterization section (as found in the Dashboard Database 4.0) were very large numbers. To present these numbers in an easily readable format, scientific notation is used. For example, the value of 1,290,000 is expressed as 1.29E+06. Note that the "E" represents "exponent" or the number 10 raised to a power. The positive ("+") sign following the "E" indicates the number of places the decimal point was moved to the left from the original number.

7 Risk Assessment Results

Risk results, expressed as MOEs, are presented in the Dashboard Database 4.0 *Risk Results* section. To view the EECs and unit exposure values used to estimate risk for the Proposed Program, refer to the *Pest Programs* or *Risk Results* section of the Dashboard Database 4.0.

An overview of the minimum summed MOEs for each application scenario is presented in **Table 25** below.

Table 25. Minimum Summed MOEs per Application Scenario

Scenario	Minimum MOE	
	Occupational	Non Occupational
PD/EP-E-11a	7.52E+05	7.12E+03
PD/EP-E-11b	2.25E+08	
PD/EP-E-11c	2.24E+06	
PD/EP-E-12a,b,c	Qualitatively Assessed	

None of the estimated MOEs exceeded the LOC for any receptor or pathway. Risk values for the post-application resident child (2-<16) presented the lowest MOEs with subchronic dermal exposure to chlorantraniliprole residues on turf being the greatest contributor to aggregate risk (pathway-specific MOE = 7.25E+03). The child receptor is most likely anticipated to have the greatest exposure due to the comparatively high transfer coefficient from older child activities when compared to the lower body weight of the 2-<3 year old index lifestage.

As described in the Episodic Ingestion of Granules section, this pathway is considered to be an irregular and infrequent event related to acute poisoning; therefore, it was not included as part of the aggregate risk profile. Furthermore, toxicity data for chlorantraniliprole and polybutene suggests that acute exposures to these ingredients following application of Acelepryn G are not of concern. As a result, although exposure to chemicals in Acelepryn G through non-dietary ingestion of granules can be estimated, no MOEs were generated.

No acute endpoints of concern were identified for chlorantraniliprole or polybutene; therefore, risk resulting (i.e., MOEs) from acute exposure to these ingredients following application of Acelepryn G was not calculated.

Risk for application of beetleGONE! tlc was not quantitatively evaluated due to exposure modeling limitations. Based on the lack of adverse impacts observed in acute toxicity tests and the background concentrations of BtG to which individuals are already expected to be exposed to, no unacceptable risk is anticipated following applications of beetleGONE! tlc. For discussion of BtG toxicity and fate, see Sections 1.7.4 and 1.9.4, respectively.

Risk for the alternative scenario in which both Acelepryn G and beetleGONE! tlc was semi-quantitatively evaluated. Risk values for the Acelepryn G-only scenario (PD/EP-E-11) are expected to be protective of risk attributable to application of Acelepryn G in the combination scenario (PD/EP-E-11-12). Similarly, since no unacceptable risk is anticipated in the

beetleGONE! tlc-only scenario (PD/EP-E-12), risk attributable to application of beetleGONE! tlc in the combination scenario is expected to be minimal.

7.1 Uncertainty Analysis

In characterizing risks from exposure to pesticide active and inert ingredients and adjuvants, it is important to address the variability and uncertainty associated with the exposure/risk estimates. The risk characterization should provide information on: (1) potential measurement errors based on the precision and accuracy of the available data, (2) variability of the input data used in the exposure/risk estimates, and (3) uncertainty that results from data gaps or the assumptions used. The risk characterization also assesses the relative importance of these components on the estimates of exposure/dose and risk.

Uncertainty may be introduced into the exposure/risk calculations at various stages of the risk assessment process. Uncertainty may occur as a result of: (1) site-specific variations of chemical-specific fate and transport that could impact chemical partitioning, retention, and degradation, (2) the selection of exposure scenarios and exposure factors, (3) and the uncertainties associated with pesticide active and inert ingredient or adjuvant toxicity data that have been extrapolated from high doses in animals to low doses in humans, and that do not account for the interactions of exposures to multiple chemical substances over a lifetime. Variability can occur as a result of variations in individual day-to-day or event-to-event exposure factors or variations among the exposed population.

7.1.1 Exposure Assessment

To address the exposure assessment uncertainties, the following assumptions were made. In some cases, as noted below, conservative assumptions likely resulted in an overestimation of actual risk.

7.1.1.1 Inert Ingredient Information Quality

The HHRA evaluated information on inert ingredients to the extent that information was available. The quality and detail of information available on inert ingredients in pesticide products can be highly variable. Disclosure of inert ingredients is generally limited. In instances where inert ingredients were not disclosed and/or no information was available to estimate risk, the extent of risk, if any, remains unknown.

In some cases, such as the evaluation of polybutene, existing data suggests that despite vast chain length possibilities or forms in the pesticide product (i.e., Acelepryn G), some characteristics can be generalized so that risk can be estimated. The exact molecular weight and form of some polymers cannot be determined, and as such, despite erring on the side of caution (e.g., assuming a chemical does not degrade in the environment through any means), its actual behavior is unknown.

7.1.1.2 Drinking Water

Pesticide EECs in drinking water were derived from USEPA's (2020c) PWC model. Assumptions used for modeling and regarding drinking water ingestion which resulted in uncertainty are discussed below. Refer to Section 1.15.1.3.7 for information on the noted limitations of PWC.

For the urban/residential application scenarios assessed, the application area was defined as a 50-acre area representing the entire area within the prescribed 200-meter distance from a Japanese beetle find. Treatments would be applied to turf and groundcover (i.e., beetle habitat) only. Within an application area, many features would not be treated such as sidewalks, roadways, and buildings. Following the approach used in previous PEIR Addenda, it was assumed approximately one-third of the entire area was treated. Since it is not possible to know the exact proportion of area that is comprised of beetle habitat within the 50-acre application area, assuming one-third of the area is treated adds uncertainty.

For surface water-sourced drinking water, the upper 90th ranked peak EEC generated by PWC was used for acute and subchronic exposure assessment, while the upper 90th ranked 90-day average EEC was used for chronic exposure assessment. By conservatively using the peak EEC in lieu of the 21-day, 60-day, or 90-day average EEC for subchronic assessment and the 90-day average EEC in lieu of the 365-day average EEC for chronic assessment, exposures for these durations, and resulting risk estimates, were likely overestimated.

For groundwater-sourced drinking water, 100-year peak EECs generated by PWC were conservatively used to assess risk for all exposure durations (i.e., acute, subchronic, and chronic exposures). As a result, exposure and risk estimates for subchronic and/or chronic assessments may be overestimated.

Individuals were conservatively assumed to consume exclusively from surface and groundwater sources impacted by the Proposed Program. Additionally, aggregated risk estimates included the MOE from both surface and groundwater with no reduction of the 95th percentile drinking water consumption each pathway assumes. Therefore, exposure estimates associated with ingestion of impacted drinking water are likely overestimated.

7.1.1.3 Model Limitations

When empirical data were not available, models are often utilized to derive environmental media concentrations and exposure values in the HHRA. To overcome the innate limitations of environmental modeling, various assumptions were made based on professional judgment. When assumptions were necessary, conservative assumptions (i.e., ones that resulted in the highest exposure estimate) were made.

When modeling environmental exposure, key transport properties may not account for dilution and partial transfer between media such as plants, soil, water, and air. Therefore, most of the EECs represent an upper-bound, conservatively high value since not all fate and transport are properties are known or have been modeled.

Limitations of each model are presented below.

7.1.1.3.1 USEPA Occupational Pesticide Handler Exposure Data (OPHED)

OPHED required the user to select from the given combinations of application techniques, settings, and Personal Protective Equipment (PPE). When a requested application scenario did

not match any of the OPHED choices, the most suitable surrogate was chosen based on professional judgment. Most studies used to derive the OPHED unit exposures were unavailable.

As a first-tier approach, unit exposures as presented in the OPHED surrogate table are used for the purposes of assessing risk to mixer-loader-applicators. The data found in this table are derived from studies that, in certain circumstances, are not readily comparable to application scenarios evaluated in this HHRA. When the studies and their details are available, the unit exposures may be refined to better represent CDFA activities under the Proposed Program. Methods associated with refinement of UEs as found in this report are discussed in Appendix B.

7.1.1.3.2 Briggs Equation

The Briggs equation was used to estimate active and inert ingredient and adjuvant concentration in vegetation. It allows for the calculation of expected tissue concentrations due to active and inert ingredient and adjuvant uptake from soil residues for plants. The Briggs equation utilizes the chemical's K_{ow} and a simple soil model to estimate active and inert ingredient and adjuvant concentrations taken up in vegetation.

The soil properties selected for each application scenario are based on USEPA-generated PRZM inputs. The assumptions associated with specific soil properties are based on a soil profile that may not reflect all potential application site conditions.

7.1.1.3.3 AgDRIFT

For this HHRA, most of the default values in the AgDRIFT model were left unchanged from the Statewide PEIR. AgDRIFT makes assumptions for a variety of parameters associated with application methods and meteorological data that may not match site specific conditions and may lead to over- or under-estimation of actual off-site drift.

7.1.1.3.4 EpiSUITE

Inert ingredients are often identified by a singular CAS #. However, despite a singular CAS#, single or multiple chemicals may be associated with this CAS#. In the case of butene, homopolymer (CAS #: 9003-29-6), certain assumed PCF values (i.e., the vapor pressure, Koc, and log Kow) reported through the USEPA (2010u) derived the reported fate information from EpiSUITE (USEPA, 2012r; 2017h). Entry of the CAS # associated with polybutene in EpiSUITE assumes a 36 carbon entity. It cannot be determined if these parameters are linked to the specific homopolymer in Acelepryn G. However, given structural considerations, this information was selected as representative of how polybutene may act in the environment.

7.1.1.3.5 USEPA Standard Operating Procedures for Residential Exposure Assessments (SOP)

USEPA's Residential SOPs are more reliable for estimating acute exposure than continuous exposure. The user is limited to the application settings, exposure pathways, and activity patterns provided in the SOP so a surrogate had to be chosen if the requested application and exposure options were not available. Using conservative surrogates, such as USEPA's Exposure Factors Handbook (EFH), provided more confidence that the resulting exposure tended toward an over-estimate compared to actual exposure.

7.1.1.3.6 USEPA Risk Assessment Guidance for Superfunds (RAGS)

RAGS methodology is most commonly used to estimate continuous exposure, but in some cases (e.g., ingestion of vegetation, dermal exposure to soil), it was used for acute exposure assessments due to lack of appropriate alternative methodology.

7.1.1.3.7 Pesticide in Water Calculator (PWC)

The EECs used for estimating risk due to ingestion of drinking water from impacted surface and groundwater sources rely on modeling data from USEPA's (2020c) PWC model. There are inherent limitations associated with environmental modeling, including those discussed here. For more information on the limitations of PWC, see the Ecological Risk Assessment.

Surface water

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 waterbodies 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 5.26-ha (13-acre) reservoir. In reality, a wide variety of waterbodies could be adjacent to application sites. Estimated concentrations from PWC would be low for waterbodies that are smaller and shallower than the modeled waterbody. However, where water bodies were larger, the estimates were likely greatly exaggerated.

Groundwater

No California-specific groundwater scenarios were available for use with PWC. The soil profile used for groundwater assessment (i.e., Tifton loamy sand) was based on soil data from Cook and Colquitt Counties in Georgia, where peanuts, cotton, and pecans are commonly grown (USEPA, 2020e). Because groundwater scenarios were designed to represent vulnerable groundwater sources and are more sand-dominant than the California-based soil profiles used for surface water assessment, impacts to groundwater quality and resulting human health risks are likely exaggerated and may not accurately reflect actual California conditions.

The modeled depth to groundwater of 65.8 feet may result in over- or underestimated EECs in areas with groundwater-derived drinking water that occurs at greater or lesser depths, respectively. In addition, it is unlikely that drinkable groundwater occurs at a depth of 0.01 feet. Inclusion of all CASGEM groundwater depth data greater than or equal to 0.01 feet likely underestimates the actual depths of aquifers used for drinking water and overestimates the concentration of chemical in water.

Groundwater concentrations were based on what would occur in an aquifer with a vertical thickness of 1 meter (3.3 feet). In reality, aquifers of a variety of thickness likely occur beneath Program application sites. Therefore, groundwater EECs and associated risk estimates may be over- or underestimated based on site-specific conditions.

7.1.2 Toxicity Assessment

To address the toxicity assessment uncertainties, the following assumptions were made. In some cases, as noted below, conservative assumptions likely resulted in an over-estimate of actual risk.

7.1.2.1 Toxicological Endpoints

The toxicity assessment evaluated non-cancerous adverse effects that were derived from animal data observed in controlled experiments. Uncertainty associated with experimental animal NOAELs extrapolated for human exposure were addressed through use of the uncertainty factors which were used to determine the level of concern. The uncertainty factors for inter-species extrapolation and intra-species variation were accounted for through the use of two 10x uncertainty factors and an additional uncertainty factor of 3 was applied to the level of concern for sensitive individuals who may be more sensitivity to adverse effects (OEHHA, 2001c, 2008a). Therefore, the higher level of concern of 300 was used to be consistent with a recent OEHHA (2020a) analysis.

There exists uncertainty in using a "freestanding NOAEL" (i.e., a point of departure that has no adverse effect associated with it, but instead is the maximum dose tested without adverse effects). Use of freestanding NOAELs is generally considered health protective as no adverse health effects are observed even at the typically high doses used in toxicity tests. There also exists uncertainty in the use of an oral endpoint for dermal and inhalation exposure pathways. Differences in metabolism and susceptibility at different sites influence the dose of a chemical that interacts at the receptor level, as well as whether the adverse effect(s) are local or systemic.

7.1.2.2 Endocrine Disruptors

Endocrine disruptors are chemicals or mixtures of chemicals that may interfere with the body's endocrine system and produce developmental, teratogenic, reproductive, neurological, and immune effects in both humans and wildlife (NIEHS, 2010a). Although endocrine disruptors are generally considered to have the potential to cause adverse effects, uncertainty exists regarding the relationship between endocrine disruptor exposure and adverse health outcomes. In many cases, only screening-level data are available, which may or may not address the potential for a chemical to interact with the endocrine system in a way that could produce an adverse effect (USEPA, 2011v). In general, these and other forms of endocrine disruptor data are not sufficient for conducting a risk assessment. Due to this uncertainty, endocrine disruption effects were not specifically evaluated in this risk assessment.

7.1.2.3 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 HHRA produce synergistic effects. Although methodologies were available for assessing synergism, no usable endpoints were available in the literature to evaluate synergistic relationships between and within active and inert ingredients analyzed in this HHRA. Therefore, synergistic effects could not be evaluated in this risk assessment.

7.1.3 Risk Characterization

Due to the lack of available data, MOEs could not be estimated for all chemicals. Therefore, risk results for the assessed scenarios reflect only the potential risk attributed for chemicals (i.e., chlorantraniliprole) for which sufficient data was available to calculate MOEs. In the case of polybutene, while environmental exposure estimates could be made conservatively assuming no environmental degradation, no NOAEL was identified to calculate MOEs.

In situations where multiple pathways are present, multiple exposures occur. An MOE was estimated for each active or inert ingredient individually for each individual exposure route and the MOEs were summed regardless of mode of action or target organs and systems to conservatively estimate the risk that may be associated with the combined exposure.

7.2 Conclusions

This HHRA was conducted to assess the potential health risk to humans from implementation of Proposed Program. The HHRA was conducted using procedures and methodologies commonly accepted and used by government agencies such as USEPA, DPR, and OEHHA, as well as the wider risk assessment profession. The HHRA relied upon the four-stage process for risk assessments: hazard identification, toxicity dose response assessment, exposure assessment, and risk characterization. In the hazard identification phase, the chemicals used, their application methods and rates, and other pertinent information was gathered. The toxicity dose-response assessment phase selected health-protective values for acute, subchronic, and chronic non-cancer health effects. Cancer slope factors (CSFs) do not exist because the available data indicate that the pesticide active and inert ingredients assessed are not known to be carcinogenic. Therefore, cancer risk was not assessed. Non-cancer health effects were based on NOAELs obtained from toxicity studies. In the exposure assessment phase, the ADD, SADD, and AADD for potentially exposed populations were estimated using various models accounting for concentration of pesticide active and inert ingredients in various environmental media and subsequent exposure of human receptors. The risk characterization phase provided a quantitative assessment of the potential for adverse effects to receptors.

For each of the application scenarios analyzed for the Proposed Program, the calculated MOE was greater than the LOC value of 300. Specifically, individual MOE values calculated for this HHRA ranged from approximately 7.25E+03 to greater than 3.25E+10. This indicates that exposure to pesticide active and inert ingredients as a result of Proposed Program activities is unlikely to result in adverse impacts to human health.

This HHRA, along with the Statewide PEIR, will be used to assist CDFA in assessing potential impacts to human health. This HHRA did not identify any new significant human health impacts or any substantial increase 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 scenarios presented in this HHRA were required.

8 References

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.

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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9 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.

10Introduction

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.

7.3 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.

7.4 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 Kalculator (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 (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.

11 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).

7.5 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!® 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.

7.6 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 (≥90% to ≤100%) and polybutene (≥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.

7.6.1 Chorantraniliprole (CAS #: 500008-45-7)

Chlorantraniliprole is a diamide insecticide that 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.

7.6.2 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).

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

Dolomite ($CaMg(CO_3)_2$ 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.

7.6.4 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.

7.6.5 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).

7.7 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_{50}).

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.

7.7.1 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.

7.7.2 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_{50}, ED_{50}, LC_{50}, or EC_{50}). 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).

7.8 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.

7.9 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).

7.9.1 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.

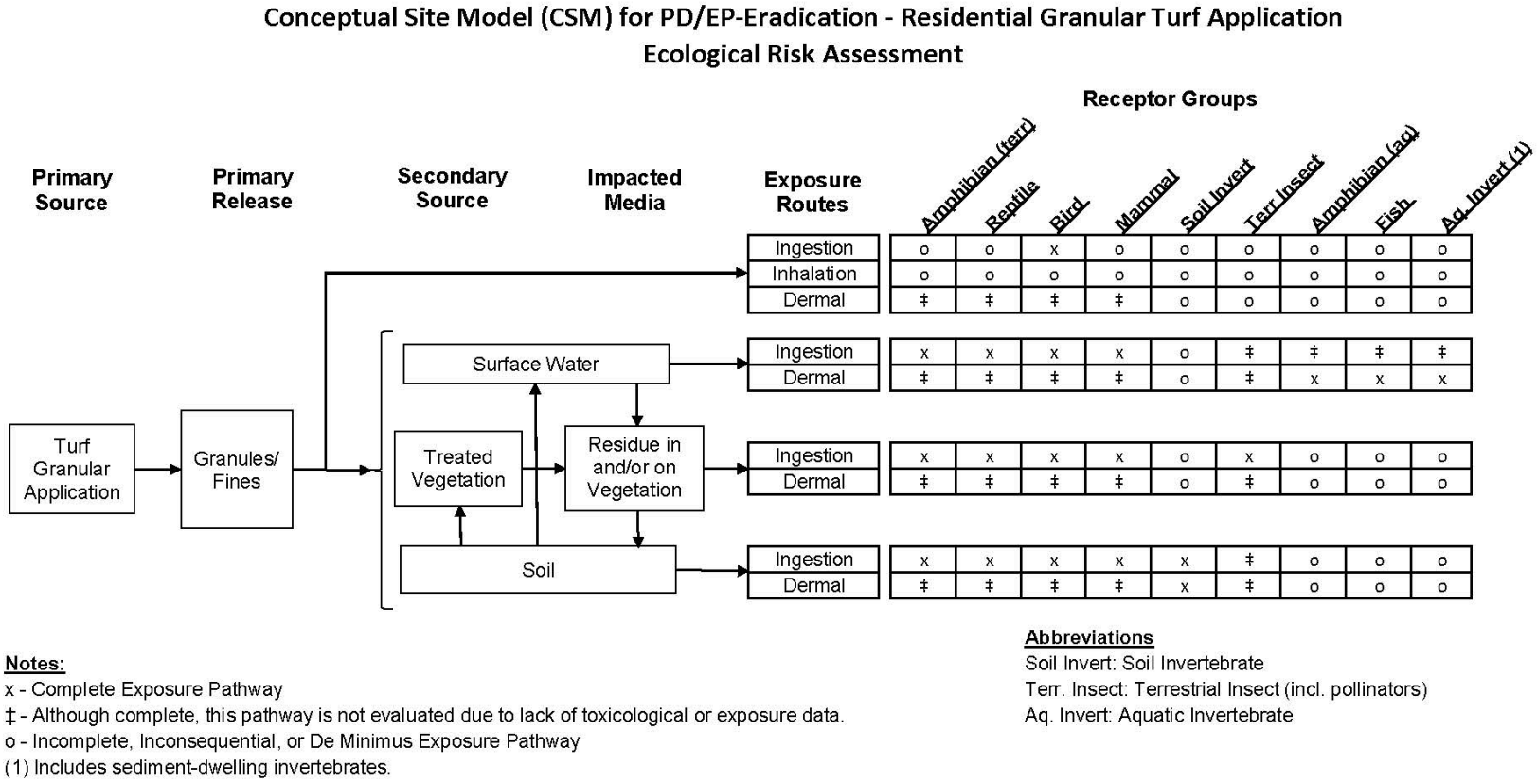

Figure Eco-1. Conceptual Site Model for residential granular applications to turf that may be made as part of CDFA's Pest Detection/Emergency Programs.

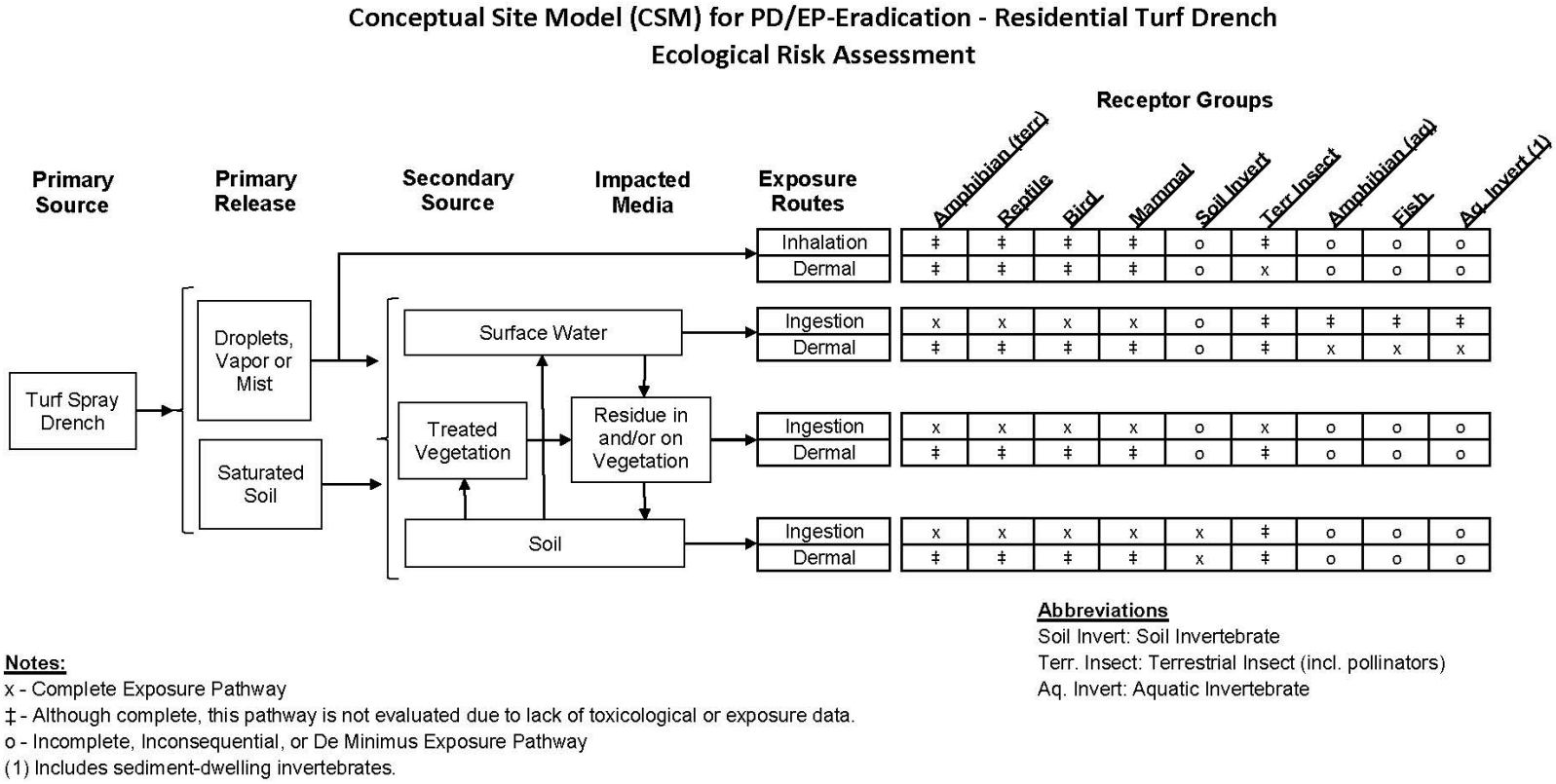

Figure Eco-2. Conceptual Site Model for residential spray drench applications to turf that may be made as part of CDFA's Pest Detection/Emergency Programs.

7.10 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.

12Exposure 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.

7.11 Acute and Chronic Exposure

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

7.12 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.

7.12.1 Concentration in/on Vegetation

7.12.1.1 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:

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

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:

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

Where:

VUF = Vegetation uptake factor
K_{ow} = Octanol/Water Partition Coefficient (unitless)
ρ = soil bulk density (g/cm^3)
θ = soil-water content by volume (cm^3/cm^3)
K_{oc} = soil organic carbon-water partitioning coefficient (cm^3/g-organic carbon or L/kg-organic carbon)
f_{oc} = fraction of organic carbon in the soil

The values of ρ, θ, 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.

$$EEC = VUF \times Soil\ Concentration$$

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.

7.12.1.2 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**.**

7.12.2 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 1st 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.

7.12.3 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.

7.12.4 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.

7.12.4.1 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.

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.

7.12.5 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.

7.12.6 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.

7.12.7 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.

7.13 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.

7.13.1 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.

13Effects 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_{50} (mg/kg)	Aquatic Organisms: Acute LC_{50} (ppm)	Wild Mammals: Acute Oral LD_{50} (mg/kg)	Non-Target Insects: Acute LD_{50} (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

o 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.

o 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.

o 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.

- *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.

14Risk 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).

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

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.

7.14 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.

7.15 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*.

7.16 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.

7.17 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.

7.17.1 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 is 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.

7.17.2 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.

7.17.3 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.

7.17.4 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.

7.17.5 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.

7.17.6 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.

7.17.7 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.

7.17.8 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	***0.83***	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	**3.48**	**3.47**
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	***0.63***	***0.63***
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)	**1.12**	**1.12**
honey bee-adult (oral)	0.22	0.22
Blennosperma vernal pool andrenid bee (contact)	**1.12**	**1.12**
Blennosperma vernal pool andrenid bee (oral)	0.22	0.22
San Joaquin tiger beetle (contact)	**1.12**	**1.12**

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	**8.47**	**8.47**
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	**18.83**	**18.82**
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	**10.13**	**10.13**
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 (Chorantraniliprole) 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	**8.47**	**8.47**
western pond turtle	0.06	0.06
tricolored blackbird	0.00	0.00
fulvous whistling-duck	**52.23**	**52.21**
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	**18.83**	**18.82**
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	**10.13**	**10.13**
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	**8.47**	**8.47**
aquatic western spadefoot	0.01	0.00
vernal pool fairy shrimp	***0.70***	0.00
Tomales isopod	**1.95**	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	**104.20**	**104.16**
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	**18.83**	**18.82**
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	**1.71**	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	**1.71**	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	**10.13**	**10.13**
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

7.18 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.

7.18.1 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.

7.18.1.1 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.

7.18.1.2 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.

7.18.2 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.

7.18.3 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_{50} was greater than 100 mg/L. Although USEPA (2017f) bases toxicity categories on acute test results, the 21-day EC_{50} 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_{50} 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_{50} > 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.

7.18.4 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 µL/L and oral LC_{50} > 2.5 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 µL/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 x 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 x 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.

7.18.5 Risk to Reptiles

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

7.18.6 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 (*Falcipennis 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.

7.18.7 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.

7.18.8 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.

7.18.9 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, 2013l). No sustained adverse effects are anticipated for populations of adult ladybird beetles (*Hippodamia convergens*) (USEPA, 2013l). 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, 2013l).

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, 2013l). 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 fervidaria*), 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, 2013l). 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, 2013l). 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 eradiation of Japanese beetles.

7.19 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.

7.19.1 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.

7.19.2 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.

7.19.3 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.

7.19.4 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.

7.19.5 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.

7.19.6 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.

7.19.7 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.

7.19.8 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 eradiation of Japanese beetles.

15Uncertainties

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.

7.20 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.

7.20.1 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.

7.20.2 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.

7.20.3 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.

7.20.4 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.

7.20.5 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.

7.21 Effects Assessment Uncertainties

7.21.1 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.

7.21.2 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).

7.21.3 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.

7.21.4 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.

16Conclusions

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.

17Literature

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.