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Final Human Health and Ecological Risk Assessment for Chlorantraniliprole Rangeland Grasshopper and Mormon Cricket Suppression Applications

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EXECUTIVE SUMMARY

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) is proposing the use of the insecticide chlorantraniliprole in its cooperative rangeland grasshopper and Mormon cricket suppression program. The proposed formulation, Prevathon®, is a suspension concentrate that can be applied by ground-based equipment or aerially at reduced rates compared to the current labelled rates of chlorantraniliprole for grasshopper control.

USDA-APHIS evaluated the potential human health and ecological risks from the proposed use of chlorantraniliprole in this assessment and determined that the risks to human health and the environment are low. The low mammalian toxicity and low probability of exposure to humans indicate the insecticide is a low risk to human health. In mammals, chlorantraniliprole has very low acute oral, dermal, and inhalation toxicity, and low chronic toxicity. Adherence to label requirements and additional program measures designed to reduce exposure to workers and the public result in low risk to all population segments. The risk of chlorantraniliprole to most nontarget fish and wildlife species is also low. Chlorantraniliprole has low toxicity and risk to terrestrial and aquatic vertebrates. Chlorantraniliprole is toxic to some aquatic invertebrates; however, program measures and the low application rates reduce the risk to all aquatic fauna. Chlorantraniliprole has low toxicity and risk to several groups of nontarget terrestrial invertebrates, including pollinators such as honey bees. The impacts of chlorantraniliprole to sensitive nontarget terrestrial invertebrates will be greatest for those insect groups that feed on treated vegetation. The risk to sensitive terrestrial invertebrates will be minimized due to program measures such as applying it only once per season, and the use of lower application rates and reduced area agent treatments.

1.0 INTRODUCTION

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) proposes the use of chlorantraniliprole in its rangeland grasshopper and Mormon cricket suppression program. This human health and ecological risk assessment (HHERA) provides a qualitative and quantitative evaluation of the potential risks and hazards to human health, nontarget fish, and wildlife as a result of exposure to chlorantraniliprole. The Program would apply the insecticide using ultra-low volume aerial or ground applications to suppress populations of rangeland grasshopper species, such as migratory grasshopper, valley grasshopper, bigheaded grasshopper, clearwinged grasshopper, and Mormon cricket. Chlorantraniliprole is an anthranilic diamide insecticide with a common mechanism of toxicity that interrupts normal muscle contraction.

The methods used to assess potential human health effects follow standard regulatory guidance and methodologies (NRC, 1983; USEPA, 2016a), and generally conform to those methods used by other Federal agencies, such as the U.S. Environmental Protection Agency, Office of Pesticide Programs (USEPA/OPP). The methods used to assess potential ecological risk to nontarget fish and wildlife follow USEPA and other published methodologies regarding eco-risk assessment, with an emphasis on those used by USEPA/OPP in the pesticide registration process.

The risk assessment is divided into four sections beginning with the problem formulation (identifying hazard), a toxicity assessment (the dose-response assessment), and an exposure assessment (identifying potentially exposed populations and determining potential exposure pathways for these populations). In the fourth section (risk characterization), the information from the exposure and toxicity assessments is integrated to characterize the risk of chlorantraniliprole applications to human health and the environment.

2.0 PROBLEM FORMULATION

Grasshoppers and Mormon crickets are closely related insects that belong to the Order Orthoptera. Nearly 400 grasshopper species inhabit the 17 western States involved in USDA-APHIS grasshopper program, but only a small percentage are pest species. Anywhere from 15 to 45 species of grasshoppers can be found in a particular rangeland ecosystem, and economic damage can occur when grasshopper populations exceed population thresholds.

Mormon crickets (*Anabrus simplex*) are flightless, shield-backed katydids. Although they do not fly, Mormon crickets are highly mobile and capable of migrating great distances. They move by walking or jumping, and may devour much of the forage in their path.

These insects damage grasses and other vegetation by consuming plant stems and leaves. Their feeding causes direct damage to plants' growth and seed production, thus reducing valuable livestock forage. In addition, the damage they cause to plants may result in soil erosion and degradation, disruption of nutrient cycles, interference with water filtration, and potentially irreversible changes in the flora and fauna of the rangeland ecosystem. In addition, some populations that develop on rangelands can invade adjacent cropland where the value of crop plants is much higher than rangeland grasses (USDA APHIS, 2015).

Chlorantraniliprole is a recently introduced insecticide in the anthranilic diamide class. The mode of action for this class of insecticides is the interruption of normal muscle contractions by activating insect ryanodine receptors (USEPA, 2008). The activation of ryanodine receptors causes an uncontrolled release of calcium from smooth and striated muscles that impair muscle regulation and cause paralysis and eventual death in insects. Although ryanodine receptors occur in mammals, the insecticide is very selective to insect ryanodine receptors (Lahm et al., 2007). Primary activity of chlorantraniliprole is through ingestion with some contact toxicity against Lepidopteran pests but also against Orthoptera, Coleoptera, Diptera, and Hemiptera pests (Hannig et al., 2009).

Registered uses of chlorantraniliprole include agricultural crops (pome fruit, stone fruit, grapes, leafy vegetables, Brassica leafy vegetables, cucurbit vegetables, fruiting vegetables, potatoes, cotton, rice, oilseeds, soybean, teff, and quinoa), and ornamentals and turf grass growing in residential, commercial, and public landscaped areas to control insects such as moths, beetles, and caterpillars (USEPA, 2008, 2012, 2016c).

The following sections discuss the Chemical Description and Product Use; Physical and Chemical Properties; Environmental Fate; and Hazard Identification for chlorantraniliprole.

2.1 Chemical Description and Product Use

Chlorantraniliprole (CAS No. 500008-45-7, $C_{18}H_{14}N_5O_2BrCl_2$) is the common name of the chemical 3-Bromo-N-[4-chloro-2-methyl-6-(methylcarbamoyl) phenyl]-1-(3-chloro-2-pyridine-2-yl)-1H-pyrazole-5-carboxamide. The chemical structure is illustrated in figure 2-1.

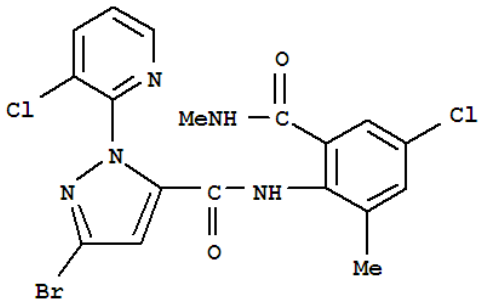

Figure 2-1 The chemical structure of chlorantraniliprole

First registered with USEPA in 2008, the technical formulation (DuPont Rynaxypyr Technical, EPA Reg. No. 352-728) has 95.3% chlorantraniliprole as the active ingredient (a.i.) (USEPA, 2008). The formulation proposed in the USDA-APHIS grasshopper program is Prevathon® (EPA Reg. No. 352-844) (USDA APHIS, 2015) which can be applied using air or ground equipment. Registered in 2011, Prevathon® is a suspension concentrate of 5.0% chlorantraniliprole and 95.0% other ingredients by weight, containing 0.43 pounds (lbs) chlorantraniliprole per gallon (DuPont, 2014). The labelled application rates are 0.027 to 0.067 lb a.i. per acre or 8 to 20 fluid ounces (fl oz) per acre, with methylated seed oil added as an adjuvant for foliar sprays at 1 gallon per 100 gallons of spray volume (1% v/v). The program uses application rates of 0.02 lb a.i. per acre for conventional treatment (4 fl oz Prevathon® with 0.32 fl oz methylated seed oil and water up to a total volume of 32 fl oz per acre) and 0.013 lb a.i. per acre (2 fl oz Prevathon® with 0.32 fl oz methylated seed oil and water up to a total volume of 32 fl oz per acre) for reduced agent area treatments (RAATs). The Prevathon® formulation has some contact activity against insects, but is most effective through ingestion of treated plant material by 2nd and 3rd instar nymphs. After exposure to Prevathon®, insects will cease feeding, become paralyzed, and typically die within 1 to 3 days (DuPont, 2014).

2.2 Physical and Chemical Properties

Chlorantraniliprole is a fine crystalline powder without any odor. It has a melting point of 208 to 210 degrees Celsius (ºC) and a vapor pressure of 1.57×10^{-13} torr. The Henry's Law constant for chlorantraniliprole is 3.1×10^{-15} atm-m^3/mol, and the average values for the soil organic carbon-water partition coefficient (K_{oc}) range between 153 liters/gram (L/g) (loam sand) and 526 L/g (loamy sand). Chlorantraniliprole has low water solubility (1.023 milligrams/L (mg/L)), but is highly soluble in some solvents (such as dimethylformamide (124 g/L) and acetone (3.446 g/L))

(USEPA, 2008). The Prevathon® formulation is a white, semi-viscous liquid with a mild alcohol-like odor. Its specific gravity (relative density) ranges between 1.02 and 1.04 (DuPont, 2015).

2.3 Environmental Fate

The environmental fate describes the processes by which chlorantraniliprole moves and is transformed in the environment. The environmental fate processes include: 1) persistence and degradation, 2) mobility and migration potential to groundwater and surface water, and 3) plant uptake.

Chlorantraniliprole can be persistent and mobile in terrestrial and aquatic environments. It is stable in aerobic soil incubated at 25 ^{o}C with a half-life ranging between 228 to 924.1 days. The half-lives in dissipation studies on bare ground plots ranged between 52 days in California to 1,130 days in Georgia. Chlorantraniliprole is expected to be mobile in soil and the aqueous environment based on its K_{oc} values and can dissipate by leaching into groundwater and runoff to surface water. The estimated aqueous photolysis half-life for chlorantraniliprole is 32.8 days. The aerobic aquatic metabolism half-life ranges from 125 to 231 days with an anaerobic aquatic metabolism half-life of 208 days. The photodegradation half-lives of chlorantraniliprole in a water-sediment system were 22 days in loamy sand sediment and 9.9 days in sandy loam sediment. Chlorantraniliprole is stable to hydrolytic degradation in pH 5 and 7 buffer solutions. Chlorantraniliprole mainly dissipates through alkaline-catalyzed hydrolysis, leaching, and runoff. Chlorantraniliprole is unlikely to volatilize to air because of its low vapor pressure (USEPA, 2008, 2011, 2012).

The environmental fate studies including hydrolysis, photodegradation in water, soil, water, and sediment metabolism identified nine degradates: IN-EQW78, IN-LBA22, IN-LBA24, IN-LBA23, IN-ECD73, IN-F6L99, IN-EVK64, IN-F9N04, and IN-GAZ70. IN-LBA24 was the greatest percentage production with 90% of applied parent produced in the photolysis study at pH 7 (USEPA, 2008).

Available data indicate that chlorantraniliprole residues do not persist on vegetation. Dissipation half-life values were typically less than 4 days on various crops (Kar et al., 2013; Malhat et al., 2012); but may persist for longer periods of time (DT_{50} = 17 days) on other crops (Szpyrka et al., 2017). A dislodgeable foliar residue study for chlorantraniliprole reported a maximum half-life of 30 days on foliage. The bioaccumulation for chlorantraniliprole is unlikely based on its low octanol/water partitioning coefficient (log Kow =2.90) (USEPA, 2008).

2.4 Hazard Identification

Chlorantraniliprole is not acutely toxic to mammals. It has no adverse short-term effects. The non-adverse effects from short-term toxicity studies included induction of liver enzymes and subsequent increase in liver weights, and increased microvesiculation of the adrenal cortex in male rats without adrenal cellular degeneration or toxicity (USEPA, 2012). Chlorantraniliprole is not neurotoxic, immunotoxic, carcinogenic, genotoxic, or a developmental toxicant (USEPA, 2012). Chlorantraniliprole demonstrates a lack of effects on maternal or fetal rats and rabbits in

oral exposure studies (USEPA, 2012). Adverse effects from an oral chronic study using the mouse include eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight (USEPA, 2012). The following sections summarize toxicity studies evaluating acute, subchronic, and chronic effects, as well as impacts to reproduction and development, the nervous, immune, and endocrine systems, and the potential for carcinogenicity and mutagenicity.

2.4.1 Metabolism

Chlorantraniliprole is rapidly absorbed in rats with peak concentrations occurring at 5 to 12 hours and is substantially excreted in 48 to 72 hours after oral administration of a single dose of either 10 or 200 mg/kilogram (kg) body weight (bw). The plasma elimination half-lives range from 38 to 82 hours. The absorbed dose was distributed extensively in tissues with low potential for accumulation. Chlorantraniliprole is eliminated primarily through feces, followed by urine excretion (USEPA, 2012).

2.4.2 Acute Toxicity

Technical chlorantraniliprole has very low acute toxicity (Category IV) via oral, dermal, and inhalation exposure routes (table 2-1) (USEPA, 2008). Comparisons to the formulated product (Prevathon®) (DuPont, 2015) show similar acute toxicity to the technical material (table 2-1). The Prevathon® formulation causes no irritation to eye and skin in rabbits, and causes no skin sensitization in the guinea pig.

Table 2-1. Comparative acute mammalian toxicity between technical and formulated chlorantraniliprole (Prevathon®).

Test	Technical	Prevathon®
Oral LD_{50}	>5,000 mg/kg	>5,000 mg/kg
Dermal LD_{50}	>5,000 mg/kg	>5,000 mg/kg
Inhalation LC_{50} (4 hours exposure)	>5.1 mg/L	>2.1 mg/L

LD_{50} or LC_{50}: the lethal dose or lethal concentration that causes death in 50 percent of the treated animals.

2.4.3 Subchronic Toxicity

Chlorantraniliprole has very low toxicity based on subchronic toxicity tests using the rat, mouse, or dog. The reported no observed adverse effect levels (NOAELs) from these studies are summarized in table 2-2 (USEPA, 2008).

Table 2-2. Subchronic mammalian toxicity values for chlorantraniliprole.

Toxicity Test/ Test Species	NOAEL (mg/kg/day)
14-day oral gavage/rat	1,000
28-day oral (feed)/rat	584 male / 675 female
28-day dermal/rat	1,000
28-day oral (feed)/mouse	1,443 male / 1,524 female
28-day oral (capsule)/dog	1,000
28-day oral (feed)/dog	1,302 male / 1,240 female
28-day oral (capsule)/dog	1,000
90-day oral (feed)/rat	1,188 male / 1,526 female
90-day oral (feed)/mouse	1,135 male / 1,529 female
90-day oral (feed)/dog	1,163 male / 1,220 female

The non-adverse effects observed from these studies include:

- weak induction of cytochrome P450 3A at all tested dose levels with statistical significance at 100 and 2,000 mg/kg/day (14-day oral study in rats),
- slight increase in liver weight at 128 and 675 mg/kg/day in females and minimal hepatocellular hypertrophy at 675 mg/kg/day due to increased amount of eosinophilic cytoplasm with hepatocytes (no histomorphologic evidence of hepatocellular damage), and a statically significant increase in uridine diphosphate glucuronosyltransferase activity in the highest dose tested (HDT) in female rats and males due to a pharmacological response (28-day oral study in rats),
- slight increase in liver weight of 658 and 1,524 mg/kg/day in female mice corresponding with a mild increase in cytochrome P450 enzyme activity (no histopathological evidence of liver toxicity), and a reduction in body weight gain in the HDT in males (no statistically significant decrease in absolute body weight) (28-day oral study in mice),
- induction of cytochrome P450 enzyme activity (28-day oral (capsule) study in dogs),
- slight increase in liver weight at the HDT in females and reduction in bilirubin in females at greater than or equal to (≥) 157 mg/kg/day, but no corresponding histopathological evidence of liver toxicity (90-day oral study in rats),
- slight increase in liver weight at the HDT in males and females, with no corresponding histopathological evidence of liver toxicity (90-day oral study in mice), and
- mild increase in liver weight in males at 1,163 mg/kg/day, with no corresponding histopathological evidence of liver toxicity (90-day oral study in dog).

2.4.4 Chronic Toxicity

Chlorantraniliprole had no adverse effects based on a 52-week oral study using dogs and a 2-year oral study with rats. The 52-week study observed non-adverse effects such as a mild increase in liver weight in the HDT in males and females. In HDT males at weeks 8 and 9, there was an increase in alkaline phosphatase with no corresponding histopathological evidence of liver toxicity, as well as an increase in body weight with an increase in food efficiency in week 9. The 2-year oral study using the rat observed increased adrenal cortical microvesiculation due to the presence of liquid in the zona fasciculata region of the adrenal gland of some male rats. The effect was related to the test substance, but not considered adverse because the adrenal morphology was in the range of what was observed in control rats, and the effect was not associated with any cytotoxicity or other evidence of structural or functional impairment of the adrenal gland. The NOAELs are summarized in table 2-3 (USEPA, 2008).

Table 2-3. Chronic mammalian toxicity values for chlorantraniliprole.

Toxicity Test/ Test Species	NOAEL (mg/kg/day)	LOAEL (mg/kg/day)
52-week oral (feed)/dog	1,164 males / 1,233 females	NE*
2-year oral (feed)/rat	805 males / 1,076 females	NE
18-month oral (feed)/mouse	158 males / 1,155 females	935 male / NE female

*NE- not established

An 18-month oral toxicity study using mice reported a NOAEL of 158 mg/kg/day (male) and 1,155 mg/kg/day (female), and a low observed adverse effect level (LOAEL) of 935 mg/kg/day in male rats based on eosinophilic foci accompanied by hepatocellular hypertrophy and increased liver weight (USEPA, 2008). USEPA used the NOAEL of 158 mg/kg/day from this study to derive a chronic oral reference dose (RfD) (see Section 3 for further discussion).

2.4.5 Nervous System Effects

Chlorantraniliprole is not neurotoxic based on acute and subchronic studies in rats. The acute oral gavage neurotoxicity study in rats (administered doses of 0, 200, 700, or 2,000 mg/kg/day in 0.5% methyl cellulose) reported a NOAEL of 2,000 mg/kg/day, and no evidence of neurotoxicity was observed at any dose tested. The subchronic oral neurotoxicity study in rats (administered doses of 0, 12.7, 64.2, 255, 1,313 mg/kg/day in male and 0, 15.1, 77.3, 304, 1,586 mg/kg/day in female) reported a NOAEL of 1,313 mg/kg/day in male and 1,586 mg/kg/day in female and no evidence of neurotoxicity was observed at any dose (USEPA, 2008).

The USEPA neurological assessment performed in conjunction with the 18-month oncogenicity study in mice also confirmed the lack of neurotoxicity. In addition, the short- or long-term exposure studies in rats, mice, and dogs observed no treatment-related clinical signs indicative of neurotoxicity (USEPA, 2012).

2.4.6 Reproductive and Developmental Effects

A two-generation reproduction study in rats using chlorantraniliprole did not find adverse effects on reproduction, fertility, sperm parameters, estrous cycle, litter size, pup survival, and histological findings indicative of reproductive toxicity. The study reported a NOAEL of 1,199 mg/kg/day (male) and 1,594 mg/kg/day (female). Effects reported in the study include a slight increase in mean liver weights in parent and F1 males and females at 238 and 318.9 mg/kg/day and above, and a slight increase in mean adrenal weights at 238 and 318.9 mg/kg/day in parents and 1,199 and 1,594 mg/kg/day in F1 males and females. Mean body weights of F1 pups (but not F2 pups) were slightly reduced at the highest dose level during lactation. There were minimal to mild increases in adrenal cortical microvesiculation in parent adult males and females (60.4 and 77.8 mg/kg/day and greater) and F1 adult males (12 mg/kg/day and greater). However, these effects were not seen in weanlings, and cytotoxicity or abnormal cellular structures were not observed under light or electron microscopy (USEPA, 2008).

Chlorantraniliprole developmental toxicity studies in rats and rabbits (administered doses of 0, 20, 100, 300, or 1,000 mg/kg/day) report no adverse effects on any parameter in pregnant females or their offspring with a reported NOAEL of 1,000 mg/kg/day (USEPA, 2008). There was no evidence of sensitivity/susceptibility in the development of young because there were no treatment-related effects on the numbers of litters, fetuses (live or dead), resorptions, sex ratio, or post-implantation loss, and no effects on fetal body weights, skeletal ossification, and external, visceral, or skeletal malformations or variations (USEPA, 2012).

2.4.7 Carcinogenicity and Mutagenicity

Chlorantraniliprole is not considered carcinogenic or mutagenic. Chlorantraniliprole has been classified as “Not Likely to be Carcinogenic to Humans” based on the following weight of evidence: 1) the submitted chronic and oncogenicity studies in rats and mice and the subchronic studies in mice, dogs, and rats reported no treatment-related tumors, and 2) the genotoxicity studies reported no mutagenic concerns (USEPA, 2008, 2013).

2.4.8 Immune System Effects

Chlorantraniliprole is not immunotoxic based on available toxicity data. The 28-day immunotoxicity study in rats (administered doses of 0, 74, 363, 1,494 mg/kg/day in males and 0, 82, 397, 1,601 mg/kg/day in females) reported no evidence of treatment-related effects on specific antibody (IgM) responses of sheep red blood cells in male or female rats at any dietary concentration tested. The NOAEL of 1,494 mg/kg/day (male) and 1,601 mg/kg/day (female) was the highest dose tested (USEPA, 2008).

The 28-day immunotoxicity study in mice (administered doses of 0, 48, 264, 1,144 mg/kg/day in male and 0, 64, 362, 1,566 mg/kg/day in female) reported no evidence of treatment-related effects on the specific antibody (IgM) responses of sheep red blood cells in either male or female

mice at any dietary concentration tested. The NOAEL of 1,144 mg/kg/day (male) and 1,566 mg/kg/day (female) was the highest dose tested (USEPA, 2008).

2.4.9 Endocrine System Effects

Under the USEPA Endocrine Disruptor Screening Program (USEPA, 2016b), chlorantraniliprole has not been evaluated for potential endocrine system effects. A literature search did not find endocrine system effects on chlorantraniliprole.

2.4.10 Toxicity of Other Ingredients and Metabolites

Approximately 95% of the Prevathon® formulation is other ingredients (DuPont, 2015). The DuPont safety data sheet (SDS) states that the formulation is not classified as a hazardous substance or mixture under the Occupational Safety and Health Administration Hazard Communication Standard with similar acute toxicity compared to the technical material. Comparative toxicity values between the technical a.i. and the proposed formulation show similar low toxicity in acute oral, dermal, and inhalation studies (table 2-1). Methylated seed oil added to the formulation is a spray adjuvant. Methyl and ethyl esters of fatty acids produced from edible fats and oils are considered food grade additives by the U.S. Food and Drug Administration (CFR 172.225).

Degradates of chlorantraniliprole identified in environmental fate studies have lower toxic potency compared to the parent compound. One degradate, IN-LBA24, is orders of magnitude less toxic than the parent compound (USEPA, 2008).

2.4.11 Fire Hazards

Chlorantraniliprole is not considered flammable based on available data. Under the National Fire Protection Association rating system, the formulation has level 1 health risk. A level 1 health risk includes “materials that can cause irritation upon exposure, but only minor injury is sustained even if no medical treatment is provided”. Other hazards during a fire include smoke and fumes. Smoke is a complex mixture of gases and fine particles produced when wood and other organic materials burn. The largest health threat from smoke is from fine particles that are a common component of fire. These microscopic particles can penetrate deep into the lungs and can cause a range of health problems, from burning eyes and a runny nose to aggravated chronic heart and lung disease. Hazardous decomposition products of the formulation include carbon dioxide and nitrogen oxides (DuPont, 2015).

3.0 DOSE-RESPONSE ASSESSMENT

3.1 Human Health Dose-Response Assessment

A dose-response assessment evaluates the dose levels (toxicity criteria) for potential human health effects, including acute and chronic toxicity.

The USEPA/OPP did not establish an acute RfD for chlorantraniliprole because no acute hazard attributable to a single dose was identified (USEPA, 2012). USEPA did not select an incidental oral endpoint for quantitative risk assessment because no hazard value was identified via the oral route in short- and intermediate-exposures. USEPA did not select a dermal endpoint for a quantitative assessment because no hazard was identified via the dermal route, and no concerns for developmental, reproductive, or neurotoxic effects were observed. USEPA did not select an inhalation endpoint for quantitative assessment because of the lack of hazard identified in acute inhalation and irritation studies, and low oral toxicity (USEPA, 2012).

The USEPA/OPP derived a chronic RfD of 1.58 mg/kg/day for chronic dietary exposure for all populations (USEPA, 2013). The chronic RfD for chlorantraniliprole was developed by applying an uncertainty factor of 100 (10x for extrapolation from animal to human (interspecies), and 10x for potential variation in sensitivity among members of the human population (intraspecies)), and a Food Quality Protection Act Safety Factor of 1x to the NOAEL using 158 mg/kg/day from an 18-month oral (feeding) study in mice (USEPA, 2013). Chlorantraniliprole is classified as "Not likely to be Carcinogenic to Humans," so a cancer potency factor was not derived for risk estimates.

The USEPA has established tolerances for chlorantraniliprole from the application of the insecticide to growing crops and for livestock and poultry that may feed on treated forage (40 CFR 180.628). The tolerance levels are 90 parts per million (ppm) for non-grass forage animal feed, grass forage, fodder, and hay, and 25 ppm for non-grass hay animal feed. The tolerance levels are 0.1 ppm for meat (cattle, goat, and sheep) and milk, and 0.5 ppm for fat and meat by-products.

3.2 Ecological Dose-Response Assessment

3.2.1 Wild Mammal, Avian and Reptile Toxicity

The acute and chronic toxicity of chlorantraniliprole to wild mammals is summarized in section 2.4 of this risk assessment that discusses mammalian toxicity data as a surrogate for potential human-related effects. In summary, chlorantraniliprole is expected to have low acute and chronic toxicity to wild mammals based on the available data.

The acute toxicity of chlorantraniliprole to birds is also very low with no acute lethal or sublethal effects noted at all doses in oral gavage or dietary studies (table 3-1). Chronic toxicity was also low in 22-week exposure studies used to evaluate reproductive impacts. The No Observable

Effect Concentration (NOEC) was reported as 120 and 250 ppm, respectively, for the bobwhite quail and mallard.

Table 3-1. Toxicity of chlorantraniliprole to select avian species.

Test Species/Duration	LD_{50}/LC_{50} (mg/kg)	NOEL/LOEL (mg/kg)
Colinus virginianus, Bobwhite quail LD_{50}	>2,250	2,250/NR*
Bobwhite quail LC_{50}	>5,620	5,620/NR
Bobwhite quail chronic reproduction	NR	120/520
Anas platyrhynchos, Mallard LC_{50}	>5,620	5,620/NR
Mallard chronic reproduction	NR	250/500

*NR = Not reported

The lowest acute No Observable Effect Level (NOEL) value was selected (2,250 mg/kg) to estimate a range of sensitivities to birds based on different body weights and food consumption (table 3-2).

Table 3-2. Adjusted acute toxicity values for different sized birds.

Avian Class	Body Weight (g)	% Body Weight Consumed	Adjusted NOEL
Small	20	114	1,620.97
Mid	100	65	2,063.57
Large	1,000	29	2,914.87

The range of adjusted NOEL values can then be compared to the exposure values for the different food items and range of bird sizes to better characterize risk to a variety of birds species that could be exposed to treated food items if they were to forage in areas that were directly treated with chlorantraniliprole. The exposure and potential risk to wild mammals and birds is discussed in this document under 4.2.1 and 5.2.2.

3.2.2 Terrestrial Invertebrate Toxicity

Available laboratory toxicity data for technical and formulated chlorantraniliprole suggests that the product is practically non-toxic to honey bees in acute oral or contact exposures (EFSA, 2013; USEPA, 2008). In another laboratory study, the 48-hour median lethal concentration (LC_{50}) was reported as greater than 100 micrograms (µg) a.i./bee, classifying chlorantraniliprole as practically non-toxic to honey bees (Zhu et al., 2015). Smagghe et al. (2013) reported that contact and pollen exposure to chlorantraniliprole had no effect on bumble bee survival, but exposure to dosed sugar water resulted in a 72-hour LC_{50} of 13.0 mg/L and a 7-week LC_{50} value

of 7.0 mg/L. Gradish et al. (2010) reported no acute or sublethal impacts to the bumble bee, *Bombus impatiens*, at recommended application rates for pest control on vegetables in greenhouse applications. Semi-field studies with two different formulations reported NOECs ranging from 52.5 to 156.16 g a.i. chlorantraniliprole/hectare (ha) (Dinter et al., 2009; USEPA, 2008). Three semi-field honey bee tunnel tests demonstrated no behavioral or flight intensity effects, nor were any hive-related impacts noted at a dose of 52.5 g/ha (Dinter et al., 2009). A similar lack of effects was noted in the bumble bees *B. terrestris* and *B. impatiens*, at an application rate of 40 g chlorantraniliprole/ha. In a field study, no effects on honey bee foraging, colony health and queen production were noted at chlorantraniliprole application rates of 230 g a.i./ha (Larson et al., 2013). The lowest reported NOEC from these studies is approximately four times the proposed RAATs application rate for chlorantraniliprole and two times the proposed full rate. Similar NOECs reported for honey bees and bumble bees have also been observed for other invertebrates such as the hover fly *Episyrphus balteatus*, ladybird beetle larvae *Coccinella septempunctata*, green lacewing *Chrysoperla carnea*, the plant bug *Typhlodromus pyri*, and predatory mite *Orius laevigatus* (USEPA, 2008, 2012). The low toxicity to nontarget terrestrial invertebrates has also been observed in greenhouse and field applications. Gradish et al. (2011) reported low acute toxicity of formulated chlorantraniliprole to the parasitoid *Eretmocerus eremicus*, the pirate bug *Orius insidiosus*, and the predatory mite *Amblyseius swirskii*, in 48-hour exposures. Brugger et al. (2010) evaluated lethal and sublethal impacts of formulated chlorantraniliprole to seven parasitic hymenopterans and found no negative impacts on adult survival, percentage parasitism, or emergence when compared to controls at rates well above the full and RAATs program rates. Tome et al. (2015) observed low toxicity of a formulation of chlorantraniliprole to two native species of stingless bees, *Partamona helleri* and *Scaptotrigona xanthotrica*. The lack of toxicity in other insect groups at rates that are toxic to grasshoppers is related to the activity of chlorantraniliprole, which is primarily through ingestion. Insects such as grasshoppers and larval Coleoptera and Lepidoptera would receive a larger dose from consuming treated plant material compared to many of the nontarget pests that have been evaluated.

Chlorantraniliprole has low toxicity to most soil borne invertebrates, with the springtail being the most sensitive test species. Lavtižar et al. (2016) evaluated the chronic effects of chlorantraniliprole to the springtail (*Folsomia candida*) in 28-day exposures with estimated half median effective concentration (EC_{50}) values ranging from 0.16 to 0.76 mg/kg in various soil types. Similar studies using the isopod *Porcellio scaber*), the enchytraeid *Enchytraeus crypticus*, and oribatid mite *Oppia nitens* showed no sublethal effects at concentrations of 1,000 mg/kg. Other soil borne invertebrates, such as earthworms, have low sensitivity to chlorantraniliprole in acute and chronic exposures with NOEC and EC_{50} values, at, or greater than 1,000 mg/kg (EFSA, 2013).

3.2.3 Terrestrial Plant Toxicity

Terrestrial plant nontarget testing using a 20% soluble concentrate formulation of chlorantraniliprole demonstrates low toxicity in seedling emergence and vegetative vigor studies (USEPA, 2008). Estimated EC_{25} values were greater than 300 g/ha, which is several times greater than the full and RAATs rates used in the program. The terrestrial plant species that were

tested are required by USEPA for pesticide registration and represent monocots and dicots of various agricultural crops.

3.2.4 Aquatic Toxicity

Chlorantraniliprole toxicity to fish is considered low based on available toxicity data that reports lethality occurring above solubility. Longer-term exposures show that sublethal impacts may occur at concentrations exceeding 0.11 mg/L (table 3-3) (Bantu et al., 2013; USEPA, 2012).

Table 3-3. Acute and chronic toxicity of chlorantraniliprole to fish.

Test Species/ Duration	**LC_{50}/EC_{50} (mg/L)**	**NOEC/LOEC (mg/L)**
Acute Tests		
96-hour LC_{50} *Lepomis macrochirus*, Bluegill sunfish	>15.1	NR/NR**
96-hour LC_{50} *Oncorhynchus mykiss*, Rainbow trout	>13.8	NR/NR
96-hour LC_{50} *Labeo rohita*, Rohu	12.7	NR/NR
96-hour LC_{50} *Cyprinodon variegatus*, Sheepshead minnow	>12.0	12.0/NR
Subchronic Tests		
Rainbow trout 31-day ELS*	NR	0.11/NR
Sheepshead minnow 35-day ELS	NR	1.28/NR

*ELS = Early life stage study; **NR = Not reported

Amphibian toxicity data for chlorantraniliprole appears to be limited to one study based on an online search of available data. Wei et al. (2014) reported a 24- and 72-hour LC_{50} of 5.37 and 4.68 mg/L, respectively, using a formulation of chlorantraniliprole. These values are slightly lower than those reported for fish, however, they are above the solubility limit for chlorantraniliprole and would not occur in the environment.

Aquatic invertebrates are more sensitive to chlorantraniliprole in acute exposures compared to fish with acute effect/lethality values ranging from 0.0116 mg/L for the cladoceran, *Daphnia magna*, to 1.15 mg/L for the mysid shrimp, *Mysidopsis bahia* (Barbee et al., 2010; USEPA, 2012; Rodrigues et al., 2016). Available median lethality data for several insect species indicate median lethality values ranging from 0.116 mg/L to greater than 0.978 mg/L (table 3-4). Aquatic invertebrate chronic toxicity is also high with the midge *Chironomus riparius* being the most sensitive test species and the mysid shrimp being the least sensitive test species in life cycle testing (USEPA, 2012; Rodrigues et al, 2015; Rodrigues et al, 2016).

Table 3-4. Acute and chronic toxicity of chlorantraniliprole to aquatic invertebrates.

Test Duration/Species	LC_{50}/EC_{50} (mg/L)	NOEC (mg/L)
Acute Tests		
48-hour EC_{50} *Daphnia magna*	0.0116	NR*
48-hour LC_{50} *Sericostoma vittatum* (caddisfly)	0.0154	NR
48-hour LC_{50} *Brachionus calyciflorus* (rotifer)	>1.00	NR
48-hour LC_{50} *Hyallela azteca* (amphipod)	>0.389	NR
48-hour LC_{50} *Gammarus pseudolimaeus* (amphipod)	0.0351	NR
48-hour LC_{50} *Chimarra atterima* (caddisfly)	0.0117	NR
48-hour LC_{50} *Centroptilum triangulifera* (mayfly)	0.0116	NR
48-hour LC_{50} *Chironomus riparius* (midge)	0.0859	NR
48-hour LC_{50} *Soyedina carolinensis* (stonefly)	>0.978	NR
96-hour LC_{50} *Procambarus clarkii* (crayfish)	0.951	0.480
96-hour LC_{50} *Mysidopsis bahia*, mysid shrimp	1.15	NR
96-hour LC_{50} *Crassostrea virginica*, Eastern oyster	0.0399	NR
Chronic Tests		
21-day *Daphnia magna* (life cycle)	NR	0.0045
28-day *Chironomus riparius* (midge) (life cycle)	NR	0.0031**
28-day Mysid shrimp (life cycle)	NR	0.695

*NR = Not reported; **LOEC = lowest observable effect concentration

Available aquatic plant toxicity data suggests low toxicity of chlorantraniliprole to freshwater and marine diatoms and algae, as well as aquatic macrophytes. Estimated EC_{50} and NOEC values were all greater than the highest test concentration used in the studies, which ranged from 1.78 to 15.1 mg/L (USEPA, 2008).

Acute aquatic toxicity data for suspension concentrates similar to those proposed in the program are comparable to the range of sensitivities that have been reported for the technical material (table 3-5). Available SDS information did not list the other ingredients contained within the formulations. Identification of the ingredients is considered confidential business information.

Table 3-5. Aquatic toxicity of suspension concentrate formulated chlorantraniliprole to aquatic organisms.

Test Duration/Species	LC_{50}/EC_{50} (mg/L)	NOEC (mg/L)
48-hour EC_{50} *Daphnia magna*	0.0071	NR*
96-hour LC_{50} Bluegill	>1.64	NR
96-hour LC_{50} Rainbow trout	>2.16	NR
72-hour EC_{50} *Pseudokirchneriella subcapitata* (*Green algae*)	>4.0	4.0

*NR = Not reported

Acute aquatic toxicity studies for the primary metabolites of chlorantraniliprole that would be expected to occur in terrestrial and aquatic systems suggest that the parent material is the most toxic form to aquatic invertebrates (table 3-6). Median effective concentrations for *D. magna* were typically greater than an order of magnitude when compared to the effects of the parent material.

Table 3-6. Aquatic toxicity of chlorantraniliprole degradates to the Cladoceran, *D. magna*.

Metabolite	Terrestrial/Aquatic Degradate	EC_{50} (mg/L)	NOEC (mg/L)
IN-EQW78*	Terrestrial/Aquatic	>0.138	0.138
IN-ECD73	Terrestrial/Aquatic	>0.0138	0.0138
IN-F9N04	Aquatic	0.03	NR**
IN-GAZ70	Terrestrial/Aquatic	>0.010	0.010
IN-F6L99	Terrestrial/Aquatic	46.8	NR
LBA24-002*	Aquatic	>10	10
LBA22-002	Aquatic	>0.24	0.24
LBA23-000	Aquatic	>0.01	0.01

*Primary metabolite; **NR = Not reported

4.0 EXPOSURE ASSESSMENT

4.1 Human Health Exposure Assessment

The exposure assessment estimates the potential exposure of humans to chlorantraniliprole. The exposure assessment begins with the use and application method for chlorantraniliprole in the grasshopper program. A complete exposure pathway for chlorantraniliprole includes (1) a release from a chlorantraniliprole source, (2) an exposure point where contact can occur, and (3) an exposure route such as ingestion, inhalation, or dermal contact by which contact can occur. In this way, the potentially exposed human population and complete exposure pathways are identified and qualitatively evaluated.

4.1.1 Identification of Potentially Exposed Human Populations and Complete Exposure Pathways

APHIS proposes to use the Prevathon® formulation via aerial or ground spray applications to suppress rangeland grasshoppers. Prevathon® is a suspension concentrate that is mixed with water and methylated seed oil for application as a foliar spray. The program uses application rates of 0.02 lb a.i. per acre for conventional treatment and 0.013 lb a.i. per acre for RAATs.

Based on the application method, workers in the program are the most likely human population segment to be exposed to chlorantraniliprole. Short-term occupational exposure to chlorantraniliprole may occur through direct contact with this compound during application (mixing, loading, applying, and post-application activities). However, direct contact exposure is minimized by adherence to label required safety procedures and the use of personal protective equipment (PPE), as further discussed in the next section. Exposure to chlorantraniliprole through drift from aerial and ground spray applications is expected to be minimal because only protected handlers may be allowed in the area during application and workers are not allowed entry into treated areas during the 4-hour restricted-entry interval (REI).

Chlorantraniliprole exposure to the general public is not expected from program use based on label requirements and adherence to label and program standard operating procedures (USDA APHIS, 2016a) that prevent potential exposure to general public. Only protected handlers may be in the area during application and entry of the general public into the treated area is not allowed during the REI period. USDA-APHIS conducts treatments on rural rangelands, where agriculture is a primary economic factor with widely scattered single rural dwellings in ranching communities with low population density. The USDA-APHIS program aerial application statement of work (2016a) requires avoiding flights over congested areas, water bodies, and other sensitive areas. The required buffer zones for water bodies are 500 feet for aerial liquid insecticides and 200 feet for ground applications. Aerial applications are not allowed while school buses are operating in the treatment area; within 500 feet of schools or recreational facilities; or when wind velocity exceeds 10 miles per hour (mph) (unless a lower wind speed is required under State law); air turbulence could seriously affect the normal spray pattern; and/or temperature inversions could lead to off-site movement of spray. The program also notifies

residents within treatment areas, or their designated representatives, prior to proposed operations to reduce the potential for incidental exposure (USDA APHIS, 2014). Label restrictions and program standard operating procedures reduce the potential exposure to chlorantraniliprole through direct contact to the general public, suggesting a lack of a significant exposure pathway.

The primary use areas for chlorantraniliprole include rangeland that could be grazed by livestock. Farmers in areas near proposed suppression areas may grow crops such as alfalfa and corn that are used for livestock. They also grow potatoes, sugar beets, wheat, barley, sweet corn, beans, and a variety of other crops (USDA APHIS, 2016b). Exposure to the general public from chlorantraniliprole through dietary food consumption (meat and dairy products) at levels higher than tolerance levels for chlorantraniliprole is not expected based on the proposed use pattern for the program which includes reduced application rates compared to those on the label.

Chlorantraniliprole has environmental fate properties that suggest a potential for transport to surface and groundwater (Section 2.3), especially in areas where soils are permeable or poorly drained, and the water table is shallow (DuPont, 2014). However, the potential exposure of the general public to chlorantraniliprole from drinking water sources from program use is not expected based on adherence to the label requirements, the proposed use rates, and USDA-APHIS program treatment guidelines (USDA APHIS, 2014; 2016a). The program restricts insecticide applications directly to water bodies, as stated on the label, and also requires a no treatment buffer from water bodies (500 foot buffer for aerial and 200 foot buffer for ground applications) to minimize the potential for migration. In addition, only one application is made per season to a treatment block and at rates below those on the label.

4.1.2 Exposure Evaluation

This section qualitatively evaluates worker exposure from direct contact while mixing and applying Prevathon® based on program use. Worker exposures are not quantified because of the lack of toxicity for acute or short-term exposures. Long-term exposure to chlorantraniliprole of workers is not expected because only one application is proposed per season.

Direct contact to chlorantraniliprole of workers during application is not expected to occur when following the label-required PPE along with proper worker hygiene. The Prevathon® formulation (DuPont, 2015) required PPE includes long-sleeved shirt and long pants, shoes plus socks for pesticide applicators and other handlers, and shirt, pants, socks, and shoes for applicators and other handlers of the diluted material. A long-sleeved shirt and long pants, shoes, plus socks, are also required PPE for early entry to treated areas permitted under the Worker Protection Standard and contact with anything that has been treated such as plants, soil, or water. DuPont also includes an 8- and 12-hour time weighted average acceptable exposure limit (AEL) of 10 mg/m^3 (total dust) and 5 mg/m^3 (respirable dust) for chlorantraniliprole in the SDS.

4.2 Ecological Exposure Assessment

4.2.1 Terrestrial Exposure Assessment

Exposure levels on vegetation and other forage items for terrestrial nontarget vertebrate organisms were calculated using the Terrestrial Residue Exposure Model (T-REX) (USEPA, 2005). T-REX provides an updated version of the Fletcher residue model that was based originally on the Kenaga nomogram used by USEPA/OPP in their risk assessment process for pesticide registration. T-REX allows the user to input variables such as use, application rate/type, percent active ingredient, soil or foliar dissipation half-life, application interval, and number of applications to calculate exposure concentrations on a variety of food items. All exposure values in this risk assessment are based on the upper bound residue estimates. Chlorantraniliprole upper bound residue estimates ranged from 0.15 parts per million on food items such as seeds and large insects to 2.40 parts per million on short grass. In addition to the calculated residue data, the T-REX model allows the user to input toxicity endpoints that can be compared to exposure values to determine if exposure levels exceed benchmark effect concentrations.

Exposure concentrations for birds and mammals can be based on mg/kg diet or mg/kg body weight. These concentrations represent those residue levels that would be expected from a direct application to the listed food items. The exposure concentrations were used to determine residues for each insecticide for different mammals and birds based on their body size and relative food consumption on a daily basis. These values can then be compared to effects data with endpoints represented as mg/kg diet (i.e., LC_{50} and NOEC). The comparison of the specific mammal and bird exposure values to the lowest available effects data endpoint is discussed in section 5.0 (risk characterization).

4.2.2 Aquatic Exposure Assessment

The method of calculating aquatic exposure concentrations for the program was through the use of two aerial drift deposition models. The models (AgDrift and AgDisp) allow for specific application information to be used as input into the model, and then determine the amount of drift that would occur at a user-defined distance from the spray block. The difference between deposition at the edge of a field and a selected buffer zone can be used as a means to reduce the total amount of insecticide that would be expected at a certain distance from the spray block. Buffer zones, in addition to the previously mentioned mitigation measures can be established, based on the reduction in exposure to levels that would not be expected to result in direct or indirect effects to individuals, populations, or species as a whole.

AgDrift and AgDisp are pesticide drift deposition models that provide the user with the ability to provide site- and application-specific information as input to determine application efficiency and off-site drift residues. AgDisp is a model which was developed by the U.S. Forest Service beginning in the early 1980's, and served as the platform for the development of the AgDrift model that has become a regulatory tool for the USEPA/OPP in the registration of pesticides (Hewitt et al., 2002; Teske and Curbishley, 2003). Both models have a tiered approach that

allows the user to choose default values or provide more specific data, based on the available information. Both models have been validated under various application scenarios in the literature (Duan et al., 1992a; Duan et al., 1992b; Teske et al., 2000; Teske and Thistle, 2004). In general, aerial application predictions slightly underestimate drift within the first 80 m, but over predict at increasing distances by a factor of two to four at distances up to approximately 300 m (Bird et al., 2002; Duan et al., 1992a,b; Teske and Thistle, 2003; Thistle et al, 2008).

For this risk assessment, the AgDrift model was used to simulate all ground applications, while AgDisp was used to simulate all aerial ultra-low volume (ULV) and bait applications. The AgDisp model was used in the aerial applications to assess buffer distances and application heights that are beyond those that have been validated using AgDrift (Teske and Thistle, 2004). Input data for the AgDrift and AgDisp models were based on pesticide labels for each product and specific application information available in the USDA-APHIS work plan for the program (USDA APHIS, 2016a). While several types of aircraft are available for application in the program, the quantitative differences in drift are minimal at the buffer zones being assessed. Therefore, the focus of the modeling work was to emphasize those parameters that have the greatest influence on drift. Multiple factors can influence pesticide drift; however, release height, wind speed and direction, and nozzle atomization/orientation are the primary factors influencing drift (Bird et al., 1996; Teske et al., 2000).

Unless otherwise specified, release height for aerial applications was set at 75 ft with a maximum allowed sustained wind speed of 10 mph, and the American Society of Agricultural and Biological Engineers (ASABE) droplet size distribution of fine to very fine (median diameter = 137.5 µm). ASABE has developed standardized parameters for different droplet size spectra that can be selected in both drift models. The very fine-to-fine droplet size spectrum selected for all of the air and ground ULV simulations is consistent with an application recommended for use in the program. For aerial applications of bait the very coarse to extremely coarse bait size was selected with a median particle size of 521.34 µm. Application rates selected for modeling were based on the maximum RAATs rates assuming 100% coverage during application. Lower RAATs rates may be used in cases where reduced application and coverage can be implemented to effectively suppress grasshopper and Mormon cricket populations.

The intent of the program is to make applications as close to the ground as possible. However, in some cases where rapid elevation changes are likely to occur, applications must be made at a height that will ensure pilot safety and the appropriate swath width. All applications were simulated on an area where the buffer was on a zero grade and there was no upslope or downslope between the spray block and sensitive habitat. In addition, the maximum height of vegetation between the spray block and habitat was no greater than 0.1 meters high. This provides a conservative estimate regarding the ability of plants and terrain to intercept drift between the spray block and sensitive areas.

A sustained 10-mile-per-hour wind speed was used as a representative maximum that is allowed in program applications in all simulations. The wind direction was assumed to be at -90^{o} directly towards the sensitive habitat for the entire length of all swaths with no reduced area of application occurring over the spray block.

Other parameters that influence drift are meteorological conditions. In addition to wind speed, both drift models allow the user to input temperature and humidity. Temperature and humidity values for this exercise were selected from all geographically representative areas where the program could potentially make applications. Meteorological data was obtained from the AgDisp model which allows the user to view a 30-year compendium of meteorological data from 239 sites in the United States (1961–1990 National Solar Radiation Data Base, Version 1.0, Solar and Meterological Surface Observational Network) (Teske and Curbishley, 2003).

The 25th percentile humidity value and the 75th percentile highest temperature were selected based on weather data from Lubbock, Texas, which reported a temperature value of 90 ^{o}F with a humidity value of 36%. Bismarck, North Dakota, and Pocatello, Idaho, were also evaluated, and based on a combination of maximum temperature and minimum humidity values for those areas, all three had similar application efficiencies and drift fractions based on their respective worst-case temperature and humidity values. Therefore, the temperature and humidity value from Lubbock, Texas, was used because it would maximize the potential for insecticide drift.

AgDisp and AgDrift provide estimates of off-site residues related to drift in terrestrial and aquatic environments. However, they do not provide an estimate of the amount of runoff that could occur into aquatic habitats. Several aquatic fate models exist to estimate environmental loading into aquatic habitats. USEPA/OPP has developed a tiered approach for the use of aquatic fate models that allow the user to estimate aquatic concentrations based on default "reasonable worst-case conditions," or to calculate estimated aquatic concentrations based on crop-specific soil and weather conditions (USEPA, 2004). None of the available models allow the user to calculate the effects of application buffers in reducing pesticide runoff.

The runoff contribution from applications in the program is considered minimal due to the application buffers that are applied adjacent to aquatic environments. The effectiveness in the use of application buffers to reduce runoff can vary based on site conditions, the type of vegetation present in the buffer, and the fate of the insecticide. However, the products used in the program and the large buffers ensure that runoff will not be a significant contribution of off-site pesticide movement when products are applied according to label specifications and USDA-APHIS policy.

5.0 RISK CHARACTERIZATION

This section qualitatively and quantitatively characterizes the risk associated with potential exposure to chlorantraniliprole.

5.1 Human Health

The potential human health risks associated with exposure to chlorantraniliprole are characterized qualitatively in this section. Chlorantraniliprole has very low acute toxicity and no adverse mammalian effects from short-and intermittent-term exposures. Adverse effects have only been observed in chronic exposures. Risks are not quantified because chlorantraniliprole has only been shown to cause adverse effects under chronic exposure while the anticipated exposure from program applications would be either acute or short-term because only one application would be made per season.

The use of chlorantraniliprole for the program will pose negligible risk to human health. Exposure to chlorantraniliprole via oral, inhalation, and dermal routes is expected to be minimized for workers by adherence to the label-required PPE. Accidental exposure may occur, but would be of low exposure frequency and short-term duration. Therefore, adverse health risk to workers associated with program applications is not expected because of the lack of toxicity in acute and short-term exposures.

Risks to the general public in the treatment areas from the ground or aerial applications are not expected because program treatments are conducted in rural rangeland areas, where agriculture is a primary economic factor with widely scattered single rural dwellings in ranching communities with low population density. The program notifies residents and implements mitigation measures beyond label requirements to ensure that no treatments occur within the required buffer zones from structures, such as homes and schools (USDA APHIS, 2016a).

There is potential for short-term post-application dermal (adults and children) and incidental oral (children only) exposure to chlorantraniliprole residues in soil because chlorantraniliprole is persistent. However, children would not be expected to be in areas where chlorantraniliprole applications may have occurred. Additionally, based on the known toxicity of chlorantraniliprole, they would have to ingest large quantities in order to result in dietary risk to this subgroup of the population. Inhalation exposure is not expected due to the low vapor pressure of chlorantraniliprole (applied/deposited residues are not expected to volatilize into the air).

Risks to the general public from dietary consumption of animal products (meat and dairy) in the treatment areas are not expected because chlorantraniliprole residue levels will be lower than the tolerance levels for chlorantraniliprole in meat and dairy, based on the lower rates used in the program. USEPA (2013) performed a conservative chronic dietary (food and drinking water) exposure and risk assessment for chlorantraniliprole. The results of the chronic analysis indicated that the chronic dietary (food and drinking water) risk estimates are below the level of concern for the U.S. population and all population subgroups.

5.2 Terrestrial and Aquatic Risk Characterization

The goal of this section is to discuss the relationship between the chemical response data discussed in section 3.2 with the exposure concentrations that were estimated for chlorantraniliprole and application methods (Section 4.2). The integration of the exposure and response analysis chlorantraniliprole characterizes the potential risk that could occur to nontarget fish and wildlife. In cases where the range of response data for chlorantraniliprole does not fall within the range of potential exposure values, USDA-APHIS concludes that potential impacts to individuals and populations are negligible. Further evaluation of the assumptions used in the risk characterization is required to refine the risk where residues exceed the response data. For this assessment, direct risk to nontarget organisms is defined as effects resulting from direct acute or chronic exposure to chlorantraniliprole. Indirect risk is defined as any impacts to prey items and vegetation that may serve as habitat or provide a food source for a group of organisms.

Aquatic residues that are shown in the following aquatic risk characterization figure are a result of the modeling efforts using AgDrift/AgDisp. For the terrestrial risk characterization, a single pathway of program insecticide exposure was considered the most significant exposure route: residue ingestion. Exposure can also occur through other pathways, such as dermal, ingestion from preening, and water consumption, but these are considered minor relative to what would be consumed in the diet. Application buffers from aquatic areas and mitigation measures to protect terrestrial species habitat will minimize the other various exposure pathways. In addition, the single-pathway model assumes that all of the dietary items contain upper bound residues and compose 100% of the diet, which is a conservative estimate for this exercise because the program will preferentially use RAATs that reduce the amount of residues on dietary items. Exposure values will then be compared to the most sensitive endpoint that was described in the effects section for birds and mammals. Risk quotient (RQ) values (RQ = Exposure/Toxicity Endpoint) will be derived from toxicity values from concentrations based on body weight and food concentrations. The advantage of the use of LD_{50}/NOEL values allows for extrapolation to different sized birds and mammals with different consumption rates and varied diets. The limitation of this type of risk characterization is that risk is based on effects data derived from a large bolus of material, typically in solution that is administered one time to the test organism. In most cases, this does not provide an accurate exposure scenario. The other type of toxicity data for vertebrate terrestrial receptors are those values that are calculated based on dietary concentrations or LC_{50}/NOEC values. These provide a more realistic exposure scenario, but they also have limitations in their use such as feeding avoidance and correlation among test species (Mineau et al., 2001). Where data is available for both toxicity endpoints, calculated RQ values for both methods will be discussed.

5.2.1 Terrestrial Risk Characterization

5.2.1.1. Direct and Indirect Risk to Mammals

The lowest reported mammalian acute and chronic NOELs were used to estimate mammalian class- and body weight-specific effect levels (table 5-1).

Table 5-1. Different mammalian class parameters used to calculate adjusted acute and chronic NOEL values.

Mammalian Class	Body Weight	Ingestion (dry) (g bw/day)	Ingestion (wet) (g/day)	% body weight consumed	(kg-diet/day)	Adjusted Acute NOEL	Adjusted Chronic NOEL
Herbivores/	15	3	14	95	1.43E-02	10,989.15	2,197.83
Insectivores	35	5	23	66	2.31E-02	8,891.40	1,778.28
	1000	31	153	15	1.53E-01	3,845.80	769.16
Granivores	15	3	3	21	3.18E-03	10,989.15	2,197.83
	35	5	5	15	5.13E-03	8,891.40	1,778.28
	1000	31	34	3	3.40E-02	3,845.80	769.16

The adjusted acute and chronic NOEL values were then compared to the upper percentile residues that would be anticipated from direct application to various food items that mammals may consume. Acute and chronic direct risk exposure levels were at least two orders of magnitude below the NOELs for various sized mammals (table 5-2). There is actually less risk than indicated by these exposure levels because no sublethal effects were observed even at the highest test concentration.

Table 5-2. Calculated mammalian risk quotient values for chlorantraniliprole assuming no application buffer zone.

Dose-based RQs (Dose-Based EEC/NOEL)	15 g mammal		35 g mammal		1,000 g mammal	
	Acute	Chronic	Acute	Chronic	Acute	Chronic
Short Grass	0.00*	0.00	0.00	0.00	0.00	0.00
Tall Grass	0.00	0.00	0.00	0.00	0.00	0.00
Broadleaf plants/small insects	0.00	0.00	0.00	0.00	0.00	0.00
Fruits/pods/large insects	0.00	0.00	0.00	0.00	0.00	0.00
Seeds (granivore)	0.00	0.00	0.00	0.00	0.00	0.00

* Values less than 0.001 EEC – estimated environmental concentration

5.2.1.2. Direct and Indirect Risk to Birds

The lowest reported avian NOEL for chlorantraniliprole was used to generate adjusted acute values for bird body weights ranging from 20 to 1,000 g (table 5-3). The adjusted values ranged

from 1,620.97 to 2,914.87 mg/kg. These values are actually higher because the lowest NOEL was the highest test concentration and even at that level, no sublethal effects were noted.

Table 5-3. Adjusted toxicity value (NOEL) for different avian class sizes.

Avian Class	Body Weight (g)	Ingestion (dry) (g bw/day)	Ingestion (wet) (g/day)	% body weight consumed	(kg-diet/day)	Adjusted NOEL (mg/kg-bw)
Small	20	5	23	114	2.28E-02	1,620.97
Mid	100	13	65	65	6.49E-02	2,063.57
Large	1000	58	291	29	2.91E-01	2,914.87

The body weight adjusted acute NOEL values were compared to the upper percentile residues that would be anticipated from direct application to various food items that birds may consume after an application of chlorantraniliprole. Acute risk exposure levels were at least two orders of magnitude below the NOELs for various sized mammals (table 5-4). Risk is actually lower than reflected by these values because no sublethal effects were observed even at the highest concentration tested.

Table 5-4. Acute avian risk quotient values for chlorantraniliprole based on the lowest acute NOEL.

Dose-based RQs (Dose-based EEC/adjusted LD_{50})	Avian Acute RQs 20 g	100 g	1,000 g
Short Grass	0.00*	0.00	0.00
Tall Grass	0.00	0.00	0.00
Broadleaf plants/small insects	0.00	0.00	0.00
Fruits/pods/seeds/large insects	0.00	0.00	0.00

* Values less than 0.001

Risk was also low for test avian species based on the lowest acute and chronic dietary NOELs and upper percentile estimates of chlorantranilipole residues applied directly to various food items (table 5-5).

Table 5-5. Acute and chronic risk quotient values for birds based on the lowest dietary acute and chronic toxicity values.

Dietary-based RQs (Dietary-based EEC/LC_{50} or NOEC)	RQs Acute	RQs Chronic
Short Grass	0.00*	0.02
Tall Grass	0.00	0.01
Broadleaf plants/small Insects	0.00	0.01
Fruits/pods/seeds/large insects	0.00	0.00

* Values less than 0.001

5.2.1.3. Direct and Indirect Risk to Amphibians and Reptiles

The direct risk to amphibians and reptiles from chlorantraniliprole is expected to be minimal. Based on the available effects data and the expected aquatic concentrations, direct effects are not expected for amphibian aquatic life stages. Based on assumptions by USEPA/OPP that are discussed in the effects analysis, the risk to reptiles and amphibians is assumed to be represented by birds and fish, respectively. While there is uncertainty in these extrapolations they can be of some use in cases where limited data is available. No amphibian toxicity data is available for chlorantraniliprole; therefore, the low risk to fish was also assumed to be the same for amphibians. Amphibians would need to be at least two orders of magnitude greater in sensitivity than fish to chlorantraniliprole. This level would still result in concentrations reaching solubility limits for chlorantraniliprole, and is an unlikely scenario.

A potential indirect effect of chlorantraniliprole applications is loss of habitat or food items. Aquatic habitat would consist of aquatic plants while aquatic food items would consist of algae, aquatic invertebrates, and small fish. To understand the potential indirect effects of these applications, chlorantraniliprole levels were compared to the available chlorantraniliprole effects data for aquatic plants, invertebrates, and fish. The details of this risk characterization are covered under the aquatic section within the potential direct and indirect risk to fish section. Indirect risk to amphibians is expected to be minimal because expected residues do not exceed any effect endpoint for aquatic plants, invertebrates, or fish. The potential for terrestrial indirect effects to amphibians and reptiles is also expected to be minimal. Chlorantraniliprole is not phytotoxic; therefore, risk to terrestrial habitat is minimal. Chlorantraniliprole is expected to have impacts on some sensitive terrestrial invertebrates that could serve as a food source but because of its selectivity and the use of RAATs, these impacts are not expected to be significant to invertebrate populations.

5.2.1.4. Risk to Terrestrial Invertebrates

Available data for terrestrial invertebrates shows that chlorantraniliprole has low toxicity to several nontarget invertebrate groups. Chlorantraniliprole does have activity against Lepidoptera and some Coleoptera larvae but at rates that are higher than those proposed in the grasshopper

program. Semi-field data suggests that lethal and sublethal risk to pollinators such as Hymenoptera is low and not expected to result in significant impacts. Available field studies in turf indicate that there is no risk to nontarget invertebrates such as ants, ground beetles, and other ground dwelling invertebrates after treating turf at rates more than twice those proposed for RAATs (Larson et al., 2012). Impacts to sensitive terrestrial invertebrates that consume treated vegetation would be expected, however, program use of only one treatment per season and RAATs will reduce the risk to this group of nontarget invertebrates.

5.2.1.5. Direct and Indirect Risk to Terrestrial Plants

Direct effects to terrestrial plants are not expected from chlorantraniliprole because of its low application rate and lack of phytotoxicity at relevant doses. Indirect risk through the loss of pollinators from treatments is also not expected to be significant. Grasshopper nymphs appear to be much more susceptible to the impacts of chlorantraniliprole than other insect groups. The current Section 3 label for Prevathon® shows that application rates are 4 to 10 times greater for efficacy in controlling lepidopteran larvae and whitefly nymph pests compared to the full and RAATs rates proposed in this program. Available laboratory, semi-field, and field studies demonstrate low toxicity to most other insect groups, and in particular honey and bumble bees, where no lethal or sublethal impacts have been observed at rates well above those proposed for use in the grasshopper program.

5.2.2 Aquatic Risk Characterization

A comparison of the available effects data for fish and aquatic invertebrates to the range of chlorantraniliprole exposure levels, estimated from drift modeling, shows that exposure levels expected from program applications are below the acute and chronic effects data for fish and aquatic invertebrates (figure 5-1). Effects to fish and other aquatic biota from consumption of contaminated aquatic prey are also not expected to be a significant pathway of exposure for chlorantraniliprole, based on the low residues and low bioconcentration factor values in aquatic systems.

Direct impacts to aquatic plants are also not anticipated because of the estimated environmental residues and available data for five aquatic plants with EC_{50} values ranging from 1.78 to 15.1 mg/L. Residues are approximately four orders of magnitude below the lowest effect concentration, suggesting that effects to aquatic plants are not expected. Aquatic plants also provide habitat to fish and aquatic invertebrates by providing shelter and food. These indirect effects to fish and aquatic invertebrates would not be expected based on the low estimated residues.

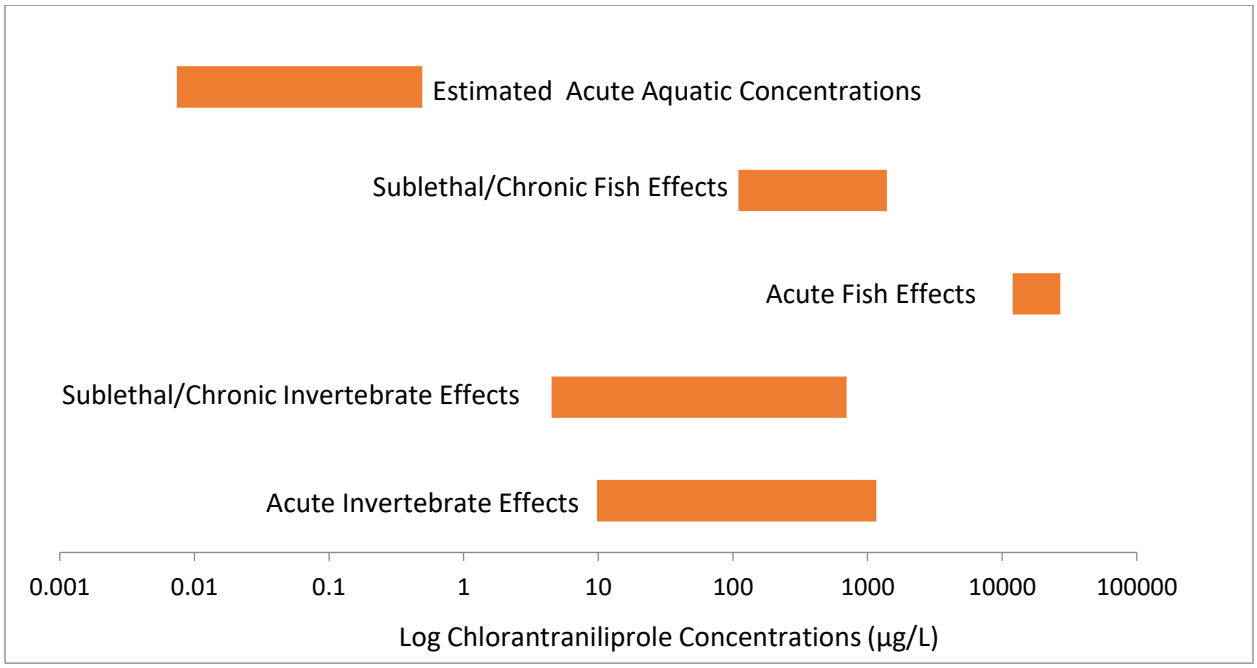

Figure 5-1. Chlorantraniliprole risk characterization for fish and aquatic invertebrates.

6.0 UNCERTAINTIES AND CUMULATIVE IMPACTS

The uncertainties associated with this risk evaluation arise primarily from lack of information about the effects of its formulations, inert ingredients, metabolites, and potential mixtures to nontarget organisms that can occur in the environment. These uncertainties are not unique to this assessment but are consistent with uncertainties in HHERAs with any environmental stressor. In addition, there is uncertainty in where an infestation may occur in a specific state, and the rest of the United States, and the extent of chlorantraniliprole use in a given infestation because its use is based on site-specific factors.

Another area of uncertainty is the potential for cumulative impacts to human health and the environment from the proposed use of chlorantraniliprole in the grasshopper suppression programs. Areas where cumulative impacts could occur are: 1) repeated worker and environmental exposures to chlorantraniliprole from program activities in conjunction with other crop use sources; 2) co-exposure to other chemicals with a similar mode of action; and 3) exposures to other chemicals in mixtures and how that may affect the toxicity of chlorantraniliprole.

Chlorantraniliprole is used for insect control on various crops. However, the USDA-APHIS grasshopper program use of chlorantraniliprole in rangelands is unlikely to be in conjunction with other insecticide uses. There may be herbicide use on rangeland but the level of treatment will depend on the value of the rangeland and whether treatments are warranted.

Cumulative impacts from the potential for co-exposure of chlorantraniliprole and other chemicals used in the program that have a similar mode of action resulting in synergism, potentiation, or additive or antagonistic effects are not expected. Chlorantraniliprole acts on the ryanodine receptor, which is not the same toxic action as other insecticides used within the program. The other insecticides used in the grasshopper program include carbaryl, malathion, and diflubenzuron. As previously stated, the program only makes one insecticide application in a given area per growing season so other program insecticides would not be applied to the same area.

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