**FINAL Problem Formulation for Malathion ESA Assessment (Steps 1 and 2)**

**Table of Contents**

[1. Introduction 4](#_Toc471801544)

[1.1. Description of the Federal Action 4](#_Toc471801545)

[1.1.1. Nature of the Regulatory Action 5](#_Toc471801546)

[1.1.1.1. Pesticide registration 5](#_Toc471801547)

[1.1.1.2. Registration Review 6](#_Toc471801548)

[1.1.1.3. Pesticide Labels 6](#_Toc471801549)

[1.1.1.4. Monitoring and Reporting 7](#_Toc471801550)

[1.1.2. Use Data (Labels) 7](#_Toc471801551)

[1.1.2.1. Current Registrations 7](#_Toc471801552)

[1.1.2.2. Inert Ingredients 9](#_Toc471801553)

[1.1.2.3. Recommended Tank Mixes 10](#_Toc471801554)

[1.1.2.4. Use Sites, Application methods, and Application Rates 12](#_Toc471801555)

[1.1.2.4.a. Summary of non-agricultural uses 13](#_Toc471801556)

[1.1.2.4.b. Summary of Agricultural and Ultra-low Volume Uses 18](#_Toc471801557)

[1.1.2.5. Outstanding Mitigations 26](#_Toc471801558)

[1.1.3. Usage Data 26](#_Toc471801559)

[1.2. 1.2. Pesticide Active Ingredient Information 29](#_Toc471801560)

[1.2.1 Mode and Mechanism of Action 29](#_Toc471801561)

[1.2.2. Fate Overview 30](#_Toc471801562)

[1.2.3. Degradates of Concern 31](#_Toc471801563)

[*1.3.* 1.3. Conceptual Model 31](#_Toc471801564)

[1.3.1. Conceptual Model for Potential Exposure Routes 31](#_Toc471801565)

[1.3.2. Risk Hypotheses 34](#_Toc471801566)

[1.4. 1.4. Analysis Plan 35](#_Toc471801567)

[1.4.1. Step 1 - May Affect/No Effect Determinations 36](#_Toc471801568)

[1.4.1.1 Action Area 37](#_Toc471801569)

[1.4.1.1.a. Use Site Footprint 37](#_Toc471801570)

[1.4.1.1.b. Thresholds of effects 38](#_Toc471801571)

[1.4.1.1.b.1 Mortality (acute) and sublethal thresholds 38](#_Toc471801572)

[1.4.1.1.c. Off-site Transport Area 39](#_Toc471801573)

[1.4.1.1.c.1 Aquatic Modeling 40](#_Toc471801574)

[1.4.1.1.c.2 Terrestrial Modeling 42](#_Toc471801575)

[1.4.1.2. Species/Critical Habitat Locations 42](#_Toc471801576)

[1.4.1.3. Overlap Analysis 43](#_Toc471801577)

[1.4.2. Step 2 – LAA/NLAA Determinations 44](#_Toc471801578)

[1.4.2.1. Lines of Evidence 45](#_Toc471801579)

[1.4.2.2. Weight of Evidence Approach 52](#_Toc471801580)

[1.4.2.2.a. Estimated exposures 56](#_Toc471801581)

[1.4.2.2.a.1. Aquatic habitats 56](#_Toc471801582)

[1.4.2.2.a.2. Terrestrial habitats 58](#_Toc471801583)

[1.4.2.2.b. Estimated effects 59](#_Toc471801584)

[1.4.2.2.b.1 Effects thresholds 59](#_Toc471801585)

[1.4.2.1.b.1.1 Direct and indirect effect thresholds based on mortality 60](#_Toc471801586)

[1.4.2.1.b.1.2. Direct and indirect effect thresholds based on sublethal endpoints 60](#_Toc471801587)

[1.4.2.2.a. Effect arrays 62](#_Toc471801588)

[1.4.2.2.b. Incident data 63](#_Toc471801589)

[1.4.2.2.c. Effects to designated critical habitat 64](#_Toc471801590)

[1.4.2.2.d. Probabilistic approach for 13 bird species 64](#_Toc471801591)

[1.4.2.2.e. Mixture Analysis 65](#_Toc471801592)

[1.4.2.2.f. Consideration of Impacts of Biotic and/or Abiotic Stressors on the Effects of Malathion 68](#_Toc471801593)

[1.5. 1.5. References 76](#_Toc471801594)

**List of Figures**

[Figure 1-1. Malathion Use Spatial Distribution (2012) and Use by Year and Crop (1992-2012). 26](#_Toc435773400)

[Figure 1-2. Adverse Outcome Pathway for Organophosphates and Acetylcholinesterase Inhibition. 28](#_Toc435773401)

Figure 1-3. [Conceptual Model for Malathion Effects on Aquatic Organisms 30](#_Toc435773402)

[Figure 1-4. Conceptual Model for Malathion Effects on Terrestrial Organisms 31](#_Toc435773403)

[Figure 1-5. Three Step ESA Consultation Approach Modified from a Figure in the NRC (2013) Report 33](#_Toc435773404)

[Figure 1-6. Step 1 - Action Area and Species' Ranges 35](#_Toc435773405)

[Figure 1-7. Example Display of All Lines of Evidence for a Risk Hypothesis Based on Confidence and Risk 53](#_Toc435773406)

**List of Tables**

[Table 1-1. Multi-A.I. Products Containing Malathion. 10](#_Toc435773435)

[Table 1-2. Summary of Tank Mixes Specified on Malathion Product Labels. 11](#_Toc435773436)

[Table 1-3. Malathion Use Summary of Non-Agricultural (Residential and Commercial) Uses 14](#_Toc435773437)

[Table 1-4. Malathion Use Summary of Agricultural Uses with Conventional Application Methods 19](#_Toc435773438)

[Table 1-5. Malathion Use Summary of Agricultural and Non-Agricultural Uses with Ultra Low Volume Applications 24](#_Toc435773439)

[Table 1-6. Endpoints and Associated Threshold Selection Strategies That Will Be Used to Delineate the Boundary of the Action Area in Step 1 37](#_Toc435773440)

[Table 1-7. Lines of Evidence for Risk Hypotheses**.** 45](#_Toc435773441)

[Table 1-8. Effects Determinations Based on Pairings of Risk and Confidence for a Line of Evidence 55](#_Toc435773442)

[Table 1-9. Generic Aquatic Habitats 56](#_Toc435773443)

[Table 1-10. Step 2 Habitats. 61](#_Toc435773444)

[Table 1-11. Impurities Reported in Technical Malathion (CalEPA 1981) 68](#_Toc435773445)

[Table 1-12. Comparison of Recently Submitted Toxicity Values to Other Reported Toxicity Values for Aquatic Species 70](#_Toc435773446)

[Table 1-13. Comparison of Recently Submitted Toxicity Values to Other Reported Toxicity Values for Terrestrial Species 74](#_Toc435773447)

#  Introduction

The purpose of this document is to support a process to evaluate whether the registered uses of malathion (PC code 057701) will result in potential risk to endangered and threatened (listed) species and/or designated critical habitat. This effort is being completed in support of the registration review process. In registration review, all pesticides distributed and sold in the United States are reevaluated every 15 years to make sure that as changes occur, products in the marketplace can still be used safely without unreasonable adverse effects[[1]](#footnote-1) to non-listed species under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and that registered uses do not jeopardize the continued existence of listed species and/or result in adverse modification of critical habitat as administered under the Endangered Species Act (ESA).

The listed species assessment process follows the recommendations of the National Research Council (NRC) of the National Academies' Committee on Ecological Risk Assessment under the FIFRA and the ESA providedin the form of a report entitled, *Assessing Risks to Endangered and Threatened Species from Pesticides* (NRC, 2013). Based on the NRC report recommendations, the agencies[[2]](#footnote-2) responsible for conducting the listed species risk assessments use a three-step consultation process to evaluate the potential risk to listed species [*i.e*., Step 1 (‘No Effect/May Affect’ determination), Step 2 (‘Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)’ determination), and Step 3 (‘Jeopardy/No Jeopardy’ determination and “adverse modification/no adverse modification” determination on effects to designated critical habitat(s)], with the understanding that the data and analyses for each step will be used, when possible, for the subsequent steps. This document, referred to as the biological evaluation (BE), represents Steps 1 and 2 in the 3-step listed species assessment process for malathion.

The problem formulation outlines the strategic framework and analysis plan for evaluating potential risk posed by the stressors of the action to listed species and their designated critical habitats. Risk hypotheses define predicted effects of malathion exposure on species and assessment endpoints and provide the framework of the analysis in terms of linking stressor, exposure, and effects. Risk hypotheses are evaluated using lines of evidence constructed from the best commercial and scientific data available. We determine whether the registered uses of malathion adversely affect individuals of listed species and their designated critical habitats.

##  Description of the Federal Action

The proposed Federal action[[3]](#footnote-3) (the Action) encompasses the U.S. Environmental Protection Agency’s (EPA) registration of the uses, as described by product labels, of all pesticide products containing malathion. The purpose of the proposed action is to provide tools for pest control on food and feed crops as well as for other non-agricultural uses that do not cause unreasonable adverse effects to the environment throughout the U.S. and its affiliated territories.

EPA’s proposed action encompasses all uses authorized by approved product labels containing malathion, its metabolites and degradates, any other active ingredients, other ingredients within the formulations, such as adjuvants and inert ingredients, and any recommended tank mixtures. These comprise the potential stressors of the action. The proposed action also includes all authorizations for use of pesticide products, including the use of existing stocks, and active labels of products containing malathion for the 15-year duration of the proposed action.

In addition, future uses will be considered as addressed by this risk assessment [*i.e*., biological evaluation (BE)] if the geographic distribution and magnitude of exposure (including application rates and methods of application) have been included in the scope of the assessment. Therefore, if new uses, rate increases, or an application method that increases exposure are approved, then re-initiation of consultation is required.

The 15-year registration cycle for Section 3 and Section 24(c) consultation or the applicable duration for other consultations will be used as the duration of the action, unless otherwise specified on the label.

### 1.1.1. Nature of the Regulatory Action

#### 1.1.1.1. Pesticide registration

Pursuant to FIFRA, before a pesticide product may be sold or distributed in the U.S., it must be exempted or registered with a label identifying approved uses by EPA’s Office of Pesticide Programs (OPP). Pesticide registration is the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. Pesticide products (also referred to as “formulated products”) may include active ingredients (a.i.s) and other ingredients, such as adjuvants and surfactants. EPA authorization of pesticide uses are categorized as FIFRA Sections 3 (new product registrations), 4 (re-registrations and special review), 18 (emergency use), or 24(c) Special Local Needs (SLN).

EPA evaluates a pesticide to ensure that it will not have unreasonable adverse effectson humans, the environment and non-target species. EPA also evaluates the impact on threatened and endangered (listed) species and their designated critical habitats. Pesticides must be registered or exempted by EPA before they may be sold or distributed in the U.S. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide’s label or labeling.

After registering a pesticide, EPA retains discretionary involvement and control over such registration. EPA must periodically review the registration to ensure compliance with FIFRA and other federal laws (7 U.S.C. §136d). A pesticide registration can be cancelled whenever “a pesticide or its labeling or othermaterial…does not comply with the provisions of FIFRA or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment.” For details on pesticide cancellation procedures under FIFRA 6(f), please see the following link:

https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative

“Restricted” pesticides may be applied only by or under the direct supervision of specially trained and certified applicators (40 CFR 171). Certification and training programs are conducted by states, territories, and tribes in accordance with national standards.

Malathion was first registered as an insecticide in 1965. An overview of the regulatory history and past risk assessments for malathion can be found in **APPENDIX** **1-1**.

#### 1.1.1.2. Registration Review

In 2006, EPA initiated a new program called registration review to reevaluate all pesticides on a regular cycle. The program’s goal is to review each pesticide active ingredient every 15 years to make sure that as the ability to assess risks to human health and the environment evolves and as policies and practices change, all pesticide products in the marketplace can still be used safely. Registration review includes Sections 3, 24(c), and 18 labels.

#### 1.1.1.3. Pesticide Labels

The label on a pesticide package or container is legally enforceable. The label provides information about how to handle and safely use the pesticide product and avoid harm to human health and the environment. Using a pesticide in a manner that is inconsistent with the use directions on the label is a violation of FIFRA and can result in enforcement actions to correct the violations.

EPA will evaluate listed species concerns within the context of registration review so that when a registration decision is made, it fully addresses issues related to listed species protection. If a risk assessment determines that use limitations are necessary to ensure that legal use of a pesticide will not adversely affect or result in jeopardy to listed species or adversely affect or modify their designated critical habitat, EPA may change the terms of the pesticide registration by requiring modification of labels that extend new limitations on pesticide use. When geographically specific use limitations are necessary, Endangered Species Protection Bulletins (Bulletins) will be referenced on the FIFRA label ensuring enforceability. Bulletins can be found at the following website: <http://www.epa.gov/oppfead1/endanger/bulletins.htm>.

#### 1.1.1.4. Monitoring and Reporting

The current Federal Action does not include any specific provision for monitoring. However, Section 6(a)(2) of the Federal Insecticide, Fungicide and Rodenticide Act requires pesticide product registrants to report adverse effects information, such as incident data (**ATTACHMENT 1-1**), about their products to the EPA. Several regulations and guidance documents have been published which provide registrants and the public with details on what, when and how to report this information. For more information, see the following website:

https://www.epa.gov/pesticide-incidents/incident-reporting-pesticide-manufacturers-registrants

### 1.1.2. Use Data (Labels)

#### 1.1.2.1. Current Registrations

Malathion is an organophosphate used as an insecticide on a wide variety of terrestrial food and feed crops, terrestrial non-food crops, aquatic food, non-agricultural indoor, outdoor sites, and for wide area public health uses. Based on an Office of Pesticide Programs Information Network (OPPIN) query (conducted Feb. 2015), there is currently 1 active technical registrant that sponsors guideline studies on malathion, and there are 96 active registrations (43 Section 3’s, 53 Section 24c Special Local Needs, and 0 Section 18 Emergency Exemptions) from 21 registrants, which include formulated end-use products and technical grade malathion (see **APPENDIX 1-2**). Malathion can be applied in a dust, liquid or encapsulated form. Aerial and ground application methods (including broadcast, fogger, and chemigation) are allowed (see **APPENDIX 1-3** for details).

Registered labels for agricultural use products require 25-foot (ground and non-ULV aerial applications), or 50-foot (ULV aerial applications) no-spray buffer zones adjacent to “any water body.” The interpretation of what constitutes a water body is left to the applicator and the state lead agency for pesticide label enforcement. All registered labels for agricultural use also include the following spray drift requirements when spraying in the vicinity of aquatic areas:

* Droplet Size
	+ Use the largest droplet size consistent with acceptable efficacy. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure.
	+ For ground boom and aerial applications, use only medium or coarser spray nozzles according to ASAE (S572) definition for standard nozzles, or a volume mean diameter (VMD) of 300 microns or greater for spinning atomizer nozzles. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.
* Wind Direction and Speed
	+ Make aerial or ground applications when the wind velocity favors on-target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 15 mph. Avoid applications when wind gusts approach 15 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application
* Temperature Inversion
	+ Do not make aerial or ground applications into areas of temperature inversions. Inversions are characterized by stable air and increasing temperatures with increasing distance above the ground. Mist or fog may indicate the presence of an inversion in humid areas. Where permissible by local regulations, the applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface. In conditions of low humidity and high temperatures, applicators should use a coarser droplet size.
* Additional Requirements for Ground Applications
	+ For ground boom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.

Currently, there are 4 malathion products that are co-formulated with other pesticidal active-ingredients. Other active ingredients co-formulated with malathion include: carbaryl (PC Code 056801), captan (PC Code 081301), and gamma-cyhalothrin (PC Code 128807) (see **Table 1-1** and **Section 1.1.2.3** for details).

**Table 1-1. Multi-A.I. Products Containing Malathion.**

|  |  |  |  |
| --- | --- | --- | --- |
| **REGISTRATION #** | **NAME** | **PERCENT ACTIVE INGREDIENT** | **ACTIVE INGREDIENT** |
| 4-122 | Bonide A Complete Fruit Tree Spray | 0.30 | Carbaryl |
| 11.76 | Captan |
| 6.00 | Malathion |
| 829-175 | SA-50 Brand Malathion-oil Citrus & Ornamental Spray | 75.00 | Mineral Oil |
| 5.00 | Malathion |
| 67760-108 | Fyfanon Plus ULV | 1.47 | Gamma-cyhalothrin |
| 92.20 | Malathion |
| 67760-131 | Malathion 851 g/L + Gamma-Cyhalothrin 12.8 g/L EC | 1.11 | Gama-cyhalothrin |
|  | 73.70 | Malathion |

#### 1.1.2.2. Inert Ingredients

An inert ingredient is any substance (or group of structurally similar substances if designated by the Agency), other than an “active” ingredient, which is intentionally included in a pesticide product. It is important to note, the term “inert” does not imply that the chemical is nontoxic.

Inert ingredients play a key role in the effectiveness of a pesticidal product. Pesticide products may contain more than one inert ingredient; however, federal law does not require that these ingredients be identified by name or percentage on the label. All inert ingredients in pesticide products, including those in an inert mixture, must be approved for use by the EPA. For those inert ingredients applied to food crops, a tolerance or tolerance exemption is required. Impurities are not included in the definition of inert ingredient. As part of the review process for all new ingredients, a screening-level ecological effects hazard assessment is conducted, in which available data on the toxicity of the inert ingredient to non-target organisms is considered.

For the most current list of inert ingredients approved for food usepesticide products, see the Electronic Code of Federal Regulations (e-CFR, inert section starts at 180.920) at: <http://www.ecfr.gov/cgi-bin/text-idx?SID=26b254e3ec275241162fb666aa219c7b&mc=true&node=pt40.24.180&rgn=div5>

The majority of inert ingredients can be found in 40 CFR 180.910-180.960. 40 CFR part 180 also contains a number of sections that include tolerances/ tolerance exemptions[[4]](#footnote-4) for specific inert ingredients where their use is usually significantly limited. The listing of nonfood use inert ingredients, including those that also have food uses, can be found in InertFinder[[5]](#footnote-5).

#### 1.1.2.3. Recommended Tank Mixes

Malathion may be applied as part of a tank mix with other pesticides (*i.e*., insecticides, miticides and fungicides). In general, active ingredients can be mixed with other products unless specifically prohibited on the label(s). Some of the current malathion labels specify that the malathion product can be tank mixed with other products/chemicals. **Table 1-2** identifies the allowable, and in some cases, recommended, tank mixes specified on malathion labels. More details on the specified tank mixes can be found in **APPENDIX 1-4**.

**Table 1-2. Summary of Tank Mixes Specified on Malathion Product Labels.**

|  |
| --- |
| **Label Language** |
| For the mosquitocide application: "Mix… in 1 gallon of water or oil-based carrier (such as kerosene, fuel oil, or diesel oil)." |
| Label instructions say to dilute with water."Ortho RosePride Rose and Shrub Disease Control (or other EPA-registered product labeled for control of diseases on roses) may be mixed with this product when listed insect(s) and diseases are found on roses. Follow directions and precautions on both labels.""FRUITS - USE IN COMBINATION WITH VOLCK OIL SPRAY." |
| APPLICATION THROUGH IRRIGATION SYSTEMS - CHEMIGATION section: "Do not tank mix this product with other pesticides surfactants or fertilizers unless prior use has shown the combination non-injurious under your conditions of use." |
| For the mosquitocide application "OIL SOLUTION": "1 part concentrate to 28 parts of a mixture consisting of 4 parts kerosene to 1 part toluene..." |
| In Mixing Directions: only specifies addition of water. "Do not combine with wettable powders unless previous use of the mixture has proven physically compatible and safe to plants. Always thoroughly emulsify this product with at least half of total water before adding wettable powders."Applications through chemigation section: "This product should not be tank-mixed with other pesticides, surfactants or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and directions for all tank-mix products." |
| Applications through chemigation section: "This product should not be tank-mixed with other pesticides, surfactants or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and directions for all tank-mix products." |
| Mosquitoes: "Mix 11 tablespoons of product per gallon of water, fuel oil, or diesel oil." |
| "Do not combine emulsifiable liquids with wettable powders in the same spray tank unless previous use of the materials being combined has proven them to be physically compatible."Chemigation: "This product should not be tank-mixed with other pesticides, surfactants, or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and directions for all tank-mixed products." |
| Chemigation: "This product should not be tank-mixed with other pesticides, surfactants, or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and directions for all tank-mixed products."Mosquito control: "This product can be mixed with a synergized pyrethrin emulsifiable concentration (such as 6% pyrethrin + 60% PBO) in accordance with the most restrictive of label limitations and precautions indicated on both this and the tank-mixed product." |
| Chemigation: "Do not tank mix this product with other pesticides, surfactants or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and direction for all tank-mixed products."Applications: For the treatment of dried fruit beetle and vinegar flies in figs mix "2.0 pts [malathion] plus 2.0 gals unsulfurized molasses as a bait spray". For treatment of fruit flies in guava, mango, and passion fruit mix "0.75 pt [malathion] + 1.0 lb partially hydrolyzed yeast protein or enzymatic yeast hydrolyzate."Mosquito control: "This product can be mixed with a synergized pyrethrin emulsifiable concentrate (such as 6% pyrethrin + 60% PBO) in accordance with the most restrictive of label limitations and precautions indicated on both this and the tank-mixed product. Label rates must not be exceeded. This product may not be mixed with any product bearing a label which specifically prohibits such mixing. Prior to tank mixing large quantities, mix a small amount in a glass jar to verify that the products are physically compatible. Depending on your operation needs, the amount of synergized pyrethrin can be reduced or adjusted. Application rates of this product and droplet distribution requirements remain the same as for this product used alone."  |
| "An oil soluble malathion concentrate containing 4.5 lbs of malathion active ingredient per gallon. For formulating thermal fogging and mist spraying oils for mosquito control work and outdoor application."Fly Control: "Dilute this concentrate 1 part to 22 parts No. 2 fuel oil to make a 3% ready-to-use spray."Mosquito Control: "Apply a 3% to 5% Malathion in fuel oil at a rate of 1/2 lb actual malathion a.i. per acre". |
| "Do not combine emulsifiable liquids with wettable powders in the same spray tank unless previous use of the materials being combined has proven them to be physically compatible."Pasture and Rangeland: "Use 1 pint in 1 gallon fuel oil as a ULV spray per acre."Mosquitos: "1 part to 28 parts water, fuel oil or diesel oil."Restrictions: "Avoid applying oil based formulations to valuable ornamental plants as injury may occur."Grasshoppers: "ULV Application: 1.2 - 1 pints in 1 gallon of diesel fuel oil per acre."Chemigation: "This product should not be tank-mixed with other pesticides, surfactants or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and directions for all tank-mixed products." |
| "Do not combine emulsifiable liquids with wettable powders in the same spray tank unless previous use of the materials being combined has proven them to be physically compatible." |
| "\*There is a great variation in the chemical composition of fuel oils which may be used as thermal fog solvents. These differences may cause sludge and/or affect the solubility of the Fyfanon ULV Mosquito." |
| "Fyfanon ULV AG can by mixed with a synergized pyrethrin emulsifiable concentrate (6% pyrethrin + 60% PBO) in accordance with the most restrictive label limitations and precautions indicated on both this and the tank-mixed product. Label rates must not be exceeded. This product may not be mixed with any product bearing a label which specifically prohibits such mixing. Prior to tank mixing large quantities mix a small amount in a glass jar to verify that the products are physically compatible... Depending on your operational needs for knock-down, the amount of synergized pyrethrin can be reduced or adjusted. Application rates of Fyfanon ULV AG and droplet distribution requirements remain the same as for Fyfanon ULV AG used alone." |
| For use on guava, mango, passion fruit: "Apply with 1 lb partially hydrolyzed yeast protein or enzymatic yeast hydrolyzate."For use on nectarines: "May be mixed with spray oil for dormant and delayed dormant applications. Follow spray oil manufacturer's directions." |
| Agricultural Crop Use: "Dilute Fyfanon PLUS ULV in once-refined cottonseed or vegetable oil sufficient to make at least one quart of finished spray per acre." |
| For use on guava, mango, passion fruit: "Apply with 1 lb partially hydrolyzed yeast protein or enzymatic yeast hydrolyzate."For use on nectarines: "May be mixed with spray oil for dormant and delayed dormant applications. Follow spray oil manufacturer's |
| Mixing directions: "Malathion 851 g/L + Gamma-cyhalothrin 12.8 g/L EC is compatible with insecticides, miticides, and fungicides and non-pressure fertilizer solutions commonly recommended, except for alkaline materials such as Bordeaux mixture lime. It is always recommended that a small jar compatibility test be run prior to tank mixing. Prepare tank mixtures in the same manner as recommended above for use of Malathion 851 g/L + Gamma-cyhalothrin 12.8 g/L EC alone. When tank mixing with herbicides, add wettable powders first, flowable second, and emulsifiable concentrates last. When a fertilizer solution is involved, it is strongly recommended that a fertilizer pesticide compatibility agent such as Unite or Compex be used."Chemigation: "As local recommendations differ, consult your local State Extension Service or other local experts for recommendations on adjuvant or diluent types (See Tank Mix Application), rates, and mixing instructions. These recommendations should be proven, through university and extension field trials, to be effective with Declare applied by chemigation." |
| "Do not combine emulsifiable liquids with wettable powders in the same spray tank unless previous use of the materials being combined has proven them to be physically compatible."Mosquito control: "For a 2% spray, dilute 1 part Malathion-5 EC with 28 parts of water, fuel oil, or diesel oil. For a 5% spray, dilute 1 part Malathion-5 EC with 11 parts of water, fuel oil, or diesel oil." |
| Chemigation: "Do not tank mix this product with other pesticides, surfactants or fertilizers unless prior use has shown the combination non-injurious under your conditions of use. Follow precautionary statements and direction for all tank-mixed products." |

#### 1.1.2.4. Use Sites, Application methods, and Application Rates

The Environmental Fate and Effects Division (EFED) in consultation with the Pesticide Re-evaluation Division (PRD), Cheminova and the U.S. Fish and Wildlife Service developed a list of all malathion registered uses. The following tables document all currently registered use sites compiled from all active malathion product labels. This document reflects all currently registered labels and any agreed upon changes to these labels from the registrants. The registrant has sent letters clarifying ambiguous non-agricultural use patterns (February 26, 2015) and a letter outlining several uses it will and will not support through the registration review process (October 9, 2015). These letters are found in **APPENDIX 1-5**. Further interpretation of label rates and label uses as they affect exposure will be discussed in the Exposure Characterization (Section 3).

The Master Use Summary is used to form the basis of this assessment; for spatial context and to align with aquatic modeling. **APPENDIX 1-6** provides a chlorpyrifos use site summary by Hydrologic Unit Code (HUC) 2 Region.

#####  1.1.2.4.a. Summary of non-agricultural uses

Malathion is currently registered for use in a variety of non-agricultural settings, including for use on 47 homeowner garden fruit and vegetable varieties, and ornamental uses for commercial and homeowner applications. **Table 1-3** details these uses below. For information on what assumptions are made regarding how uses are modeled in the absence of label information, see **APPENDIX 1-7**.

 **Table 1-3. Malathion Use Summary of Non-Agricultural (Residential and Commercial) Uses.**

| **Use Site** | **Method** | **Maximum Single Application Rate** **(lb a.i./A)** | **Maximum Application Rate (per year in lb a.i./acre) (for all formulations combined, unless otherwise noted)** | **Maximum Application Number (per year)**  | **Minimum Retreatment Interval** |
| --- | --- | --- | --- | --- | --- |
| Apples | Ground | NS1 | NS | 2 | 7 |
| Apricots | Ground | 1.5 | NS | 2 | 7 |
| Asparagus | Ground | 1.25 | NS | 2 | 7 |
| Avocado | Ground | 1.25 | NS | NS | 30 |
| Beans | Ground | NS2 | NS | NS | 7 |
| Beets | Ground | 1.25 | NS | 3 | 7 |
| Blueberry | Ground | 1.25 | NS | 3 | 5 |
| Broccoli | Ground | 1.25 | NS | 2 | 7 |
| Brussels sprouts | Ground | 1.25 | NS | 2 | 7 |
| Cabbage | Ground | 1.25 | NS | 6 | 7 |
| Caneberries | Ground | 2 | NS | 3 | 7 |
| Cantaloupe | Ground | 1 | NS | 2 | 7 |
| Carrots | Ground | 1.25 | NS | 2 | 7 |
| Cauliflower | Ground | 1.25 | NS | 2 | 7 |
| Celery | Ground | 1.5 | NS | 2 | 7 |
| Cherries (tart and sweet) | Ground | 1.75 | NS | 4 | 3 |
| Citrus (CA only) | Ground | 7.5 | NS | 1 | NA |
| Citrus (excluding CA) | Ground | 4.5 | NS | 1 | NA |
| Collards | Ground | 1 | NS | 3 | 7 |
| Corn, sweet/pop | Ground | 1 | NS | 2 | 5 |
| Cucumber | Ground | 1.75 | NS | 2 | 7 |
| Dandelion | Ground | 1.25 | NS | 2 | 7 |
| Eggplant | Ground | 1.56 | NS | 4 | 5 |
| Endive (escarole) | Ground | 1.25 | NS | 2 | 7 |
| Flies | Ground | 0.18 | NS | NS | NS |
| Garlic | Ground | 1.56 | NS | 3 | 7 |
| Grapes | Ground | 1.88 | NS | 2 | 14 |
| Kale | Ground | 1 | NS | 3 | 5 |
| Kohlrabi | Ground | 1.25 | NS | 2 | 7 |
| Kumquat | Ground | 4.5 | NS | 1 | 30 |
| Leek | Ground | 1.56 | NS | 2 | 7 |
| Lemons (FL only) | Ground | 4.5 | NS | 1 | NS |
| Lettuce (head) | Ground | 1.88 | NS | 2 | 6 |
| Lettuce (leaf) | Ground | 1.88 | NS | 2 | 5 |
| Mango | Ground | 0.9375 | NS | 10 | 7 |
| Melons (other than watermelon) | Ground | 1 | NS | 2 | 7 |
| Mustard | Ground | 1 | NS | NS | 5 |
| Mustard greens | Ground | 1 | NS | NS | 5 |
| Okra | Ground | 1.2 | NS | NS | 7 |
| Onion (bulb and green) | Ground | 1.56 | NS | NS | 7 |
| Ornamental and/or shade trees | Ground/Spot Treatment | NS | NS | NS | 10 |
| Ornamental flowering plants | Ground/Spot Treatment | NS | NS | NS | NS |
| Ornamental flowers and bushes | Ground/Spot Treatment | NS | NS | NS | NS |
| Ornamental herbaceous plants | Ground/Spot Treatment | NS3 | 2 | NS | NS |
| Ornamental non-flowering plants | Ground/Spot Treatment | NS3 | 2 | NS | NS |
| Ornamental woody shrubs and vines | Ground/Spot Treatment | NS3 | NS | NS | NS |
| Ornamentals (trees, shrubs, flowers) | Ground/Spot Treatment | NS | NS | NS | NS |
| Ornamentals, all | Ground/Spot Treatment | NS | NS | NS | NS |
| Outdoor insects | Ground/Spot Treatment | NS | NS | NS | NS |
| Outdoor ornamentals | Ground/Spot Treatment | NS4 | 6 | 7 | NS |
| Outdoor residential (mosquitoes, other nuisance insects) | Ground/Spot Treatment | NS | NS | NS | NS |
| Outdoor residential areas | Ground/Spot Treatment | NS | NS | NS | NS |
| Outdoor treatment, general (flies, mosquitoes, etc) | Ground | 0.125 | NS | NS | NS |
| Parsley | Ground | 1.5 | NS | NS | 7 |
| Peaches | Ground | 3 | NS | NS | 11 |
| Pears | Ground | 1.25 | NS | NS | 7 |
| Peas | Ground | 1 | NS | NS | 7 |
| Pecans | Ground | 2.5 | NS | NS | 7 |
| Peppers | Ground | 1.56 | NS | NS | 5 |
| Potatoes | Ground | 1.56 | NS | NS | 7 |
| Pumpkins | Ground | 1 | NS | NS | 7 |
| Radish | Ground | 1 | NS | NS | 7 |
| Rice | Ground | 1.25 | NS | NS | 7 |
| Rutabagas | Ground | 1 | NS | NS | 7 |
| Shallot | Ground | 1.56 | NS | NS | 7 |
| Spinach | Ground | 1 | NS | NS | 7 |
| Squash, summer | Ground | 1.75 | NS | NS | 7 |
| Squash, winter | Ground | 1 | NS | NS | 7 |
| Strawberry | Ground | 2 | NS | NS | 7 |
| Sweet potatoes | Ground | 1.56 | NS | NS | 7 |
| Swiss chard | Ground | 1 | NS | NS | 7 |
| Tomatoes | Ground | 1.56 | NS | NS | 5 |
| Turnips (greens) | Ground | 1.25 | NS | NS | 5 |
| Turnips (roots) | Ground | 1.25 | NS | NS | 7 |
| Watercress | Ground | 1.25 | NS | 5 | 3 |
| Watermelons | Ground | 1.5 | NS | 4 | 7 |

1 Reg. No. 4-122 does not specify a maximum application rate. Reg. No. 4-99 specifies a maximum rate of 2.2 lbs a.i./A.

2Reg. Nos. 239-739 and 46515-19 do not specify maximum application rates. Reg. Nos. 4-99, 28293-123, 33955-394, and 4-412 specify maximum application rates between 1.1 and 1.5 lbs a.i./A

3Reg. Nos. 33955-394, 45385-43, and 7401-10 do not specify maximum application rates. Reg. Nos. 4-99 and 4-412 specify maximum rates of 4.5 lbs a.i./A and 4.4 lbs a.i./A, respectively.

4Reg. No. does not specify a maximum application rate. Reg. No. 28293-123 specifies a maximum rate of 5.1 lbs a.i./A

#####  1.1.2.4.b. Summary of Agricultural and Ultra-low Volume Uses

Malathion is currently registered for use on 115 agricultural crops. Maximum single application rates on crops are as high as 7.5 lbs a.i./A for citrus in California. Other high single application rates are for avocado (4.7 lbs a.i./A), citrus outside California (4.5 lbs a.i./A), kumquat (4.5 lbs a.i./A), and pine seed orchards (4.5 lbs a.i./A). All other agricultural applications are for 3 lbs a.i./A or less. Though it is not a broadcast use, the highest use rate presented below is for grain storage facilities and transport of 26.14 lbs a.i./A. No limits in application rate or number of applications are specified for several uses, including beans, grain storage facilities and transport, and lentils. Table **1-4** below details these uses. For information on what assumptions are made regarding how uses are modeled in the absence of label information, see **APPENDIX 1-7**.

**Table 1-4. Malathion Use Summary of Agricultural Uses with Conventional Application Methods.**

| **Use Site** | **Method** | **Maximum Single Application Rate** **(lb a.i./A)** | **Maximum Application Rate (per year in lb a.i./acre) (for all formulations combined, unless otherwise noted)** | **Maximum Application Number (per year)**  | **Minimum Retreatment Interval** |
| --- | --- | --- | --- | --- | --- |
| Alfalfa | Ground/Aerial | 1.25 | NS | NS | 14 |
| Apricots | Ground/Aerial | 1.5 | NS | 2 | 7 |
| Asparagus | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Avocado | Ground/Aerial | 4.7 | NS | 2 | 30 |
| Barley | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Beans | Ground/Aerial | NS | NS | NS | NS |
| Beets | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Blueberry | Ground/Aerial | 1.25 | NS | 3 | 5 |
| Broccoli; Chinese Broccoli; Broccoli Rabb | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Brussels sprouts | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Cabbage | Ground/Aerial | 1.25 |  NS | 6 | 7 |
| Caneberries | Ground/Aerial | 2 | NS | 3 | 7 |
| Cantaloupe | Ground/Aerial | 1 | NS | 2 | 7 |
| Carrots | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Cauliflower | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Celery | Ground/Aerial | 1.5 | NS | 2 | 7 |
| Chayote fruit | Ground/Aerial | 1.75 | NS | 2 | 7 |
| Chayote root | Ground/Aerial | 1.56 | NS | 2 | 7 |
| Cherries (tart and sweet) | Ground/Aerial | 1.75 | NS | 4 | 3 |
| Chestnut | Ground/Aerial | 2.5 | NS | 3 | 7 |
| Chinese Cabbage | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Chinese Cabbage; Mustard | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Chinese Mustard | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Christmas tree plantations | Ground/Aerial | 3.2 | NS | 2 | NS |
| Citrus | Ground/Aerial | 4.5 | NS | 1 | NA |
| Citrus (CA only) | Ground/Aerial | 7.5 | NS | 1 | NA |
| Clover | Ground/Aerial | 1.25 | NS | NS | 14 |
| Collards | Ground/Aerial | 1 | NS | 3 | 7 |
| Corn (field) | Ground/Aerial | 1 | NS | 2 | 7 |
| Corn (sweet and pop) | Ground/Aerial | 1 | NS | 2 | 5 |
| Cotton | Ground/Aerial | 2.5 | NS | 3 | 7 |
| Cucumber | Ground/Aerial | 1.75 | NS | 2 | 7 |
| Currant | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Dandelion | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Eggplant | Ground/Aerial | 1.56 |  NS | 4 | 5 |
| Endive | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Fence rows/hedge rows | Ground/Aerial | 0.24 | NS | NS | NS |
| Figs | Ground/Aerial | 2 | NS | 2 | 5 |
| Flax | Ground/Aerial | 0.5 | NS | 3 | 7 |
| Garlic | Ground/Aerial | 1.56 | NS | 3 | 7 |
| Grain storage facilities (empty) | Ground | 26.14 | NS | NS | NA |
| Grain Storage Facilities and Transport (wheat, corn, oats, barley and rye) | Ground | 26.14 | NA | 3 | 60 |
| Grain Storage Facilities and Transport (wheat, corn, oats, barley and rye) | Ground | NS | NA | NS | NS |
| Grapes (raisin, table, wine) | Ground/Aerial | 1.88 | NS | 2 | 14 |
| Grass (forage) | Ground/Aerial | 1.25 | NS | NS | NA |
| Grass, Bermuda | Ground/Aerial | 1.25 | NS | NS | NA |
| Guava | Ground/Aerial | 1.25 | NS | 13 | 3 |
| Honeydew | Ground/Aerial | 1 | NS | 2 | 7 |
| Hops | Ground/Aerial | 0.63 | NS | 3 | 7 |
| Horseradish | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Kale | Ground/Aerial | 1 | NS | 3 | 5 |
| Kohlrabi | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Kumquat | Ground/Aerial | 4.5 | NS | 1 | 30 |
| Leek | Ground/Aerial | 1.56 | NS | 2 | 7 |
| Lentils | Ground/Aerial | NS | NS | NS | NS |
| Lespedeza | Ground/Aerial | 1.25 | NS | NS | 14 |
| Lettuce (head) | Ground/Aerial | 1.88 | NS | 2 | 6 |
| Lettuce (leaf) | Ground/Aerial | 1.88 | NS | 2 | 5 |
| Macadamia nut | Ground/Aerial | 0.94 | NS | 6 | 7 |
| Mango | Ground/Aerial | 0.9375 | NS | 10 | 7 |
| Melons (other than watermelon) | Ground/Aerial | 1 | NS | 2 | 7 |
| Mint | Ground/Aerial | 0.94 | NS | 3 | 7 |
| Mushrooms | Ground/Aerial | 1.7 | NS | 4 | 3 |
| Mustard Greens | Ground/Aerial | 1 | NS | 3 | 5 |
| Nectarines | Ground/Aerial | 3 | NS | 3 | 7 |
| Non-agricultural uncultivated areas/soil | Ground/Aerial | 0.6 | NS | NS | NS |
| Oats | Ground/Aerial | 1 | NS | 2 | 7 |
| Okra | Ground/Aerial | 1.2 | NS | 5 | 7 |
| Onion (bulb and green) | Ground/Aerial | 1.56 | NS | 2 | 7 |
| Papaya | Ground/Aerial | 1.25 | NS | 8 | 3 |
| Parsley | Ground/Aerial | 1.5 | NS | 2 | 7 |
| Parsnip | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Passion Fruit | Ground/Aerial | 1 | NS | 8 | 7 |
| Peaches | Ground/Aerial | 3 | NS | 3 | 11 |
| Pears | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Peas (dry, succulent) | Ground/Aerial | 1 | NS | 2 | 7 |
| Pecans | Ground/Aerial | 2.5 | NS | 2 | 7 |
| Peppers | Ground/Aerial | 1.56 | NS | 2 | 5 |
| Pine seed orchards | Ground/Aerial | 3.2 | NS | 2 | 7 |
| Pineapple | Ground/Aerial | 2 | NS | 3 | 7 |
| Potatoes | Ground/Aerial | 1.56 | NS | 2 | 7 |
| Pumpkins | Ground/Aerial | 1 | NS | 2 | 7 |
| Radish | Ground/Aerial | 1 | NS | 3 | 7 |
| Rice; Wild Rice | Ground/Aerial | 1.25 | NS | 2 | 7 |
| Rutabagas | Ground/Aerial | 1 | NS | 3 | 7 |
| Rye | Ground/Aerial | 1 | NS | 3 | 7 |
| Salsify | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Shallot | Ground/Aerial | 1.56 | NS | 2 | 7 |
| Sorghum | Ground/Aerial | 1 | NS | 2 | 7 |
| Spinach | Ground/Aerial | 1 | NS | 2 | 7 |
| Squash, summer | Ground/Aerial | 1.75 | NS | 3 | 7 |
| Squash, winter | Ground/Aerial | 1 | NS | 3 | 7 |
| Strawberry | Ground/Aerial | 2 | NS | 4 | 7 |
| Sweet potatoes | Ground/Aerial | 1.56 | NS | 2 | 7 |
| Swiss chard | Ground/Aerial | 1 | NS | 2 | 7 |
| Tomatoes; Tomatillos | Ground/Aerial | 1.56 | NS | 4 | 5 |
| Trefoil (birdsfoot) | Ground/Aerial | 1.25 | NS | NS | 14 |
| Turnips (greens) | Ground/Aerial | 1.25 | NS | 3 | 5 |
| Turnips (roots) | Ground/Aerial | 1.25 | NS | 3 | 7 |
| Vetch | Ground/Aerial | 1.25 | NS | NS | 14 |
| Walnuts | Ground/Aerial | 2.5 | NS | 3 | 7 |
| Watercress | Ground/Aerial | 1.25 | NS | 5 | 3 |
| Watermelons | Ground/Aerial | 1.5 | NS | 4 | 7 |
| Wheat (spring and winter) | Ground/Aerial | 1 | NS | 2 | 7 |
| Yams | Ground/Aerial | 1.56 | NS | 2 | 7 |

Malathion is currently registered for use on 27 agricultural crops for ultra low volume (ULV) applications. It is also registered for use on pine seed orchards and wide area public use for ultra low volume applications in non-agricultural areas. Maximum single application rates on crops are as high as 1.22 lbs a.i./A for cotton. **Table 1-5** details these uses below. For information on what assumptions are made regarding how uses are modeled in the absence of label information, see **APPENDIX 1-7**.

**Table 1-5. Malathion Use Summary of Agricultural and Non-Agricultural Uses with Ultra Low Volume Applications.**

| **Use Site** | **Method1 (Formulation/ product)2** | **Maximum Single Application Rate** **(lb a.i./A)** | **Maximum Application Rate (per year in lb a.i./acre) (for all formulations combined, unless otherwise noted)** | **Maximum Application Number (per year)**  | **Minimum Retreatment Interval** |
| --- | --- | --- | --- | --- | --- |
| Alfalfa | Ground/Aerial | 0.61 | NS | NS | 14 |
| Barley | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Beans (dry, snap, Lima)  | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Beans (dry, succulent) | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Blueberry | Ground/Aerial | 0.77 | NS | 3 | 10 |
| Cherries (sweet) | Ground/Aerial | 1.22 | NS | 4 | 7 |
| Cherries (tart) | Ground/Aerial | 1.22 | NS | 6 | 7 |
| Christmas tree plantations | Ground/Aerial | 0.9375 | NS | 2 | NS |
| Citrus  | Ground/Aerial | 0.175 | NS | 3 | 7 |
| Clover | Ground/Aerial | 0.61 | NS | NS | 14 |
| Corn (field) | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Corn (sweet and pop) | Ground/Aerial | 0.61 | NS | 2 | 5 |
| Cotton | Ground/Aerial | 1.22 | NS | 3 | 7 |
| Fence rows/hedge rows | Ground/Aerial | 0.24 | NS | NS | NS |
| Grass, Bermuda | Ground/Aerial | 0.92 | NS | NS | NA |
| Kumquat | Ground/Aerial | 0.175 | NS | 2 | 7 |
| Lespedeza | Ground/Aerial | 0.61 | NS | NS | 14 |
| Lupine | Ground/Aerial | 0.61 | NS | 1 | NA |
| Mosquitoes/Wide Area Public Health | Ground/Aerial | 0.23 | NS | NS | NS |
| Non-agricultural uncultivated areas/soil | Ground/Aerial | 0.9281 | NS | NS | NS |
| Oats | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Pasture and Rangeland | Ground/Aerial | 0.92 | NS | NS | 7 |
| Pine seed orchards | Ground/Aerial | 0.9375 | NS | 2 | 7 |
| Rice; Wild Rice | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Rye  | Ground/Aerial | 0.61 | NS | 1 | NA |
| Sorghum | Ground/Aerial | 0.61 | NS | 2 | 7 |
| Trefoil (birdsfoot) | Ground/Aerial | 0.61 | NS | NS | 14 |
| Vetch | Ground/Aerial | 0.61 | NS | NS | 14 |
| Wheat (spring and winter) | Ground/Aerial | 0.61 | NS | 2 | 7 |

#### 1.1.2.5. Outstanding Mitigations

All of the mitigations proposed in the Malathion Reregistration Eligibility Decision (RED, May 2009) have been addressed; therefore, there are no outstanding mitigations from the RED process for malathion. The registrant has sent letters clarifying ambiguous non-agricultural use patterns (February 26, 2015) and a letter outlining several uses it will and will not support through the registration review process (October 9, 2015). These letters are found in **APPENDIX 1-5**.

### 1.1.3. Usage Data

The risk assessments are based on labeled uses; however, usage data can be informative for characterization and exploration of mitigation options. Considering agricultural uses, there has been a general trend of decreased malathion usage since the 1990’s as use on cotton for USDA’s Boll Weevil Eradication Program has declined (**Figure 1-1**). Based on 2012 data, usage on alfalfa, orchards and grapes, vegetables and fruit are the crop groups with highest usage of malathion. (See **APPENDIX 1-8**, for details). Since crops with high malathion usage are varied, the geographic extent of malathion use across the United States is also widespread. The spatial distribution of the 2012 agricultural usage data is presented in **Figure 1-1**. This map illustrates agricultural use of malathion throughout the United States.



**Figure 1-1. Malathion Use Spatial Distribution (2012): Use by Year and Crop (1992-2012).** (from http://water.usgs.gov/nawqa/pnsp/usage/maps/show\_map.php?year=2012&map=MALATHION&hilo=L&disp=Malathion).

No national-level malathion usage data are available for registered non-crop uses sites, including homeowner uses, ornamental uses, and wide area public health uses.

## 1.2. Pesticide Active Ingredient Information

### 1.2.1 Mode and Mechanism of Action

Malathion is an organophosphate insecticide used to kill insects systemically and on contact. As a phosphorothioate organophosphate, malathion is subject to metabolic activation within an organism into its oxon form. The rate at which a phosphorothioate pesticide is transformed to its oxon and the rate at which the oxon is subsequently detoxified can influence toxicity. Organophosphate toxicity is based on the inhibition of the enzyme acetylcholinesterase, which cleaves the neurotransmitter acetylcholine (AChE). Inhibition of AChE interferes with proper neurotransmission in cholinergic synapses and neuromuscular junctions. This can lead to sublethal effects (*e.g.,* increased respiration, lethargy) and mortality. **Figure 1-2** depicts the Adverse Outcome Pathway for animals exposed to organophosphates. Based on the AOP for animals exposed to malathion, endpoints representative of AChE inhibition are included in the mortality and behavioral lines of evidence. Since plants do not have AChE, this AOP does not apply to plants.



**Figure 1-2. Adverse Outcome Pathway for Organophosphates and Acetylcholinesterase Inhibition** (the figure is from Russom, et al. 2014).

### 1.2.2. Fate Overview

The major routes of degradation of malathion are aerobic and anaerobic biodegradation and hydrolysis. Under alkaline conditions (pH 9), hydrolysis of malathion occurs more rapidly, with a half-life of approximately 12 hours, than in acidic conditions (pH 5; 107 days). Malathion appears to degrade rapidly in soil under both aerobic and anaerobic conditions. The reported metabolic half-lives vary from 0.3 to 11 days in registrant submitted studies depending on soil type and soil moisture. Information on leaching and adsorption/desorption indicate that parent malathion is considered moderately mobile according to Food and Agricultural Organization (FAO) mobility classification system. The environmental fate of the minor (*i.e.*, occurs at less than 10% of malathion applied in environmental fate studies), yet toxic malathion transformation product, malaoxon, indicates that it has nearly identical persistence and mobility characteristics as parent malathion. Available terrestrial field dissipation data indicate that malathion has a dissipation half-life of less than one day on soils with pH 6.1 to 6.6, with little leaching observed. Given little observed leaching, degradation drives dissipation with aerobic soil metabolism being the most significant path of degradation. Additional details (including references) regarding the environmental fate of malathion are provided in Chapter 3 and APPENDIX 3-1.

### 1.2.3. Degradates of Concern

The primary route for dissipation of malathion is metabolism to the less toxic malathion dicarboxylic and monocarboxylic acids. Malathion metabolizes readily in moist, microbially active soils. However, if malathion is in contact with metabolically inactive surfaces such as dry soils or impervious surfaces common in non-agricultural settings, photo-oxidation to the toxic degradate malaoxon can occur. Field data indicate that up to 10% of malathion can be transformed to malaoxon in these conditions. Oxidation to malaoxon can also be catalyzed in the presence of chlorine. To a much more limited degree than in chlorine catalyzed or photo-oxidation conditions, malathion can metabolize to malaoxon under other circumstances, but malaoxon is not a major degradate (*i.e.*, occurs at more than 10% of malathion applied in environmental fate studies) in that pathway. Malaoxon dissipates and degrades similarly to malathion with rapid metabolism in aerobic conditions and rapid hydrolysis in alkaline conditions. Therefore, short duration malaoxon concentration peaks (less than one day) may be expected in non-agricultural streams during run-off events. Stream monitoring efforts associated with the discontinued Mediterranean Fruit Fly Eradication Program found malaoxon concentrations as high as 328 ppb. NAWQA surface water monitoring detected malaoxon in 0.1% of samples for which it was tested with a peak detection of 0.2 ppb. See **APPENDIX 1-9** for more information.

For the reasons described above and detailed in **APPENDIX 1-9**, this assessment will include a qualitative discussion of the potential risks associated with malaoxon and their potential to impact the effects determinations associated with malathion.

## 1.3. Conceptual Model

### 1.3.1. Conceptual Model for Potential Exposure Routes

Direct deposition of malathion onto treated sites as well as transport via spray drift, runoff and volatilization resulting in atmospheric (including long range) transport are depicted in the conceptual models (**Figures 1-3** and **1-4**) as sources that result in the movement of malathion into aquatic and terrestrial habitats. The movement away from the site of application in turn represents exposure pathways for a broad range of biological receptors of concern (non-target organisms) and the potential attribute changes, *i.e.*, effects such as reduced survival, growth and reproduction, in the receptors due to malathion (and its degradates of concern) exposure.

Malathion Applied to Use Site

(Including Degradates of Concern)



**Figure 1-3. Conceptual Model for Malathion Effects on Aquatic Organisms** (including consideration of degradates, other ingredients in the malathion formulations applied, and recommended tank mixtures). Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk. For ‘Attribute Change’, the terms ‘Individual Organisms’, ‘Food Chain’, and ‘Habitat Integrity’ are equivalent to ‘Individual Fitness’, ‘Indirect Effects Related to Prey’, and ‘Indirect Effects Related to Physical and Biological Features of Habitat’, respectively.

 

Malathion Applied to Use Site

(Including Degradates of Concern)

**Figure 1-4. Conceptual Model for Malathion Effects on Terrestrial Organisms** (including consideration of degradates, other ingredients in the malathion formulations applied, and recommended tank mixtures). For ‘Attribute Change’, the terms ‘Individual Organisms’, ‘Food Chain’, and ‘Habitat Integrity’ are equivalent to ‘Individual Fitness’, ‘Indirect Effects Related to Prey’, and ‘Indirect Effects Related to Physical and Biological Features of Habitat’, respectively.

### 1.3.2. Risk Hypotheses

Risk hypotheses define predicted effects of malathion exposure on species and assessment endpoints. They provide the framework of the analysis in terms of linking the stressor, exposure, and effects and link directly to the protection goals of Step 2. The risk hypotheses that are used to make the effects determinations for each species and designated critical habitat are provided below. The specific lines of evidence that will be used to test these hypotheses are described in **Section 1.4.2.1**, below.

* Use of malathion, according to registered labels[[6]](#footnote-6), results in exposure that reduces the fitness of an individual of a listed species based on direct effects.
* Use of malathion, according to registered labels6, results in exposure that reduces the fitness of an individual of a listed species based on indirect effects.
* Use of malathion, according to registered labels6, results in effects to designated critical habitat by adversely impacting primary constituent elements (PCEs) or other important physical and biological features (PBFs).[[7]](#footnote-7)

## 1.4. Analysis Plan

As mentioned previously, and as recommended by the NRC, the agencies use a three-step consultation process to evaluate the potential risk to listed species, with the understanding that the data and analyses for each step will be used, when possible, for the subsequent steps (see **Figure 1-5**). The analysis plan presented here describes the process for Steps 1 and 2.



**Figure 1-5. Three Step ESA Consultation Approach Modified from a Figure in the NRC (2013) Report.** Step 1 consists of two parts: 1) establishing the action area for the proposed action, and 2) overlaying the species ranges and critical habitat designations onto the action area to determine which species and critical habitats overlap with the uses as allowed by the labels. This step identifies which species and critical habitats have the potential to be affected by the proposed action (warranting a “may affect” determination), and which species would not be affected by the stressors of the proposed action (e.g., no overlap, and thus warranting a “no effect” determination). Step 1 does not identify the degree of effect that would be anticipated (e.g., an insignificant effect), or whether the risk of exposure of adverse effects is unlikely to occur (e.g., a discountable effect) where the action area overlaps with listed resources. In the parlance of the ESA, these categories of effect[[8]](#footnote-8) are related to Step 2.

Any species and/or critical habitat that warrants a “may affect” determination in Step 1 continues for further analysis in Step 2[[9]](#footnote-9). Potential direct and indirect effects to listed resources will be considered to determine whether effects to individuals of listed species and/or PCEs/PBFs would be either: a) “insignificant,” “discountable, ” or “completely beneficial,”[[10]](#footnote-10) resulting in a “may affect, not likely to adversely affect [NLAA] determination; or b) adverse, resulting in a “may affect, likely to adversely affect” (LAA) determination. The NLAA determinations would be submitted to the Services with a request for concurrence with the determinations, while the listed resources with a LAA determination would be considered by the Services in their Biological Opinions (Step 3). The Step 3 analyses are beyond the purview of this analysis plan, but would determine whether the proposed action was likely to jeopardize listed species and/or adversely modify or destroy designated critical habitat. Steps 1 and 2 are described in greater detail in the following paragraphs. Step 3 is not discussed further in this document.

### 1.4.1. Step 1 - May Affect/No Effect Determinations

For any listed species whose range and/or designated critical habitat overlaps spatially with the action area (see below, **Figure 1-6**), a ‘May Affect’ determination will be made and additional analyses will be conducted to make the final NLAA/LAA effects determination. Conversely, for any listed species whose range and/or designated critical habitat does not overlap spatially with the action area, a ‘No Effect’ determination will be made and no further analyses for that species or its critical habitat(s) will be conducted (see Steps 1 and 2 in **Figure 1-6**). However, species ranges that do not overlap with the action area will be included in the analysis if those species are dependent on a species that is in the action area (*e.g*., ESA-listed orca whales are dependent upon Chinook salmon as major food resources) (see **Figure 1-6**). The following sections will describe the process of Step 1 for malathion.



**Figure 1-6. Step 1 - Action Area and Species' Ranges.**

#### 1.4.1.1 Action Area

The action area is defined by the Endangered Species Act as, “all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action” (50 CFR §402.2). Based on an analysis of the Federal action, the action area is defined by the actual and potential use of the pesticide and areas where that use could result in effects. For this analysis, ArcGIS v. 10.3 and information on effects thresholds and results from offsite transport models (see below) will be used to establish the spatial extent of the action area and to serve as the basis for determining which species ranges and critical habitats overlap with the action area. Specific descriptions of the spatial datasets used for determining the action area are described below.

##### 1.4.1.1.a. Use Site Footprint

The footprint layer represents the application site for agricultural and non-agricultural label uses. The Cropland Data Layer (CDL), produced by the United States Department of Agriculture (USDA), is used to spatially represent potential agricultural use sites. The CDL is a land cover dataset that has over 100 cultivated classes that the Agency groups into 11 general classes (see **ATTACHMENT 1-2**). In addition, 6 years of the most recent CDLs, from 2010-2015, are aggregated to account for crop rotations. (In the future, as data become available, 10 years of the most current data available will be used).

The agricultural classes are further refined by comparing county level National Agricultural Statistics Service (NASS) Census of Agriculture (CoA) acreage reports to county level CDL acreages. If a county’s CDL acreage for a given class is lower than the NASS acreage, the CDL class’s extent is expanded within cultivated areas until the CDL acreage matches the NASS Census acreage (see **ATTACHMENT 1-3**). This reduces land cover mapping errors by adjusting the extent of each category to the best available census values.

Non-agricultural label uses include a wide range of land cover and land use categories. Each label use is considered and represented by the best available land cover data. Generally, the National Land Cover Dataset (NLCD) is used to represent non-agricultural label uses. When the NLCD is inadequate, other data sources are used as appropriate (see **ATTACHMENT 1-3**, for details).

##### 1.4.1.1.b. Thresholds of effects

###### 1.4.1.1.b.1 Mortality (acute) and sublethal thresholds

The boundary of the action area is based on a threshold defined by the lowest exposure concentration found to be toxic. [The endpoints considered to determine the boundary are described in **Table 1-6** (for details see **ATTACHMENT 1-4**)]. The most sensitive species in the environment that results in the farthest distance from the use site(s), based on the effects thresholds described in **Table 1-6**, is used to set the action area boundary. The aquatic component of the action area incorporates downstream transport of malathion from the use site. Additional considerations describing delineation of aquatic and terrestrial components of the action area are described in the sections below.

**Table 1-6. Endpoints and Associated Threshold Selection Strategies That Will Be Used to Delineate the Boundary of the Action Area in Step 1.**

| **Taxon** | **Mortality** | **Sublethal Effects** |
| --- | --- | --- |
| Birds1 | Concentration (or dose) that would result in a chance of 1 in a million of causing mortality to an individual. This is calculated by using HC05 of SSD2 of LC50, LD50, or EC50 values for taxa and representative slope. If SSD cannot be derived, most sensitive LC50, LD50, or EC50 for taxa will be used and most representative slope.  | The lowest available NOAEC, NOAEL or other scientifically defensible effect threshold (ECx). Endpoints are generally from *in vivo* studies that are conducted with whole organisms, are representative of environmentally relevant exposure~~s~~ routes, and are able to be quantitatively or qualitatively linked to effects on survival, growth or reproduction. |
| Mammals1 |  |
| Reptiles |  |
| Terrestrial-phase amphibians |  |
| Aquatic-phase amphibians |  |
| Fish |  |
| Aquatic invertebrates |  |
| Terrestrial invertebrates |  |
| Aquatic plants | Not Applicable | Aquatic plants: *Non-vascular* - Concentration equal to the lowest value among the available NOAEC and EC05 values for non-vascular aquatic plants.*Vascular* - Concentration equal to the lowest value among the available NOAEC and EC05 values for vascular aquatic plants.Terrestrial and wetland plants: *Monocots* - Concentration equal to the lowest value among the monocot NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies.*Dicots* - Concentration equal to the lowest of the dicot NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies.*Non-angiosperm* - Concentration equal to the lowest of the NOAEC and EC05 values from the available seedling emergence and vegetative vigor studies. |
| Terrestrial plants |  |
| Wetland plants |  |

1Lowest LD50 or NOAEL/LOAEL for birds and mammals determined by normalizing results to 100 g body weight for birds and 15 g body weight for mammals prior to establishing threshold values.

2 SSD = Species Sensitivity Distribution; the method used to derive the SSDs is described in **ATTACHMENT 1-5**.

##### 1.4.1.1.c. Off-site Transport Area

###### 1.4.1.1.c.1 Aquatic Modeling

The extent to which exposure concentrations in surface water and benthic sediment pore water may affect listed aquatic animals and plants downstream from the chemical’s use footprint are simulated using a Pesticide Root Zone Model (PRZM)[[11]](#footnote-11) and Variable Volume Water Model (VVWM)[[12]](#footnote-12), using the Pesticide Water Calculator shell (PWC, December 2015)[[13]](#footnote-13), which is used to generate estimated environmental concentrations (EECs) that may occur in flowing water bodies, and EPA’s Downstream Dilution tool. The PWC is used to simulate pesticide runoff and spray drift from an agricultural field to an adjacent water body following applications to crops. The Tier II Pesticides in Flooded Applications Model (PFAM v1.104) is used to estimate aquatic exposure for flooded pesticide applications.  PFAM simulates pesticide transformation on and dissipation from flooded agricultural sites, such as cranberry bogs or rice, following pesticide use. To further aid in this effort, the Services assigned aquatic and aquatic-associated listed species into 10 generic habitat bins, nine of which are aquatic[[14]](#footnote-14) (for details on the aquatic bins modeled, see **Section 1.4.2.2.1.1**, below).

Using the PWC, EECs for the different HUC 2 regions (there are 21 HUC 2 regions in the United States) are estimated using the maximum permitted label application rates, the ESA scenario for developed areas (*i.e*, the scenario for rights-of-way), the HUC 2 regionally-specific watershed dimensions, and the low flow aquatic bin (Bin 2, flow rate = 0.001 m3/s, width = 2 m, and depth = 0.1 m). The highest 1-in-15 year daily maximum EEC from the modeling runs, along with the lowest aquatic effects endpoint, *i.e*. threshold, is then used with the downstream dilution tool to estimate the distance downstream where concentrations are high enough to cause potential effects. The 1-in-15 year EEC is the maximum annual, daily aquatic concentration, developed from the 30-year distribution of maximum annual daily environmental concentrations, which, on average, will be exceeded only once every 15 years. It is important to note that for any single 15-year period, the 1-in-15 year value may be exceeded more than once, or not at all. The downstream dilution tool is used to evaluate a raster file (*e.g.*, the binary land cover rasters) to determine the percent use area, based on a chemical’s use footprint, for each HUC 12 watershed in the United States, then agglomerates all upstream watersheds. For the binary land cover raster, the program counts all of the 'yes' and 'no' pixels that fall within a given HUC-12 watershed based on the presence/absence of uses corresponding to the land cover, and sums all of the 'yes' and 'no' pixels in any upstream HUC-12s, to give a percent land cover for any given HUC-12 pour point (*e.g.*, end of stream reach which “pours” into the next HUC 12). The pour point is identified using the NHDPlus data in conjunction with the land cover datasets and the boundaries of the HUC 12 watershed.

The extent to which spray drift exposure concentrations in surface water and benthic sediment pore water downwind from the chemical’s use footprint may affect listed aquatic animals and plants is simulated using the AgDRIFT model (version 2.1.1, December, 2011). For aerial applications, the AgDRIFT model encompasses three tiers, starting with Tier 1, which uses basic information on drop size distribution, and progresses to Tier 3, which uses more detailed application information (*e.g.*, atmospheric and meteorological conditions, release height, aircraft parameters) and the AGDISP algorithms, to estimate offsite deposition. For ground applications, AgDRIFT only allows for the use of simple deposition curves, so there is only one tier of modeling. The distance to the threshold concentration is estimated using AgDRIFT and is based on the smallest static aquatic bin (Bin 5, width = 1 m, length = 1 m, depth = 0.1 m) and the maximum, single application rate. For aerial applications (except for mosquito adulticide applications), initial analysis will be conducted using the Tier 1 module of AgDRIFT. If the module generates an “out of range” value, then the Tier 3 module is explored. If the 2,500 foot limit is exceeded in the Tier 3 module, then a distance of 2,500 feet is reported. For ground or airblast applications, the Tier 1 module of AgDRIFT is used. If the 997 foot limit of the Tier 1 module is exceeded, then the distance of 1,000 feet is reported. The 2,500 ft and 1,000 ft distance for air and ground applications, respectively, are based on the limits of the spray drift model. In cases where the limit of the model is exceeded, the ratio of the concentration at the limiting distance to the threshold is estimated and reported. Additionally, extrapolation beyond the limits of the spray drift model, which are scientifically defensible,, may be explored.

For mosquito adulticide applications, the AGDISP model (version 8.26, December, 2011) is used. AGDISP is based on a Lagrangian trajectory approach[[15]](#footnote-15) to the solution of the spray material equations of motion, and includes simplified models for the effects of the aircraft wake and aircraft-generated and ambient turbulence. The AGDISP model includes an additional predictive method, a Gaussian extension to the AGDISP model, which enables the aerial application model to extend its prediction distance to 20 km downwind, a distance well beyond its validation distance of 800 m, with an approach for which restrictions and approximations are well understood and documented. The transition from the Lagrangian model to the Gaussian model occurs beyond the distance where the aircraft vortices are no longer influencing particle motion. The Gaussian extension of the AGDISP model can be used for specific circumstances such as aerial applications of mosquito adulticides and other pesticides with very fine to fine droplet size spectra[[16]](#footnote-16) at release heights of 50 ft above ground.

For malathion, given its potential widespread use throughout the United States, the use footprint resulted in inclusion of all waterways in the United States.

###### 1.4.1.1.c.2 Terrestrial Modeling

The terrestrial portion of the action area is set by defining the spatial extent of potential use sites based on label information and appropriate spatial layers (*e.g.*, CDL). This area is buffered by the distance from the edge of the field where spray drift is deposited at levels of concern to any taxa (*i.e.*, the most sensitive taxon). Of the available toxicity data, the most sensitive endpoints for malathion are for terrestrial invertebrates. The AgDRIFT model is used to assess offsite exposure from drift, using application information, spray quality parameters, and other associated drift information provided on the labels. Where labels are silent on such information, default parameters specified in EPA’s Guidance on Modeling Offsite Deposition[[17]](#footnote-17) are used. The analysis with AgDRIFT indicates that for aerial and ground spray applications, drift deposited at the bounds of the model (*i.e.*, 1,000 feet for ground and 2,500 feet for aerial) exceeds the endpoints for terrestrial invertebrates [*i.e*., NOAEL = 0.0009 lb a.i./acre (E86585)]. Again, for malathion, given its potential widespread use throughout the United States, the use footprint resulted in inclusion of the entire United States.

#### 1.4.1.2. Species/Critical Habitat Locations

All available species and designated critical habitat location files were provided by the FWS and NMFS for species listed as Endangered, Threatened, Experimental Population, Proposed Endangered, Proposed Threatened, Proposed Experimental Population, or Candidate[[18]](#footnote-18) under Endangered Species Act.

*Species Locations:*

The FWS requested from the species experts in their Regional and Field Offices the most refined range data (*e.g*., sub-county level data where possible) for all listed species under their jurisdiction. NMFS provided Geographic Information System (GIS) maps for its species. The species ranges were provided in the form of a GIS spatial file to run the co-occurrence analysis (see **ATTACHMENT 1-6** for details).

*Critical Habitat Locations:*

The FWS and NMFS provided tables of species with designated critical habitat and the corresponding location files on their respective websites. All available critical habitat location files were downloaded from the NMFS Regional websites and the ECOS Portal (<http://ecos.fws.gov/crithab>). For those not available on the ECOS Portal, critical habitat location fileswere received directly from the Services. A list of species with designated critical habitat can be found in **ATTACHMENT 1-6**.

#### 1.4.1.3. Overlap Analysis

If a species or its designated critical habitat co-occurs with the action area, this species receives a “May Affect” determination. To make this determination, a co-occurrence analysis is run by overlaying the species location files received from the Services with the action area file(s) and using the ArcGIS Zonal Statistics tool to count the number of action area pixels found within overlapping species location features.

Prior to running the co-occurrence analysis, the native projections[[19]](#footnote-19) for all species location files are documented and verified as being complete. Standard species identification information[[20]](#footnote-20) is added to the attribute tables to help with species tracking during the co-occurrence analysis. When necessary, species location files are re-projected to match the spatial projection(s) of the action area. For a subset of aquatic species, all Hydrologic Unit Code – 12 (HUC-12) occurring within the range and/or critical habitat files were used to represent the range (see ATTACHMENT 1-6 for the list). Finally, files are merged into separate range and critical habitat composite files by species group for use in the co-occurrence analysis. Each composite file contains the respective spatial location information for all listed species as provided by the Services or downloaded from their website(s)**.**

The Zonal toolbox from the ArcGIS Spatial Analyst toolbox is used to run the co-occurrence analysis. This tool overlays and compares the action area raster(s) to each of the species location composite files. The tool parameters are set to count the number of action area pixels found within each overlapping feature of the species location composite files (**ATTACHMENT 1-6**).

For species/critical habitats that do not overlap with the action area, the call will be ‘No Effect’ and no further analyses will be required (i.e., there is no need for Steps 2 and 3). For species and/or critical habitats that do overlap with the action area, the call for that species and/or its critical habitat will be “May Affect,” and the analysis will proceed with Step 2. This process is iterative [i.e., if additional information becomes available during the course of conducting Step 2 that indicates that the action area is not adequate for the action(s) being assessed, the action area can be revisited]. See Attachment 1-6 and Chapter 4 for the results of the co-occurrence analysis.

### 1.4.2. Step 2 – LAA/NLAA Determinations

The purpose of Step 2 is to conclude a determination of either “Not Likely to Adversely Affect” (NLAA)[[21]](#footnote-21) or “Likely to Adversely Affect” (LAA)[[22]](#footnote-22) for listed species and/or designated critical habitats within the action area. To determine whether the call for a species and/or designated critical habitats is an NLAA or LAA, a similar process as described above for Step 1 is used with the exception that only endpoints relevant to the specific listed species being assessed and their habitats are considered (*e.g*., those endpoints related to the specific taxon, prey items and habitat of the species being assessed). Exposure values are based primarily on fate and transport model results that assess the range of labeled uses of the pesticide (rates, methods). For aquatic exposures, the PWC (an upgrade to PRZM/EXAMS), AgDRIFT and AGDISP models are used to predict aquatic exposure in generic habitats, referred to as bins, relevant to groups of listed species with similar habitat preferences (for details on the aquatic bins modeled, see **Section 1.4.2.2.a.1**, below).  Exposure results for the bin most appropriate for the species and/or critical habitat being assessed are used.  For terrestrial exposures, TerrPlant, AgDRIFT, AGDISP and T-REX are used.  In this step (*i.e.,* Step 2), a refined version of T-REX, which accounts for species-specific characteristics (*e.g*., body size, diet, *etc*.), is used. In order to efficiently assess the risks of malathion to the hundreds of listed terrestrial species, EFED’s current terrestrial exposure models were combined into a single tool that is referred to as the TED (Terrestrial Effects Determination) tool. For details on the terrestrial exposure modeling, see **Section 1.4.2.2.a.2** below and **ATTACHMENT 1-7**.

The following sections will summarize how effects to listed species and critical habitats will be analyzed using lines of evidence, how the evidence is weighed, and how exposure will be estimated in both aquatic and terrestrial habitats. Other relevant topics such as use of probabilistic approaches, consideration of incident data, analysis of mixtures, and the influence of environmental factors on toxicity are also briefly discussed.

#### 1.4.2.1. Lines of Evidence

The lines of evidence (LOE) used to test the risks hypotheses (see **Section 1.4.2.1**, above) are outlined in **Table 1-7**. These represent general lines of evidence relevant to all listed taxa and their designated critical habitats. These lines of evidence evaluate the risk hypotheses by describing the potential for direct effects and/or indirect effects to listed species and designated critical habitats. For designated critical habitats, any potential for direct or indirect effects to a listed species, as related to the relevant PCEs and/or PBFs, based on the lines of evidence, are considered for the effect determination regardless if the listed species is present within and/or currently inhabits the designated critical habitat (as not all designated critical habitats are currently occupied by individuals of a listed species).

More specific lines of evidence, relevant to particular listed species or designated critical habitats, may be applied to specific effects determinations depending on the available information. Any additional specific lines of evidence used to make an effects determination will be discussed in the sections relevant to the particular listed species and/or designated critical habitat.

**Table 7-7. Lines of Evidence for Risk Hypotheses.**

| **Line-of-evidence** | **Exposure Value(s) Used to Assess the Line-of-evidence** | **Measure of Effect**  | **Types of studies/ information** | **Interpretation** |
| --- | --- | --- | --- | --- |
| 1. Mortality from direct, acute exposure from the use of malathion according to registered labels2 (direct effect) | Peak estimated exposure values and field-scale monitoring1 data | Mortality to an individual: One-in-a-million probability of killing an individual [for the HC05 (if an SSD can be calculated) or the most sensitive mortality endpoint for the representative taxon (if an SSD cannot be calculated)].  | LC50/LD50 and slope (Laboratory toxicity studies) | If one-in-a-million threshold is exceeded by registered uses, the line of evidence is sufficient for an LAA determination (Step 2) |
| Distribution of estimated exposure values3 | Mortality (no defined threshold)4 | LC50/LD50 and slope (Laboratory toxicity studies) | Describe the likelihood of an individual mortality at expected concentrations |
| Environmental exposures5 | Mortality (no defined threshold) | Mortalities reported in incident reports and field studies(Incident reports and field studies) | Review data and summarize highly probable and probable incidents- qualitative discussion |
| 2. Reduced growth of an individual (potential to decrease survival and/or reproduction) from the use of malathion according to registered labels (direct effect) | Estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect(s) | Growth: Most sensitive NOAEC for growth for the representative taxon  | Size: e.g., weight, length, biomass(Laboratory studies)  | Describe the magnitude of effect on growth at the expected concentrations6 |
| Distribution of estimated exposure values | Growth (no defined threshold) | Size: e.g., weight, length, biomass(Laboratory studies) | Describe the likelihood of an effect on growth at expected concentrations |
| 3. Reduced or impaired reproduction of an individual from the use of malathion according to registered labels (direct effect) | Estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect(s) | Reproductive endpoint (e.g., number of offspring, delayed maturation): Most sensitive NOAEC for reproductive endpoints for the representative taxon | Reproductive endpoint(Laboratory studies)  | Describe the magnitude of effect on reproductive endpoints at the expected concentrations |
| Distribution of estimated exposure values | Reproductive endpoint (no defined threshold) | Reproductive endpoint (including abundance and population effects)(Laboratory and field studies) | Describe the likelihood of an effect on reproductive endpoints at expected concentrations |
| 4. Impaired behavior that could result in increased mortality or decreased growth or reproduction from the use of malathion according to registered labels (direct effect) | Estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect(s) | Behavioral endpoint relevant to growth, survival, and/or reproduction (e.g., locomotion, eating behavior, reproductive behavior, predator avoidance, ability to migrate): Most sensitive NOAEC for endpoints for the representative taxon | Behavioral endpoint relevant to growth, survival, and/or reproduction (Laboratory studies) | Describe the magnitude of an effect on reproductive, growth, and/or mortality endpoints at the expected concentrations |
| Distribution of estimated exposure values | Behavioral endpoint (no defined threshold) | Behavioral endpoint relevant to growth, survival, and/or reproduction (Laboratory and field studies) | Describe the likelihood of an effect on reproductive, growth, and/or mortality endpoints at the expected concentrations |
| 5. Impaired sensory function from the use of malathion according to registered labels (direct effect) | Estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect(s) | Sensory function endpoint (that could impact predator avoidance, prey detection, homing abilities, reproduction, etc.): Most sensitive NOAEC for endpoints for the representative taxon | Endpoints relevant to sensory abilities(Laboratory studies) | Describe the magnitude of an effect on reproductive, growth, and/or mortality endpoints at the expected concentrations |
| Distribution of estimated exposure values | Sensory function endpoint (no defined threshold) | Endpoints relevant to sensory abilities(Laboratory and field studies) | Describe the likelihood of an effect on reproductive, growth, and/or mortality endpoints at the expected concentrations |
| 6. Indirect effects to listed individuals from the use of malathion according to registered labels | Peak estimated exposure values or field-scale monitoring data | Mortality (for loss of prey, pollinator, seed disperser, host species; or alteration of habitat): 10% effect level [for the HC05 (if an SSD can be calculated) or the most sensitive mortality endpoint for the representative taxon (if an SSD cannot be calculated)]. | LC50/LD50 and slope (Laboratory toxicity studies) | Describe if the threshold is exceeded or not at expected concentrations |
| Distribution of estimated exposure values | Mortality (no defined threshold) | LC50/LD50 and slope (Laboratory toxicity studies) | Describe the likelihood of effects on prey base, habitat, pollinators, etc. at expected concentrations |
| Environmental exposures | Mortality (for loss of prey, pollinator, seed disperser, host species; or alteration of habitat) (no defined threshold) | Mortalities reported in incident reports and field studies(Incident reports and field studies) | Review data and summarize highly probable and probable incidents- qualitative discussion |
| Estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect(s) | Reduced growth and/or reproduction (for loss of prey, pollinator, seed disperser, host species; or alteration of habitat): Most sensitive LOAEC for growth or reproduction for the representative taxon | Growth and reproduction endpoints(Laboratory and field studies) | Describe if the threshold is exceeded or not at expected concentrations |
| Distribution of estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect(s) | Reduced growth and/or reproduction (for loss of prey, pollinator, seed disperser, host species; or alteration of habitat) (no defined threshold) | Growth and reproduction endpoints(Laboratory and field studies) | Describe the likelihood of effects on prey base, habitat, pollinators, etc. at expected concentrations |
| 7. Differences in toxicity observed when exposed to mixtures | Available monitoring studies, usage data, and label information (*e.g*., recommended tank mixtures, multi-a.i. products) | Mortality, growth, reproduction, behavior, etc. (direct effects) | Mortality, growth, reproduction, behavioral, etc. as related to mixtures(laboratory and field studies) | The effects of mixtures will be qualitatively evaluated. The description of combined toxicity will assume additive toxicity (response or concentration addition) unless adequate data are available to determine if antagonism or synergism is more likely with specific mixture/species combinations.  |
| 8. Factors such as bacteria/viral prevalence, temperature, or pH in the environmental baseline enhances the susceptibility of listed species to malathion | Estimated exposure values or field-scale monitoring studies relevant to the duration of exposure that elicited the effect | Mortality, growth, reproduction, behavior, etc. (direct effects) | Mortality, growth, reproduction, behavioral, etc. as related to environmental factors such as, pH, temperature, or bacteria/viral(laboratory and field studies)  | Report assessment endpoint and measurement endpoints. Compare exposure estimates and measures of environmental levels of the stressor. Discuss qualitatively. |

1 Field-scale monitoring data are based on results from monitoring at specific locations and times that are associated with information on specific applications (with knowledge of application rate, field characteristics, water characteristics, and meteorological conditions) (based on information in NRC, 2013).

2 Includes parent active ingredient, formulations, and degradates of concern

3 The distribution of values, when possible, are based on temporal, geospatial, and use variability (see the exposure sections of this document for details; **Sections 1.4.2.2.a**).

4 ‘No defined threshold’ means that a predetermined threshold of effect/exposure has not been determined; the contribution of the effects/exposure data to the line of evidence will be based on the relevance of the measurement endpoints and exposure conditions along with the robustness of the study. This allows flexibility in applying the many types of studies potentially informing a line of evidence.

5 Monitoring data can be divided into 2 categories: (1) field studies (see footnote 1), and (2) general monitoring studies (NRC 2013). General monitoring studies are not coordinated with specific applications of pesticides, therefore, it is unlikely that they capture the maximum concentrations that exist in the environment. In this approach, general monitoring data are compared to available thresholds. If measured concentrations of malathion exceed established thresholds, this may serve to increase the confidence that this chemical poses a risk to a particular species (through direct or indirect effects) (see **Section 1.4.2.2.b.1**, for details).

6 Knowing the magnitude of effect for endpoints associated with a given line of evidence is useful for assessing risk. For this biological assessment the magnitude of effect is reported from toxicity studies reviewed to determine threshold values (see **ATTACHMENT 1-8** for information on the review process).

#### 1.4.2.2. Weight of Evidence Approach

A weight-of-evidence (WoE) approach is a systematic method of evaluating confidence in risk information from multiple sources. The WoE approach in the BE consists of multiple steps (explained in further detail below; also see **ATTACHMENT 1-9**):

* + Frame Risk Hypotheses that link directly to the protection goals of Step 2
	+ Construct “Lines of Evidence” (LOE) that assess the risk hypotheses
	+ Use of the following criteria to evaluate each LOE:
		- Exposure
			* Relevance
			* Robustness
		- Effects data
			* Biological Relevance
			* Species surrogacy
			* Robustness
	+ Use of the aforementioned criteria to assign weight (or confidence) in the data available for each line of evidence
	+ Comparison of the exposure concentration data with effects data to establish overlap (or risk) and assign weight to that risk
	+ Integration of results from each line of evidence to support or refute the associated risk hypothesis

Studies and data collected for Step 1 are assigned to the appropriate line-of-evidence within each risk hypothesis.

**Collectively the risk hypotheses pose the question:**

Do we expect that effects to individuals of a listed species or its designated critical habitat exposed to malathion (according to registered labels) will not be discountable, insignificant, or completely beneficial?

Lines-of-evidence (LOE) are constructed based on assessment endpoints. General lines of evidence for malathion are described above in **Section 1.4.2.1** and are repeated below:

**A. Lines of evidence for direct effects are:**

1. Mortality to an individual of a listed species from direct, acute exposure from the use of malathion according to registered labels (includes parent active ingredient, formulations, and degradates of concern)
2. Reduced growth of an individual (potential for decreased survival and/or reproduction) from the use of malathion according to registered labels
3. Reduced or impaired reproduction of an individual from the use of malathion according to registered labels
4. Impaired behavior that could result in increased mortality or decreased growth or reproduction of an individual from the use of malathion according to registered labels
5. Impaired sensory function that could result in increased mortality or decreased growth or reproduction of an individual from the use of malathion according to registered labels

**B. Lines of evidence for indirect effects:**

1. Decline in availability of prey/food of a listed species.
2. Impacts to suitability of habitat of a listed species.

**C. Lines of evidence for factors that could affect the magnitude of both direct and indirect effects:**

1. Potential effects due to degradates.
2. Differences in effects observed when exposed to chemical mixtures (formulations, tank mixtures, environmental mixtures)
3. Impacts of non-chemical stressors on the effects of the assessed pesticide, such as bacteria/viral prevalence, temperature, or pH in the environmental baseline.

The weight of a line-of-evidence is an expression of confidence in knowledge about the effects caused by a pesticide according to registered labels and the exposures which would lead to such effects.

Criteria used to assess exposure estimates ultimately answer the question, “how confident are we that exposure estimates represent environmental concentrations that could occur based on allowable labeled use?” Exposure data are evaluated using two criteria, “relevance” and “robustness” (see **ATTACHMENT 1-9**, for details). In the same way exposure data are assessed, the effects data are evaluated to answer the question, “how confident are we that toxicity data accurately predict an effect to the listed species?” Criteria used to evaluate this question include biological relevance, species surrogacy, and robustness, (these are defined in **ATTACHMENT 1-9**).

Based on consideration of these criteria for the exposure and effects data, the weight (or confidence) in the line of evidence is assigned a rank of high, medium or low.

Risk is established by comparing the overlap of exposure with effect levels from toxicity studies for each line of evidence. Consideration is given to the degree of overlap between exposure and effects data. Based on this analysis, risk is assigned a rank of high, medium, or low. An overall risk finding (high, medium, low) and a finding on the overall confidence (high, medium, low) in the available exposure and effects data is made for each line of evidence.

Next, each line of evidence for a given risk hypothesis is plotted in a graph according to the risk and confidence associated with the line of evidence (*e.g*., **Figure 1-7**). Each risk hypothesis is assessed to determine if the lines of evidence support or refute it. For species that have designated critical habitat, an additional risk hypothesis is evaluated.



**Figure 1-7. Example Display of All Lines of Evidence for a Risk Hypothesis Based on Confidence and Risk.**

**Table 1-8** shows the appropriate finding for pairings of confidences and risk estimates. The effect determination represents a finding for a listed species on whether the action, as proposed, is not likely to adversely affect (NLAA) or is likely to adversely affect (LAA). For the direct and indirect lines of evidence (*i.e*., LOEs A. 1 through 5 and B. 1 and 2, above), a combination of ‘risk estimate’ and ‘confidence’ that results in an LAA for any single line of evidence – as described in **Table 1-8**- is sufficient to make an LAA effects determination for the species [or Distinct Population Segment (DPS)/Evolutionarily Significant Unit (ESU)] or critical habitat as a whole. Therefore, for each of these specific LOEs, if one or more of the ‘risk estimate’/’confidence’ combinations results in an ‘LAA,’ then a LAA effects determination for the species (DPS/ESU) or critical habitat as a whole will be made.

The lines of evidence that could impact the magnitude of direct or indirect effects (*i.e*., LOEs C. 1 through 3, above) are not used solely to make NLAA/LAA determination, but rather used in association with the other LOEs. If the available data provide evidence that the stressors related to these LOEs increase the effects of malathion to impair or reduce an individual’s fitness or affect PCEs/PBFs, then this could result in an LAA determination.

For some ‘risk’ and ‘confidence’ pairings, the NLAA or LAA call will be made on a case-by-case basis (those denoted by an asterisk in **Table 1-8**). When applicable, the EPA and the Services will discuss the available information further to decide on the appropriate effects determination (*i.e*., NLAA or LAA).

**Table 1-8. Effects Determinations Based on Pairings of Risk and Confidence for a Line of Evidence**

|  |  |  |
| --- | --- | --- |
| **Risk Estimate (for any line of evidence)** | **Confidence** | **Effect Determination** |
| High | High | LAA |
| High | Med | LAA |
| High | Low | LAA |
| Medium | High | LAA |
| Medium | Medium | LAA |
| Medium | Low | NLAA or LAA\* |
| Low | High | NLAA |
| Low | Medium | NLAA or LAA\* |
| Low | Low | NLAA or LAA\* |

\* The selection of the appropriate effects determination associated with this ‘risk’ and ‘confidence’ pairing may require additional discussion with FWS and NMFS.

The WoE approach considers both estimates of exposure and estimates of effects. The methods by which exposures and effects are estimated for each species are discussed below.

##### 1.4.2.2.a. Estimated exposures

###### 1.4.2.2.a.1. Aquatic habitats

To estimate exposure in surface water, ten generic habitat types were modeled (**Table 1-9**): three to simulate flowing waterbodies (Bins 2-4); three to simulate static waterbodies (Bins 5-7) and three to simulate estuarine/marine habitats (Bins 8-10). The habitats vary in depth, volume, and flow. Aquatic-associated terrestrial habitats (Bin 1) include riparian habitats or other land-based habitats adjacent to waterbodies that may occasionally be inundated with surface water, provide habitat used by aquatic organisms and semi-aquatic organisms, or influence the quality of the aquatic habitats. The listed species assessed were assigned to the appropriate bin, based on habitat requirements (see **ATTACHMENT 1-10**). Environmental fate models are used to generate estimated exposure concentrations (EECs) for malathion. The concentration estimates serve as the exposure values, which are compared to toxicity endpoints. The extent to which exposure concentrations in surface water and benthic sediment pore water may affect listed aquatic animals and plants from spray drift, runoff, and erosion from the chemical’s use site are simulated using the PWC. The daily average (*e.g.*, 1-in-15 year return frequency annual daily average EECs) and chronic (1-in-15 year return frequency annual 21-day and 60-day average EECs) for the different HUC 2 regions are estimated for the various use rates specified on the labels using the PWC, the appropriate ESA scenario, the HUC 2 regionally-specific watershed dimensions, and the associated aquatic bins (see **Table 1-9**). The 1-in-15 year EECs are used in the ESA assessment to account for the length of the action, as determined through the length of the registration review cycle. EPA currently lacks tools to model concentrations in tidal and marine environments. Generally, estimates developed for aquatic Bin 2 are used as surrogate exposure levels for intertidal nearshore waterbodies (Bin 8), and estimates developed using aquatic Bin 3 are used as surrogate exposure levels for subtidal nearshore waterbodies (Bin 9). Additionally, aquatic Bin 5 is used as a surrogate for tidal pools occurring during low tide (aquatic Bin 8). In each of these cases, however, other life history considerations may have influenced the surrogate bin assignments to vary by species. As aquatic Bin 10 is seldom associated with exposure from runoff and soil erosion, exposure concentrations are modeled assuming spray drift only.

**Table 1-9. Generic Aquatic Habitats.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Generic Habitat | Depth (meters) | Width (meters) | Length (meters) | Flow (m3/second) |
| 1 – Aquatic-associated terrestrial habitats | NA | NA | NA | NA |
| 2- low-flow | 0.1 | 2 | length of field1  | 0.001  |
| 3- Moderate-flow | 1 | 8 | length of field  | 1  |
| 4- High-flow | 2 | 40 | length of field  | 100  |
| 5 – Low-volume | 0.1 | 1 | 1 | 0 |
| 6- Moderate-volume | 1 | 10 | 10 | 0 |
| 7- High-volume | 2 | 100 | 100 | 0 |
| 8- Intertidal nearshore | 0.5 | 50 | Length of field | NA |
| 9- Subtidal nearshore | 5 | 200 | Length of field | NA |
| 10- Offshore marine | 200 | 300 | Length of field | NA |

1length of field – The habitat being evaluated is the reach or segment that abuts or is immediately adjacent to the treated field. The habitat is assumed to run the entire length of the treated area.

Exposure concentrations in surface water and benthic sediment pore water, downwind from the chemical’s use, are evaluated using AgDRIFT and AGDISP, as previously described in Section 1.5.1.1.c.1. NA indicates that concentrations were not calculated.

Details used for modeling exposures for the listed aquatic species (i.e., fish, aquatic invertebrates, marine mammals, marine reptiles and corals) are included in **ATTACHMENTS 1-11** to **1-15**.

In addition to modeled exposure estimates, monitoring data are also available. Monitoring data can be divided into 2 categories: (1) field studies, and (2) general monitoring studies (NRC 2013).

Field studies are defined as the monitoring of specific applications of the pesticide at the field-scale under well-described conditions. These studies provide the information needed to make direct comparison to exposure model estimates, including the rate, method, treatment location relative to monitoring stations, meteorological conditions, characteristics of the treated site, and characteristics of the habitat sampled. Studies lacking this information are defined as general monitoring studies.

General monitoring studies provide information on pesticide concentrations in the environment at specific locations and times. They may also be coordinated with the use of pesticides at some level (*e.g.*, at the watershed level). Since general monitoring studies are not coordinated with specific applications of pesticides, it is unlikely that they capture the maximum concentrations that exist in the environment (*i.e.*, at or near the site of application). Further, valid comparisons to model estimates cannot be made with general monitoring data because they lack the specific information that is needed for such comparisons.

Malathion and malathion-oxon have been measured in various environmental media, including surface water, groundwater, air, and precipitation. Samples were collected from sites distributed throughout the United States as part of several environmental monitoring programs (*e.g.*, NAWQA). All of the available studies with malathion were characterized as general monitoring. Although data from these monitoring studies may not have been co-located with specific applications of pesticides under well-described conditions (*e.g.*, application rate, field characteristics, water characteristics, and meteorological conditions), EPA considers this information useful as it documents concentration levels detected at species locations from previous pesticide use.  As recommended by NRC (2013), data from general monitoring studies are not used to estimate pesticide concentrations after a pesticide application (*i.e.*, predict maximum exposure concentrations) or to evaluate the performance of EPA’s fate and transport models.  Rather, EPA presents the data in **APPENDIX 1-10** and as part of the exposure assessment to qualitatively inform the WoE evaluation. While general monitoring data typically underestimate potential exposure, the documentation of a pesticide in listed species habitats at concentrations that exceed effects thresholds provides evidence to support conclusions of likely to adversely affect. The general monitoring studies also provide useful information for describing the environmental baseline condition of species habitats, including the occurrence of chemical mixtures and the presence of abiotic stressors that can increase risk.

In this approach, monitoring data are compared to available thresholds. If measured concentrations of malathion exceed established thresholds, this may serve to increase the confidence that this chemical poses a risk to a particular species (through direct or indirect effects). The relevance of monitoring data will be considered (*e.g*., how the overlap of timing of the samples relate to major changes to the use of malathion). Monitoring data that potentially reflect out of date use patterns will have lower weight compared to more recently collected samples that reflect current use patterns of malathion. When considering general monitoring data, because they do not necessarily reflect the higher concentrations of malathion in the sampled environment, risk cannot necessarily be precluded if measured concentrations in a media relevant to a listed species do not exceed thresholds.

###### 1.4.2.2.a.2. Terrestrial habitats

In the terrestrial environment, exposure is estimated for animals located on the treated area as well as on non-target areas adjacent to the treated field. Pesticide exposure to animals is quantified based on direct applications and spray drift transport. Measures of exposure are based on models that predict EECs using maximum labeled application rates and methods. In EFED’s standard ecological risk assessment, the models used to predict EECs on food items of animals are T-REX (terrestrial plants and arthropods), T-HERPS and KABAM (aquatic plants, invertebrates and fish). Because chlorpyrifos is known to metabolize in fish and a metabolism rate constant could not be established, empirically based invertebrate and fish BCF values were used in lieu of KABAM in order to estimate pesticide concentrations in fish and aquatic invertebrates. AgDRIFT and AGDISP are used to estimate spray drift deposition away from the treated field. These models are parameterized using relevant reviewed environmental fate data and product labels. Supporting documentation for each model is available online at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>

Because the diets of listed species include food items that are not included in the current versions of T-REX and KABAM, additional approaches were developed to account for potential exposures through diet. The T-HERPS approach for deriving EECs for animals that consume mammals and birds was expanded to apply to birds and mammals. The earthworm fugacity model was used for species that consume soil-dwelling invertebrates.

In addition to dietary exposures, other routes will be considered for vertebrate animals, including consumption of contaminated drinking water, dermal contact or direct spray, and inhalation of volatilized residues or spray droplets. These methods are based on those used by the Terrestrial Investigation Model (TIM) and presented to the FIFRA Scientific Advisory Panel (SAP) in 2001 and 2004. Details on the body weights and diets used for specific species of birds, mammals, reptiles and amphibians are included in **ATTACHMENTS 1-16** to **1-19**.

For assessing direct effects to listed terrestrial invertebrates and indirect effects to species that consume invertebrates, a modified version of T-REX is used. This method is loosely based on the exposure method for bees that was developed by EPA, Canada’s Pest Management Regulatory Agency (PMRA) and California’s Department of Pesticide Regulation (CADPR) in 2012[[23]](#footnote-23). In this approach, dietary-based and contact-based exposures are assessed. Details used for modeling exposures for the listed species of terrestrial invertebrates are included in **ATTACHMENT 1-20**.

For plants, exposure is assessed for areas adjacent to the field that receive spray drift and runoff from the treated field. The model used to derive runoff EECs relevant to terrestrial and wetland plants is TerrPlant. AgDRIFT is also used to estimate spray drift deposition away from the treated field. Details used for modeling exposures for the listed species of terrestrial plants are included in **ATTACHMENT 1-21**.

In order to efficiently assess the risks of malathion to the hundreds of listed terrestrial species, EFED’s current models (i.e., T-REX, T-HERPS, earthworm fugacity, TerrPlant and AgDRIFT) were combined into a single tool that is referred to as the TED (Terrestrial Effects Determination) tool. This tool also includes other food items not covered by these models and the ability to consider exposure via consumption of aquatic organisms (e.g., fish). In addition, this tool incorporates non-dietary exposure routes for vertebrates (i.e., inhalation, drinking water and dermal) as well as exposures to terrestrial invertebrates. A detailed description of the methods for estimating exposures to terrestrial animals is provided in **ATTACHMENT 1-7**.

##### 1.4.2.2.b. Estimated effects

###### 1.4.2.2.b.1 Effects thresholds

In Step 2, toxicity values and other data (e.g., incident data) for direct and indirect effects to listed species are analyzed using a WoE approach. These data are organized into lines of evidence that inform risk hypotheses and ultimately the effect determinations (NLAA or LAA) for listed species. Effects thresholds represent just one component of information considered within each line of evidence in the overall WoE. The overall effects determination for each species and critical habitat being assessed will be based on the WoE approach described in **Section 1.4.2.2.**

Studies used for thresholds (including a subset of studies used to develop SSDs) were reviewed. Studies submitted to the agency from registrants are reviewed using the agency’s Standard Evaluation Procedures (SEP). Studies from the open literature are reviewed largely using the approach outlined in the agency’s guidance for evaluating ecological toxicity data in the open literature (USEPA 2011;<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open> ). Modifications from the guidance that were used are detailed in **ATTACHMENT 1-8**.

1.4.2.1.b.1.1 Direct and indirect effect thresholds based on mortality

For mortality, either the one-in-a-million chance of mortality as established in Step 1 for each particular taxon (*e.g*., fish) is used as a threshold, or data for a more appropriate surrogate, when available (*e.g.,* trout data for a listed salmonid) are used. If enough data from appropriate surrogates are available to create a SSD for the surrogates, the 5th percentile of the SSD or a surrogate LD50, LC50, or ECx from the subset of data may be used. For listed species which lack more appropriate surrogate data, the taxon-specific threshold derived in Step 1 is also used for the NLAA/LAA analysis (for details, **see ATTACHMENT 1-4**).

The potential for indirect effects (*e.g.,* effects on diet, habitat, and pollinators) is based on malathion toxicity to the taxa that are relevant to the listed species being assessed. For potential indirect effects based on prey lethality for those species without obligate relationships, for example, the exposure that results in a 10% effect for the 5th percentile species on an SSD for the prey species, is used as a threshold. If not enough data are available for a SSD, the 10% effect for the most sensitive prey species tested in that taxon is used. The 10% effect is determined using the most sensitive LD50 and the corresponding slope, if available (if not available a default slope of 4.5[[24]](#footnote-24) is used) (see **Table 1-10**, below).

1.4.2.1.b.1.2. Direct and indirect effect thresholds based on sublethal endpoints

For sublethal effects to plants, the level that corresponds to the reproduction or growth NOAEC, NOAEL, or EC05 for the most appropriate surrogate species is used as the sublethal threshold. If data on a specific surrogate are not available, the most sensitive species tested in a taxon is used (as described above). For species with obligate relationships[[25]](#footnote-25), the potential for indirect effects to the obligate species is based on the effects endpoints identified for assessing the potential for direct effects to a species as described above (see **Table 1-10**).

For deriving a threshold based on sublethal direct effects to listed animals, the lowest available NOAEC or NOAEL or other scientifically defensible effect threshold (ECx) that can be quantitatively or qualitatively linked to survival or reproduction of a listed individual is used. For deriving a threshold for indirect effects, the LOAEC or LOAEL or other scientifically defensible effect threshold (ECx) for growth or reproduction is used (see **ATTACHMENT 1-4**, for details).

**Table 1-10. Step 2 Habitats.** [these values are used to derive thresholds for use, along with other data, in the weight-of-evidence (WoE) approach for making NLAA and LAA determinations for listed species and critical habitats].

| **Taxon (Direct Effects) (Indirect Effects) or Taxa on which a listed species depends** | **Mortality**  | **Sublethal Effects** |
| --- | --- | --- |
| Birds1 | Direct Effects: Same as those identified in **Table 1-10** unless species surrogate data can be used.Indirect Effects: Concentration (or dose) that would result in a decrease of 10% of individuals (i.e. the EC10). This is calculated by using HC05 of SSD of LC50/LD50 or EC50 values and representative slope. If SSD cannot be derived, most sensitive LC50/LD50 or EC50 will be used. | Direct effects: Lowest available NOAEC/NOAEL or other scientifically defensible effect threshold (ECx) that can be linked to survival or reproduction of a listed individual will be used. Indirect Effects: LOAEC/LOAEL for growth or reproduction will be used (see text for details). |
| Mammals1 |  |
| Reptiles |  |
| Terrestrial-phase amphibians |  |
| Aquatic-phase amphibians |  |
| Fish |  |
| Aquatic invertebrates |  |
| Terrestrial invertebrates |  |
| Aquatic plants | None | Direct Effects: Same as those identified in **Table 1-10**.Indirect Effects: *Aquatic plants*: Concentration equal to the lowest available LOAEC and EC25 value for aquatic plants*Terrestrial and wetland plants*: Concentration equal to the lowest LOAEC and EC25 value from the available seedling emergence and vegetative vigor studies |
| Terrestrial plants |  |
| Wetland plants |  |

1Lowest LD50 or NOAEL/LOAEL for birds and mammals determined by normalizing results to 100 g body weight for birds and 15 g body weight for mammals prior to establishing threshold value.

##### 1.4.2.2.a. Effect arrays

Effects Arrays enable the examination of all available ecotoxicity data relative to a range of potential exposure values for a pesticide. Use of the array format also allows for a visual representation for summarizing this information. The Effects Arrays allow for:

* + - * + Identification of taxa, families, and species of concern that may be affected by exposure to a pesticide;
				+ Identification and evaluation potential exposure pathways of concern;
				+ Identification of effects (mortality and sublethal effects) and effects thresholds used to assess direct and indirect effects to a listed species;
				+ Description of the type and range of effects for species at expected exposure concentrations; and
				+ Prioritization of studies that may need further review to inform the WoE process.

Sources of toxicity data used to build the Effects Arrays include registrant-submitted studies as well as open literature studies and government reports contained within the ECOTOX database. Studies located and coded into ECOTOX must meet acceptability criteria, as established in the *Interim Guidance of the Evaluation Criteria for Ecological Toxicity Data in the Open Literature, Phase I and II* (http://www.epa.gov/pesticides/science/efed/policy\_guidance/team\_authors/endangered\_species\_reregistration\_workgroup/esa\_evaluation\_open\_literature.htm). The intent of the acceptability criteria is to ensure data quality and verifiability.

All sublethal and lethal endpoints (based on study NOEC/LOAEC, ECx and LCx values) that meet the ECOTOX acceptability criteria are presented in the Effects Arrays. As a result, the arrays include a diversity of studies, effects, and endpoints. For example, there may be studies with different test duration, test conditions, and/or test species. Some studies may have tested TGAI, while others used formulated products or tank mixtures. Different endpoints may be reported (NOAECs, LOAECs, ECx, or LCx), and the magnitude of effect associated with some endpoints (*i.e*., NOAEC, LOAEC) are not reported. These sources of variability/uncertainty will be taken into account when using effects arrays to inform specific lines-of-evidence for the WoE analysis.

Effects Arrays are constructed using the Data Array Builder v.1.0, which batch processes all of the available data for a particular taxonomic grouping and unit of measurement into graphs that display all of the effects data. The graphs display data by the measured effect, as defined within the ECOTOX database (the ECOTOX code list can be found at: <http://cfpub.epa.gov/ecotox/blackbox/help/codelist.pdf>). In the arrays, the data are arranged generally as they relate to the different lines of evidence (discussed above). More information on how to construct and evaluate the Effects Arrays is provided in **ATTACHMENT 1-22**.

##### 1.4.2.2.b. Incident data

A pesticide incident is defined as any exposure or effect from a pesticide’s use that is not expected or intended. Pesticide incidents may involve humans, pets, wildlife, plants, domestic animals and honey bees. Ecological incident reports (those involving wildlife and plants) are typically used by EPA as a line of evidence (in a WoE approach) for making risk conclusions in pesticide risk assessments. Incident data can provide evidence that exposure pathways for a particular pesticide are complete and that exposure levels are sufficient to result in field-observable effects. In short, incident reports provide important information on what can happen to non-target plants and wildlife when a pesticide is used in the ‘real world’, and they can help support or refute risk predictions based on laboratory data.

Because incident data are not typically reported or collected systematically, a lack of reported incidents cannot be used as evidence that incidents could not or do not exist from registered uses of the chemical(s) being considered. Incident reports for non-target organisms normally provide information only on mortality events and plant damage. Except for phytotoxic effects in terrestrial plants, sublethal effects, such as abnormal behavior, reduced growth or impaired reproduction, are rarely reported.

The primary sources of ecological incident information that OPP uses are the Incident Data System (IDS), the Ecological Incident Information System (EIIS), and the Avian Incident Monitoring System (AIMS) (see **ATTACHMENT 1-1** for details). These databases contain information from pesticide incident reports. The incident reports are derived from a variety of sources [those submitted directly to OPP (*e.g*., by pesticide registrants, the public, and state, federal, and local government agencies) and those available through other sources (*e.g*., the United States Geological Survey’s Contaminant Exposure and Effects – Terrestrial Vertebrate Database, the open literature and media accounts)].

The available incident data are evaluated for relevance based on EFED’s current incident guidance[[26]](#footnote-26). This evaluation includes decisions on which incidents to exclude from further consideration (*e.g*., because they were determined to be unrelated to a pesticide). A WoE analysis of the combined knowledge obtained from all of the "included" incidents is conducted, along with a characterization of the certainty of the incident information in identifying exposure pathways that lead to risk to plants and/or animals in the field. Factors that are considered in this analysis include the following: certainty level of the incidents; legality determination of incidents; number of incidents; number of animals and/or plants affected in the incidents; evidence of exposure revealed through residues measured in tissue and environmental samples; the agreement of observed incidents with risks predicted by risk assessments; the agreement of observed incidents with risks predicted by laboratory and field studies; patterns of certain types of uses causing certain types of incidents; and evidence that incidents occurred from typical circumstances versus unusual circumstances. Special emphasis is placed on reported incidents involving any federally-listed species.

##### 1.4.2.2.c. Effects to designated critical habitat

Actions are evaluated to determine whether the use of a pesticide would measurably affect the PCEs/PBFs of the assessed species’ designated critical habitats.  Both short-term and long-term effects to the PCEs are considered for a given critical habitat designation, and presence of the species is not a determining factor for the NLAA/LAA conclusion. For example, relevant PCEs for aquatic species or aquatic-associated species are generally expected to address those related to water quality, but also include PCEs related to important life history stages where "water quality" may not be the main focus of the PCEs. Examples include, but are not limited to spawning and rearing areas, migratory corridors with no physical or water quality impediments, cover (e.g., where a chemical might affect presence or complexity of overhanging/riparian vegetation), abundance of prey organisms, *etc*.  Critical habitat PCEs for terrestrial organisms may have considerations in terms of presence of contaminants or other chemicals, presence/structure of vegetation and other habitat features, prey base, pollinators, or other important physical and biological features. Therefore, these PCEs are identified as assessment endpoints.

In many cases, EPA anticipates that the assessment endpoints used to evaluate the potential for direct and indirect effects to listed species are equivalent to those used to evaluate potential effects to PCEs for a given designated critical habitat.  Furthermore, if a potential for direct or indirect effects for a listed species is identified, then there is also a potential for effects to critical habitat (where critical habitat has been designated for that species).

##### 1.4.2.2.d. Probabilistic approach for 13 bird species

One of the recommendations of the NRC was to base conclusions of whether a use is likely or not likely to adversely affect individuals of listed species based on probabilistic methods. At this time, tools are not available to conduct probabilistic risk assessments for all listed species; however, more information than has traditionally been used in assessments can be integrated into the effects determinations. For instance, species sensitivity distributions can be used to represent species responses and variability in exposures over time.

EPA’s existing refined tools for birds are used when possible to illustrate the capabilities of probabilistic models for providing lines of evidence in making effects determinations and for informing risk mitigation options that may be implemented on pesticide labels. These models include the Terrestrial Investigation Model (TIM v. 3.0) and the Markov Chain Nest Productivity Model (MCnest). A preliminary review of currently listed and proposed bird species indicate that these models may be appropriate for quantifying risks to 13 listed bird species (see **ATTACHMENT 1-16**). The models may also be used to assess indirect effects to those listed avian species that rely upon birds as prey (*e.g*., raptors).

TIM (v3.0) is a multimedia exposure/effects model that can be used to address generic or specific species avian mortality levels from acute pesticide exposure over a user-defined exposure window. This time frame corresponds to one growing season of the treated crop or a single sub-annual pesticide application window. The spatial scale considered by the model is at the field level. Specific field dimensions are undefined. It is assumed that the field and surrounding area meet habitat and dietary requirements for the modeled species. During the simulation, birds use the treated field and edge habitat to meet their requirements for food and water. TIM also accounts for exposure via dermal and inhalation routes for birds on the field or on adjacent habitat that receives spray drift. It is expected that the relative importance of these routes of exposure will vary based on the properties of the pesticide, its use, as well as the characteristics of the simulated bird species.

The Markov Chain Nest Productivity Model (or MCnest) integrates existing toxicity information, from three standardized avian toxicity tests, with information on species life history and the timing of pesticide applications relative to the timing of avian breeding seasons, to quantitatively estimate the impact of pesticide-use scenarios on the annual reproductive success of bird populations. MCnest provides risk assessors with a tool to go beyond the current screening-level approaches for assessing reproductive effects by estimating the proportional change in reproductive success. MCnest translates toxicity information into the currency needed for conducting a population-level assessment of pesticide risks. Details on MCnest are available online at: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#mcnest>

##### 1.4.2.2.e. Mixture Analysis

Environmental mixtures containing malathion have been identified as a stressor of the action for this ESA Section 7 consultation. Environmental mixtures result from the offsite transport of malathion and other chemical constituents (*e.g.*, other active ingredients, inerts, adjuvants, etc.), through the use of single or co-formulated products or tank mixes, at individual or multiple locations. Species and habitats exposed to these types of mixtures may be at greater risk of adverse effects than exposure to malathion alone; as a result the potential effects of exposure to mixtures is assessed qualitatively in Step 2. While conceptually responses to environmental mixtures can be predicted, it is not feasible to estimate exposure concentrations and predicted responses for all possible mixture combinations. In most cases, the concentrations of potential mixture constituents are unknown. Furthermore, it is not practical to test the toxicity of every possible chemical combination that may be encountered by listed species in the environment. Despite the complexity of assessing mixture risk, the scientific literature on mixture toxicity is considered to determine the risk of mixtures in order to inform a qualitative line of evidence.

Step 1 – A mixtures analysis is not conducted as part of the Step 1 “may affect” determination. The threshold for the “may affect” determination is co-occurrence of malathion’s labeled use sites and modeled drift and runoff with a species’ range.

Step 2 – Available product labels, usage information, monitoring data, and toxicity information are used to qualitatively assess the mixtures line of evidence.

Additive toxicity of malathion with other chemicals is the default assumption based on inter-agency discussions and the NAS NRC report recommendations. Additive mixture toxicity can be evaluated using either “concentration-addition” or “response-addition” assumptions using single active ingredient toxicity data and exposure estimates. In the case of compounds with a shared mechanism of action (*e.g.,* organophosphates such as malathion), concentration-addition is assumed unless data indicate that antagonism or synergism is more likely with specific mixtures and species combinations. This approach is consistent with the best available science (*e.g.*, Belden *et al*., 2007; Backhaus and Faust, 2012; Cedergreen, 2014) and the NRC recommendations. Caution is exercised in using the concentration-addition assumption as a default approach when mechanistic data or concentration-response toxicity data are unavailable. Response-addition is the appropriate additive model for compounds that have dissimilar mechanisms of action unless available data indicate that antagonism or synergism is more likely with specific mixture and species combinations. The NRC report states that “mixture components will contribute to the response only when present in the environment at concentrations that elicit relevant response... [and] such components do not need to be considered when present at concentrations below their toxic thresholds.” (NRC, 2013)

The following information is used to evaluate potential exposure to environmental mixtures:

**Environmental mixture monitoring data.** Available monitoring data (*e.g*., NAWQA) are used to identify active ingredients that commonly co-occur in the environment. Response to environmental mixtures is qualitatively evaluated assuming additive toxicity (response or concentration addition) unless available data indicate that antagonism or synergism is more likely with specific mixture and species combinations.

**Formulated products.** Environmental mixtures occurring from the application of co-formulated products are qualitatively evaluated. The description of combined toxicity assumes additive toxicity (response or concentration addition) unless available data indicate that antagonism or synergism is more likely with specific mixture and species combinations. The toxicity information considered include studies of responses to mixtures as well as the sensitivity of different species to the single active ingredients included in formulation mixtures.

For most multi-a.i. products registered in the U.S., acute oral mammalian toxicity data and terrestrial plant toxicity data are available on the formulated products. Because the acute mammalian toxicity studies are available for single active ingredients and multi-a.i. products and are conducted using consistent study designs, these data can be used to explore mixture toxicity in this taxon (*i.e.*, mammals). This analysis of the multi-a.i. products, which is in addition to the consideration of the mixture toxicity data available in the open literature, involves a comparison of the acute oral endpoints (*i.e*., LD50 values) for the technical grade product and the formulated products. If there are multiple studies with the technical formulation for which confidence intervals (CI) are provided for the LD50, then the CI with the smallest lower CI for the LD50 (*i.e.*, most toxic LD50,) after correcting for %a.i., is compared to the LD50 upper CI for each formulation, after correcting for %a.i. If these confidence intervals do not overlap, then the formulated mixture is considered to be more toxic. Based on this approach, one of three conclusions for the formulations can be reached:

• Formulation is no more toxic than single active ingredient

• Formulation is more toxic than single active ingredient

• There is insufficient data to establish difference in toxicity

In the case of malathion, a qualitative examination of the trends in LD50 values, with the associated confidence intervals, across the range of percent active ingredient, reveals no definitive conclusions. For all of the malathion products analyzed, the data are insufficient to establish a difference in toxicity between the technical grade product and formulated products (see **APPENDIX 1-11**).

With regards to other taxa, the combined toxicity for multi-a.i. products assumes additive toxicity unless available data from other submitted studies or the available open literature indicate otherwise.

**Tank mixes.** Environmental mixtures resulting from the application of tank mixtures are characterized based on label recommendations and typical use patterns (*e*.*g.*, California Pesticide Use Reports). Responses to tank mixtures are qualitatively evaluated assuming additive toxicity (response or concentration addition) unless available data indicate that antagonism or synergism is more likely with specific mixture and species combinations.

Beyond the acute mammalian data available for multi-a.i. products, toxicity data for mixtures may also be available for a variety of taxa from data captured in ECOTOX searches. Studies containing toxicity data on mixtures are normally rejected by ECOTOX (which focuses on toxicity data for single chemicals) and listed in the bibliography as ‘rejected’ studies. However, some studies found ‘acceptable’ in ECOTOX may also contain mixture data if the study also involved results from a single chemical. These ‘rejected’ and ‘accepted’ mixture references are identified in **APPENDIX 1-12** along with the taxonomic group(s) the study included.

Further discussion of the risks to environmental mixtures containing malathion is discussed in **APPENDIX 4-2**.

##### 1.4.2.2.f. Consideration of Impacts of Biotic and/or Abiotic Stressors on the Effects of Malathion

Potential impacts of environmental conditions on the effects of malathion are discussed qualitatively. Environmental factors that are known to alter the toxicity of a chemical include, pH, temperature, and low oxygen content. In cases where chemical-specific toxicity data are available, they will be incorporated into this line of evidence for the appropriate taxa. This line of evidence will be used to determine whether it is reasonable to assume that the effects of malathion on non-target organisms may increase due to other stressors that may be attributed to the organism’s environment (excluding other pesticides).

Technical malathion has historically contained impurities that can account for up to 5% of the insecticide. California Department of Food and Agriculture reported 15 impurities (**Table 1-11**) in an ultra-low volume malathion formulation (CalEPA 1981). In some respects, it appears that the malathion technical registrant has taken measures to reduce impurities in more recent malathion technical products (MRID 49316501).

**1-11. Impurities Reported in Technical Malathion (CalEPA 1981).**

|  |  |
| --- | --- |
| **Impurity as Listed in** CalEPA (1981) | **% in Technical** |
| Diethyl fumarate | 0.90 |
| Diethylhydroxysuccinate | 0.05 |
| O,O-dimethylphosphorothioate | 0.05 |
| O,O,O-trimethyl phosphorothioate | 0.45 |
| O,O,S-trimethyl phosphorodithioate | 1.20 |
| Ethyl nitrite | 0.03 |
| Diethyl-bis (ethoxycarbonyl) mercaptosuccinate | 0.15 |
| S-1,2-ethyl-O,S-dimethyl phosphorodithioate [isomalathion] | 0.20 |
| S-(1-methoxycarbonyl-2-ethoxycarbonyl)ethyl-O,O-dimethyl phosphorodithioate | 0.60 |
| Bis-(O,O-dimethyl thionophosphoryl) sulfide | 0.30 |
| Diethyl methylthiosuccinate | 1.00 |
| S-ethyl-O,O-dimethyl phosphorodithioate | 0.10 |
| S-1,2-bis (ethoxycarbonyl) ethyl-O,O-dimethyl phosphorothioate [malaoxon] | 0.10 |
| Diethyl ethylthiosuccinate | 0.10 |
| Sulfuric acid | 0.05 |

The relative concentration of malathion impurities can vary depending not only on manufacturing processes but also storage conditions. Umetsu *et al.* (1977) concluded “Storage of technical malathion for 3 to 6 months at 40 oC resulted in materials that were noticeably more toxic to mice.” Therefore, the composition and toxicological properties of the technical malathion are not only affected by initial purity after manufacturing, but also by storage conditions of technical malathion and end use products.

Based on reported data, it appears that some malathion (and other organophosphate) impurities can increase malathion toxicity and also are toxic alone, but there are almost no data available on their environmental fate. The persistence of a phosphorothioate impurity (O,O,S-trimethyl phosphorothioate) was shown to be 18.7 times longer than malathion in an aerobic soil metabolism study (Miles and Takashima 1991). Some phosphorothioates and -dithioates have been studied with a reported effect of inducing a delayed toxic effect to mammals at lower levels than pure malathion (Ali Fouad and Fukuto 1982, Umetsu *et al* 1977, Fukuto 1983, Aldridge *et al* 1979, Toia *et al* 1980). A phosophorothioate and -dithioate impurity identified by CalEPA (1981) is of lower toxicity than impurities reported in older formulations (Toia *et al* 1980). One hydrolysis product, diethyl fumarate, which has also been present as an impurity in technical malathion is approximately three times more toxic to fathead minnows than malathion (Bender 1969).

The available toxicity data for malathion represent studies that have been conducted over the course of several decades and have involved the use of many different technical grade products. Given the potential increase in purity of malathion (and thereby presumed reduction in potentially toxic impurities) over the years, a comparison of recently submitted toxicity data with technical malathion to other available toxicity data (as reported in ECOTOX and/or other submitted studies) of similar duration and endpoint (generally 48- or 96-hr EC/LC50 values for aquatic species) was conducted to compare potential differential sensitivity (**Table 1-12**). While the following paragraphs describe comparisons for both aquatic and terrestrial animals, the overall conclusion is that there does not appear to be compelling information to exclude toxicity data at this time solely due to the source of technical malathion or the date when the study was conducted.

While the comparisons used toxicity data of the same test duration, it is recognized that there are sources of uncertainty, including:

* Differences between study test protocols (e.g., source of organisms, dilution water, flow-through vs. static designs);
* Toxicity data for the same species were not available (*i.e*., *Gammarus pseudolimnaeus*), and, therefore, toxicity data using species within the same genus were compared;
* Only studies which used an end-use product (formulation) were available for some species (*i.e*., oyster, midge); and
* Comparable toxicity data were not available for the mayfly.

However, even considering these uncertainties, the reported toxicity values for several species are similar, or are well within one order of each other. For example, for the mysid shrimp, while there is an approximate 2X difference in the reported LC50 value between the recent study (MRID 49389401, study conducted 2013-2014) and MRID 41474501 (study conducted in 1990), their 95% confidence intervals overlap. Furthermore, the other reported mysid shrimp LC50 values (*i.e*., Ecotox# 968, 2280) are also similar to these values. For the amphipod, *Gammarus*, even though a direct comparison to the recently tested species could not be conducted, toxicity values for other Gammarid species are similar to the toxicity value from a more recent study. The toxicity values for the sheepshead minnow and green sunfish were also similar. There are cases where the toxicity values do not appear to be similar for which the recent toxicity value is greater or lesser than other toxicity values. For example, the recent crayfish toxicity values are substantially higher than the other toxicity values which used a formulation, whereas the medaka fish recent toxicity value is lower than the open literature value.

**Table 1-12. Comparison of Recently Submitted Toxicity Values to Other Reported Toxicity Values for Aquatic Species**.

| **Aquatic Species** | **Recently Submitted Toxicity Data** | **Other Reported Toxicity Data** |
| --- | --- | --- |
| 48 or 96-hr1 Toxicity Value (95% CI) (µg/L);(Test Design)2 | % Purity | Reference / Year | 48 or 96-hr1 Toxicity Values (95% CI) (µg/L); (Test Design) | % Purity | Reference / Year |
| Crayfish (*Procambarus clarkii*) | 21,000 (18,000-26,000) | 96.8 | MRID 49534901 / 2014 | 1,750(±0.45 SD) (S) | 50 | Ecotox# 71856 (Jimenez *et al*.) / 2003 |
|  | 1,340 (±0.2 SD) (S) | NR | Ecotox#20475 (Cano *et al*) / 1999 |
| Grass shrimp (*Palaemontetes pugio*) | 67(52-91) (mixed age juveniles) | 96.8 | MRID 49534902 / 2014 | Adults -38.19 (31.9-45.7)18-d old – 13.24 (9.9-17.7)Newly hatched – 9.06 (7.6-10.7) (R) | Tech grade3 | Ecotox# 14346 (Key *et al*) / 1998 |
|  | Postlarvae – 39.92 (32.5-50.1) (R) | Tech grade3 | Ecotox# 92616 (Key *et al*) / 2006 |
| Amphipod (*Gammarus pseudolimnaeus*) | 2.1(1.6-2.7) | 96.8 | MRID 49389402 / 2014 | 0.5-0.9(*G. fasciatus*) (S) | 95 | Ecotox# 6797 (Mayer & Ellersieck) / 1986  |
|  | 4.65 (3.47-6.21) (S)2.29 (1.74-3.03)(*G. palustris*) (R) | Tech grade4 | Ecotox# 51439 (Leight *et al*.) / 1999 |
|  | 0.33 (0.3-0.36)(*G. pulex*) (S) | 97.785 | Ecotox# 153561 (Ashauer *et al*) / 2011 |
| Mayfly (*Centroptilum triangulifer*) | 23(20-26) | 96.8 | MRID 49479001 / 2014 | NA | -- | -- |
| Midge (*Chironomus tentans*) | 3.5(2.9-4.1) | 96.8 | MRID 49479002 / 2014 | 26,900 (20,000-36,200)(*C. riparius*) (R) | 40 (Carbophos) | Ecotox# 77206 (Frumin *et al*) / 1992 |
| Oyster (*Crassostrea virginica*) | 2,700(1,900-3,700) based on shell deposition inhibition | 96.8 | MRID 49389403 / 2014 | 1,900(could not be calculated) (FT)  | 57 | MRID 42249901 / 1992 |
| Mysid shrimp (*Americamysis bahia*) | 4.8(2.4-8.4) | 96.8 | MRID 49389401 / 2014 | 2.2 (1.5-2.6) (FT) | 94 | MRID 41474501 / 1990 |
|  | <1-d old – 3.0 (2.6-4.0)5-d old- 3.1 (2.8-3.5)10-d old – 2.6 (2.3-2.9) (FT) | 71.5 | Ecotox# 968 (Goodman *et al*.) / 1988 |
|  | 3.2-5.7 (multiple tests, different feeding regimes) (S) | 92 | Ecotox# 2280 (Cripe *et al*) / 1989 |
|  | 11 (9.1-11) (S)  | NR (obtained from EPA) | Ecotox# 13513 (Cripe *et al*) / 1990 |
| Green Sunfish (*Lepomis cyanellus*) | 130(120-150) | 96.8 | MRID 49364101 / 2014 | 146-175(S) | 95 | Ecotox# 6797 (Mayer & Ellersieck) / 1986  |
| Medaka (*Oryzias latipes*) | 1,500(720-2,700) | 96.8 | MRID 49364102 / 2014 | 9,700 (S) | 99.1 | Ecotox# 89099 (Wolfe *et al*) / 1995 |
| Mosquitofish (*Gambusia affinis*) | 2,900(2,400-3,500) | 96.8 | MRID 49422801 / 2014 | 112,000 (S) | 56.1 | Ecotox#5806 (Naqvi *et al*) / 1988 |
|  | 300 (±0.075 SD) (S) | NR | Ecotox#20475 (Cano *et al*) / 1999 |
| Coho salmon (*Oncorhynchus kisutch*) | 720(310-1200) | 96.8 | MRID 49479003 / 2014  | 170-177(S) | 95 | Ecotox# 6797 (Mayer & Ellersieck) / 1986  |
| Sheepshead minnow(*Cyprinodon variegatus*) | 47.4(could not be calculated) | 96.6 | MRID 49055701 / 2011 | 33 (14-63) (FT) | 94 | MRID 41174301 |
|  | 51 (NR) (FT) | 95 | Ecotox# 5074 (Hansen *et al*) / 19776 |
|  | 55 (FT) | 57 | MRID 41252101 |
| Frog (*Xenopus laevis*) | 4,700(3,900-5,600) | 96.0 | MRID 48409302 / 2011 | Embryos- 10,900(16,600-11,300) (S) | >90 | Ecotox# 66505 (Snawder *et al*) / 1989 |

1 All studies were of 96-hr duration, except for studies with mayfly or midge, which were 48-hr

2 All studies in this column were conducted using flow-through test systems

3 Purity other than technical grade was not reported; source – Micro Flo Company (Sparks, GA)

4 Purity other than technical grade was not reported; source – donated by Marine Ecotoxicology Division at the National Marine Fisheries Service

5 14-C labelled material was used; Un-labelled material was of analytical grade from Sigma-Aldrich, Buchs, Switzerland; units reported as nmol/L in paper, reviewer converted to µg/L.

6 Referred to Parrish *et al*. 1977 for purity as this is a more complete description of studies reported in E5074.

FT= flow-through; S = static; R=static renewal; NR=not reported

Additionally, in a recently submitted 34-day early-life cycle study with sheepshead minnow (MRID 48705301, 2011), the most sensitive endpoint was 16 µg a.i./L (NOAEC 8.2 µg/L), based on survival and clinical signs (purity 96%). A life-cycle toxicity test conducted with sheepshead minnow using technical-grade malathion (95%) in 1977, reported a NOAEC of 4 µg a.i./L based on reductions in offspring survival at 9 µg a.i./L. Parental survival was affected at 18 µg/L. Therefore, the observed toxicity values for these two studies are considered similar, even with the differences in test duration and time of conduct.

Studies with fathead minnow were conducted, which evaluated acute toxicity using both pure malathion (99.4%) and pure malathion spiked with 0.8% isomalathion (MRID 49252802 and 49252801; 2013). While a greater number of mortalities occurred after 24 and 48 hours with the spiked malathion compared to pure malathion, by the end of the study (96 hour duration), the 96-hr LC50 values were similar between the two test compounds with values of 28 mg/L (95% CI: 20-40 mg/L) and 27 mg/L (95% CI: 20-40 mg/L) for the pure malathion and spiked malathion, respectively.

A similar comparison was attempted for terrestrial animals, with toxicity data for birds and honey bees available for comparison which included both recently submitted data and other data sources (**Table 1-13**). However, as with the aquatic species, toxicity values (*i.e.*, the honey bee contact exposure route, ring-necked pheasant studies) were similar between the recently submitted data and other reported values.

**Table 1-13. Comparison of Recently Submitted Toxicity Values to Other Reported Toxicity Values for Terrestrial Species**.

| **Terrestrial Species** | **Recently Submitted Toxicity Data** | **Other Reported Toxicity Data** |
| --- | --- | --- |
| Recent Toxicity Value (95% CI) | % Purity  | Reference / Year | Other Reported Toxicity Values (95% CI) | % Purity  | Reference / Year |
| Honeybee(*Apis mellifera*) | Contact 48-hr LD50: 0.189 µg a.i./bee (0.1-0.4) | 96.0 | MRID 49270301 / 2013 | 0.25-0.27 (NR) | Tech | MRID 05001991 & 05004151 / 1968 |
|  | 0.709 (NR) | Tech | MRID 0001999 / 1967 |
|  | 0.46 (NR) | Tech | MRID 05008990 /  |
| Oral 48-hr LD50: 1.66 µg a.i./bee (0.995-4.992) | 96.0 | MRID 49270302 / 2013 | 0.38 (NR) | Tech | MRID 05001991& 05004151 / 1968 |
| Mallard duck (*Anas platyrhynchos*) | 8-day LC50: >5850 mg a.i./kg-diet | 96 | MRID 48963303 / 2012 | >5000 mg/kg-diet | 95 | MRID 00022923 / 1984 |
| 14-day LD50: >2250 mg a.i./kg-bw | 96 | MRID 48963307 / 2012 | 1485(1020-2150) | 95 | MRID 00160000 / 1984 |
| Ring-necked pheasant (*Phasianus colchicus*) | 8-day LC50: 2505 mg a.i./kg-diet (2074-3025) | 96 | MRID 48963301 / 2012 | 2639 (2220-3098) | 95 | MRID 00022923 / 1984 |
| 14-day LD50: 136 mg a.i./kg-bw (108-170) | 96 | MRID 48963305 / 2012 | 167(120-231) | 95 | MRID 00160000 / 1984 |

NR= not reported

Overall, while there is variability in the degree to which the more recently submitted studies align with other toxicity studies between species, there is observed concordance for both aquatic and terrestrial species. As such, there does not appear to be compelling information to exclude toxicity data at this time solely due to source of technical malathion or date of study conduct. However, when evaluating studies for use as a threshold (mortality or sublethal) or for a line of evidence (i.e., growth, reproduction, behavior, sensory), toxicity studies where information about the test material source/impurity profile was known were used when available. However, all the available toxicity data are presented in summary graphs/arrays in Chapter 2 (Effects Characterization) to allow for a greater understanding of the breath of the toxicity data available.

While stated as an impurity above, in **Table 1-13**, similar to several other organophosphate insecticides, malathion degrades and is metabolized into an oxon product referred to as malaoxon. Chemically, the only difference between malathion and malaoxon is the substitution of oxygen for sulfur at its double bond to phosphorous. Metabolic conversion of malathion into malaoxon is called activation because it is the malaoxon metabolite that is responsible for most of the insecticidal activity of malathion, as well as most of its toxicity to other nontarget animals. Thus, malaoxon is the primary degradation product/metabolite considered to be a significant concern for ecological risk. Toxicity and fate information for malaoxon are discussed in **APPENDIX 3-1**.

## 1.5. References

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1. An unreasonable adverse effect on the environment is defined in FIFRA as, “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the FFDCA (21 U.S.C. §346a).” [7 U.S.C. 136(b)]. FFDCA is the Federal Food, Drug, and Cosmetic Act which authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues in foods. [↑](#footnote-ref-1)
2. The Agencies include the U.S. Environmental Protection Agency (USEPA), National Marine Fisheries Service (NMFS), and the U.S. Fish and Wildlife Service (USFWS). [↑](#footnote-ref-2)
3. On December 12, 2007, EPA, U.S. National Marine Fisheries Service (NMFS), and U.S. Fish and Wildlife Service (FWS) agreed that the Federal action for EPA’s FIFRA registration actions is defined as the “authorization for use or uses described in labeling of a pesticide product containing a particular pesticide ingredient.” [↑](#footnote-ref-3)
4. See https://nepis.epa.gov/Exe/ZyNET.exe/9100CFQL.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1986+Thru+1990&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C86thru90%5CTxt%5C00000020%5C9100CFQL.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL for details on what tolerances and tolerance exemptions are. [↑](#footnote-ref-4)
5. InertFinder is an online database for searching substances used as inert ingredients in pesticide products. It can be found at: <http://iaspub.epa.gov/apex/pesticides/f?p=101:1>: [↑](#footnote-ref-5)
6. Considers all of the known stressors of the action (*e.g*., parent active ingredient, formulations, mixtures, and degradates of concern) and abiotic or biotic factors likely present in the environment that may alter the toxicity of malathion to an individual of a listed species or their prey-base/habitat. These factors may include bacterial/viral prevalence, temperature, water quality parameters such as organic carbon, pH, DO, or salinity, or other environmental baseline factors. [↑](#footnote-ref-6)
7. Primary Constituent Elements (PCEs) are those physical and biological features (PBFs) of a landscape that a listed species needs to survive and reproduce. Where PCEs have not been specified in a critical habitat designation, effects to PBFs will be addressed. The term "PCEs/PBFs" will be used throughout the remainder of this document in reference to the relevant physical and biological features of designated critical habitat. [↑](#footnote-ref-7)
8. Under the ESA, an insignificant or discountable effect is not the same as “no effect”. [↑](#footnote-ref-8)
9. Any species and/or critical habitat that warranted a “no effect” determination would not be considered in Step 2. [↑](#footnote-ref-9)
10. Based on the *Endangered Species* *Consultation Handbook: Procedures for Conducting Consultation and Conference Activities under Section 7 of the Endangered Species Act* (FWS and NMFS, 1998): “Beneficial effects are contemporaneous positive effects without any adverse effects to the species. Insignificant effects relate to the size of the impact and should never reach the scale where take occurs. Discountable effects are those extremely unlikely to occur.” (pp. xv – xvi). [↑](#footnote-ref-10)
11. Young, D.F. and Fry, M.M., 2014. A Model for Predicting Pesticide in Runoff, Erosion, and Leachate: User Manual, U.S. Environmental Protection Agency, Washington, DC. USEPA/OPP 734F14002 [↑](#footnote-ref-11)
12. Young, D. F., 2014. The Variable Volume Water Model, U.S. Environmental Protection Agency, Washington, DC. USEPA/OPP 734F14003. [↑](#footnote-ref-12)
13. The exposure models can be found at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment [↑](#footnote-ref-13)
14. The remaining bin (Bin 1) is included in the generic list due to its proximity to, or in some cases, continuity with, aquatic habitats. [↑](#footnote-ref-14)
15. Langrangian trajectory theory tracks the movement of the spray particles released from the nozzle until they are deposited or drift beyond the maximum distance of the model, using a moving frame of reference, unlike Gaussian modeling which looks at particles as if they are normally distributed along a line of travel and use a stationary frame of reference. [↑](#footnote-ref-15)
16. The droplet size spectra are defined by the American Society of Agricultural and Biological Engineers (ASABE). For the ‘very fine to fine’ droplet size spectra, droplets range in size from 61 to 235 microns. [↑](#footnote-ref-16)
17. Guidance on Modeling Offsite Deposition of Pesticides via Spray Drift for Ecological and Drinking Water Assessments. Environmental Fate and Effects Division, Office of Pesticide Programs, US Environmental Protection Agency, Washington, DC. Dec. 20, 2013.( http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2013-0676-0002) [↑](#footnote-ref-17)
18. For definitions, see *Endangered Species Consultation Handbook: Procedures for Conducting Consultation and Conference Activities under Section 7 of the Endangered Species Act (FWS and NMFS, 1998).* [↑](#footnote-ref-18)
19. Native projection refers to the geographic and/or projected coordinate systems of the file when received. When necessary the files are re-projected to match the projection of the action area prior to running the co-occurrence analysis.   [↑](#footnote-ref-19)
20. Standard species identification information refers to basic descriptive information of a species identified as helpful for tracking purposes such as species common name, scientific name, current listing status, species group, and species identification number (USFWS Entity ID). [↑](#footnote-ref-20)
21. "May affect, but not likely to adversely affect" means that all effects are beneficial, insignificant, or discountable.  Beneficial effects have contemporaneous positive effects without any adverse effects to the species or habitat.  Insignificant effects relate to the size of the impact and include those effects that are undetectable, not measurable, or cannot be evaluated.  Discountable effects are those extremely unlikely to occur.  These determinations require written concurrence from the Service. (see <http://www.fws.gov/midwest/Endangered/section7/ba_guide.html>) [↑](#footnote-ref-21)
22. "May affect, and is likely to adversely affect" means that listed resources are likely to be exposed to the action or its environmental consequences and will respond in a negative manner to the exposure. (again see, (see <http://www.fws.gov/midwest/Endangered/section7/ba_guide.html>) [↑](#footnote-ref-22)
23. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0004 [↑](#footnote-ref-23)
24. A slope of 4.5 is considered a ‘typical’ slope based on a cross-section of dose-response data available in 1975 – when the ‘typical’ slope was estimated for the *Special Review of Pesticides; Criteria and Procedures; Final Rule* [40 CFR Part 154: 49005; 49007; 49016 § 154.7(a)(3), (4), (5), and (6)]. [↑](#footnote-ref-24)
25. Obligate relationships occur when one species is interdependent with or highly reliant on another species in a way that one cannot survive without the other. [↑](#footnote-ref-25)
26. Guidance for Using Incident Data in Evaluating Listed and Non-listed Species Under registration review. <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-using-incident-data-evaluating-listed-and> [↑](#footnote-ref-26)