Fruit Fly Cooperative Eradication Program
Soil Insecticide Applications in Florida

Environmental Assessment
March 2015
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Appendix A. Aquifer Pesticide Pollution Susceptibility
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I. Purpose and Need

Several species of non-native fruit fly pose a serious threat to agriculture in the United States. There are six genera of non-native fruit flies that pose the greatest economic and environmental threat in the United States (Anastrepha, Bactrocera, Ceratitis, Dacus, Rhagoletis, and Toxotrypana) (APHIS, 2001). Non-native fruit flies have a wide host range with greater than 250 species of fruit and vegetables, including citrus. In response, the U.S. Department of Agriculture’s Animal and Plant Health and Inspection Service (APHIS) has developed cooperative eradication programs with State agencies where fruit fly introductions and commercial and residential production of host species may occur. These programs employ an integrated pest management (IPM) strategy that includes a range of chemical and nonchemical methods that have effectively eradicated non-native fruit fly introductions in the United States since 1984 (APHIS, 2001). Components of cooperative eradication programs may include exclusion through quarantines and inspection as well as detection and prevention. Quarantines are established in areas where fruit flies have been detected to restrict the movement of host material to other areas where non-native fruit flies have not been detected. Control measures can employ various nonchemical and chemical options. Chemical options may include applications of insecticides and/or the use of detecton and control attractants that can be applied using various methods. One chemical control option is to treat the soil with an insecticide in places where an non-native mated female fruit fly, fruit fly larvae, egg or pupae is detected. Insecticide applications may take place at the drip line of fruit fly host plants that are within 400-meters(m) of an non-native mated female fruit fly, fruit fly larvae, egg or pupae detection. A similar treatment option is used as part of the quarantine requirement for nurseries where containerized host plants must be treated prior to shipment.

The IPM strategies APHIS has employed have evolved to include new methods of control based on proven technologies that can be successfully integrated into the fruit fly program. One area where this can occur is in the use of new chemical treatments. Historically, the organophosphate insecticide diazinon has been used in Florida as a soil drench in nursery treatments, and in applications to host plants within the 400-m detection of a non-native mated female fruit fly, fruit fly larvae, egg or pupae. The pyrethroid insecticide lambda cyhalothrin is being proposed as a replacement product for diazinon in Florida. Lambda cyhalothrin has been proven effective for these types of treatments and is registered for this use pattern in Florida under a 24(c) registration. A 24(c) is a special local use need registration by States for pesticides and is approved by the EPA Office of Pesticide Programs. The detection of fruit flies and need for these treatments have been infrequent in Florida with the last outbreak occurring in Broward County in 2011. However, it is critical to the
success of the program to have these products available in potential future outbreaks so that non-native fruit flies can be eradicated where they are detected and valuable agricultural products allowed to move during the quarantines.

APHIS has the responsibility for taking actions to exclude, eradicate, and/or control plant pests under the Plant Protection Act of 2000 (7 United States Code (U.S.C.) 7701 et seq.). Within Florida there is approximately 9.2 million acres where non-native fruit fly host plants are grown. Infestation and establishment within areas where host plants occur would result in significant economic loss as well as allow expansion to other states. APHIS requires the use of insecticides under certain conditions as part of its integrated approach for eradication of non-native fruit flies. Diazinon has been the approved treatment for soil drench application. This proposed action is necessary to prevent further spread of non-native fruit flies and help to eradicate these species where they are detected.

This environmental assessment (EA) has been prepared consistent with the National Environmental Policy Act of 1969 (NEPA) and APHIS’ NEPA implementing procedures (7 Code of Federal Regulations (CFR) part 372) for the purpose of evaluating how the proposed action, if implemented, may affect the quality of the human environment.

APHIS first evaluated the environmental impacts of fruit fly control technologies in the “Fruit Fly Cooperative Control Program, Final Environmental Impact Statement—2001” (APHIS, 2001). APHIS reexamined its findings and introduced an additional tool for eradication in the “Use of Genetically Engineered Fruit Fly and Pink Bollworm in APHIS Plant Pest Control Programs, Final Environmental Impact Statement—2008” (APHIS, 2008). Both documents consider fruit fly risks and mitigations at the programmatic level. This EA incorporates the findings of those documents, where applicable, by reference. Environmental documentation for APHIS fruit fly control programs may be viewed online via the following links: APHIS fruit fly control program environmental documentation and APHIS GE control applications for plant health.

II. Alternatives

This EA analyzes the potential environmental consequences associated with the proposed action to switch from the use of the insecticide diazinon to an alternative insecticide lambda cyhalothrin in the fruit fly cooperative eradication program in Florida.
A. No Action

The no action alternative would not implement the use of lambda cyhalothrin as a soil drench application in the fruit fly cooperative eradication program. These applications are made in instances where a fruit fly larva, egg, pupae, or mated female are found or in fruit fly host production nurseries under quarantine. Diazinon is no longer registered for this use and no other insecticides are currently available for soil treatments in the fruit fly cooperative eradication program.

B. Preferred Alternative

The preferred alternative is the use of the insecticide lambda cyhalothrin as a replacement for diazinon when any non-native mated female, larvae, egg or pupae of non-native tephritid fruit flies are detected in the state of Florida and in nurseries with host material under fruit fly quarantine. Applications of lambda cyhalothrin would occur on the following sites: (a) within the drip line of fruit-bearing fruit fly host plants that are located within a 400-m radius from an non-native mated female fruit fly, fruit fly larvae, egg or pupae find, and (b) as a regulatory treatment on host containerized nursery stock and to soil around nursery stock to allow nursery stock to move out of the quarantine area. All other aspects of the fruit fly cooperative eradication program would continue as described in previous environmental documentation.

III. Affected Environment

This chapter describes the existing conditions at and near the proposed sites for treatment of the non-native fruit flies in Brevard, Broward, Charlotte, Citrus, Collier, Desoto, Glades, Hardee, Hendry, Hernando, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Marion, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Saint Lucie, Sarasota, Seminole, Sumter, and Volusia Counties. In these counties, treatments could occur at any time of the year (Figure 1). In addition, the counties of Alachua, Bay, Clay, Duval, Escambia, Flagler, Nassau, Okaloosa, Putnam, Saint Johns, Santa Rosa, could be treated on a seasonal basis from April to November (Figure 1). These data and information form the basis for assessing the potential impacts of the action and “no action” alternative evaluated in section IV of this EA. Relevant issues evaluated in this chapter include:

- Land Characteristics and Agricultural Production
- Climate
- Air Quality
- Water Quality
- Vegetation
- Wildlife

Figure 1. Trapping counties under proposed action. Source: APHIS, 2015.
A. Land Characteristics and Agricultural Production

“Land characteristics” as defined in this EA include the physical features and soil resources within Brevard, Broward, Charlotte, Citrus, Collier, Desoto, Glades, Hardee, Hendry, Hernando, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Marion, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Saint Lucie, Sarasota, Seminole, Sumter, and Volusia, Alachua, Bay, Clay, Duval, Escambia, Flagler, Nassau, Okaloosa, Putnam, Saint Johns, and Santa Rosa Counties. Wildlife, vegetation, water resources, air quality, human populations, and weather and climate patterns that may be associated with land in or near the proposed trapping counties are discussed in detail in their own subsections of the EA.

Florida is home to 18,801,310 individuals as of 2010 (U.S. Census Bureau, 2014). Florida has approximately 9.25 million acres of farmland upon which non-native fruit fly host plants could grow. In 2011, Florida reported over $8.26 billion in agricultural revenue, of which $1.8 billion was from citrus (Florida Department of Agriculture and Consumer Services, 2013). Twenty-two counties list citrus in their top 3 agricultural commodities (USDA - NASS, 2012). Fruit fly susceptible crops account for a third of the top 3 crops in the proposed trapping area (USDA - NASS, 2012). Of the $8.26 billion in total revenue, $4 billion is exported to 170 foreign countries (Florida Department of Agriculture and Consumer Services, 2013). Currently, over 300 different commodities are grown in the State on more than 47,500 farming operations (Florida Department of Agriculture and Consumer Services, 2013). Florida is the top producer of oranges, grapefruit, fresh snap beans, sweet corn, watermelons, fresh cucumbers, fresh market tomatoes, squash and sugarcane, second in the value of vegetable production, greenhouse and nursery products, bell peppers, strawberries, and tangerines (Florida Department of Agriculture and Consumer Services, 2013). The high production levels of potentially impacted produce (i.e., table citrus, juicing citrus, peppers, etc.) throughout the State could denote a major economic challenge to Florida agriculture and, in turn, U.S. consumption and exports of these products if non-native fruit flies were to become established in Florida.

The focus counties lie within an area designated by the Natural Resources Conservation Service (NRCS) as the Atlantic Coastal Plain. Atlantic Coastal Plain soils formed from sediments deposited over a broad coastal plain (USDA - NRCS, 2006). The proposed insecticide treatments are limited to the Atlantic and Gulf Coast Lowland Forest and Crop Region and the Florida Subtropical Fruit, Truck Crop, and Range Region. The predominant soils are Entisols with lesser amounts of Alfisols, Histosols, and Spodosols. Predominant soils are poorly developed, fine to coarse-
textured and well-drained (USDA - NRCS, 2006). The different physical and chemical properties of soils in these counties support different types of flora and fauna. The predominant vegetation in Florida was a mixture of pine, hardwood forests, and grasslands prior to conversion to agriculture.

**B. Climate**

The climate in Alachua, Bay, Clay, Duval, Escambia, Flagler, Nassau, Okaloosa, Putnam, Saint Johns, and Santa Rosa Counties is considered subtropical. Temperatures in the summer are hot, with average high temperatures near 100 degrees Fahrenheit. Winter weather is mild, with average minimum temperatures near 45 degrees Fahrenheit. Precipitation averages 47 inches annually, with more precipitation in the summer than in the winter.

Glades, Hendry, Lee, Martin, Miami-Dade, Monroe, Okeechobee, and Palm Beach are considered tropical climates (Kottek et al., 2006). Winter weather is mild, with average minimum temperatures near 60 degrees Fahrenheit. Precipitation averages 62 inches annually, with more precipitation in the summer than in the winter.

**C. Air Quality**

The Clean Air Act (CAA)(42 U.S.C. §§ 7401 et seq.) is the primary Federal legislation that addresses air quality. In any given region or area of the United States, air quality is measured by the concentration of pollutants in the atmosphere, and is influenced by surface topography and prevailing meteorological conditions. The EPA established National Ambient Air Quality Standards (numerical concentration-based standards) for six criteria pollutants that impact human health and the environment (40 CFR § 50). These pollutants are common and accumulate in the atmosphere as a result of natural processes and normal levels of human activity. They include carbon monoxide (CO), nitrogen dioxide (NO₂), ozone (O₃), sulfur dioxide (SO₂), small particulate matter, and lead (Pb).

Pollutant emission types are categorized as either primary or secondary (§ 50). Primary standards represent maximum levels of background air pollution that are considered safe for humans, including sensitive groups such as asthmatics, children, the elderly, and people with heart disease. Secondary standards provide public welfare protection, including the protection of animals, vegetation, crops, and other public resources (EPA, 2012a).

Particulate matter emissions can have different health effects depending on the particle size; therefore, EPA developed separate National Ambient
Air Quality Standards for coarse particulate matter (PM10) and fine particulate matter (PM2.5) (40 CFR § 50). Fine particulate matter, also known as a primary pollutant, is emitted from sources such as diesel engines, power plants, and refineries as a fine dust or liquid mist (soot). This matter can become a secondary pollutant as a result of a chemical reaction between two primary pollutants by forming nitrate and sulfate compounds. Precursors of fine particulate matter include SO2, NOx, VOC, and ammonia. Metropolitan areas have greater levels of PM2.5 than other areas of the country.

The EPA has delegated responsibility for ensuring compliance of the National Ambient Air Quality Standards to States and local agencies. The Florida Department of Environmental Protection (FDEP) is the State agency responsible for monitoring and regulating air quality, along with the local governments of Broward, City of Jacksonville, Hillsborough, Manatee, Miami-Dade, Orange, Palm Beach, Pinellas, and Sarasota. The FDEP divides the State of Florida into districts roughly based on county geography, although some larger municipalities are separate districts (figure 2).

![Florida Department of Environmental Protection Air Quality Control Areas](figure2.png)

FDEP collects data for the Florida Air Quality Index based on EPA standards; small particulate matter and ozone because they are the two pollutants that pose the greatest threat to human health. FDEP does not
maintain a website with air quality data, thus Air Quality Index values were taken from the EPA (EPA, 2014). According to EPA, scores for year-round trapping counties typically fall in the “good” range and occasionally in the “moderate” range. Days designated as unhealthy for sensitive groups are relatively rare with only 5 of 22 counties reporting any unhealthy days. The number of unhealthy days ranged from zero to three. The seasonal trapping areas had similar numbers of days in the “good” range with occasional “moderate” air quality days (EPA, 2014).

Greenhouse gases are gases emitted from natural processes and human activities that trap heat in the atmosphere. While greenhouse gases help regulate the earth’s temperature, they also contribute to global climate change. Greenhouse gases consist of water vapor, carbon dioxide (CO₂), methane, NO (nitrous oxide), O₃ (ozone), hydrocarbons, and chlorofluorocarbons.

D. Water Quality

Florida is relatively flat, has a high water table, and has many major surface water features. Lake Okeechobee, Okefenokee Swamp, the Everglades, Big Cypress, and Green Swamp are some of the largest freshwater features found in Florida. In addition to surface water, aquifers are important sources of drinking and irrigation water in a portion of the state. Florida has two sole source aquifers, the Volusia-Florida Aquifer and Biscayne Aquifer. The EPA defines a sole source aquifer as “an aquifer that supplies at least 50 percent of the drinking water consumed in the area overlying the aquifer. These areas may have no alternative drinking water source(s) that could physically, legally and economically supply all those who depend on the aquifer for drinking water” (EPA, 2012b). Due to the geology of Florida, much of the state’s aquifers are susceptible to pollution from pesticides (Appendix A).

Florida has a long history of human settlement which has resulted in modification and impacts to many waterways. Impaired waterways are required to be reported and submitted to the EPA under section 303 (d) of the Clean Water Act. States identify all waters where required pollution controls are insufficient to attain or maintain water quality standards, and establish priorities for development of total maximum daily loads (TMDLs) based on pollution severity and the sensitivity of water uses (40 C.F.R. §130.7(b)(4)). States also provide a long-term plan for attaining TMDLs within 8 to 13 years from the first listing of a waterway or body as impaired (EPA, 2012c).

EPA policy allows states to remove water bodies from the list after they have developed a TMDL or after other changes to correct water quality problems have been made. Occasionally, a water body can be taken off the
list as a result of a change in water quality standards or removal of designated uses. It must be noted however, designated uses cannot be deemed unattainable and removed until a thorough analysis clearly shows that they cannot be attained (EPA, 2012c).

<table>
<thead>
<tr>
<th>Pollution Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrients</td>
<td>2,889</td>
</tr>
<tr>
<td>Organic Enrichment</td>
<td>1,183</td>
</tr>
<tr>
<td>Metals (Other Than Mercury)</td>
<td>1,131</td>
</tr>
<tr>
<td>Pathogens</td>
<td>607</td>
</tr>
<tr>
<td>Mercury</td>
<td>477</td>
</tr>
<tr>
<td>Turbidity</td>
<td>391</td>
</tr>
<tr>
<td>Ammonia</td>
<td>41</td>
</tr>
<tr>
<td>Cause Unknown - Impaired</td>
<td>25</td>
</tr>
<tr>
<td>Biota</td>
<td></td>
</tr>
<tr>
<td>Cause Unknown</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>6,759</td>
</tr>
</tbody>
</table>

**Table 1. Summary of Pollution Types in Trapping Counties. Source: EPA, 2012c.**

A review of the data provided to the EPA under section 303 (d) of the Clean Water Act reveals that 6,759 impairments have been listed for lakes and streams in the trapping counties. The causes of these impairments vary but the most common are nutrients, organic enrichment, and mercury (Table 1). The number of section 303 (d) non-compliant waterway segments ranged from 1,527 in Monroe County to 5 in Hernando County (Figure 3) (EPA, 2012c). Water quality related pesticide data is limited for some parts of Florida. The most common pesticides detected were atrazine (100% of samples), atrazine desethyl (85% of samples), fipronil sulfone (83% of samples), simazine (79% of samples), 2,4-D (77% of all samples), and imidacloprid (77% of samples) (Florida Department of Environmental Protection, 2014). Neither diazinon or lambda cyhalothrin were tested for in any samples (Cooper, 2015; Dodson, 2015).
E. Vegetation

The affected environment discussed in this document occurs within two distinct ecoprovinces known as the Outer Coastal Plain Mixed Forest Province and the Everglades Province. The two provinces can be further divided into three distinct ecoregions, the Southeastern USA Plains, the Southeast Coastal Plain and the Everglades (Bailey, 2009). Most of Florida lies in the Outer Coastal Plain Mixed Forest Province, a humid region covering much of the southeast region of the United States. Extensive loss of historic plant communities has occurred due to human
impacts on the ecosystem. Longleaf pine (*Pinus palustris*) was the dominant tree species prior to the arrival of the colonists; however, longleaf pine’s current extent has been reduced by as much as 98 percent (Wear and Greis, 2002). Other forest types existed such as beech (*Fagus grandifolia*), sweetgum (*Liquidambar styraciflua*), southern magnolia (*Magnolia grandiflora*), laurel and live oaks (*Quercus hemisphaerica* and *Quercus virginiana*, respectively), and various pines such as slash pine (*Pinus elliottii*) and pond pine (*Pinus serotina*). Floodplains include bottomland oaks (this group includes up to 17 species (Gardiner, 2001)), red maple (*Acer rubrum*), green ash (*Fraxinus pennsylvanica*), sweetgum (*Liquidambar styraciflua*), and American elm (*Ulmus americana*), and areas of bald cypress (*Taxodium distichum*), pond cypress (*Taxodium ascendens*), and water tupelo (*Nyssa aquatica*). Native forests have been cleared for lumber and converted to industrial pine plantations which favor faster growing species such as slash pine and loblolly pine (*Pinus taeda*). Longleaf pine and other forests have also been converted to cropland, pasture, mining, and urban uses (EPA, 2011).

The Everglades Province occupies the southern tip of Florida and covers approximately 5 million acres. This province is “characterized by flat plains with wet soils, marsh and swamp land cover with everglades and palmetto prairie vegetation types” (EPA, 2011) such as sawgrass (*Cladium mariscus*). “Relatively slight differences in elevation and landform have important consequences for vegetation and the diversity of habitat types” (EPA, 2011). Historically, this ecoregion extended from Lake Okeechobee to the Gulf of Mexico; however, intensive human alteration of this ecosystem has altered both the quality and quantity of the habitat in this ecoregion (Kambly and Moreland, 2009).

Many of these provinces have become fragmented due to land development and for agricultural cultivation. Areas where fruit fly host plants may occur are typically in agricultural areas or in residential/developed areas. These developed areas may be interspersed with native vegetation habitats that still exist in parks and other natural areas.

**F. Wildlife**

Florida is home to a diverse wildlife population. The state is home to many species of economic and ecological interest such as the white-tailed deer (*Odocoileus virginianus*), black bear (*Ursus americanus*), Florida panther (*Puma concolor coryi*), American alligator (*Alligator mississippiensis*), American crocodile (*Crocodylus acutus*) and manatee (*Trichechus manatus*). Many other species also exist in Florida as well occupying natural and developed areas. Species protected under the Endangered Species Act (ESA) are also present in Florida. Forty-six
federally endangered animal species, and 27 threatened animal species occur, or have historically occurred in Florida (U.S. Fish and Wildlife Service, 2015). In addition, nineteen animal species are considered state threatened. Forty-nine federally listed endangered plant species and 14 threatened plant species occur in Florida (Florida Department of State, 2004; U.S. Fish and Wildlife Service, 2013; Florida Department of Agriculture and Consumer Services, 2014). Four-hundred-forty-five state-listed endangered plant species occur in Florida, one-hundred-eighteen plants are listed as threatened (Florida Department of State, 2004; Florida Department of Agriculture and Consumer Services, 2014).

Florida is relatively rich in conservation lands. For example, Florida has 179 state parks and 67 lands conserved under the Comprehensive Everglades Restoration Plan (CERP). In addition, the Florida Forever Board of Trustees Projects accounted for 520 projects with a total of 8,016 parcels that are conserved. Furthermore, the Forever Florida program has acquired an additional 289 additional parcels (Florida Natural Areas Inventory, 2014). The U.S. Fish and Wildlife Service (FWS) maintains 29 wildlife refuges, one fish hatchery and 23 parcels for the Farm Service Agency (Figure 4)(U.S. Fish and Wildlife Service, 2014). Many of these lands occur within counties where applications could occur if a larval fruit fly or mated female is detected.
Figure 4. Conserved land in trapping counties. Modified from (Florida Natural Areas Inventory, 2014; U.S. Fish and Wildlife Service, 2014).
IV. Environmental Impacts

A. No Action

A lack of a treatment option for a soil drench in cases where non-native mated female, larvae, egg or pupae are detected or in host production nurseries would result in reduced effectiveness for the cooperative eradication program. The result would be an increased potential for non-native fruit flies to become established and spread within Florida, and possibly elsewhere in the United States. This would result in economic impacts to the citrus industry in Florida due to yield reductions related to infested fruit, and an inability to ship products because quarantine requirements could no longer be met to ensure safe shipment of commodities out of the state. As previously mentioned, approximately 25 percent of Florida’s agricultural economy is based on citrus which would be impacted by the establishment of non-native fruit fly species in the state. Increased production costs would be anticipated with increased insecticide use to eradicate non-native fruit flies.

Increased pesticide use is anticipated and could result in increased risk to human health and the environment. Increased pesticide loading from unregulated fruit fly treatments could impact water quality as well as fish and wildlife species that occur in proximity to treated areas. In an APHIS fruit fly cooperative eradication program soil drench treatment applications are made by or under the supervision of licensed State or Federal employees in residential areas where mated female, larvae, egg or pupae of non-native fruit flies are detected. Treatments by less qualified persons using higher risk pesticides could potentially result in increased risk to human health and the environment.

B. Preferred Alternative

Under the preferred alternative applications of lambda cyhalothrin would occur on the following sites: (a) within the drip line of fruit-bearing plants that are located within a 400-m radius from an non-native mated female fruit fly, fruit fly larvae, egg or pupae find, and (b) as a regulatory treatment on host containerized nursery stock, and to soil around nursery stock to allow nursery stock to move out of the quarantine area. No other aspects of the fruit fly cooperative eradication program would be modified beyond the proposed replacement of diazinon with lambda cyhalothrin.

The use of lambda cyhalothrin as part of an integrated cooperative eradication strategy would ensure that non-native fruit flies are eradicated once they are detected and allow nursery stock to comply with quarantine requirements prior to movement. The successful implementation of an eradication program would protect other commodities that would be
susceptible to fruit flies and provide economic benefits for growers. The replacement of diazinon with lambda cyhalothrin would not result in increased risk to human health and the environment. Specific information regarding toxicity and fate of lambda cyhalothrin as it relates to program use is discussed in appendix B and summarized in the following human health and ecological and environmental quality sections.

Lambda cyhalothrin is not expected to have significant impacts to human health (Appendix B). The proposed use pattern and toxicology data suggest that risks would be minimal to all segments of the population. Toxicity from oral, dermal, and inhalation exposures is considered low to moderate for the active ingredient. The proposed formulation demonstrates reduced acute toxicity when compared to effects when exposed to the technical active ingredient. In other toxicity studies, including subchronic and chronic exposures, lambda cyhalothrin has not been shown to be mutagenic, carcinogenic, or to cause developmental or reproductive effects at relevant doses.

The segment of the population at highest risk is applicators, however, exposure to lambda cyhalothrin will be reduced by following label requirements regarding the use of personal protective equipment. For the public, proper notification of residents prior to any soil drench treatment on their property will reduce the potential for exposure to and risk from lambda cyhalothrin. Applications of lambda cyhalothrin will be targeted and ground-based, delivering large coarse droplets directly to the soil or to a containerized host plant in a nursery setting; this is designed to minimize the potential for off-site transport of the active ingredient. Lambda cyhalothrin exhibits chemical fate properties that suggest it would not be mobile and subject to transport to surface or groundwater that would serve as a source for drinking water. Label restrictions regarding application buffers and vegetative filter strips adjacent to aquatic habitats will further reduce the potential for any contamination to any surface drinking water.

Lambda cyhalothrin has low to moderate toxicity to terrestrial wildlife such as birds and mammals (Appendix B). Lambda cyhalothrin is highly toxic to most terrestrial invertebrates, including pollinators. The method of application to soils at the drip line of select host trees within a 400-m radius of a non-native mated female fruit fly, fruit fly larvae, egg or pupae detection minimizes the impacts to sensitive terrestrial invertebrates that may consume treated plant material, or occur in soil at the application site. The historical low frequency of these types of applications and the application method suggest that any impacts to sensitive terrestrial invertebrates would be localized to the treatment area and would be transient. Applications in nurseries will typically occur to containerized plants. Nurseries are highly disturbed areas. Other applications would be expected to occur in managed areas such as residential or other properties.
with landscaping. Natural areas such as refuges and other lands of conservation importance would not be areas where fruit fly host trees would occur. Natural areas may occur adjacent to some of these managed areas but the method of application diminishes the risk to these resources.

Lambda cyhalothrin is highly toxic to fish and aquatic invertebrates. (Appendix B). Acute median lethality values are in the parts per trillion to low parts per billion range for fish and aquatic invertebrates. Label restrictions regarding application buffers and vegetative filter strips will minimize transport to aquatic habitats. The environmental fate of lambda cyhalothrin suggests it would bind to soil and sediment and reduce the bioavailability to fish and aquatic invertebrates in water. Impacts to sediment-dwelling aquatic species would be low based on label restrictions reducing the potential for runoff and the high binding affinity of lambda cyhalothrin to soil and sediment. Lambda cyhalothrin is not expected to have significant impacts to air quality based on its environmental fate that suggests it will not partition into the atmosphere from water or soil. In addition, ground treatments use a large droplet size that will minimize drift. Pollution and particulate emissions monitored under the CAA are not anticipated to be impacted by the application of lambda cyhalothrin based on its chemical fate and historical low frequency of use for these applications in Florida.

C. Cumulative Effects

Cumulative impacts are those impacts on the environment which result from the incremental impact of a proposed action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

The selection of the preferred alternative described in this EA for the non-native fruit fly eradication program is not anticipated to have a significant cumulative impact on human health or the environment. There will be an increase in insecticide loading in cases where a soil application is needed in response to the detection of an mated female or larval non-native fruit fly detection; however, it is anticipated that with a cooperative integrated approach, insecticide use would be less compared to permanent establishment of non-native fruit flies in Florida that could occur under the no action alternative. Insecticide use would not be expected to have significant cumulative impacts to soil, air, or water quality beyond baseline conditions because of the proposed method of application, the low frequency of use, the environmental fate of lambda cyhalothrin, and in the case of surface water, the use of label restrictions which prevent application near surface waters. Lambda cyhalothrin may be used in
Florida for other purposes; however, its use in areas where non-native fruit fly detections would be likely to occur are expected to be minimal.

**D. Threatened and Endangered Species**

Section 7 of the Endangered Species Act (ESA) and its implementing regulations require Federal agencies to ensure their actions are not likely to jeopardize the continued existence of threatened or endangered species or result in the destruction or adverse modification of critical habitat. APHIS consults with FWS when non-native fruit fly detections in Florida trigger quarantine and eradication treatments. Federally listed species and critical habitat are not expected to occur where lambda cyhalothrin treatments are likely to take place, such as in residential areas and plant nurseries. In cases where they do co-occur, APHIS will consult with the appropriate FWS office to ensure compliance with ESA.

**E. Other Considerations**

Executive Order (EO) 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,” focuses Federal attention on the environmental and human health conditions of minority and low-income communities, and promotes community access to public information and public participation in matters relating to human health and the environment. This EO requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high or adverse human health or environmental effects. The human health and environmental effects from the proposed applications are expected to be minimal and are not expected to have disproportionate adverse effects to any minority or low-income family. Treatments will only occur after proper public notification for any residents who have host trees requiring a soil drench. Any fruit will be removed eliminating dietary exposure from consuming fruit from treated trees.

EO 13045, “Protection of Children from Environmental Health Risks and Safety Risks,” acknowledges that children, as compared to adults, may suffer disproportionately from environmental health and safety risks because of developmental stage, greater metabolic activity levels, and behavior patterns. This EO (to the extent permitted by law and consistent with the agency’s mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children. Based on the results of the human health risk assessment no disproportionate risks to children are anticipated.
from the proposed use of lambda cyhalothrin when following program and label requirements.

Consistent with the National Historic Preservation Act of 1966,APHIS has examined the proposed action in light of its impacts to national historic properties. Treatments for fruit fly are not anticipated on historic properties however in cases where there may be these types of treatments they would be coordinated with the State Historic Preservation Officer and other appropriate contacts.

V. Listing of Agencies and Persons Consulted

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Center for Plant Health Science and Technology
Plant Protection and Quarantine
1730 Varsity Drive, Suite 400
Raleigh, NC  27606

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine
Florida Fruit Fly Exclusion & Detection Programs
915 10th Street East
Palmetto, FL 34221

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Policy and Program Development
Environmental and Risk Analysis Services
4700 River Road, Unit 149
Riverdale, MD  20737
VI. References

APHIS – See U.S. Department of Agriculture, Animal and Plant Health Inspection Service


Code of Federal Regulations. 40 § 130.7(b). Protection of the environment - water quality planning and management.


EPA – See U.S. Environmental Protection Agency

Florida Department of Agriculture and Consumer Services. 2013. 2013 Florida agriculture by the numbers. Florida Department of Agriculture and Consumer Services.

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Florida Natural Areas Inventory. 2014. Gis data.


Florida Department of Agriculture and Consumer Services. 2013. 2013 florida agriculture by the numbers. Florida Department of Agriculture and Consumer Services.


Florida Department of Environmental Protection. 2014. Testing florida surface waters for pesticides – a pilot study.


U.S. Environmental Protection Agency. 2014. Air quality index report. 
U.S. Fish and Wildlife Service. 2014. Usfws national cadastral data 
USDA - NRCS. 2006. Land resource regions and major land resource 
areas of the united states, the caribbean, and the pacific basin. 
United States Department of Agriculture - Natural Resources 
Conservation Service.
USDA - Forest Service, USDA - Forest Service, Asheville, N.C
Appendix A. Aquifer Pesticide Pollution Susceptibility

Florida Sole Source Aquifers

Florida Superficial Aquifer Pesticide Pollution Susceptibility

Legend
- BISCAYNE AQUIFER SSA
- BISCAYNE AQUIFER SSA STREAMFLOW AND RECHARGE SOURCE ZONES
- VOLUSIA-FLORENN AQUIFER SSA
- Uninjected
- All Year
- Seasonal

Legend
- 0 - 50
- 51 - 100
- 101 - 150
- 151 - 200
- 201 - 250

Data Source: State of Florida
Coordinate System: NAD 1983

USDA-APHIS-PPD
Environmental Services
4700 River Road, Unit 149
Riverdale, MD 20737

Date: January 7, 2015
J. Overlin

Florida Intermediate Aquifer Pesticide Pollution Susceptibility

Floridan Aquifer Pesticide Pollution Susceptibility

Legend
- 0 - 50
- 51 - 100
- 101 - 150
- 151 - 200
- 201 - 250

County Boundaries

Miles
Appendix B. Lambda cyhalothrin Human Health and Ecological Risk Assessment
EXECUTIVE SUMMARY

United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine (PPQ) is proposing to use the insecticide lambda-cyhalothrin (LTC) in its cooperative fruit fly eradication program. LTC is a pyrethroid insecticide that has not previously been used in the program in Florida. The proposed formulation, Warrior II with Zeon Technology® (Warrior II), is a capsule suspension containing the active ingredient LTC (22.8%). The proposed application method is a soil application. The Warrior II formulation is a restricted use pesticide due to toxicity to fish and aquatic organisms. It is used only by certified applicators, or persons under their direct supervision, and only for those uses covered by the certified applicator’s certification.

USDA APHIS evaluated the potential human health and ecological risks from the proposed use of Warrior II in this assessment and determined that the risks to human health and the environment are negligible. The lack of risk to human health and the environment is based on the low probability of exposure to human health and the environment and favorable environmental fate and effects data. LTC has moderate acute oral, dermal, and inhalation toxicity. The proposed method of application and adherence to label requirements substantially reduces the potential for exposure to humans and the environment, including nontarget fish and wildlife. Adverse health risks to workers are not expected based on the application method and low potential for exposure to LTC when applied according to label directions. Adverse health risk from accidental exposure such as splash to unprotected body areas is not expected for a well-trained certified applicator. Adverse health risk to the general public is not expected based on the soil drench application method and requirements for public notification, as well as destruction of fruit in treated areas as specified on the label. Adverse health risks from associated consumption of treated soil by children are also not expected based on conservative estimates of risk to this group of the population. Fruit fly eradication efforts in Florida where this proposed treatment could be utilized are fairly infrequent with the last event occurring in Broward County in 2011.

Off-site movement from LTC applications are expected to be minimized by the application method and environmental fate for the product. Risk to non-target terrestrial wildlife is expected to be minimal because of the targeted methods of application, where the product is applied, and the toxicity profile for LTC. LTC is highly toxic to aquatic organisms; however, the method of application, environmental fate and current label restrictions regarding the protection of aquatic resources will minimize the risk.

1.0 INTRODUCTION

This human health risk assessment (HHRA) and ecological risk assessment (ERA) provide a qualitative and quantitative evaluation of the potential risks and hazards to human health, non-target fish, and wildlife as a result of exposure to LTC under the proposed soil drench application to eradicate various species of non-native fruit flies (e.g., Mediterranean fruit fly, Mexican fruit fly, oriental fruit fly, etc.) that enter the United States.
The methods used in this HHRA to assess potential human health effects following standard regulatory guidance and methodologies (NRC, 1983; USEPA, 2014a), and generally conform to other Federal agencies such as U.S. Environmental Protection Agency, Office of Pesticide Programs (USEPA/OPP). The methods used in this ERA to assess potential ecological risk to non-target fish and wildlife follow EPA 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), then 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 are integrated to characterize risk of LTC applications to human health and the environment.

2.0 PROBLEM FORMULATION

Fruit flies in the family Tephritidae are among the most destructive and well-publicized pests of fruits and vegetables around the world. Non-native fruit flies in the genera *Anastrepha*, *Bactrocera*, and *Ceratitis* pose the greatest risk to U.S. agriculture. Tephritid fruit flies spend their larval stages feeding and growing on over 400 host plants. Introduction of these pest species into the United States causes economic losses from destruction and spoiling of host commodities, costs associated with implementing control measures, and loss of market share due to quarantines and restrictions on shipment of host commodities. The extensive damage and wide host range of tephritid fruit flies become obstacles to agricultural diversification and trade when non-native fruit fly species become established in these areas (USDA, APHIS 2013). APHIS PPQ is proposing to use LTC to control fruit flies as a replacement for diazinon.

LTC is a restricted-use, broad-spectrum insecticide for controlling most major aphid, caterpillar, and beetle pests on crops as well as public health pests such as mosquitoes and cockroaches in non-agricultural areas. The registered crops include fruits, vegetables, and row and field crops (e.g. alfalfa, corn, cotton, rice, soybean, and winter wheat) (USEPA, 2010a).

LTC is a pyrethroid insecticide (a class of insecticides with a similar structure to pyrethrins, a group of naturally occurring insecticides). Through contact (ingested or exposed externally), LTC penetrates the insect cuticle to disrupt nerve conduction within minutes (NPIC, 2001; He et al., 2008). LTC interferes with the normal functioning of nerve cells of an organism by disrupting sodium channels involved in the generation and conduction of nerve impulses leading to cessation of feeding, loss of muscular control, and causing rapid paralysis, and eventual death of an insect (NPIC, 2001; USEPA, 2007; and He et al., 2008).

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

LTC (CAS No. 91465-08-6, C\textsubscript{23}H\textsubscript{19}ClF\textsubscript{3}NO\textsubscript{3}) is a 1:1 mixture of two stereoisomers, (S)-\(\alpha\)-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethyl cyclopropanecarboxylate and (R)-\(\alpha\)-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3, 3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate. The chemical structures are illustrated in Figure 2-1.

First registered with USEPA in 1988, LTC is the active ingredient (a.i.) in several brand name products including KARATE\textsuperscript{®}, KARATE ZEON\textsuperscript{®}, ICON\textsuperscript{®}, BESIEGE\textsuperscript{TM}, COMMODORE\textsuperscript{®}, DEMAND\textsuperscript{®}, ENDIGO\textsuperscript{®}, ENGEO\textsuperscript{®}, HALLMARK\textsuperscript{®}, MATADOR\textsuperscript{®}, WARRIOR II\textsuperscript{®}, and KUNG FU\textsuperscript{®} (Syngenta, 2015). PPQ is proposing to use Warrior II with Zeon Technology\textsuperscript{®} (Warrior II) (EPA Reg. No. 100-1295) in the fruit fly program. Warrior II is a capsule suspension containing 2.08 lb of active ingredient per gal (22.8% of active ingredient of LTC and 77.2% of other ingredients). Other ingredients include titanium dioxide and petroleum distillate. The Warrior II formulation is a restricted use pesticide because of its toxicity to fish and aquatic organisms. It is used only by certified applicators, or persons under their direct supervision, and only for those uses covered by the certified applicator’s certification. The application will be performed in accordance with the label conditions for Warrior II and the recent FIFRA Section 24(c) Special Local Need Label (EPA SLN No. FL-150003).

2.2 Physical and Chemical Properties

LTC is a colorless to beige solid with a mild odor (NPIC, 2001). The Warrior II formulation is a white liquid with an aromatic odor (Syngenta, 2010). LTC has a low vapor pressure and Henry’s law constant, and has low water solubility. It has a high water–soil organic carbon partition coefficient (Koc) indicating its preferential affinity to organic matter. It also has a high octanol–water partition coefficient (Kow). The physical and chemical properties are summarized in table 2-1.
### Table 2-1. Physical and chemical properties of lambda-cyhalothrin.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Lambda-cyhalothrin</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS No.</td>
<td>91465-08-6</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>C&lt;sub&gt;23&lt;/sub&gt;H&lt;sub&gt;19&lt;/sub&gt;ClF&lt;sub&gt;3&lt;/sub&gt;NO&lt;sub&gt;3&lt;/sub&gt;</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>449.9</td>
</tr>
<tr>
<td>Density (g/mL at 25°C)</td>
<td>1.33</td>
</tr>
<tr>
<td>Melting point (°C)</td>
<td>49.2</td>
</tr>
<tr>
<td>Boiling point (°C at 0.2 mmHg)</td>
<td>187–190</td>
</tr>
<tr>
<td>Henry law constant (Pa·m&lt;sup&gt;3&lt;/sup&gt;/mole)</td>
<td>0.018</td>
</tr>
<tr>
<td>Vapor pressure (mPa at 20°C) (mm Hg at 25°C)</td>
<td>0.0002 (1.5 x 10&lt;sup&gt;-9&lt;/sup&gt;)</td>
</tr>
<tr>
<td>Water solubility (mg/L)</td>
<td>0.005</td>
</tr>
<tr>
<td>Solubility in solvents such as acetone (mg/L)</td>
<td>500,000</td>
</tr>
<tr>
<td>Octanol-water partitioning (log K&lt;sub&gt;ow&lt;/sub&gt; at 20°C)</td>
<td>7.00</td>
</tr>
<tr>
<td>Soil adsorption K&lt;sub&gt;oc&lt;/sub&gt; (cm&lt;sup&gt;3&lt;/sup&gt;/g)</td>
<td>247,000–330,000</td>
</tr>
</tbody>
</table>

Source: He et al., 2008

### 2.3 Environmental Fate

The environmental fate describes the processes by which LTC moves and is transformed in the environment. The environmental fate processes include: 1) mobility, persistence, and degradation in soil, 2) movement to air, 3) migration potential to groundwater and surface water, and 4) plant uptake.

LTC is not mobile and tends to strongly sorbsorb to organic matter in soil based on its high K<sub>oc</sub> (ranging between 247,000 and 330,000 cm<sup>3</sup>/g). LTC has a low potential to leach as dissolved residues in percolating water because of its low water solubility and high mean K<sub>oc</sub>. A 28-day leaching study showed that a majority of the LTC residues were recovered within the top 15 cm of the soil where the top 10-cm soil layer contained 50 percent clay and 26.3 g/kg organic carbon (Laabs et al., 2000).

In the water column, LTC tends to adsorb to suspended particulate materials such as clay particles and organic matter, transport with the suspended particulates through aquatic systems, and settle in the sediments. Sorption of LTC to suspended solids or bottom sediments may reduce its short-term bioavailability and mitigate its acute toxicity to aquatic organisms (He et al., 2008).

LTC is considered nonvolatile based on its low Henry’s Law constant and vapor pressure (table 2-1). Volatilization of LTC from soil and water surfaces occurs slowly. In comparison to soil where LTC strongly adheres to soil, volatilization from foliage occurs more rapidly because of the reduced surface area (ATSDR, 2003).

LTC is moderately persistent in the environment. A representative soil half-life for LTC is 30 days with values ranging from 28-84 days (NPIC, 2001). LTC degrades in the environment
through a combination of biotic and abiotic mechanisms (photolysis, hydrolysis, and microbial biodegradation) (He et al., 2008; USEPA, 2007). LTC undergoes some photolysis in water, but is somewhat stable in soil (with little degradation, on the order of ~13 percent in 35 days) (USEPA, 2007). Studies show that LTC in water and soil when exposed to sunlight photodegrades, with half-lives of 24.5 days (pH 5 and 25°C) and 53.7 days, respectively (He et al., 2008). In water, LTC is stable and no hydrolysis occurs at a pH below 8. According to two different authors, it hydrolyzed in water at a pH of 9 with a half-life of approximately 9 days (He et al., 2008) or 13 days (USEPA, 2007). LTC biodegrades at moderate rates (half-lives ranging from 12 to 72 days) under both aerobic and anaerobic soil metabolism conditions. LTC aquatic biodegradation is slow with metabolism half-lives ranging from 113-142 days (USEPA, 2007). Laboratory studies show that the half-lives in aerobic soil and anaerobic aquatic conditions are 42.6 days and 21.9 days, respectively (He et al., 2008). The reported half-lives for LTC in soil and water are summarized in table 2-2.

Table 2-2. Reported half-lives for lambda-cyhalothrin in soil and water.

<table>
<thead>
<tr>
<th>Environmental Fate Parameter</th>
<th>Reported Half-life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrolysis</td>
<td>Stable @ pH 5 and 7, pH 9 (8.66 days)</td>
</tr>
<tr>
<td>Soil Photolysis</td>
<td>53.7 days</td>
</tr>
<tr>
<td>Aqueous Photolysis</td>
<td>24.5 days @ pH 5 and 25°C</td>
</tr>
<tr>
<td>Soil Metabolism Biodegradation (both aerobic and anaerobic)</td>
<td>12 to 72 days</td>
</tr>
<tr>
<td>Aquatic Metabolism Biodegradation</td>
<td>113 to 142 days</td>
</tr>
<tr>
<td>Aerobic Soil Degradation</td>
<td>42.6 days</td>
</tr>
<tr>
<td>Anaerobic Aquatic Degradation</td>
<td>21.9 days</td>
</tr>
</tbody>
</table>

Source: He et al., 2008;USEPA, 2007.

LTC partitions to lipids suggesting a high potential to bioconcentrate due to its high octanol–water partition coefficient (K<sub>ow</sub>) and low water solubility. The reported bioconcentration factor (BCF) in fish is 2,240 (He et al., 2008).

LTC in soil is not easily taken up by the roots of vascular plants because it strongly adsorbs to soil (ATSDR, 2003). However aquatic macrophytes can take up LTC in water from roots. Through translocation, LTC uptake partitions into upper plant biomass. The uptake rates of various macrophytes are species and pesticide specific. Wetlands, detention ponds, and vegetated ditches have shown to be effective mitigation measures to reduce the quantity of runoff and suspended solids (He et al., 2008).

2.4 Hazard Identification

LTC is a hazard to human health due to its acute neurotoxicity (USEPA 2010b). The neuromuscular system is the main target organ for LTC (USEPA 2007). Based on acute oral, dermal and inhalation toxicity, USEPA/OPP classified LTC as moderately toxic (Category II). The eye irritation data shows that it is a moderate eye irritant (Category II), but it is not a skin
irritant (Category IV) or a skin sensitizer. Dermal exposure to LTC and many other pyrethroids may cause numbness or tingling of the skin (commonly referred as paresthesia).

2.4.1 Toxic Effects:

The primary acute toxic effect of LTC is neurotoxicity. The mode of action of LTC is that it reacts with the voltage-gated membrane sodium channels of nerve cells, prolonging the time during which the channels are open. This results in altered nerve function, which manifests either as a series of short bursts or a prolonged burst, and is caused by repetitive discharge of nerve signals or stimulus-dependent nerve depolarization. The basic function of nerve cells involves repeated polarization and depolarization associated with neural activation or firing. These processes are controlled by channels which allow for the influx of ions into nerve cells. Both pyrethroids and pyrethrins inhibit the closing of sodium channels and thus disrupt normal nerve function. Only about 0.6 percent of the sodium channel gates need to be affected in order to elicit signs of neurotoxicity (ATSDR, 2003).

2.4.2 Pharmacokinetics:

Metabolic studies in rats and dogs show that cyhalothrin is well absorbed after oral administration, extensively metabolized as a result of ester cleavage to the cyclopropanecarboxylic acid and 3-phenoxybenzoic acid, and eliminated as polar conjugates in urine. Residues in fats were eliminated with a half-life of 23 days (IPCS, 1990). Studies in rats show that LTC was widely distributed following both intravenous and oral exposures (Anadon et al., 2006). The highest concentrations were detected in the hypothalamus and the myenteric plexus (i.e., an area of unmyelinated fibers enervating the gastrointestinal tract). The plasma half-lives after intravenous and oral administration in rats were 8.55 and 14.43 hours, respectively. The whole body elimination half-lives after intravenous and oral exposures were 7.55 hours and 10.27 hours, respectively. The half-lives in nerve tissues were substantially greater (12-34 hours) than half-lives in plasma, which is consistent with the mechanism of action of LTC and other pyrethroids. An occupational human exposure study reported an average plasma half-life of 6.4 hours for LTC and several other pyrethroids (Leng et al., 1997).

2.4.3 Human Incidents:

USEPA performed a human incident review based on the OPP incident data system (IDS) and the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) database (USEPA, 2010c). The review showed several incidents involving LTC. These incidents were low, moderate, and high severity with a majority of the cases from exposure at home using LTC products (indoors or outdoors) or under an occupational setting (mixing, loading, applying, or reentering the treated fields, and inadvertent exposure). The most frequently reported symptoms were associated with dermal, respiratory, neurological, gastrointestinal, and ocular systems. The following sections provide more detailed discussions on the human incidents and symptoms identified from each database.
The IDS (2000 to 2010) recorded 403 case reports allegedly attributable to LTC. USEPA identified 159 incidents (excluding lawsuits and suicides) that occurred in the United States from 2007 to April 2010. Symptoms of human exposure to LTC reported in the IDS (2007-April 2010) include the following:

1) dermal – itchiness, redness, hives, burning sensation, irritation, and blisters;
2) neurological – headache, dizziness, disorientation, confusion, memory dysfunction, unable to concentrate, numbness, and tingling sensations, unsteady movements, muscle weakness, muscle spasms, and seizures;
3) respiratory – coughing, difficulty in breathing, asthma-like symptoms, exacerbation of chronic obstructive pulmonary disease, sore throat, burning sensation in the throat, nasal passage and chest, hoarseness of voice, inability to take a deep breath due to chest pain and blood in sputum;
4) ocular – corneal abrasion, sensation of foreign body, burning sensation, pain, photophobia, itchiness, and swelling and redness of eye;
5) gastrointestinal – vomiting, diarrhea, abdominal pain, and stomach cramps;
6) fever, muscle aches, flu-like symptoms; and
7) anaphylactic shock.

The NIOSH SENSOR (1998-2007) reported 217 cases of LTC exposure. The USEPA reviewed 159 of these human exposure cases of LTC as a single chemical. Among the 159 cases, 145 were of low severity, 14 were of moderate severity, and there were no fatalities. The reported health effects included gastrointestinal, ocular, neurological, dermal, respiratory, and cardiovascular symptoms. Most exposures occurred through drift of the pesticide in indoor and outdoor residential non-occupational situations or in an occupational setting.

The LTC dermal penetration study in humans indicates a dermal absorption estimation of 1 percent, which is much less than the 16 percent dermal absorption estimation in rats (USEPA, 2002). LTC contact with exposed human skin can result in paresthesia (temporary itching, tingling, burning or numbness) at sufficiently high doses. The abnormal skin sensations (tingling, burning, prickling), particularly in the facial region, are unique temporary symptoms of pyrethroid exposure, and the symptoms normally disappear within 24 hours (NPIC, 2001; Syngenta, 2010). Other occupational symptoms reported include nasal and throat irritation for workers who sprayed LTC indoors (ATSDR, 2003; Moretto, 1991).

2.4.4 Acute Toxicity:

Technical grade LTC has moderate acute toxicity (Category II) via oral, dermal, and inhalation routes. The oral LD$_{50}$ of the Warrior II formulation is 180 mg/kg for female rats based on results from similar products, which is in the same toxicity category as the technical grade. The dermal LD$_{50}$ of the Warrior II formulation is higher than 2,000 mg/kg in rabbits, which has low toxicity (Category III). The inhalation LC$_{50}$ of the Warrior II formulation is 3.12 mg/L in female rats. Table 2-1 summarizes the acute toxicities for the technical grade and Warrior II formulation, which has very low toxicity (Category IV). Studies on eye and skin irritation in rabbits show that LTC is a mild eye irritant (Category II), but it is not a skin irritant (Category IV) for the technical grade (USEPA, 2002). The Warrior II formulation is moderately skin irritating.
(Category III). The technical grade is not a dermal sensitizer in the guinea pig. However, the Warrior II formulation is a skin sensitizer (Syngenta, 2010). Skin irritation consistent with paresthesia has been documented in workers handling LTC (Spencer and O’Malley, 2006; Moretto, 1991).

Table 2-1. Acute technical and Warrior II formulation lambda-cyhalothrin toxicities for testing mammals.

<table>
<thead>
<tr>
<th>Toxicity Study</th>
<th>Lambda-cyhalothrin Technical</th>
<th>Warrior II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Oral LD₅₀ (rat)</td>
<td>56 mg/kg (♀)/79 mg/kg (♂) (II)</td>
<td>180 mg/kg (♀)* (II)</td>
</tr>
<tr>
<td>Acute Dermal LD₅₀</td>
<td>632 mg/kg(♂)/696 mg/kg (♀) (rat) (II)</td>
<td>&gt;2,000 mg/kg (rabbit)* (III)</td>
</tr>
<tr>
<td>Acute Inhalation LC₅₀ (rat)</td>
<td>0.065 mg/L(♂&amp;♀) (II)</td>
<td>3.12 mg/L (♀)-4 hours (IV)</td>
</tr>
<tr>
<td>Primary Eye Irritation</td>
<td>Mild irritant (II)</td>
<td>Mildly Irritating* (II)</td>
</tr>
<tr>
<td>(rabbit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Skin Irritation</td>
<td>Not an irritant (IV)</td>
<td>Moderately Irritating* (III)</td>
</tr>
<tr>
<td>(rabbit)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal Sensitization</td>
<td>Not a sensitizer</td>
<td>A skin sensitizer (derived from component)</td>
</tr>
<tr>
<td>(Guinea pig)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The toxicity information for Warrior II was based on results from similar product(s).

2.4.5 Subchronic and Chronic Toxicity:

A 21-day subchronic dermal toxicity study in rats reported a No Observed Adverse Effect Level (NOAEL) of 10 mg/kg/day and a Lowest Observed Adverse Effect Level (LOAEL) of 50 mg/kg/day, based on clinical signs of neurotoxicity and decreased body weight and body weight gain.

A 21-day subchronic inhalation study in rats reported an inhalation NOAEL of 0.08 mg/kg/day and a LOAEL of 0.90 mg/kg/day based on clinical signs of neurotoxicity, decreased body weight gains, increased incidence of punctate foci in the cornea, slight reductions in cholesterol (female), and slight changes in selected urinalysis parameters.

A 28-day subchronic dietary study in mice reported a No Observed Effect Concentration (NOEC) of 500 parts per million (ppm) (64.2 mg/kg bw/day in males and 77.9 mg/kg bw/day in females) and a Lowest Observed Effect Level (LOEL) of 2,000 ppm (≈309 mg/kg bw/day in males and ≈294 mg/kg bw/day in females) (the next higher dietary concentration). At the concentration of 2,000 ppm, signs of neurotoxicity (i.e., abnormal gait and posture) and other effects of toxicity (including weight loss, slight changes in hematology and organ weights) were observed.

In two 90-day subchronic dietary studies using rats, a NOEL of 50 ppm (≈2.5 mg/kg bw/day) and a LOEL of 250 ppm (≈12.4 mg/kg bw/day), with reported body weight loss in both studies.
Statistically significant decrease in food conversion efficiency was observed in female rats in one of the studies.

The 2-year chronic studies in rats and mice indicate that mice may be more tolerant than rats to dietary administration of LTC based on a dietary NOEL of 50 ppm (2.5 mg/kg bw/day) with a LOAEL of 250 ppm (12.5 mg/kg bw/day) in rats, compared to a dietary NOEL of 100 ppm (15 mg/kg bw/day) and a LOAEL of 500 ppm (75 mg/kg bw/day) in mice. The LOAEL for rats is based on decreased body weight with no signs of neurotoxicity. The LOAEL for mice is also based on decreased body weight, piloerection, and abnormal posture in some test animals.

A chronic oral study was performed in dogs by administration of LTC in gelatin capsules at doses of 0.1, 0.5, or 3.5 mg/kg bw/day for 1 year. At the lowest dose of 0.1 mg/kg bw/day, no adverse effects were observed. At 0.5 mg/kg bw/day, signs of neurotoxicity (abnormal gait) were observed in some animals from weeks two through nine. At 3.5 mg/kg bw/day, signs of neurotoxicity (ataxia, tremors, convulsions, and vomiting) were observed during the first 2 weeks. Based on this study, USEPA determined the dose of 0.1 mg/kg bw/day as a NOAEL and the dose of 0.5 mg/kg bw/day as a LOAEL for chronic exposures, and the doses of 0.5 mg/kg bw/day as a NOAEL and 3.5 mg/kg bw/day as the LOAEL for acute exposure (USEPA, 2007).

2.4.6 Nervous System Effects:

The acute oral neurotoxicity study in rats (USEPA, 2002) administering doses of 2.5, 10, or 35 mg/kg reported a NOAEL of 10 mg/kg and a LOAEL of 35 mg/kg based on clinical signs of neurotoxicity (i.e., piloerection, ataxia, salivation, lacrimation, and decreased motor activity).

The 21-day subchronic dermal and inhalation studies in rats, the 28-day subchronic dietary study in mice, and the chronic oral dog study previously discussed exhibited clinical signs of neurotoxicity.

2.4.7 Reproductive or Developmental Effects:

The results of a 3-generation reproduction study in rats testing LTC at doses of 0, 0.5, 1.5, or 5 mg/kg bw/day showed a decrease in adult and fetal body weight and body weight gain at 5 mg/kg bw/day. USEPA (2002) determined that 1.5 mg/kg bw/day as the NOAEL for both parents and offspring. However, no effects were observed in reproductive parameters (i.e., gross signs of toxicity, the length of the estrous cycle, assays on sperm and other reproductive tissue, and the number, viability, and growth of offspring). The developmental NOEL was determined to be 5 mg/kg bw/day (USEPA, 2002).

Developmental studies evaluate the potential to cause birth defects (teratogenic effects) and other effects during development or immediately after birth. The results of the developmental studies for cyhalothrin in both rats and rabbits show no developmental toxicity. At doses of 10 mg/kg bw/day, there were no signs of toxicity. In rats, signs of neurotoxicity and reduced body weight and food consumption were observed in dams (maternal toxicity) at 15 mg/kg bw/day. USEPA reported a NOAEL of 15 mg/kg bw/day based on no effects to the offspring. In rabbits, decreases in body weight and food consumption were noted at 30 mg/kg bw/day. USEPA
reported a developmental NOAEL of 30 mg/kg bw/day based on no observed effects to offspring (USEPA, 2002).

Two studies involving the use of an ICON® formulation of LTC (Ratnasooriya et al., 2002; 2003) reported developmental and reproductive effects. One study (Ratnasooriya et al., 2002) reported a decrease in mating behavior in male rats at oral doses about 6.3 and 10 mg/kg bw. The other study (Ratnasooriya et al., 2003) reported a significant increase in embryo implantation losses at 8.3 and 12.5 mg/kg bw/day, with a NOAEL of 6.3 mg/kg bw/day.

A study conducted in Algeria (Lebaili et al., 2008) reported evidence of testicular damage in rats exposed to very high concentrations (about 15,000 or 23,000 ppm) of LTC formulated as KARATE® 2.5 EC in drinking water.

2.4.8 Carcinogenicity and Mutagenicity:

USEPA classifies LTC as “not likely to be carcinogenic to humans” based on the lack of evidence of carcinogenicity in mice and rats (USEPA, 2002; 2007). The chronic feeding/carcinogenicity study in rats did not show evidence of carcinogenic activity (the highest dose in the study was 12.5 mg/kg bw/day). The chronic feeding study in mice observed an increase in mammary tumors in female mice at doses of up to 75 mg/kg bw/day. However, the significance of this effect was questionable because the incidence of mammary tumors in the matched control group was low, compared with historical control groups. The study did not show increases in any other tumor types.

Among eight mutagenicity studies (four studies for technical LTC and four studies for technical cyhalothrin) reviewed by USEPA (2002), five studies indicate no mutagenic activity and the other three studies for cyhalothrin are inconclusive because of issues associated with the experimental designs of the studies. LTC tested negative in all four studies including a reverse mutation assay in *Salmonella typhimurium*, a forward mutation assay in L5178Y mouse lymphoma cells at concentrations below the solubility limit, a mouse micronucleus test in C57B1/6J mice, and an *in vitro* cytogenetics study in human lymphocytes. Cyhalothrin tested negative in one study (a reverse mutation assay in *S. typhimurium*). A study from the open literature using human lymphocyte cultures (Naravaneni and Jamil, 2005) reports that LTC was positive in a comet assay (for strand breaks in DNA). Other studies (intraperitoneal injections and oral administration of LTC) (Celik et al., 2003; 2005a,b) report chromosome aberrations in rat bone marrow. A weak positive mutagenic response (less than threefold of background) at 0.5 to 10 μmol/plate was reported in an *in vitro* study assessing LTC using the Ames Salmonella assay at doses between 0.125 and 50 μmol/plate (Saleem et al., 2014).

2.4.9 Endocrine System Effects:

USEPA (2002) concludes that “There is no evidence that LTC induces any endocrine disruption.” ATSDR’s review (2003) indicated several pyrethroids affecting endocrine function, but did not specify LTC. LTC is not among the group of 99 pesticide active ingredients on the initial and second lists to be screened under the USEPA Endocrine Disruptor Screening Program. However, the lists of chemicals were generated based on exposure potential, not based on
whether the pesticide is a known or likely potential endocrine disruptor (USEPA, 2014b). LTC may affect endocrine function based on some published studies in the open literature discussed below.

A 21-day gavage study in rats (Akhtar et al., 1996) showed that serum triiodothyronine (T3), thyroxine (T4) and T3/T4 ratios were significantly suppressed and serum thyroid stimulating hormone levels were significantly increased after administering LTC at a dose of approximately 0.73 mg/kg bw/day. No other signs of toxicity or body weight gain were observed at this dose (USDA FS, 2010).

An in vivo study (Ratnasooriya et al., 2003) pregnant rats were exposed to ICON® (a formulation of LTC used in Sri Lanka) by gavage at doses of 6.3, 8.3, or 12.5 mg a.i./kg bw/day for 7 days. The primary adverse reproductive effect observed in this study was increased pre-implantation losses, which was blocked by co-administration of progesterone. The study did not observe effects on birth weight, fetal morphology, pre-natal development, and other standard reproductive parameters.

A study in a breast carcinoma cell line (Zhao et al., 2008) indicated that LTC may have estrogenic activity. At concentrations as low as $10^{-7}$ M (about 45 μg/L), LTC promoted cell proliferation (mimicked the effect of estrogen). Addition of an estrogen receptor antagonist at a concentration of $10^{-9}$ M blocked the cell proliferation.

### 2.4.10 Immune System Effects:

USEPA review of LTC (USEPA, 2002) does not address immune system effect. ATSDR raised concern for the effects of some pyrethroids on immune function as well as neurodevelopmental and reproductive functions at levels below those that induce signs of neurotoxicity (ATSDR, 2003). Two immunotoxicity studies with cyhalothrin (Righi and Palermo-Neto, 2005; Righi et al., 2009) report a decrease in macrophage activity at doses of 1 and 3 mg/kg bw/day but not at 0.6 mg/kg bw/day after an in vivo 7-day exposure.

### 2.4.11 Toxicity of Other Ingredients:

Approximately 77 percent of the Warrior II formulation contains other ingredients. Petroleum solvent and titanium dioxide are the two identified ingredients in this category (Syngenta, 2010). However, their percentages are not specified. The Syngenta safety data sheet indicates that the target organs for petroleum solvent are skin, eye, respiratory tract, and central nervous system (CNS). Repeated exposure to petroleum solvent may cause skin dryness or cracking, irritation to the eyes, nose, throat, and lungs, or CNS depression. If swallowed, petroleum solvent may be aspirated and cause lung damage. The safety data sheet also indicated that titanium dioxide is considered “Possibly Carcinogenic to Humans” (IARC Group 2B). The target organ for titanium dioxide is the lung. Prolonged exposure to titanium dioxide causes respiratory irritation and may lead to pulmonary fibrosis.
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 developed an oral Reference Dose (RfD) of 0.005 mg/kg for an acute dietary exposure scenario for the general population including infants and children (USEPA, 2002). The acute RfD for LTC was derived by applying an uncertainty factor of 100 to the NOAEL of 0.5 mg/kg from the chronic oral study in the dog.

The USEPA/OPP also derived a chronic RfD of 0.001 mg/kg for a chronic dietary exposure scenario for all populations (USEPA, 2002). The chronic RfD for LTC was developed by applying an uncertainty factor of 100 to the NOAEL of 0.1 mg/kg from a chronic oral study in the dog.

The USEPA/OPP classified LTC as “not likely to be carcinogenic to humans” and did not derive a cancer potency factor.

The USEPA established tolerances for the combined residues of LTC and its isomers on plants and livestock. The tolerances for pome and stone fruits are 0.3 and 0.5 ppm, respectively (40 CFR 180.438).

3.2 Ecological Dose-Response Assessment

3.2.1 Wild Mammal, Avian and Reptile Toxicity

Toxicity data for wild mammal species and LTC are not available; however, the data reported in laboratory test mammals can be used as a surrogate for potential effects in acute and chronic exposures. Effects data for mammals is summarized in the previous section discussing toxicity to human health.

Avian toxicity of LTC has been characterized in the bobwhite quail and mallard, which are standard surrogate test organisms used in the registration of a pesticide. Dietary LC$_{50}$ values for the mallard and bobwhite quail were greater than 3,948 and 5,300 ppm, respectively (USEPA, 2015). The only oral LD$_{50}$ study was for the mallard with a reported median lethality value of greater than 3,150 mg/kg. Available oral and dietary dosing studies suggest LTC is practically non-toxic to birds. Chronic reproduction studies report NOECs of greater than 30 and 50 ppm for the bobwhite and mallard, respectively (USEPA, 2015).

No reptile toxicity data for LTC reptile appears to be available based on a search of the available literature and databases. USEPA/OPP assumes that avian toxicity is similar to reptile toxicity in their risk assessment process. There is uncertainty in this assumption based on differences
between the two taxa; however, due to the lack of data, the same assumption is being made in this assessment.

### 3.2.2 Terrestrial Invertebrate Toxicity

LTC is considered highly toxic to most terrestrial invertebrates, including pollinators. The acute contact LD$_{50}$ for the honey bee is 0.038 µg/bee and the oral LD$_{50}$ in oral studies is 0.96 µg/bee, suggesting LTC is highly toxic to honeybees. Based on the proposed use pattern for LTC, soil invertebrates would be the most likely non-target terrestrial invertebrates to be exposed after treatment. Soil arthropods are more sensitive to LTC than earthworms based on available data (Frampton et al., 2006). The reported hazard concentration that would impact five percent (HC$_{05}$) of the soil invertebrate fauna was estimated to be 0.09 mg/kg dry soil. Garcia et al. (2008) reported a range of acute and sublethal effects to the earthworm, *Eisenia fetida*, based on various soil types. Reported LC$_{50}$/NOECs ranged from 23.9 and 10 ppm in tropical soils, to 139.9 and 31.6 in European soils.

### 3.2.3 Terrestrial Plant Toxicity

No terrestrial phytotoxicity data appears to be available for LTC. USEPA/OPP does not typically require phytotoxicity information to be collected for the registration of insecticides. The mode of action for LTC suggests that toxicity would be low. In addition, LTC has a variety of agriculture and non-agricultural uses and there is no information from those uses that would demonstrate impacts to target crops where it has been applied.

### 3.2.4 Aquatic Toxicity

LTC is considered very highly toxic to aquatic vertebrates and invertebrates. Representative toxicity data for warm water and cold water fish species show typical median lethality values ranging from 0.078 to 7.92 µg/L (EPA, 2015; Kumar et al., 2011; USDA FS, 2010) (table 3-1).
Table 3-1. Representative toxicity of LTC to fish.

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Scientific Name</th>
<th>LC$_{50}$ (µg/L)</th>
<th>NOEC (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bluegill sunfish</td>
<td><em>Lepomis macrochirus</em></td>
<td>0.21</td>
<td>0.10</td>
</tr>
<tr>
<td>Rainbow trout</td>
<td><em>Oncorhynchus mykiss</em></td>
<td>0.19-0.24</td>
<td>0.03-0.051</td>
</tr>
<tr>
<td>Golden orfe</td>
<td><em>Leuciscus idus</em></td>
<td>0.078</td>
<td>0.055</td>
</tr>
<tr>
<td>Channel catfish</td>
<td><em>Ictalurus punctatus</em></td>
<td>0.16</td>
<td>NR</td>
</tr>
<tr>
<td>Fathead minnow</td>
<td><em>Pimephales promelas</em></td>
<td>0.70</td>
<td>NR</td>
</tr>
<tr>
<td>Sheepshead minnow</td>
<td><em>Cyprinodon variegatus</em></td>
<td>0.807</td>
<td>0.29</td>
</tr>
<tr>
<td>Carp</td>
<td><em>Cyprinus carpio</em></td>
<td>0.50</td>
<td>NR</td>
</tr>
<tr>
<td>Three-spined stickleback</td>
<td><em>Gasterosteus aculeatus</em></td>
<td>0.40</td>
<td>NR</td>
</tr>
<tr>
<td>Guppy</td>
<td><em>Poecilia reticulata</em></td>
<td>2.2</td>
<td>NR</td>
</tr>
<tr>
<td>Catfish</td>
<td><em>Clarias batrachus</em></td>
<td>5.1</td>
<td>NR</td>
</tr>
<tr>
<td>Catfish</td>
<td><em>Channa punctatus</em></td>
<td>7.92</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR = Not reported

Acute toxicity data for LTC and amphibians is limited to a *Rana* species where the 48-hour LC$_{50}$ was reported as 4 µg/L (Pan and Liang, 1996). Saghir et al. (2014) noted changes in the gonads of adult frogs exposed to LTC at concentrations ranging from 8 to 12 µg/L. The species was not given in the study and it should be noted the dosing levels were above median lethality values for fish.

Chronic toxicity to fish is also high with a reported NOEC of 0.25 µg/L in an early life stage study using the sheepshead minnow, and a NOEC of 0.031 µg/L in a fish full life cycle study using the fathead minnow.

Toxicity to freshwater and marine aquatic invertebrates is also high with EC/LC$_{50}$ values ranging from the low parts per trillion to low parts per billion range (EPA, 2015, Maund et al., 1998) (table 3-2). Chronic toxicity is also high with a reported NOEC 0.002 µg/L for the cladoceran, *D. magna* in 21-day reproduction study (Maund et al., 1998).

The low water solubility and strong binding affinity of LTC can reduce the bioavailability and toxicity to aquatic organisms (Maund et al., 1998; Hamer et al., 1999).
Table 3-2. Aquatic toxicity of LTC to aquatic invertebrates.

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Scientific Name</th>
<th>LC$<em>{50}$/EC$</em>{50}$ (ug/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphipod</td>
<td><em>Gammarus pulex</em></td>
<td>0.0014-0.0068</td>
</tr>
<tr>
<td></td>
<td><em>Hyalbela azteca</em></td>
<td>0.0023</td>
</tr>
<tr>
<td>Phantom midge</td>
<td><em>Chaoborus sp.</em></td>
<td>0.0028</td>
</tr>
<tr>
<td>Mosquito</td>
<td><em>Culex tritaeniorhynchus</em></td>
<td>0.001</td>
</tr>
<tr>
<td>Cladoceran</td>
<td><em>Daphnia magna</em></td>
<td>0.051-0.23</td>
</tr>
<tr>
<td>Mysid</td>
<td><em>Americamysis bahia</em></td>
<td>0.0041</td>
</tr>
<tr>
<td>Water hoglouse</td>
<td><em>Asellus aquaticus</em></td>
<td>0.026</td>
</tr>
<tr>
<td>Water boatman</td>
<td><em>Corixa sp.</em></td>
<td>0.030</td>
</tr>
<tr>
<td>Mayfly</td>
<td><em>Cloeon dipterum</em></td>
<td>0.038</td>
</tr>
<tr>
<td>Water mite</td>
<td><em>Hydracarina</em></td>
<td>0.047</td>
</tr>
<tr>
<td>Damsel fly</td>
<td><em>Ischnura elegans</em></td>
<td>0.13</td>
</tr>
<tr>
<td>Pacific oyster</td>
<td><em>Crassostrea gigas</em></td>
<td>&gt;590</td>
</tr>
</tbody>
</table>

The range of effects concentrations for aquatic invertebrates that have been established in laboratory studies have also been observed in LTC-dosed microcosm and mesocosm studies that have been summarized in the literature (USDA FS, 2010; Van Wijngaarden et al., 2005).

4.0 EXPOSURE ASSESSMENT

4.1 Human Health Exposure Assessment

The exposure assessment estimates the potential exposure of humans to LTC. The exposure assessment begins with the use and application method for LTC in the fruit fly program. A complete exposure pathway for LTC includes (1) a release from a LTC 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 (USEPA, 1989). In this way, the potentially exposed human populations and complete exposure pathways are identified. Finally, exposures for the identified human populations are qualitatively and quantitatively evaluated for each exposure pathway.

4.1.1 Identification of Potentially Exposed Human Populations and Complete Exposure Pathways

LTC in the Warrior II formulation is applied as a soil drench. Drift from the soil drench application is minimal because large coarse droplets are applied in close proximity to the targeted area. Based on the application method, workers (i.e., certified applicators, or persons under their direct supervision) in the program are the most likely human population segment to be exposed to LTC. The potential exposure pathways for these workers include direct contact (i.e., incidental ingestion, inhalation, and dermal contact) to LTC during application. However, direct contact exposures are minimized with the use of personal protective equipment (PPE). Accidental exposure may occur from splash or transfer from contaminated gloves or clothing to
an unprotected skin area (face). The occurrence for accidental exposure is unlikely with well-trained certified applicators.

By providing adequate notice about a planned treatment program, as specified in the FIFRA Section 24(c) Special Local Need Label (Syngenta, 2014), the general public (e.g., residents) are not recognized as a potentially exposed segment of the human population. APHIS will notify residents whose property will be treated with soil drenches in writing 24 hours prior to treatment. With the notification to the public in place, potential residential exposure to LTC is very low. The label requires applications to be made by or under the supervision of a licensed state or federal employee with the following specifics to prevent the pesticide mixture to remain on the surface of the treated areas:

- pre-drench areas prior to the pesticide application with sufficient water (up to 20 gallons per 1000 sq. ft.) to break the surface tension of soil to allow adequate penetration of the pesticide mixture;
- make treatments to ensure that no surface liquid remains in order to avoid non-target exposure of humans, animals, and nontarget species; and
- remain on-site until the application has been absorbed into the soil when absorption is slow.

A complete exposure pathway associated with direct contact to LTC from the soil drench application is not identified for the general public. There is the potential for a resident child to be exposed to LTC in treated soil via pica behavior (a pattern of eating non-food materials, such as dirt or paper) generally seen in young children. Ten to 32 percent of children ages 1 to 6 exhibit this type of behavior (MedlinePlus, 2014). In this exposure scenario, the potential exposure for a resident child is expected to be limited because families would be notified of treatments. However, as a conservative approach, the potential exposure and risk for this unusual exposure scenario are further quantified.

A complete exposure pathway is not identified for dietary consumption of fruit from treated fruit bearing trees. LTC applied through soil drench is unlikely to be taken up by the roots of vascular plants and be present in any fruit (see Section 2.3). Second, APHIS will remove and destroy all fruit from fruit-bearing host plants where soil drench applications were made, eliminating dietary exposure to LTC.

A complete exposure pathway is not identified for the groundwater medium. LTC has low water solubility and adsorbs strongly to soil (see Section 2.3). As a result, leaching into groundwater from soil by the soil drench application is not expected.

A complete exposure pathway is not identified for the surface water medium. Significant surface runoff is not expected to occur from the soil drench application based on program and label requirements, as well as the reported low mobility for LTC.
4.1.2 Exposure Evaluation

This section qualitatively evaluates worker exposure from direct contact pathways while mixing and applying LTC based on the application rate for the soil drench scenario. The section also quantitatively evaluates the potential exposure to LTC in soil for a child from the unusual soil ingestion behavior (pica).

Under the FIFRA Section 24(c) label, the application rate is a single maximum rate of 0.0092 lb a.i. per 1000 sq. ft. of soil surface (equals 0.56 fl. oz. of product in 15.5 gallon of water per 1000 sq. ft). The Warrior II product is mixed in the field (0.73 fl. oz. product in 20 gallons of water to form a solution/suspension). The pesticide mixture is applied in areas within the drip line of fruit-bearing host plants that are located within a 400 meter radius from a non-native fruit fly larval, pupal, egg, or mated female find. It is also applied as a regulatory treatment to host nursery stock and to soil around nursery stock to allow nursery stock to move within and out of the quarantine area.

Direct contact to LTC during application is not expected to occur under normal conditions with proper worker hygiene and properly functioning PPE. The PPEs for applicators and other handlers as specified on the label include a long-sleeved shirt and long pants, chemical-resistant gloves (Category G, such as barrier laminate or Viton® > 14 mils), shoes plus socks, and protective eyewear. LTC has a low vapor pressure and low Henry’s law constant, and is not volatile. A respirator is not required for handling this product for commercial applications and/or on-farm applications because the potential for inhalation exposure is unlikely. For the manufacture, formulation, and packaging of the product, Syngenta in the MSDS (Syngenta, 2010) recommends the use of effective engineering controls to comply with the occupational exposure limit (i.e., Syngenta Occupational Exposure Limit (OEL) of 0.04 mg/m³ TWA (skin) for LTC).

To quantify the potential exposure to LTC in soil for a child from pica, an upper bound soil concentration was estimated using the label application rate for a soil drench scenario based on the following assumptions:

- A single maximum rate of 0.0092 pounds of LTC per 1000 square ft of soil surface from the Warrior II 24(c) label;
- Top 1 inch of soil depth containing LTC based on 0.5 to 1 inches of soil drench; and
- Default soil bulk density of 1.4 g/cm³ for sandy loams and loams soil type (USDA NRCS, 2014)

Acute and chronic exposure intake values were calculated using the following USEPA soil ingestion exposure intake equations:

\[
\text{Acute Exposure Intake} = \left(\frac{\text{Soil Concentration} \times \text{Soil Ingestion Rate}}{\text{Body Weight}}\right)
\]

\[
\text{Chronic Exposure Intake} = \left(\frac{\text{Soil Concentration} \times \text{Soil Ingestion Rate} \times \text{Exposure Duration} \times \text{Exposure Frequency} \times \text{Conversion Factor}}{\text{Averaging Time} \times \text{Body Weight}}\right)
\]

(USEPA, 2002).
Information on exposure parameters such as soil ingestion rate, exposure duration, exposure frequency, averaging time, and body weight, and calculated acute and chronic exposure intake values are presented in Attachment A.

4.2 Ecological Exposure Assessment

4.2.1 Terrestrial Exposure Assessment

Exposure to terrestrial vertebrates such as wild mammals, birds, and reptiles is expected to be minimal. LTC applications occur to soil under the drip line of trees or to containerized plants within nurseries that are under quarantine. Wild mammals, birds, and reptiles would not be expected to forage in containerized plants. In other cases where a treatment is made to a fruit fly host tree within 400-m of a fruit fly detection, these applications are made only to soil within the dripline of the host tree, resulting in a low probability of exposure. There is the potential for terrestrial vertebrates to forage under these trees for soil borne invertebrates where they could consume treated soil and soil invertebrates that may contain LTC residues. However, based on the typical food consumption rate for various sized mammals, birds, and reptiles, and the toxicity profile for LTC, there is not a plausible exposure scenario where they would consume LTC residues from soil or soil borne invertebrates that could result in adverse effects. Significant exposure to pollinators, such as honey bees is also not expected because LTC is being applied directly to soil and not to flowering parts of host trees. LTC is not systemic and soil applications would not result in detectable levels of LTC in pollen and nectar. There is the potential for exposure to soil borne terrestrial invertebrates. Upper limit estimated soil residues are 1.3 mg/kg based on conservative assumptions regarding application rates (Attachment A).

4.2.2 Aquatic Exposure Assessment

Aquatic exposure is expected to be low for the proposed use of LTC in the fruit fly program based on the proposed use pattern and label restrictions designed to protect water quality. Applications are made directly to soil to individual trees within the 400-m radius of a non-native fruit fly detection, or to containerized plants that are located in nurseries under quarantine. The method of application reduces the chance of any significant drift from these applications and the environmental fate and label restrictions will reduce runoff. LTC has low water solubility and a high binding affinity for soil and sediment which will reduce runoff. Material that is not bound to soil or organic matter will preferentially bind to sediment once it enters water, reducing the bioavailability and risk to water column non-target aquatic species. Current label requirements regarding application buffers near water bodies, and the presence of a vegetative filter strip will further reduce the potential for significant aquatic residues. These mitigation measures have been shown to be beneficial for reducing runoff of pesticides, including LTC (Moore et al, 2001; He et al., 2008).
5.0 RISK CHARACTERIZATION

5.1 Human Health

Risks associated with adverse human health are characterized qualitatively and quantitatively in this section. Under the APHIS proposed applications, the use of LTC for the fruit fly eradication program should pose minimal risks to human health. Fruit fly quarantines are fairly infrequent and usually do not occur every year. The last fruit fly quarantine in Florida was in 2011 in Broward County.

Exposure to LTC via oral, inhalation, and dermal routes is expected to be minimized by workers (i.e., certified applicators) adherence to the label required PPE. Although LTC is a hazard to humans because of its acute toxicities via the oral, inhalation, and ocular routes, the low potential for exposure to LTC suggests that adverse health risk to workers is not expected. Accidental exposure from splash to unprotected body areas may occur. The exposure frequency is considered low for this exposure scenario because only certified applicators working with State and Federal agencies, or person under their guidance, will be making applications. Therefore, risk from accidental exposure is minimal.

The risks to the public associated with potential exposure to LTC during soil drench applications, and dietary consumption of fruit from the treated fruit-bearing trees are low based on notification of the public and destruction of fruit in treated areas. Pica behavior is reported in only 10 to 32 percent of children ages 1 to 6. Consequently, the risks associated with residential children being accidentally exposed to treated soil through pica behaviors are low because children of this age and with this disorder primarily are under adult supervision.

To quantify the risk from child (age 1-6) exposure to soil from pica behavior, hazard quotients (HQs) were calculated using the following USEPA soil ingestion risk estimation equation for non-carcinogens:

\[
\text{Acute HQ} = \frac{\text{Acute Exposure Intake}}{\text{Reference Dose}} \\
\text{Chronic HQ} = \frac{\text{Chronic Exposure Intake}}{\text{Reference Dose}} \quad \text{(USEPA, 2002)}.
\]

Only non-cancer risks were evaluated because USEPA classified LTC as “not likely to be carcinogenic to humans”. The calculated acute and chronic HQ values (table 5-1) were below the USEPA’s level of concern (HQ=1) suggesting minimal risk to LTC exposure from soil ingestion behavior (pica) by children. The risk calculation sheets are included in Attachment A.
Table 5-1. Hazard quotients estimated for child exposure to soil from pica behavior.

<table>
<thead>
<tr>
<th></th>
<th>Upper Estimation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated soil concentration</td>
<td>1.3 mg/kg</td>
</tr>
<tr>
<td>Acute exposure intake</td>
<td>8.4E-04 mg/kg-day</td>
</tr>
<tr>
<td>Chronic exposure intake</td>
<td>1.9E-04 mg/kg-day</td>
</tr>
<tr>
<td>Acute reference dose</td>
<td>0.005 mg/kg-day</td>
</tr>
<tr>
<td>Chronic reference dose</td>
<td>0.001 mg/kg-day</td>
</tr>
<tr>
<td>Acute HQ</td>
<td>0.17</td>
</tr>
<tr>
<td>Chronic HQ</td>
<td>0.19</td>
</tr>
</tbody>
</table>

5.2 Terrestrial and Aquatic Risk Characterization

The risk of LTC use to non-target terrestrial vertebrates is expected to be very low. Available toxicity data for mammals and birds and the proposed use pattern suggest that the probability of exposure to a significant amount of LTC that would result in adverse effects is very low. Primary exposure and risk for terrestrial vertebrates would be through the consumption of treated soil and any associated soil invertebrates. The low frequency of these treatments in the program, the targeted application to soil in either containerized plants or the drip line of host trees in a small area, suggest that non-target birds and mammals would have to consume many times their daily food consumption rates to receive a dose that could result in an effect. Indirect effects through loss of prey items for insectivores is also not expected because applications are targeted to either containerized plants, where non-target mammals and birds would not forage or to small areas under the drip line of host trees. These treatments and their frequency of use in the program would not result in significant terrestrial invertebrate population declines that could impact prey consumption by insectivorous mammals and birds. LTC would be expected to impact some soil borne terrestrial invertebrates. The HC05 of 0.09 mg/kg is below the estimated upper level LTC concentrations that were calculated in the human health soil exposure exercise (1.3 mg/kg). The exposure estimate is below available earthworm acute and chronic exposure endpoints suggesting that impacts to soil invertebrates would be mostly to sensitive arthropods. Any impacts would be limited to directly below the drip line where applications are being made and are not expected to have impacts over a large area.

Aquatic risks from the proposed use pattern of LTC are expected to result in low risk to aquatic vertebrates and invertebrates. LTC is highly toxic to aquatic biota; however, the use pattern in the fruit fly program, the low frequency of use in the program, and the associated current label restrictions that require protection of aquatic areas are expected to result in low risk to aquatic vertebrates and invertebrates. In addition, the method of application reduces off-site transport from drift, and any transport would occur from runoff. LTC in runoff would be adsorbed to soil particles, and other organic matter, further reducing its availability to water column aquatic fauna. Exposure and risk would be greatest for aquatic biota that use or occupy the sediment in an aquatic habitat; however, these risks are expected to be low.
6.0 UNCERTAINTIES AND CUMULATIVE IMPACTS

The uncertainties associated with this risk evaluation arise primarily from lack of information about the effects of LTC, its formulations, metabolites, and potential mixtures to non-target organisms that can occur in the environment. These uncertainties are not unique to this assessment but are consistent with uncertainties in human health and ecological risk assessments with any environmental stressor. In addition, there is uncertainty in where a non-native fruit fly detection may occur in Florida, and the rest of the United States, and the extent of LTC 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 LTC in the fruit fly eradication programs. Areas where cumulative impacts could occur are: 1) repeated worker and environmental exposures to LTC 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 LTC.

Temporal variability in the occurrence of multiple stressors, as well as their effects, is not well understood. As an example, available water quality monitoring data in the United States indicate the presence of multiple natural and anthropogenic contaminants. Sources for these chemicals can occur from point and non-point sources, and the relative contribution from each is dependent on land use in a given watershed. Based on the most recent United States Geological Survey National Water Quality Assessment (USGS–NAWQA) data for pesticides, frequency of occurrence for two or more pesticides in surface water exceeds 80 percent nationally (Gilliom et al., 2006). When considering other organics and trace metals, the combination of mixtures can become extremely large, especially when spatial and temporal variability in mixtures that can occur in a given watershed are considered. The seasonal variability in mixtures of pesticides and other contaminants has been well documented nationally in urban and agricultural areas (Ryberg et al., 2010; Gilliom et al., 2006; Stone et al., 2014). An analysis of all detections from agricultural streams indicated more than 6,000 unique mixtures of 5 pesticides (Gilliom et al., 2006). Pyrethroid insecticides, including LTC, have been identified as a component of these mixtures in water/sediment monitoring data in both urban and agricultural settings (Weston et al., 2004; 2009; 2011; Hintzen et al., 2009). As would be expected, based on the large variability in mixtures, the ecological and human health response data for these types of exposure scenarios is very limited for all organic and inorganic chemicals including those proposed in the program.

Cumulative impacts may occur from LTC use from other APHIS programs and in relation to other chemicals that have a similar or different mode of action, and can result in synergism, potentiation, additive, or antagonistic effects. The potential for co-exposure to other pesticides within the program with the same toxic action is not expected. The other pesticide used in the fruit fly eradication program is spinosad. Spinosad over-activates the central nervous system of insects via the nicotinic acetylcholine receptors. LTC disrupts normal nerve function by inhibiting the closing of the voltage-gated membrane sodium channels of nerve cells. LTC contains a cyano group (i.e., a carbon-nitrogen triple bond) and is structurally considered a Type II pyrethroid. The neurotoxicity of LTC is similar to other commonly used Type II pyrethroids such as gamma-cyhalothrin, cyfluthrin, cypermethrin, deltamethrin, esfenvalerate, fenvalerate,
fenpropathrin, flucythrinate, flumethrin, fluvalinate, and tralomethrin (ATSDR, 2003). However, the fruit fly program does not use any of the other Type II pyrethroids. Non-APHIS uses of LTC include food and non-food crop uses such as indoor and outdoor use in homes, hospitals, and other buildings; greenhouse, ornamental plant, and lawn insecticides; insecticide products for use on cattle; termite treatments; insecticide products for use on right-of-ways; and aerially-applied insecticides (NPIC, 2001). Cumulative impacts from the proposed use of LTC is expected to be incrementally minor due to the proposed use pattern of LTC, and the historical low frequency of positive non-native fruit fly detections in Florida.
7.0 REFERENCES


USEPA. 2007. Memorandum, Lambda-cyhalothrin, human health risk assessment for the proposed food/feed uses of the insecticide on cucurbit vegetables (Group 9), tuberous and corm vegetables (Subgroup 1C), grass forage, fodder, and hay (Group 17), barley, buckwheat, oat, rye, wild rice, and pistachios. Petition Numbers 5F6994, 3E6593, and 6E7077.


Attachment A
Risk Estimates for Soil Ingestion in Children (ages 1-6) with Pica

Attachment A includes equations and assumptions used for risk estimations of soil ingestion in children (ages 1-6) with pica behavior.

**Equations:**
- Acute Exposure Intake = \( \frac{C \times IR}{BW} \)
- Chronic Exposure Intake = \( \frac{C \times IR \times ED \times EF \times CF}{AT \times BW} \)
- Hazard Quotient (HQ) = \( \frac{\text{Exposure Intake}}{\text{RfD}} \)

Where:
- Exposure Intake – mg/kg/day
- HQ - unitless
- C – Soil concentration (mg/g)
- IR – Ingestion rate (g/day)
- BW – Body weight (kg)
- ED – Exposure duration (year)
- EF – Exposure frequency (days/year)
- CF – Conversion factor (kg/mg)
- AT – Averaging time (days)
- RfD – Reference dose (mg/kg/day)

**Assumptions for soil concentration estimation:** Based on the Warrior II 24(c) label, a single maximum rate of 0.0092 pounds of lambda-cyhalothrin per 1000 square ft of soil surface was used for the soil concentration calculation.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Input Values</th>
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<tbody>
<tr>
<td>Amount of lambda-cyhalothrin per 1000 ft(^2)</td>
<td>0.0092 lb (4173.0464 mg)</td>
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<tr>
<td>Soil surface area</td>
<td>1000 ft(^2)</td>
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<tr>
<td>Depth of surface soil (assumed top 1 inch)</td>
<td>1 inch (0.083 ft)</td>
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<tr>
<td>Soil volume (soil surface area x depth)</td>
<td>83.3333 ft(^3) (2359736.27 cm(^3))</td>
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<tr>
<td>Soil bulk density*</td>
<td>1.4 g/cm(^3)</td>
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<tr>
<td>Soil weight (soil volume x density)</td>
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<tr>
<td>Estimated soil concentration (mg a.i./kg soil)</td>
<td>1.3 mg/kg</td>
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</tbody>
</table>

* Default soil bulk density for sandy loams and loams (USDA NRCS, 2014)
### Assumptions for risk estimation:

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<thead>
<tr>
<th>Input Parameters</th>
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<tr>
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<td>USEPA, 2000</td>
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<td>Chronic Ingestion Rate (IRc) mg/day</td>
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<td>Exposure Duration (ED) year</td>
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<td>Exposure Frequency (EF) (days/year)</td>
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<td>Biodegradation time for lambda-cyhalothrin in soil without vegetation (NPIC, 2001)</td>
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<td>Conversion Factor (CF) (kg/mg)</td>
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<td>Acute Reference Dose (RfD) (mg/kg-day)</td>
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<td>Chronic Reference Dose (RfD) (mg/kg-day)</td>
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<td>USEPA, 2002</td>
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<tr>
<td>Acute Hazard Quotient (HQ)</td>
<td>0.17</td>
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</tr>
<tr>
<td>Chronic Hazard Quotient (HQ)</td>
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<td>calculated</td>
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