OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
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Malathion

Proposed Interim Registration Review Decision
Case Number 0248

July 2024

Approved by: Jean Overstreet

Jean Overstreet
Director
Pesticide Re-evaluation Division

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for malathion (PC Code 057701, case 0248). The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) mandates a periodic review of existing pesticide registrations every 15 years, referred to as registration review. During registration review, the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard. Where appropriate, the Agency may issue an Interim Registration Review Decision (ID) before completing a final registration review decision. However, issuance of an ID is not a decision on whether a pesticide's registrations continue to satisfy the FIFRA standard for registration. Rather, the ID may include mitigation measures and changes to labeling that EPA has determined would address risks of concern, identify data or information needed to complete registration review, and include schedules for submitting such data, conducting the new risk assessment, and completing the registration review. The Agency is issuing this PID for malathion to identify risk mitigations that EPA has determined would address risks of concern for malathion, as presented in Section IV and Appendices A and B.

Malathion is a contact organophosphate (OP) insecticide used to control a wide variety of insect pests. Malathion was first registered in the United States in 1956 and has three technical registrants. The mode of action for malathion toxicity involves inhibiting the enzyme acetylcholinesterase (AChE). Malathion metabolizes (activates) to malaoxon which is the active AChE inhibiting moiety. Since malaoxon plays a role in the toxicity of malathion, the exposure/risk assessments to determine potential risks of concern also considered the toxicity and potential exposure to malaoxon.

EPA has registered products containing malathion for use on agricultural crops, Christmas tree farms and pine seed orchards, ornamentals, and outdoor (commercial and residential) perimeter treatments, pick-your-own crops, residential gardens, residential outdoor mosquito control, and public health mosquito (adulticide) control. Malathion products are registered primarily as emulsifiable or ready-to-use liquid concentrate formulations, with one dust product that is limited to grain storage. Malathion registered products may be applied via aerial, air blast, chemigation, ground boom, or handheld equipment types. Single maximum application rates of malathion range from 0.18 pounds of active ingredient per acre (lbs ai/A) for bait spray applications to 7.5 lbs ai/A on citrus fruit.

The Agency is issuing a PID for malathion so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). EPA has worked with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively known as the Services) to improve the consultation process for national threatened and endangered (listed) species for pesticides

under the Endangered Species Act (ESA).[1] The Agency fully evaluated malathion's risks to federally listed species. EPA has completed its listed-species assessment and consultation with the Services. The Services issued Biological Opinions[2] (BiOps) that EPA has implemented through approving registration and labeling amendments. During this registration review, EPA completed endocrine screening for malathion under the Federal Food, Drug, and Cosmetic Act (FFDCA).[3] For more information on the listed-species assessment and the endocrine screening for the malathion registration review, see Appendices C and D.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how and where malathion is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Proposed Interim Registration Review Decision* (presenting EPA's proposed decision on mitigation measures to address risks of concern identified at this point in the registration review process); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Summary of Malathion Registration Review

On January 24, 2009, the Agency formally initiated registration review for malathion with the opening of the registration review docket[4] for the case.[5] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of malathion:

- June 2009 – EPA posted the *Malathion Registration Review Summary Document: Initial Docket Preliminary Work Plan* (PWP) (June 18, 2009), *Malathion. Human Health Assessment Scoping Document in Support of Registration Review* (June 10, 2009), and *Registration Review – Preliminary Problem Formulation for Ecological Risk, Environmental Fate, and Endangered Species Assessments for Malathion* (April 22, 2009) to the public docket for a 60-day public comment period.

- December 2009 – EPA posted the *Malathion Final Work Plan* (FWP) (December 17, 2009) to the public docket. The Agency received six comments on the PWP. Comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP. The Agency required the following guideline ecological studies: Guideline

[1] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[2] Biological Opinions website, available online.
[3] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).
[4] Malathion website on regulations.gov
[5] 40 C.F.R. § 155.50

835.4300 – Modified aerobic aquatic metabolism (malathion), Guideline 835.4100 – Modified aerobic soil metabolism (malathion), Guideline 835.4100 – Aerobic soil metabolism (malaoxon), Guideline 835.2120 – Hydrolysis (malaoxon), Guideline 835.1230 – Leaching/adsorption/desorption (malaoxon), Guideline 835.6100 – Environmental Chemistry Analytical Methods – soil (malathion; malaoxon), Guideline 835.6200 – Environmental Chemistry Analytical Methods – water (malathion; malaoxon), Guideline 850.2100 – Avian acute oral toxicity (malathion; malaoxon), Guideline 850.1010, 850.1075 – Freshwater acute toxicity in invertebrates and fish (malaoxon), Guideline 850.1350 – Life-cycle toxicity in marine/estuarine invertebrate (malathion), Guideline 850.1400 – Early life-stage toxicity in marine/estuarine fish (malathion) aerobic aquatic metabolism study with malaoxon, (Guideline 835.4300), and a special study examining the formation of malaoxon on dry surfaces. The Agency also required the following human health studies: immunotoxicity (Guideline 870.7800), field trial studies (Guideline 860.1500) for the following commodities: celery, apple, cotton gin byproducts, corn (sweet stover), and sorghum forage and stover, and a processing study (Guideline 860.1520) for flax.

- August 2010 – EPA issued a generic data call-in (GDCI) on August 12, 2010 for malathion to obtain data needed to conduct the registration review risk assessments (GDCI-057701-830). All studies were submitted to EPA.

- August 2015 – The Agency completed its weight of evidence review of the Tier I assays required under the Endocrine Disruptors Screening Program (EDSP) in *EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals* (June 29, 2015). There was no convincing evidence for potential interaction with the estrogen pathway, androgen pathway, or thyroid pathway. Malathion was not recommended for additional endocrine testing.

- March 2016 – EPA posted the *Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion* (draft BEs) for a 60-day public comment period. The Agency received 78,000 comments with 120 substantive comments meriting detailed review. The Agency summarized and responded to these comments in *Response to Comments on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion* (January 17, 2017). The comments suggested revisions to the draft BE including a revised modeling approach for flowing aquatic waterbodies, error correction and improved transparency, the addition and deletion of species based on changes in listing status, and refinements to some of the aquatic species' ranges.

- September 2016 – EPA posted *Malathion: Human Health Draft Risk Assessment for Registration Review* (June 9, 2016) (2016 HH DRA) for a 60-day public comment period. The Agency received 36 comments from commenters. The Agency has summarized and responded to these comments in Section I.B. below. The comments did not change the

risk assessments or registration review timeline for malathion. However, updates were made in the 2024 HH DRA.

- January 2017 – EPA posted the *Final Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion*. EPA found that malathion was not likely to adversely affect 41 listed species, likely to adversely affect 1778 listed species, not likely to adversely affect 10 critical habitats, and likely to adversely affect 784 critical habitats. EPA then consulted with the U.S. FWS and NMFS (collectively known as the Services) to initiate the third step in the Endangered Species Act (ESA) pesticide consultation process for malathion.

- December 2017 – NMFS posted its BiOp. Then, EPA reinitiated consultation and NMFS agreed to issue a revised BiOp (in June 2022).

- February 2022 – FWS posted the final *Biological and Conference Opinion on the Registration of Malathion Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act* (Final Malathion FWS BiOp). FWS concluded that implementing the proposed conservation measures will make malathion not likely to jeopardize the continued existence of species analyzed in Final Malathion FWS BiOp. In addition, FWS concluded that implementing conservation measures in the BiOp is likely to prevent the destruction or adverse modification of critical habitat.

- June 2022 – NMFS posted the *Revised Conference and Biological Opinion on the Environmental Protection Agency's Registration Review of Pesticide Products containing Chlorpyrifos, Malathion, and Diazinon* (Final Malathion NMFS BiOp). With the additional conservation measures mentioned in the BiOp, NMFS concluded that malathion is not likely to jeopardize the continued existence nor destroy or adversely modify the designated critical habitat of ESA-listed species under NMFS' jurisdiction.

- August 2023 – Malathion labels were approved and stamped with label amendments proposed in the FWS and NMFS Final Malathion BiOps.

- March 2024 – EPA posted *Malathion: Updated Human Health Draft Risk Assessment for Registration Review* (January 22, 2024) (2024 HH DRA) and *Malathion: Revision to the Streamlined Draft Ecological Risk Assessment for Registration Review* (2024 Eco DRA) using updated information and risk assessment techniques, including incorporation of a physiologically-based pharmacokinetic-pharmacodynamic (PBPK-PD) model. At that time, EPA indicated that it would be accepting public comment on the updated 2024 HH DRA and 2024 Eco DRA at a later date when it accepts public comment on the PID.

- June 2024 – EPA completed the PID for malathion and made it available in the public docket for a 60-day public comment period. Along with the PID, EPA posted the following documents to the public docket:

- *Information on Critical and High Benefit Uses for Three Organophosphate Insecticides: Malathion, Acephate, and Dimethoate* (September 14, 2023)
- *Assessment of Usage and Benefits of Malathion (PC # 057701) in Fruit Crops (June 10, 2024)*
- *Assessment of Usage and Benefits of Malathion as a Mosquito Adulticide and Federal and State Insect Pest Management Programs (PC # 057701) (June 10, 2024)*
- *Malathion: Responses to Comments on the Draft Human Health Risk Assessment for Registration Review (D414107) (June 21, 2024)*
- *Assessment of Usage and Benefits of Malathion for Vegetable Crops (PC # 057701) (June 24, 2024)*
- *Malathion (PC # 057701) Overview of Use and Usage, and Description of Pest Management Benefits, and Impacts of Potential Risk Mitigation in Alfalfa, Pine Seed Orchards, Pine Seedling Propagation, and Residential Homeowner Use Sites (June 24, 2024)*

B. Summary of Public Comments on the 2016 HH Draft Risk Assessment and Agency Responses

During the 60-day public-comment period plus 30-day extension period for the original Malathion Human Health Draft Risk Assessment (September 22, 2016 to December 21, 2016), the Agency received 36 substantive public comments, including six requests for extension of comment period. Comments were submitted by Adams County Mosquito Control District in Othello, Washington; Responsible Industry for a Sound Environment (RISE); Washington Friends of Farms & Forests; R.I.S.K. Consultancy; The IR-4 Project; National Cotton Council (NCC); Office of Pest Management Policy, United States Department of Agriculture (USDA); Mount Vineyard; Arkansas Boll Weevil Eradication Foundation (ABWEF); California Speciality Crops Council (CSCC); Tennessee Department of Agriculture; Tennessee Boll Weevil Eradication Foundation, Inc.; Arizona Cotton Research and Protection Council (ACRPC); FMC Corporation and Cheminova A/S; California Specialty Crops Council (CSCC); Beyond Pesticides; CropLife America (CLA); Minor Crop Farmer Alliance (MCFA); Oklahoma Boll Weevil Eradication Organization; Tennessee Department of Agriculture; American Mosquito Control Association (AMCA); Center for Biological Diversity; California Citrus Quality Council (CCQC); California Fresh Fruit Association; Florida Department of Agriculture and Consumer Services (FDACS); Earthjustice on behalf of clients, United Farm Workers et al.; Western Growers (WG); Minor Crop Farmer Alliance (MCFA); Department of Entomology, Lindcove Research and Extension Center, University of California, Riverside; American Farm Bureau Federation (AFBF); and Texas Boll Weevil Eradication Foundation (TBWEF).

Many of the submissions included comments on the human health risk assessment and methodology. The 2016 HH DRA has been substantively revised, and therefore, many comments that were previously submitted are now out-dated. The 2024 revised human health risk assessment, which supersedes the 2016 assessment, will be available for public comment

with the issuance of this PID. Comments received on the 2016 HH DRA were considered and addressed in the 2024 revised human health risk assessment. The Agency summarized and responded to all substantive comments and comments of a broader regulatory nature below. For more information, please see *Malathion: Responses to Comments on the Draft Human Health Risk Assessment for Registration Review (D414107*). The Agency thanks all commenters for participating and has considered all comments in developing this PID.

Comments Submitted by FMC Corporation and Cheminova (Docket ID: EPA-HQ-OPP- 2009-0317-0114)

Comment: FMC stated simple refinements could be made to EPA's assessment so that very few exposure scenarios would exceed EPA's level of concern. FMC commented on the 2016 HH DRA.

EPA Response: The Agency made refinements to the 2016 HH DRA in the 2024 HHDRA. For additional remarks, please see the HH RTC document.

Comments Submitted by the Adams County Mosquito Control District in Othello, Washington; Washington Friends of Farms & Forests; The IR-4 Project; NCC; USDA; Mount Vineyard; ABWEF; CSCC; Tennessee Department of Agriculture; Tennessee Boll Weevil Eradication Foundation, Inc.; ACRPC; MCFA; Oklahoma Boll Weevil Eradication Organization; CCQC; California Fresh Fruit Association; Department of Entomology, Lindcove Research and Extension Center, University of California, Riverside; AFBF; and TBWEF (Docket ID: EPA-HQ-OPP-2009-0317-0108; EPA-HQ-OPP-2009-0317-0098; EPA-HQ-OPP-2009-0317-0110; EPA-HQ-OPP-2009-0317-0115; EPA-HQ-OPP-2009-0317-0092; EPA-HQ-OPP-2009-0317-0103; EPA-HQ-OPP-2009-0317-0102; EPA-HQ-OPP-2009-0317-0104; EPA-HQ-OPP-2009-0317-0095; EPA-HQ-OPP-2009-0317-0106; EPA-HQ-OPP-2009-0317-0107; EPA-HQ-OPP-2009-0317-0118; EPA-HQ-OPP-2009-0317-0100; EPA-HQ-OPP-2009-0317-0099; EPA-HQ-OPP-2009-0317-0116; EPA-HQ-OPP-2009-0317-0097; EPA-HQ-OPP-2009-0317-0090; EPA-HQ-OPP-2009-0317-0101; EPA-HQ-OPP-2009-0317-0105; EPA-HQ-OPP-2009-0317-0119)

Comment: Adams County Mosquito Control District in Othello, Washington; Washington Friends of Farms & Forests; The IR-4 Project; NCC; USDA; Mount Vineyard; ABWEF; CSCC; Tennessee Department of Agriculture; Tennessee Boll Weevil Eradication Foundation, Inc.; ACRPC; MCFA; Oklahoma Boll Weevil Eradication Organization; CCQC; California Fresh Fruit Association; Department of Entomology, Lindcove Research and Extension Center, University of California, Riverside; AFBF; and TBWEF emphasized malathion's importance in mosquito control, spotted wing drosophila control, scale insect control, cotton and boll weevil eradication programs, Rangeland Grasshopper and Mormon Cricket Suppression Program, the Exotic Fruit Fly Program, specialty crops, citrus, grapes, soft fruits. In addition, the IR-4 project provided a mosquito control droplet report.

EPA Response: The Agency thanks these organizations for the benefits and use information. EPA considered this information when developing this PID.

Comments Submitted by the RISE, Washington Friends of Farms & Forests, R.I.S.K. Consultancy, The IR-4 Project, NCC, USDA, Tennessee Department of Agriculture, Beyond Pesticides, CLA, MCFA, Oklahoma Boll Weevil Eradication Organization, AMCA, California Fresh Fruit Association, FDACS, WG, AFBF (Docket ID: EPA-HQ-OPP-2009-0317-0108; EPA-HQ-OPP-2009-0317-0098; EPA-HQ-OPP-2009-0317-0081; EPA-HQ-OPP-2009-0317-0112; EPA-HQ-OPP-2009-0317-0110; EPA-HQ-OPP-2009-0317-0115; EPA-HQ-OPP-2009-0317-0104; EPA-HQ-OPP-2009-0317-0094; EPA-HQ-OPP-2009-0317-0111; EPA-HQ-OPP-2009-0317-0107; EPA-HQ-OPP-2009-0317-0100; EPA-HQ-OPP-2009-0317-0096; EPA-HQ-OPP-2009-0317-0116; EPA-HQ-OPP-2009-0317-0113; EPA-HQ-OPP-2009-0317-0117; EPA-HQ-OPP-2009-0317-0101)

Comment: RISE, Washington Friends of Farms & Forests, The IR-4 Project, NCC, USDA, Tennessee Department of Agriculture, Beyond Pesticides, CLA, MCFA, Oklahoma Boll Weevil Eradication Organization, AMCA, California Fresh Fruit Association, FDACS, WG, and AFBF expressed concern with applying an FQPA 10X safety factor based on associations presented in epidemiology studies. These organizations also urged EPA to use actual pesticide use data, water monitoring data, and realistic inputs in drinking water modeling assessments instead of models with conservative assumptions that give pesticide concentration estimates that are unlikely to occur. California Fresh Fruit Association stated that monitoring water data is available. R.I.S.K. Consultancy and USDA performed human health literature searches.

EPA Response: The Agency thanks these organizations for their comments which have been considered while developing this PID. The Agency has determined that there are reliable data to support reduction of the 10X FQPA safety factor to 1X for all dietary and non-occupational exposure scenarios, as discussed in the 2024 HH DRA. The Agency performed an evaluation of DNT potential for malathion using chemical-specific data from epidemiological, animal toxicity, and in vitro assays and concluded that 10% AChE inhibition is protective of potential neurodevelopmental effects for malathion. This evaluation along with data to inform other FQPA considerations (e.g., completeness of the database, uncertainty in the exposure databases) supported reduction of the FQPA safety factor to 1X. For additional information, please see the 2024 HHDRA.

The Agency has characterized available non-targeted water monitoring data for malathion and found highest detections to be within the same order of magnitude as highest modeled concentrations. The Agency has continued to refine the scenarios supporting drinking water modeling but use of new scenarios did not substantially change estimated drinking water concentrations.

Comments Submitted by Beyond Pesticides (BP) and Center for Biological Diversity (CBD) (Docket ID: EPA-HQ-OPP-2009-0317-0094, EPA-HQ-OPP-2009-0317-0109)

Comment: BP raised concerns regarding the neurological risks associated with spray drift risks, residential risks from mosquito control, and occupational risks from exposure to malathion. BP was also concerned about residential labels with personal protective equipment (PPE). BP suggested that organophosphates, like malathion, be phased out. CBD raised concerns about unreasonable adverse effects in food and drinking water and occupational risks, argued the 2016 HH DRA had flaws, and suggested cancelling all uses of malathion that result in level of concern exceedances. CBD said an aggregate risk assessment was not performed. CBD said reasoning was faulty if residential handler assessments did not include products simply because the labels included PPE. CBD stated EPA did not use the most sensitive endpoint for oral and dermal exposure routes.

EPA Response: The Agency thanks BP and CBD for their comments. These comments have been taken into consideration when updating the DRAs and developing this PID. The Agency recently added mitigation to the malathion labels to address updated personal protective protection language, improve spray drift management, lower application rates and number of applications for several crops, cancel several uses, and add buffers that help protect humans and the environment. It is noted that a new PBPK-PD model was used in the current human health risk assessment to establish human points of departure (PODs) based on the red blood cell (RBC) AChE inhibition at a maximum peak level of 10%. This modeling approach reduces the uncertainty inherent in a traditional risk assessment that relies on an animal POD and the application of a default uncertainty factor (UF) for interspecies extrapolation. With use of the PBPK-PD model, no human health risks of concern were identified for the currently registered uses of malathion, including aggregate risk assessment. The Agency has evaluated all the available hazard data for malathion and determined that AChE inhibition continues to be the most sensitive effect that is protective of other effects observed in the database. This included an evaluation of DNT potential using chemical-specific data for malathion that concluded that 10% AChE inhibition is protective of potential neurodevelopmental effects. Regarding labels with residential handler uses that also include PPE, EPA is proposing to update label language so that no PPE is expected or required on labels with residential handler uses. Please see the 2024 HH DRA HH RTC for further explanation of EPA's response on these topics.

Comments Submitted by Earthjustice on behalf of clients, United Farm Workers et al. (Docket ID: EPA-HQ-OPP-2009-0317-0093)

Comment: Earthjustice on behalf of United Farm Workers, Farmworker Justice, Natural Resources Defense Council, Pesticide Action Network, California Rural Legal Assistance Foundation, Migrant Clinicians Network, National Hispanic Medical Association, and Farmworker Association of Florida voiced concerns for farm workers and environmental conservation. Earthjustice suggested that EPA should revoke all malathion tolerances because of unacceptable dietary risks, revoke tolerances and cancel all uses to prevent

neurodevelopmental harm to children. Earthjustice stated that EPA failed to fully account for endocrine disruption activity. Earthjustice stated EPA's model does not protect bystanders and farmworkers from spray drift, dust, take-home exposures, and volatilization. Earthjustice stated that the 2016 HH DRA shows unacceptable and underestimated risks to farmworkers. Earthjustice stated that EPA must protect against environmental justice impacts. Finally, Earthjustice stated that EPA must conduct a cumulative organophosphate risk assessment and cumulative risks associated with organophosphate-carbamate mixtures.

EPA Response: The Agency thanks Earthjustice for the information provided. This information has been considered in updating the DRAs and writing this PID. The Agency recently added mitigation to the malathion labels to address updated personal protective protection language, improve spray drift management, lower application rates and number of applications for several crops, cancel several uses, and add buffers that help protect humans and the environment. EPA is not making any new findings regarding the potential cumulative risks of malathion and other OPs that share a common mechanism of toxicity at this time. EPA intends to make those conclusions collectively for all registered OPs after completing the individual OP assessments[6]. As OPP assesses each OP during the Registration Review process, OPP will determine if there is any new information since the 2006 CRA was conducted that would affect the conclusions of the 2006 CRA. Should the Agency determine that new information (e.g., changes in use pattern, risks of concern) could potentially impact the CRA, the Agency will revisit the OP CRA after all of the OPs in the class have been assessed.

Malathion was evaluated by EPA as part of the List 1 Endocrine Disruptor Screening Program (EDSP) and the weight-of-evidence (WOE) analysis was completed by the Agency in 2015. There was no convincing evidence for potential interactions with the estrogen, androgen, or thyroid pathways (Malathion WOE Conclusions).[7] Please see Appendix D for additional information on EDSP related to malathion. Please see the HH RTC for further explanation of tolerances, neurodevelopmental issues, and other human heath issues.

II. USE AND USAGE

A. Malathion Use

Malathion is registered for use on both agricultural and non-agricultural sites. Agricultural food and feed sites are alfalfa, amaranth, apricot, arugula, asparagus, avocado, barley, beans (dry and succulent), beets (garden), birdsfoot trefoil, blackberry, blueberry, boysenberry, broccoli, broccoli (chinese), broccoli raab (rapini), Brussels sprouts, cabbage, cabbage (Chinese), cantaloupe, carrot (roots), cauliflower, cavalo broccolo, celery, celtuce, chayote, cherry (sweet and tart), chervil, chestnut, chrysanthemum (edible), clover, collards, corn (field, pop and sweet), corn salad, cotton, cucumber, currant, dandelion, dewberry, dock (sorrel), eggplant,

[6] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides
[7] https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0027

endive, figs, flax, Florence fennel, garlic, gooseberry, grapefruit, grapes, grass (forage/hay), guava, hops, horseradish, kale, kohlrabi, kumquat, leek, lemon, lespedeza, lettuce, lime, loganberry, lupine, macadamia nut, mango, melon, mint, mizuna, mushroom, mustard (Chinese), mustard greens, mustard spinach, nectarine, oats, okra, onion (bulb and green), orach, orange, papaya, parsley, parsnip, passion fruit, pastureland, peach, pear, peas, pecan, peppermint, peppers, pineapple, potato, pumpkins, purslane, radish, rangeland, raspberry, rice, rutabaga, rye, salsify, shallot, sorghum, spearmint, spinach, squash, strawberry, sweet potatoes, Swiss chard, tangelo, tangerine, tomato, tomatillo, turnip, vetch, walnuts, watercress, watermelons, wheat, wild rice, and yams. Certain stored grain commodities may also be treated post-harvest with malathion (corn, barley, oats, rye, and wheat).

Malathion is registered for non-agricultural and non-food agricultural uses on the following sites: Christmas tree plantations, ornamental/residential turf (i.e. lawns; spot treatment only), ornamental plants (herbaceous, woody shrubs/vines, and trees), grain storage facilities (e.g. silos, grain elevators), home gardens (including fruits and vegetables for consumption), perimeter of buildings (outdoors; including residential dwellings), pine seed orchards (only on slash pine in the southeastern U.S.), uncultivated areas (such as fence rows, hedge rows and rights-of-way along roadways or electrical utilities), and wide-area mosquito control.

Some labelled use sites and rates are limited to application by federal and state pest control programs, such as the Boll Weevil Eradication Program, California's Beet Curly Top Virus Control Program, United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) Rangeland Grasshopper and Mormon cricket suppression program, and USDA-APHIS Fruit Fly Exclusion and Detection Program.

Malathion-containing products are formulated as dust (for use on stored grain), emulsifiable concentrates, or ready-to-use liquid concentrates (for ultra-low volume [ULV] applications).

Malathion products can be applied using ground, aerial, chemigation, and handheld equipment. Methods for both ULV and non-ULV applications are allowed on a subset of registered sites and maximum application rates vary across these methods.

B. Malathion Usage

Agricultural Usage

Usage values presented in this section are based on the most recent data available from each usage data source. The primary usage source is Kynetec USA, Inc., an agricultural market research firm. These data are supplemented with USDA NASS Chemical Use Survey data and, for crops where at least 80% of national acreage is in California, CDPR Pesticide Use Reporting data. Usage data are available for a number of crops, but many small-acreage and non-crop sites are not surveyed at a nationally representative level. Because not all crops are surveyed, the calculations presented below may slightly underestimate total national usage. The values

presented in this document may differ from those presented in other EPA documents, such as the Screening Level Usage Analysis (SLUA) or Summary Use and Usage Matrix (SUUM), because different timeframes of usage are represented.

Nationally, users reported applying over 400,000 pounds of malathion active ingredient (lbs ai) to at least 270,000 total acres treated (TAT) annually between 2017 and 2021.[8,9,10] Although malathion usage has seen a decline in national agriculture usage in recent years when compared to the previous decade (annual average of at least 850,000 lbs ai on 700,000 acres during the years 2007-2016), usage remains high among a variety of agricultural sites (Table 1).

Table 1. National average agricultural usage for all surveyed crops reporting usage of malathion, 2017-2021.

Crop	Percent Crop Treated (PCT) [a]	Annual Pounds AI Applied	Annual Total Acres Treated[b]	Single Application Rate (lbs ai/acre)	Annual Number of Applications Per Acre
Fruits					
Raspberries	60	20,000	14,000[c]	1.38	1.5
Blueberries	34	57,000	53,000 [c]	1.10	2.0
Blackberries	18	2,300	1,400 [c]	1.68	1.2
Pears	16	15,000	11,000	1.39	1.4
Strawberries	16	26,000	14,000	1.92	2.0
Figs	11	1,300	800	1.72	1.1
Cherries	10	17,000	13,000	1.28	1.1
Oranges	8	53,000	45,000	1.18	1.0
Vegetables					
Onions	7	10,000	8,400	1.24	1.0
Asparagus	6	2,100	1,800	1.18	1.5
Pumpkins	3	2,000	2,700	0.74	1.2
Peppers	2	1,200	1,000	1.12	1.2
Tomatoes	2	18,000	12,000	1.50	2.6
Cucumbers	2	7,000	4,000	1.75	2.0
Sweet Corn	2	9,000	8,800	1.03	1.0
Brussels sprouts	NC	4,700	3,700	1.27	1.4
Field Crops					

[8] Kynetec USA, Inc. 2022. "The AgroTrak® Study from Kynetec USA, Inc." iMap Software. Database Subset: 2017-2021. [Accessed December 2023].
[9] United States Department of Agriculture National Agricultural Statistics Service (USDA NASS). 2023. QuickStats. Database Subset: 2017-2021. Available at: https://quickstats.nass.usda.gov/ [Accessed December 2023].
[10] California Department of Pesticide Regulation (CDPR). 2023. California Pesticide Information Portal (CalPIP). Database Subset: 2017-2021. Available at: https://www.cdpr.ca.gov/index.htm [Accessed January 2024].

Crop	Percent Crop Treated (PCT) [a]	Annual Pounds AI Applied	Annual Total Acres Treated[b]	Single Application Rate (lbs ai/acre)	Annual Number of Applications Per Acre
Rice	1	31,000	25,000	1.25	1.0
Alfalfa	<1	85,000	74,000	1.16	1.1

Sources: Kynetec 2022; Blueberry, blackberry, and raspberry data from USDA NASS, 2023; Brussels sprout and fig data from CDPR 2023

NC: PCT inestimable due to a known reporting error for the crop area planted for some counties within the California Department of Pesticide Regulation (CDPR) dataset

[a] Percent Crop Treated is defined as Base Acres Treated, the number of acres treated at least once, divided by the number of crop acres grown.

[b] Total Acres Treated is defined as the number of acres treated, accounting for multiple treatments to the same physical acre.

[c] Total acres treated is not reported by USDA NASS; This value is calculated by dividing reported pounds of AI applied by the average single application rate.

Among crops that are surveyed for insecticide usage, malathion usage is not reported on a substantial percentage of national acreage of most crops for which it is registered (i.e., low Percent Crop Treated (PCT) or no usage reported). Surveyed crops reporting little to no malathion usage (not listed in Table 1) include apricots, avocado, broccoli, cabbage, cantaloupes, carrots, cauliflower, celery, corn, cotton, garlic, grapefruit, grapes (table and wine), lemons, lettuce, nectarines, peaches, pecans, potatoes, sorghum (milo), spinach, squash, walnuts, watermelons, wheat (spring and winter). This suggests malathion is not used extensively in their production nationally. Additionally, honeydew melons and tangerines are surveyed for insecticide usage, but the data are withheld by USDA NASS to avoid disclosing information for individual operations. Therefore, EPA is unable to estimate likely usage of malathion in the production of honeydew and tangerines.

While low average annual PCT with malathion was observed in alfalfa (Table 1), this high acreage crop accounted for about one third of malathion agricultural crop usage in terms of treated acres from 2017 to 2021. Blueberries and oranges were the next highest usage crops in terms of treated acres.

Average number of applications per year varied by crop. Field crops tended to use less frequent applications: for example, in alfalfa, cotton, field corn, rice, sorghum, sweet corn, and wheat (spring and winter), malathion was applied only 1 or 1.1 times per year. Specialty crops tended to apply malathion more frequently: for example, in blueberries and strawberries, acres treated with malathion were treated on average two times per year.

Surveys targeting the industrial vegetation management market (survey years: 2019, 2022) reported on insecticide usage in rangeland and pasture.[11,12] These surveys reported an annual average of 170,000 pounds of malathion applied to 340,000 acres in the rangeland and pasture sector. Malathion was the top insecticide in terms of acres treated in rangeland and pasture and represented about 20% of insecticide sales in terms of dollars in this market.

For post-harvest insecticide treatment of stored grain commodities, recent surveys (years 2017, 2020) indicate that approximately 920,000 pounds of malathion was sold annually in this market. Reported usage of malathion was entirely on-farm treatments of stored grains.[13,14]

Federal and state agricultural pest control programs such as the Boll Weevil Eradication Program, California's Beet Curly Top Virus Control Program, United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) Rangeland Grasshopper and Mormon cricket suppression program, and USDA-APHIS Fruit Fly Exclusion and Detection Program report using malathion for the control of target pests. However, there are no publicly available data sources to estimate the extent of malathion usage by these government programs. The absence of such data should not be interpreted as lack of usage.

Non-Agricultural Usage

Usage information across non-agricultural and non-food/feed agricultural sites is limited but provides some broad indication of sites in which malathion is used.

Residential malathion usage

Recent market surveys (years: 2019, 2022) of residential consumer use of insecticides report approximately 480,000 lbs of malathion sold in this market annually.[15,16] Regionally, almost half of national outdoor insecticide sales in the residential consumer market occur in the U.S. South (spanning from Texas to the mid-Atlantic).

Pest management professionals use both chemical and non-chemical control methods to control pests within and around the exterior of commercial and residential establishments. A

[11] Kline and Company. 2020. Industrial Vegetation Management Markets 2019: United States Market Analysis and Opportunities. [Accessed January 2024].
[12] Nonagricultural Market Research Data (NMRD). 2023. Study of industrial vegetation management in 2022. [Accessed January 2024].
[13] Kline and Company. 2018. Stored Grain Insect Control 2017: United States Market Analysis and Opportunities. [Accessed January 2024].
[14] Nonagricultural Market Research Data (NMRD). 2022. Study of stored grain for insect control in 2020. [Accessed January 2024].
[15] Kline and Company. 2020. Consumer Markets for Pesticides and Fertilizers 2019: U.S. Market Analysis and Opportunities. [Accessed January 2024].
[16] Nonagricultural Market Research Data (NMRD). 2023. Study of consumer markets for pesticides and fertilizers in 2022. [Accessed January 2024].

2021 survey of this market sector reported approximately 180,000 pounds of malathion sold.[17] All reports of malathion sold within this survey were indicated as mosquito control products. Malathion represented less than 10% of the market in terms of dollars for products used by professional applicators for localized mosquito control in yards and around the exteriors of buildings.

Professional malathion usage

While insecticide usage in ornamental plant production was surveyed in 2021, no usage of malathion was reported, suggesting low levels of usage of the active ingredient in the production of ornamentals.[18]

Surveys targeting the industrial vegetation management market (survey years: 2019, 2022) reported pesticidal usage in forestry, and rights-of-way sectors (specifically railroad, roadsides, electrical utilities, and pipelines). About 11,000 acres treated with malathion were reported across the roadway and electric utility sectors (less than 5% of the acres treated with insecticides in these sectors).[19,20] No usage was reported in the railway or forestry sectors. Regionally, over 75% of national insecticide sales in the industrial vegetation management market occur in the U.S. South (spanning from Texas to the mid-Atlantic).

Low levels of malathion were reported to be used in fly control for animal production (livestock) in a 2017 survey.[21] A similar study in 2021 reported no malathion usage, further indicating low levels of malathion usage in this sector.[22]

No nationally representative usage data is available for pine seed orchards and Christmas tree production. A lack of data does not indicate a lack of usage. The U.S. FWS made an estimate of malathion usage on slash pine seed orchards in the 2022 BiOp through expert elicitation and concluded that approximately 25 acres per year are treated.[23]

[17] Nonagricultural Market Research Data (NMRD). 2022. Study of professional pest management in 2021. [Accessed January 2024].
[18] Nonagricultural Market Research Data (NMRD). 2022. Study of turf and ornamental usage in 2021. [Accessed January 2024].
[19] Kline and Company. 2020. Industrial Vegetation Management Markets 2019: United States Market Analysis and Opportunities. [Accessed January 2024].
[20] Nonagricultural Market Research Data (NMRD). 2023. Study of industrial vegetation management in 2022. [Accessed January 2024].
[21] Kline and Company. 2018. Pest Control in Production Animal Health 2017: U.S. Market Analysis and Opportunities. [Accessed January 2024].
[22] Nonagricultural Market Research Data (NMRD). 2022. Study of production animal health in 2021. [Accessed January 2024].
[23] United States Fish and Wildlife Service (USFWS), 2022. Biological and Conference Opinion on the Registration of Malathion Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, Available at: https://www.fws.gov/media/biological-and-conference-opinion-registration-malathion. [Accessed March 2024]

Public health usage - wide-area mosquito adulticide

Wide-area (Public Health) mosquito control is performed by mosquito control districts managed by the state. Recent national surveys (years: 2018, 2020, 2022) of mosquito adulticide usage reported an annual average of 750,000 lbs of malathion being applied to 19 million acres of land.[24,25,26] This accounted for over 20% of total acres treated for mosquito adult control, including multiple treatments to the same acre. Nationally, malathion usage has been increasing over the last 5 years, with over five times the usage reported in 2022 as compared to 2018 in both the pounds of malathion applied and the acres treated with malathion. Malathion was most commonly applied through ground applications. Although the Agency does not have regionally specific usage data available at this time, approximately 70% of all mosquito adulticides were sold in the South, particularly in states bordering the Gulf of Mexico.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2024 HH DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this human health risk assessment in support of the registration review of malathion. This 2024 HH DRA is an update to the previously conducted draft human health risk assessment of the registered uses of malathion required during Registration Review. No new uses of malathion have been registered since the 2016 human health risk assessment. For additional details on the 2024 HH DRA, see *Malathion: Updated Human Health Draft Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2009-0317).

1. Risk Summary and Characterization

Malathion metabolizes into malaoxon which is the active moiety that inhibits AChE. This inhibition results in the accumulation of acetylcholine and ultimately to neurotoxicity in the central and/or peripheral nervous system. AChE inhibition is the most sensitive endpoint in the toxicology database in multiple species, durations, life stages, and routes. EPA assessed human health data for malathion in the manner discussed below and found no human health risks of concern from the registered uses of malathion.

Since the 2016 HH DRA, a human lifestage physiologically based pharmacokinetic-pharmacodynamic (PBPK-PD) model was developed for malathion. PBPK-PD models consist of a

[24] Kline and Company. 2019. Mosquito Control 2018: United States Market Analysis and Opportunities. [Accessed January 2024].
[25] Nonagricultural Market Research Data (NMRD). 2021. Study of mosquito control in 2020. [Accessed January 2024].
[26] Nonagricultural Market Research Data (NMRD). 2023. Study of mosquito control in 2022. [Accessed January 2024].

series of differential equations that incorporate biological and physiological components to simulate the absorption, distribution, metabolism, and excretion (ADME) of chemicals as well as the biological processes associated with the toxicological effect. The model was used in the current human health risk assessment to predict human points of departure (PODs) based on the red blood cell (RBC) AChE inhibition at a maximum peak level of 10%. This modeling approach reduces the uncertainty inherent in a traditional risk assessment that relies on an animal POD and the application of a default uncertainty factor (UF) for interspecies extrapolation. More specifically, the model simulated the ADME of malathion and malaoxon, and the subsequent inhibition of RBC AChE by malaoxon after oral, inhalation, and dermal exposure to malathion or malaoxon from birth to adulthood for a variety of occupational and residential exposure scenarios and lifestages. Dermal, inhalation, and incidental oral (where applicable) risk estimates were combined since the toxicological endpoint, AChE inhibition, was the same for all routes of exposure.

In the case of malathion and malaoxon, the Agency considered new information since the completion of the 2016 HH DRA and conducted an updated weight-of-evidence evaluation of DNT potential for malathion and malaoxon using chemical-specific data across multiple lines of evidence (toxicological studies in laboratory animals, epidemiological studies, and *in vitro* DNT new approach methodologies [NAMs] battery). The totality of the data considered in the DNT weight of evidence evaluation indicates that potential DNT effects observed for malathion or malaoxon would occur in the presence of substantial AChE inhibition, which is the basis for the current risk assessment endpoints and PODs. Therefore, AChE inhibition is considered protective of potential DNT effects, as supported by (1) no positive results for malathion or malaoxon in the DNT battery using human cells, (2) no positive results for malaoxon in the DNT battery using rat cells, (3) average blood concentrations simulated using *in vivo* AChE-based PODs were orders of magnitude lower than DNT-based AC50 values for malathion in rats, and (4) offspring effects observed in the guideline DNT study occurred at doses higher than or similar to those eliciting AChE inhibition. Epidemiology evidence related to DNT outcomes demonstrated there was insufficient evidence of a clear associative or causal relationship between malathion exposure and potential DNT outcomes.

Therefore, a risk assessment based on AChE inhibition is considered protective of any potential downstream neurodevelopmental effects. Furthermore, as discussed in the revised HH DRA, the toxicological databases are complete and adequate for characterizing malathion and malaoxon toxicity. Malathion and malaoxon are OPs with an established neurotoxic mode of action/adverse outcome pathway (MOA/AOP) with PODs derived from the most sensitive effect of AChE inhibition. There is no evidence of increased quantitative sensitivity/susceptibility to offspring following exposure to malathion/malaoxon based on AChE inhibition, and although the assessments were refined, exposure is not expected to be underestimated. Therefore, the 10X FQPA SF is reduced to 1X for all dietary and non-occupational exposure scenarios. Similarly, application of a UFDB for occupational scenarios is not necessary.

Additionally, use of the human PBPK-PD model removes the need for accounting for interspecies extrapolation, and thus, allows for the elimination of the interspecies UF (1X). However, a 10X default intraspecies uncertainty factor was retained.

Dietary (Food + Water) Risks

Acute and steady-state dietary assessments for food-only, drinking water-only, and aggregate (food and drinking water) were conducted for malathion and its malaoxon metabolite which identified no risk estimates of concern. Acute margin of exposures (MOEs) for food plus water range from 170-340 (level of concern or LOC=10) and therefore are not of concern. The LOC of 10 for this approach includes the relevant uncertainty/safety factors (SF) (1X interspecies extrapolation, 10X intraspecies variability, and 1X FQPA SF). The steady-state MOEs for food plus water range from 300-560 (LOC=10) and therefore are not of concern. Infants (<1 year old) and/or children 1-2 years were the population subgroup with the highest risk estimate. See the 2024 HH DRA and supporting documents for further explanation of the exposure and risk assessments using Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) and the PBPK-PD models.

Residential Handler Risks

Adult residential handlers may have dermal and inhalation exposure to malathion used on garden fruits and vegetables, ornamentals, outdoor perimeter treatment, and mosquito control. However, EPA assessed these potential exposures and concluded that residential adult handler risk estimates are not of concern (i.e., MOEs are greater than the LOC of 10); estimated MOEs range from 270-8,200,000.

Residential Post-Application Risks

Malathion may be applied in areas including residential gardens and pick-your-own farm settings resulting in potential post-application dermal malathion and malaoxon exposures to adults and children 6 to <11 years. Residential post-application dermal exposures and risks were estimated with use of chemical-specific dislodgeable foliar residue (DFR) data for both malathion and malaoxon. These DFR data, submitted by the registrant in support of registered products, measured only the parent, malathion. To account for potential post-application exposures to malaoxon, it was assumed that 5% of measured malathion residues convert to malaoxon on foliar surfaces and is then available for transfer to people.

Estimated adult and child 6 to <11 years old malathion + malaoxon dermal residential post-application exposures and risks are not of concern (i.e., estimated MOEs are greater than the LOC of 10); estimated MOEs range from 80 to 840.

Bystander Risks

Adult and child bystanders may have dermal exposure and children 1 to <2 years old incidental oral exposure to malathion and malaoxon due to spray drift from agricultural applications, inhalation of pesticide volatiles after a nearby application, and in residential settings following public health mosquito adulticide applications. Bystander risk assessments were conducted using turf transferable residue (TTR) data, inhalation toxicity and air monitoring data, and assuming 5% conversion of malathion to malaoxon and concluded the MOEs for spray drift, 120-790; for volatile inhalation of nearby applications, 280-3,800,000; and for public health mosquito ULV adulticide applications, 90-15,000, are not of concern (i.e., estimated MOEs are greater than the LOC of 10).

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide (malathion and malaoxon) exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency aggregates (add) the exposures from these sources and compares the aggregate risk to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. The acute aggregate MOEs for malathion food plus malaoxon food and water (170-340) and steady state aggregate MOEs for malathion food, and malaoxon food and water and residential malathion plus malaoxon exposures (70 for adult and 180 for children 6 to <11 years old) are above the LOC (MOE of 10) and are not of concern.

Cumulative Risks

OPs, such as malathion, share the ability to inhibit AChE through phosphorylation of the serine residue on the enzyme, leading to accumulation of acetylcholine and ultimately cholinergic neurotoxicity. This shared MOA/AOP is the basis for the OP common mechanism grouping per EPA's *Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999). The 2002 and 2006 OP cumulative risk assessments (CRA) used brain AChE inhibition in female rats as the source of dose response data for the relative potency factors and PODs for each OP, including malathion. There were no risks of concern identified in the 2006 update of the OP cumulative risk assessment.[27]

EPA is not making any findings regarding the potential cumulative risks of malathion and other OPs that share a common mechanism of toxicity at this time. EPA intends to make those conclusions collectively for all registered OPs after completing the individual OP assessments. As EPA assesses each OP during the Registration Review process, it will determine if there is any new information since the 2006 CRA was conducted that would affect the conclusions of the 2006 CRA. Should the Agency determine that new information (e.g., changes in use pattern, risks of concern) could potentially impact the CRA, the Agency will revisit the OP CRA after all of

[27] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides

the OPs have been assessed. Where no such information exists, EPA will reaffirm the conclusions of the previous CRA.

Occupational Handler Risks

Occupational handlers may have dermal and inhalation exposures to parent malathion only. EPA estimated combined dermal and inhalation occupational handler exposures for all registered uses and concluded the risk estimates are not of concern (i.e., all MOEs are above the LOC of 10); estimated MOEs range from 18 to 7,700,000. Handlers are required to wear baseline clothing (i.e., long-sleeved shirt and long pants, and shoes plus socks) and some variety of PPE (e.g., protective eyewear, chemical-resistant apron, chemical-resistant headgear, and chemical-resistant gloves) for most malathion products. Only the one dust formulated label (EPA Reg No. 1015-69) requires the use of coveralls and a respirator.

Occupational Post-Application Risks

Post-application workers may have dermal exposure to malathion and malaoxon. EPA estimated occupational post-application exposures for malathion and malaoxon and concluded that risk estimates on the day of product application are not a risk of concern (i.e., estimated MOEs are greater than the LOC of 10); MOEs range from 10-990. All registered uses were analyzed using DFR study data and assuming 5% conversion of malathion to malaoxon following application. Current Restricted-Entry Intervals (REIs) (12 to 72 hours) are in line with the active ingredients classified as Toxicity Category III and IV for acute dermal, eye irritation, and primary skin irritation and are considered protective of post-application exposure.

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for malathion at this time. If new policies or procedures are created, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for malathion.

2. Human Incidents and Epidemiology

EPA reviewed malathion incidents reported to both the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides. From January 1, 2014, to February 25, 2021, there were 66 human incidents reported to the Main IDS and 194 human incidents reported to the Aggregate IDS that involved malathion. In addition, there were 193 human cases reported to SENSOR-Pesticides (2010-2017), 115 human incidents reported to California Pesticide Illness Surveillance Program (PISP), and 172 human incidents reported to National Pesticide Information Center (NPIC). In the most recent review of available incidents, EPA found most malathion incidents were low in severity (78% in IDS, 73% in (SENSOR)-Pesticides, and 79% in National Pesticide Information Center (NPIC)). In both OPP's IDS and SENSOR, malathion incidents appear to be decreasing over time. Main IDS reported most exposure during application and indoors. NPIC found most malathion cases were related to indoor spills. SENSOR-Pesticides (2010-2017) found the main contributing factor in malathion

case reports involved pesticide user spills or splashes for both occupational and residential users. Of the occupational malathion cases reported in SENSOR-Pesticides, nearly 75% involved agricultural workers exposed to pesticide residues while working in treated fields. The PISP (2012-2017) found that most malathion incidents involved fieldworkers exposed to either pesticide residue or from off-site movement of the pesticide. Reported symptoms include mostly neurological, gastrointestinal and respiratory effects. The Agency intends to monitor human incidents for malathion and will conduct additional analyses if necessary.

Since the last risk assessment, EPA reviewed epidemiologic literature on malathion to assess the epidemiologic evidence on the potential adverse effects of malathion exposure and adverse human health effects. The Agency conducted searches of the Agricultural Health Study (AHS) publications and peer-reviewed literature (PubMED, PubMED Central, and Science Direct) that reported on the potential association between malathion exposure and carcinogenic and noncarcinogenic health effects. There were individual studies that identified positive associations between malathion and adverse health outcomes; however, the overall evidence was based on a small body of studies (i.e., typically only one or two studies per health outcome) that often had substantive limitations with respect to the study design, exposure assessment approach, or outcome assessment. HED concluded that overall, there was insufficient epidemiologic evidence to suggest a clear associative or causal relationship exists between malathion exposure and the adverse health outcomes examined in the available epidemiologic literature.[28]

3. Tolerances

Malathion is registered for uses that result in residues in or on food. Generally, a tolerance or tolerance exemption must cover these potential residues, or the affected food is considered adulterated.[29] The Agency has established tolerances for malathion under 40 C.F.R. § 180.111.

Cancellation of Livestock Commodity Tolerances (40 CFR § 180.111 (a)(3)): The qualitative nature of the residue resulting from oral dosing of ruminants and poultry is adequately understood and neither malathion nor malaoxon were detected in any tissue. The ruminant and poultry metabolism studies demonstrated rapid metabolism and extensive incorporation of malathion into natural products. In addition, based on the request for cancellation of all direct animal treatment uses (FR vol. 56, No. 52, FRL-3874-4), residues of malathion in livestock commodities represent a Category 3 situation under 40 CFR §180.6(a), i.e., there is no reasonable expectation of finite residues.

During the risk assessment process EPA also determine that the tolerance expression for 40 CFR §180.111 (a)(1), the tolerances in (a)(2) can be moved to (a)(1) and (a)(2) may be deleted. The current tolerances on livestock commodities should be removed (40 CFR § 180.111 (a)(3)). Also,

[28] *A. Aldridge et al., Task Group No. 00491986, 01/22/2024).*
[29] 21 U.S.C. §§ 342, 346(a).

40 CFR §180.111(4) (i) (ii) (iii), (5), (6) and (7) (i) (ii) can be removed from the CFR listing since they are no longer relevant. For information on the tolerance actions, see Section IV.C, below.

4. Human Health Data Needs

The human health database for malathion is considered complete.

B. Ecological Risks

The Agency has summarized the 2024 Eco DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of malathion.[30] Prior to this 2024 Eco DRA, malathion went through a EPA Biological Evaluation (2017 BE), a 2022 FWS BiOp, and a 2022 NMFS BiOp to address federally threatened or endangered ("listed") species obligations. To implement the BiOps, EPA approved labeling changes requested by the registrants of pesticide products containing malathion to include the necessary mitigations in the opinions and published bulletins to Bulletins Live! Two. For additional details on the 2024 Eco DRA, 2017 BE, 2022 FWS BiOp, and 2022 NMFS BiOp, see *Malathion: Revision to the Streamlined Draft Ecological Risk Assessment Amendment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2009-0317) and Biological Evaluations and Opinions on EPA's Protecting Endangered Species from Pesticides website.[31]

1. Risk Summary and Characterization

The most recent Biological Evaluation (BE) written by EPA was completed in 2017. The final NMFS salmonid BiOp for malathion was published on the EPA website in August 2022. The final U.S. FWS BiOp was completed in February 2022 and posted in March 2022. The NMFS BiOp was completed and posted in June 2022. Previously, a federally listed threatened or endangered species (hereafter referred to as "listed" species) assessment was conducted for malathion. The 2024 Eco DRA builds on the toxicity and risk conclusions made in the 2017 BE and updates the exposure assessment with recent proposed label changes, from August 2023. The 2024 Eco DRA is based on the 2017 BE risk profile because the new estimated environmental concentrations (EECs) do not substantially change the exposure, and in turn, the risk profile.

Malathion is an organophosphate insecticide that kills insects on contact. Organophosphate toxicity is based on the inhibition of the enzyme AChE. Inhibition of AChE interferes with proper neurotransmission in cholinergic synapses and neuromuscular junctions which can lead to sublethal effects (e.g., increased respiration, lethargy) and mortality. Malathion is a moderately mobile chemical that biodegrades aerobically and anaerobically as well as degrades through hydrolysis with a half-life from 0.3 to 11 days. Malathion transforms into malaoxon at less than 10% of parent application rate.

[30] The 2024 Eco DRA only addresses potential risks to species not listed under the Endangered Species Act. The Agency completed malathion's listed-species assessment. For more details, see Appendix C.
[31] See https://www.epa.gov/endangered-species on the world wide web.

Movement of malathion into aquatic and terrestrial habitats include direct deposit onto treated sites and transport via spray drift, runoff, and volatilization. This movement away from the site of application represents potential exposure pathways for non-target organisms which may affect survival, growth, and reproduction.

There are potential risks of concern from malathion agricultural, mosquito control, and/or residential uses to the following taxa: fish, aquatic invertebrates, birds, mammals, terrestrial amphibians, aquatic and terrestrial plants, and terrestrial invertebrates.

In the 2024 Eco DRA, the three highest risk use patterns of malathion (i.e., corn, cotton, and citrus) were assessed.

The 2024 ecological DRA addresses risk to all non-listed species within the United States. The malathion risk conclusions for non-listed taxa remain the same as those identified in the previous malathion BEs and the 2023 exposure assessments, so the 2024 assessment restates the malathion risk conclusions of the older assessments. The consultation and mitigation efforts for malathion uses that were previously completed and implemented with the Services apply to only listed species. The consultation-based mitigations restrict the geographic and species-specific scope of the assessment to only listed species. The 2024 DRA addendum is thus necessary to address risk to non-listed species.

Terrestrial Risks

Spray drift and runoff from treated sites mostly from agricultural and residential uses result in potential risks of concern for terrestrial taxa. Mosquito adulticide use is a potential risk of concern for birds, amphibians, and terrestrial invertebrates.

Mammals

There are acute and chronic risks of concern for mammals. Highest risk use patterns (i.e., corn, cotton, and citrus) were analyzed. Acute dose-based risks are not of concern for malathion use on corn (acute RQs range from 0 to 0.14; LOC = 0.5). However, chronic dose-based risks (chronic RQs range from 0.14 to 21.83; LOC = 1) and chronic dietary-based risks (chronic RQs range from 0.16 to 2.52; LOC = 1) include risks of concern from malathion use on corn.

Acute dose-based risks are not of concern for malathion use on cotton, except for eating short grass (acute RQs range from 0 to 0.64; LOC = 0.5). Chronic dose-based risks (chronic RQs for cotton range from 0.63 to 99.63; LOC = 1) and dietary-based risks (chronic RQs for cotton range from 0.72 to 11.48; LOC = 1) include risks of concern for malathion use on cotton.

Acute dose-based risks are not of concern for malathion use on citrus (acute RQs range from 0 to 0.34; LOC = 0.5). However, chronic dose-based risks (chronic RQs for citrus range from 0.33

to 52.52; LOC = 1) and dietary-based risks (chronic dietary RQs range from 0.38 to 6.05; LOC = 1) include risks of concern for malathion use on citrus, except for eating seeds.

Birds, Reptiles, and Terrestrial-Phase Amphibians

There are acute and chronic risks of concern for birds (which are surrogates for reptiles and terrestrial-phase amphibians). Highest risk use patterns (i.e., corn, cotton, and citrus) were analyzed. Acute dose-based risks (acute RQs range from 0.02 to 7.77; LOC = 0.5) include risks of concern, but dietary-based risks (chronic RQs range from 0.02 to 0.25; LOC = 0.5) are not of concern for malathion use on corn. However, chronic dietary-based risks (chronic RQs range from 0.29 to 4.58; LOC = 1) are of concern, except for fruits, pods, and seeds for malathion use on corn.

Acute dose-based risks to birds include risks of concern (acute RQs range from 0.07 to 35.45; LOC = 0.5). Acute dietary-based risks are not of concern for malathion use on cotton, except for eating short grass (acute RQs range from 0.07 to 1.14; LOC = 0.5). Chronic dietary-based risks are of concern for malathion use on cotton (acute RQs range from 1.30 to 20.88; LOC = 1).

Acute dose-based risks include risks of concern (acute RQs range from 0.12 to 18.69; LOC = 0.5), but dietary-based risks are not of concern for malathion use on citrus, except for eating short grass (dietary RQs range from 0.04 to 0.60; LOC = 0.5). Chronic dietary-based risks are of concern for malathion use on citrus, except for fruits, pods, and seeds (chronic RQs range from 0.69 to 11.01; LOC = 1).

Terrestrial Invertebrates

There is potential risk of concern for terrestrial invertebrates from malathion use. This potential risk would be from agricultural, residential, and mosquito adulticide uses. However, malathion is not heavily used in agriculture, and it has a short half-life. EPA relies on data about honey bees as a surrogate for terrestrial invertebrate species. Based on the available data, EPA has determined that malathion uses may present risks of concern to honey bees. However, BiOp language incorporated on the labels provides new spray drift language, application restrictions around blooming period of several crops, and pollinator protection management language.

Terrestrial Plants

There is potential risk of concern to terrestrial plants from malathion use. While direct effects are not indicated, reported incidents of aquatic plants suggest that risk are possible. While there are potential risks of concern, malathion has a short half-life. BiOp label language incorporated new spray drift mitigation and buffer language that should reduce exposure from agricultural, residential, and mosquito adulticide uses of malathion nationwide.

Aquatic Risks

Spray drift and runoff from treated sites mostly from agricultural and residential uses are potential risks of concern for aquatic taxa. Mosquito adulticide use is a potential risk of concern to aquatic invertebrates. The mosquito adulticide use is of less of a concern, because this type of application is less likely to result in aquatic exposure than from agricultural uses. Malathion has a short half-life.

Freshwater and Estuarine/Marine Fish

There are acute risks of concern for fish. Highest risk use patterns (i.e., corn, cotton, and citrus) and use sites with high usage (e.g., berries and alfalfa) were analyzed. For freshwater fish, the potential acute risks are of concern (acute RQs range from 15 to 49; LOC = 0.5); but the chronic risks are not of concern (chronic RQs range from 0.03 to 0.12; LOC = 1). For estuarine/marine fish, the acute risks are of concern (acute RQs range from 5 to 17; LOC = 0.5); but the potential chronic risks are not of concern (chronic RQs range from 0.24 to 0.94; LOC = 1).

Aquatic Invertebrates

There are acute and chronic risks of concern for aquatic invertebrates. Highest risk use patterns (i.e., corn, cotton, and citrus) and use sites with high usage (e.g., berries and alfalfa) were analyzed. For freshwater invertebrates, the potential acute risks (RQs range from 30 to 95; LOC = 0.5) and chronic risks (chronic RQs range from 212 to 820; LOC = 1) are of concern. For estuarine/marine invertebrates, potential acute risks (acute RQs range from 13 to 41; LOC = 0.5) and chronic risks (chronic RQs range from 13 to 51; LOC = 1) are of concern.

Aquatic Vascular and Non-Vascular Plants

There is potential risk of concern to aquatic plants. While direct effects are not indicated, aggregate reported incidents of plants suggest that risks are possible. While there are potential risks of concern, malathion has a short half-life. BiOp label language incorporated new spray drift mitigation, runoff, and buffer language that should reduce exposure from agricultural, residential, and mosquito adulticide uses of malathion nationwide.

2. Ecological Incidents

The Agency's incident database (IDS) was accessed on February 27, 2024. EPA identified nine incidents from 2015 to 2023 associated with malathion use and effects to plants and bees. Seven incidents were associated with terrestrial plants and two incidents were associated with terrestrial invertebrates. Of the two incidents on terrestrial invertebrates, one was from a misuse (either accidental or intentional) and the legality of the other incident was undetermined. For terrestrial plants, the legality of two incidents were registered uses, meaning that they appeared to be associated with labeled uses of malathion. The legality of the other five terrestrial plant incidents were undetermined meaning that the incident report did not include enough information for EPA to determine if the incident was associated with a legal

use or misuse. All of these incidents were assigned a “possible” certainty. Possible certainty means that the pesticide possibly could have caused the incident, but there are other possible explanations that are at least as plausible. For example, the incident may include other active ingredients that may be more toxic and/or found at higher exposure levels, or there may be no environmental sampling or other evidence of exposure to support a causative relationship between the active ingredient and the environmental effect described in the incident report.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for malathion is considered complete.

C. Benefits Assessment

Benefits for Mosquitocide, State and Federal Insect Pest Management
Among other uses, malathion is registered for certain wide-area uses including mosquito control and federal and state insect management programs to control the boll weevil in cotton, Mormon cricket and grasshoppers in rangeland, beet leafhopper within the Beet Curly Top Virus Control Program (BCTVCP) in California, and invasive Tephritid fruit flies in quarantine areas nationwide.

For wide-area mosquito control, malathion is one of the top three most used mosquito adulticides by mosquito control districts and other public health government agencies. Overall, malathion provides high benefits as an inexpensive insecticide option that can effectively provide quick reductions in adult mosquito populations when used by mosquito control districts as a public health tool within an integrated mosquito management program. Mosquito-borne diseases, such as those caused by the West Nile and Zika viruses, are among the world's leading causes of illness and death and pose a significant risk to people in the United States. Using pesticides like malathion to control mosquito populations is important to maintaining public health.

Malathion is also a primary component of other pest control programs managed by government agencies, including Mormon cricket and grasshopper management in rangelands, invasive fruit fly and boll weevil eradication programs wherever these invasive pests are detected, as well as beet leafhopper in California. Malathion’s broad-spectrum of efficacy allows flexibility in timing of applications to large areas for management of pests at large spatial scales. Each of these programs uses only malathion or a small handful of insecticides as part of a multi-tiered pest management program involving other integrated pest management practices such as monitoring, trapping, or sterile insect release techniques. Available insecticide alternatives allowed under each program either do not work as quickly or provide the same level of control as malathion. Other efficacious insecticides may be available to the end-user, but adoption would require broad programmatic changes to well-established government programs, so their implementation may not be feasible or could risk reintroduction of invasive species to some previously eradicated areas.

Benefits for Fruit Crops

Malathion has high benefits in the production of cherries and figs. In cherries and figs, growers do not have other efficacious tools available for pest control very close to harvest, a critical period for pest control, as other insecticides that are effective for control of common late season berry pests have pre-harvest intervals of 7-14 days. In the absence of malathion, many growers of cherries and figs who rely on malathion to manage late season pest pressures would suffer yield and quality losses.

Malathion provides benefits in cultivated blueberry production that range from high to low, depending on regional climate, harvest timing, and target pest(s). Since only two other chemical classes have similar efficacy to malathion against both spotted wing drosophila (SWD) and blueberry maggot, malathion provides high benefits where these pests co-occur. Malathion is an organophosphate with a very short (1-day) PHI that growers can use as a rotational tool for resistance management. Therefore, malathion has overall medium benefits in the production of cultivated blueberries across the U.S. In wild blueberries, malathion has low benefits, because many effective alternatives with a short PHI are available to growers that are likely treating for spotted wing drosophila less often than cultivated berry growers.

Malathion has medium-to-high benefits as an economical rotational tool for resistance management when used against spotted wing drosophila in California and Pacific Northwest caneberries. Like blueberries, malathion's 1-day PHI provides flexibility in application timing, especially for growers who harvest every one to two days. Malathion has high usage, and alternatives from only two other chemical classes (pyrethroids and spinosyns) are frequently used, including options that are notably more expensive than malathion.

Malathion has medium-to-high benefits for tropical fruits for control of mealybugs, lace bugs, and scale insects. Broad-spectrum foliar sprays (such as malathion) are typically not recommended due to negative impacts on natural enemies. However, in cases where target pest populations reach damaging levels and broad-spectrum insecticide usage is warranted, malathion is a frequently used and recommended effective control option. There are few alternatives to malathion for high pressure of these pests. In the absence of malathion, tropical fruit growers may have difficulty managing resistance.

Malathion confers low benefits in the production of other fruit crops, including oranges, pear and strawberry due to low usage or the availability of cost-effective efficacious alternatives.

Benefits for Vegetable Crops

Based on information received during the public comment period, EPA assessed the benefits of malathion in cucurbits, onion, tomatoes, and asparagus use sites. Due to minimal reported usage of malathion in the other registered vegetable crops, which implies that malathion does not represent a significant tool for the control of target pests, EPA concludes that such vegetable crops derive low benefits from malathion.

In cucurbit use sites, available usage data indicates that malathion is primarily applied to target aphids and cucumber beetles. EPA concludes that malathion offers moderate benefits because of its potential role in resistance management and its comparatively higher application flexibility. The resistance management potential is due to the unavailability of other insecticides with malathion's mode of action (MOA) and the flexibility component is due to the limitation of neonicotinoid alternatives to be applied after plant bloom.

For onions, malathion seems to provide low benefits to growers for the control of onion thrips due to the availability of effective alternatives throughout the growing season that may have lower cost per treated acre.

Benefits for tomatoes are analyzed separately for processing and fresh market tomatoes, produced predominantly in California and Florida, respectively. For California tomatoes, malathion offers low benefits as there are many effective alternatives of similar costs. For Florida tomatoes, malathion offers low to moderate benefits, as there are only a few chemistries that have similar broad-spectrum efficacy and cost per acre as malathion. Consequently, growers may need to combine multiple chemistries if they had to replace malathion.

In asparagus production, malathion seems to provide low benefits as there are several effective and similarly priced chemical alternatives recommended by extension guidelines. There is reported usage of alternative insecticides with no significant indication of a reliance on malathion. Further, some alternatives are similarly priced while some others appear to be more expensive than malathion.

Benefits for Other Uses

In alfalfa production, malathion offers low to moderate benefits to users due to its broad-spectrum activity against pests, including the ability to simultaneously treat against two of alfalfa's key pests (i.e., alfalfa weevil and aphids). This, in addition to malathion's 0-day pre-harvest interval (PHI), provides users increased flexibility and saves them the need of performing additional insecticide applications or tank mixing products.

In slash pine seed orchards, malathion might provide low to moderate benefits in managing slash pine flower thrips during occasional outbreaks, as it is among one of few chemical control options available. For use on pine seedlings, malathion likely has low benefits due to the availability of multiple alternatives with different modes of action as well as non-chemical control methods against target pests.

In residential homeowner use products for the treatment of ornamentals, lawns, and gardens, malathion provides benefits due to its broad-spectrum activity, versatility across various

settings within such, and by being the only organophosphate with such attributes available as a homeowner product.

As risks associated with malathion were driven by ecological exposure and not to human health, indoor uses of malathion, such as treatment of stored grain or mushroom cultivation were not assessed for benefits because they are not associated with ecological risks of concern.

Many other registered use sites not discussed in this section, such as corn, rice, and commercial ornamental production, exhibit low usage and therefore suggest that users either have other cost-effective tools available to control pests which malathion is effective against, or that the pests which malathion is effective against are not problematic in these use sites. EPA concludes that malathion has low benefits in these sites.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

The Agency is issuing this PID in accordance with 40 C.F.R. §§ 155.56 and 155.58. Based on the Agency's review of malathion at this time in the registration review process, EPA is proposing certain changes to the affected registrations and their labeling to be implemented through label amendments and/or registration changes. EPA proposes that the mitigations identified in Sections IV.A–B and Appendices A-B will address specific risks of concerns identified at this point in the ongoing registration review process.

At the end of the registration review process, EPA will decide whether each malathion pesticide registration "continues to satisfy the FIFRA standard for registration."[32] However, this PID is not a proposed decision on whether malathion registrations continue to satisfy the FIFRA standard for registration and implementing the mitigation proposed in this PID may not be sufficient for EPA to determine that malathion registrations do so ultimately. EPA may determine that additional mitigations or other measures are necessary in its interim registration review decision.

The Agency has completed consultation with the Services for all currently registered uses of malathion, as well as any FIFRA Section 18 or 24(c) for malathion, considered by this PID.

A. Proposed Risk Mitigation and Rationale

As stated in Section III of the document, the updated human health assessment of malathion and its degradate malaoxon concluded there are no human health risks of concern for

[32] 40 C.F.R. §§ 155.40(a), 155.57; 7 U.S.C. § 136a(g); *see also* 7 U.S.C. §§ 136a(c)(5) (FIFRA registration standard), 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). This document is not a "registration review decision" within the meaning of FIFRA Section 3(g) and 40 C.F.R. § 155.57.

malathion; however, potential risks to several of the assessed ecological taxa were identified. Potential risk concerns of malathion use were identified for fish, aquatic and terrestrial invertebrates, terrestrial amphibians, birds, aquatic and terrestrial plants, and mammals. Substantial nationwide mitigation from the BiOps have already been implemented on labels to reduce ecological exposure. Proposed mitigation to further reduce potential ecological risks of concern include adding mandatory spray drift language for boomless ground applications, updating the advisory spray drift language for all spray applications, and a 96-hour water holding time before releasing floodwaters after the treatment of rice.

In keeping with EPA's best labeling practices and current approach for insecticides, EPA is also proposing to update glove language, respirator and its fit language, mixer/loader stinger (i.e., removable chemical extraction probe) usage language, mixer/loader water soluble bag language, and label clarification for cotton. EPA is also proposing to separate mosquito adulticide use labels from other use labels. Any comments to these proposed mitigations are welcome during the public comment period.

1. Personal Protective Equipment

The Agency proposes updating the gloves statements currently on relevant labels as necessary, consistent with Chapter 10 of the Label Review Manual.[33] In particular, EPA proposes removing any references to specific categories in EPA's chemical-resistance category selection chart and specifying the appropriate types of glove.[34] The proposed clarification does not fundamentally change the PPE that workers currently must use. For label clarification, EPA is proposing to remove requirement for specific clothing and/or PPE if the product is intended for residential use only.

The Agency proposes updating the respirator statement currently on malathion labels as necessary. The proposed clarification does not fundamentally change the PPE that workers currently must use.

2. Spray Drift Management

The Agency proposes label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all applicable malathion products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. These label changes are also expected to reduce the extent of exposure for—and may reduce impacts to—listed species whose range or critical habitat co-occur with the use of malathion.

The BiOp label language added new spray drift language for mosquito adulticide as well as agricultural aerial, airblast, and ground boom applications. To be consistent with standardizing label language, EPA proposes the following boomless ground spray drift mitigation language to

[33] Label Review Manual, https://www.epa.gov/pesticide-registration/label-review-manual.
[34] For specific label language, see Appendix B.

be included on all applicable malathion product labels for products applied by liquid spray application. EPA is proposing spray drift language to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics.

For Boomless Ground Applications:

- Do not apply when wind speeds exceed 10 miles per hour at the application site.
- Do not apply during temperature inversions.

The mandatory spray drift language for boomless sprayers is expected to have minimal impacts on the malathion users.

The Agency is also proposing to add advisory spray drift management language to applicable malathion labels as necessary to reduce off-target spray drift and consistently protect against a baseline level of spray drift across all malathion products. When submitting labeling consistent with this PID, labeling must not include any advisory language that contradicts the new mandatory spray drift statements noted in this PID.

3. 96-hour Rice water holding time

The Agency proposes a 96-hour holding time before floodwaters may be released after treatment to rice. This is an increase from the 24-hour holding time requirement from the BiOps. Based on a lowest fish endpoint of 4.1 µg/L (acute freshwater fish), EPA determined it would take a minimum 6-day holding period for released rice paddy water to result in a RQ of <100. There is still risk of concern (RQ > 100) at the 24-hour holding time. This suggests some mitigation is warranted. Usage data indicates that essentially all of malathion use on rice is low usage (less than 1%) in California, and USDA informed EPA that California rice growers already use a 96-hour holding time. This mitigation will reduce exposure to non-target organisms and have little impacts on the users.

4. Label update for all liquid products where there are mixers and loaders involved in mixing concentrate

Results from a 2019 study by the Agricultural Handler Exposure Task Force (AHETF), a consortium of pesticide manufacturing companies, indicate that incorrect probe extraction for suction/extraction systems, resulted in direct exposure to liquid chemical concentrate for mixers and loaders. This monitoring data measured high exposure to the liquid concentrate, when mixers/loaders removed chemical extraction probes in suction/extraction systems, without rinsing them prior to removal from the pesticide container. The AHETF submitted the dataset to the Agency that excludes monitoring of those workers who handled unrinsed chemical extraction probes and recommended that the Agency take additional regulatory actions to ensure workers do not remove and handle chemical extraction probes still coated with the concentrated liquid formulation. Reflecting the results of the 2019 task force data and also to ensure that all mixers and loaders of liquid formulations are protected from direct

exposure to liquid concentrate, EPA proposed the following label language to be included on all liquid formulation product labels for mixers and loaders:

"Removable chemical extraction probes (also known as "stingers") used in suction/extraction systems must be rinsed within the pesticide container prior to removal."

EPA expects little impact on users from this requirement.

5. Label clarifications

EPA is also proposing several label clarifications that will ensure consistency among labels. Several cotton label clarifications include the following: (1) the minimum application retreatment interval for non-BWEP cotton is 7 days, and (2) for the BWEP use on cotton, the minimum application retreatment interval for cotton is 3 days.

EPA is proposing to create sublabels for mosquito adulticide use in federal, and state programs. EPA is also proposing to update the water-soluble packaging language, if applicable, and add the Mode of Action box.

B. Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. Throughout the registration review process, EPA has sought to include all communities and persons, including minority, low-income, and indigenous populations who may be disproportionately overburdened by the exposure to malathion.

One community which may experience disproportionate exposure to pesticides is agricultural farmworkers. EPA has conducted assessments of risks to farmworkers who handle malathion or may be exposed to malathion and has not found risks of concern for malathion. EPA has also evaluated the risks to people living adjacent to treated fields, which may include many farmworker families, and has not found risks of concern for malathion. Another community which may experience disproportionate dietary exposure is subsistence fishing communities. EPA conducted assessments of risks to subsistence fishers who may be exposed to malathion and has not found risks of concern. EPA has also evaluated risk to residential handlers (such as homeowners) and adults/children that may be exposed to residues after pesticide application and has not found risks of concern.

The Agency requests information on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (e.g., as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors

and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to malathion compared to the general population or who may otherwise be disproportionately affected by the use of malathion as a pesticide.

C. Tolerance Actions

The Agency plans to exercise its FFDCA authority to update the tolerance expression to appropriately cover the metabolites and degradates of malathion and to specify the residues to be measured for each commodity for enforcement purposes. EPA anticipates amending the tolerance expression to read as follows:

Tolerances are established for residues of the insecticide malathion, including its metabolites and degradates, in or on the commodities in Table 1. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of malathion (diethyl 2-[(dimethoxyphosphinothioyl) thio) butanedioate) and malaoxon, its oxygen analog butanedioic acid, 2-[(dimethoxyphosphinyl)thio]-1,4-diethyl ester, calculated as the stoichiometric equivalent of malathion, in or on the commodity.

The Agency also plans to exercise its FFDCA authority to modify the tolerances for malathion as summarized in Table 2, below.

Table 2. Tolerance Summary for Malathion (40 CFR §180.111)

Commodity/Correct Commodity Definition	Established Tolerance (ppm)	HED-Recommended Tolerance (ppm)	Comments
1(a) General- Malathion + Malaoxon			
Alfalfa, forage	135	135	
Alfalfa, hay	135	135	
Almond, hulls	50	50	
Almond	--	8	Commodity definition revision
Almond, postharvest	8	remove	
Apple	8	8	
Apricot	8	8	
Grain, aspirated fractions[1]	--	2700	
Avocado	8	8	
Barley, grain	--	15	Commodity definition revision
Barley, grain, postharvest	8	remove	
Barley, hay[2]	--	30	
Barley, straw	50	50	
Beet, garden, roots	8	8	
Beet, garden, leaves	--	8	
Beet garden, top	8	remove	
Beet, sugar, roots	1	1	
Beet, sugar, tops	8	remove	
Blackberry	8	8	
Blueberry	8	8	
Boysenberry	8	remove	Covered by blackberry.

Table 2. Tolerance Summary for Malathion (40 CFR §180.111)			
Commodity/Correct Commodity Definition	**Established Tolerance (ppm)**	**HED-Recommended Tolerance (ppm)**	**Comments**
Carrot, roots	8	8	
Chayote, fruit	8	8	
Chayote, tuberous roots	--	8	Commodity definition revision
Chayote, roots	8	remove	
Cherry, sweet	--	8	Commodity definition revision
Cherry, tart	--	8	
Cherry	8	remove	
Chestnut	1	1	
Clover, forage	135	135	
Clover, hay	135	135	
Corn, field, forage	8	8	
Corn, field, grain	--	8	Commodity definition revision
Corn, field, grain, postharvest	8	remove	
Corn, field, stover	30.0	30	Corrected value to be consistent with HED Rounding Class Practice.
Corn, pop, grain	--	8	Commodity definition revision
Corn, pop, grain, postharvest	8	remove	
Corn, sweet, forage	8	8	
Corn, sweet, kernel plus cob with husks removed	2	2	
Cotton, gin byproducts[1]	--	2000	
Cotton, undelinted seed	20.0	20	Corrected value to be consistent with HED Rounding Class Practice.
Cowpea, forage	135	135	
Cowpea, hay	135	135	
Cranberry	8	8	
Cucumber	8	8	
Currant	8	8	
Date	--	8	Commodity definition revision
Date, dried fruit	8	remove	
Dewberry	8	remove	Covered by blackberry.
Fungi, edible, group 21[2]	-	8	Commodity definition revision
Mushroom	8	remove	
Eggplant	8	8	
Fig	8	8	
Flax, seed	0.1	0.1	
Garlic, bulb	8	8	
Gooseberry	8	8	
Grape	8	8	
Grass, forage, fodder and hay, group 17, forage	--	200	
Grass, forage	200	remove	
Grass, forage, fodder and hay, group 17, hay	--	270	

Table 2. Tolerance Summary for Malathion (40 CFR §180.111)			
Commodity/Correct Commodity Definition	**Established Tolerance (ppm)**	**HED-Recommended Tolerance (ppm)**	**Comments**
Grass, hay	270	remove	
Grapefruit	8	8	
Guava	8	8	
Hazelnut	1	1	
Hop, dried cones	1	1	
Horseradish	8	8	
Kumquat	8	8	
Leek	8	8	
Lemon	8	8	
Lentil, dry seed	--	8	
Lentil, seed	8	remove	
Lespedeza, forage	135	135	
Lespedeza, hay	135	135	
Lime	8	8	
Loganberry	8	8	
Lupin, seed	8	remove	Covered by Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E and Vegetable, legume, bean, succulent shelled, subgroup 6-22C
Mango	8	8	
Melon subgroup 9A	--	8	
Melon	8	remove	
Nectarine	8	8	
Nut, macadamia	1	1	
Oat, forage	4.0	4	Corrected value to be consistent with HED Rounding Class Practice
Oat, grain	--	15	
Oat, grain, postharvest	8	remove	Commodity definition revision
Oat, hay[1]	--	30	
Oat, straw	50	50	
Okra	8	8	
Onion, bulb	8	8	
Onion, green	8	8	
Orange	8	8	
Papaya	1	1	
Parsnip, roots	--	8	Commodity definition revision
Parsnip	8	remove	
Passionfruit	8	8	
Pea, field, hay	8	8	
Pea, field, forage	--	8	Commodity definition revision
Pea, field, vines	8	remove	
Peach	8	8	
Peanut, hay	8	8	
Peanut	--	8	Commodity definition revision

Table 2. Tolerance Summary for Malathion (40 CFR §180.111)			
Commodity/Correct Commodity Definition	**Established Tolerance (ppm)**	**HED-Recommended Tolerance (ppm)**	**Comments**
Peanut, postharvest	8	remove	
Pear	8	8	
Pecan	8	8	
Pepper, bell	--	8	Commodity definition revision
Pepper, nonbell	--	8	
Pepper	8	remove	
Peppermint, fresh leaves	--	8	Commodity definition revision
Peppermint, tops	8	remove	
Pineapple	8	8	
Plum	8	8	
Plum, prune, dried	--	8	
Plum, prune	8	remove	
Potato	8	8	
Pumpkin	8	8	
Quince	8	8	
Radish, roots	--	8	Commodity definition revision
Radish	8	remove	
Raspberry	8	8	
Rice, grain	--	30	Commodity definition revision
Rice, grain, postharvest	8	remove	
Rice, wild, grain	--	8	
Rice, wild	8	remove	
Rutabaga, roots	--	8	Commodity definition revision
Rutabaga	8	remove	
Rye, forage	4.0	4	Corrected value to be consistent with HED Rounding Class Practice
Rye, grain	--	8	Commodity definition revision
Rye, grain, postharvest	8	remove	
Rye, straw	50	50	
Safflower, seed	0.2	0.2	
Salsify, roots	8	8	
Salsify, black, leaves	--	8	Commodity definition revision
Salsify, tops	8	remove	
Shallot, bulb	8	8	
Sorghum, grain, forage[1]	8	40	
Sorghum, grain, grain	--	8	Commodity definition revision
Sorghum, grain, grain, postharvest	8	remove	
Sorghum, grain, stover[1]	--	40	Commodity definition revision
Soybean, forage	135	135	
Soybean, hay	135	135	
Soybean, seed	8	8	
Soybean, vegetable, edible podded	--	8	Commodity definition revision
Soybean, vegetable, succulent shelled	--	8	

Table 2. Tolerance Summary for Malathion (40 CFR §180.111)			
Commodity/Correct Commodity Definition	**Established Tolerance (ppm)**	**HED-Recommended Tolerance (ppm)**	**Comments**
Soybean, vegetable, succulent	8	remove	
Spearmint, fresh leaves	--	8	Commodity definition revision
Spearmint, tops	8	remove	
Squash, summer	8	8	
Squash, winter	8	8	
Strawberry	8	8	
Sunflower, seed	--	8	Commodity definition revision
Sunflower, seed, postharvest	8	remove	
Sweet potato, tuber	--	1	Commodity definition revision
Sweet, potato, roots	1	remove	
Tangerine	8	8	
Tomato	8	8	
Trefoil, forage	135	135	
Trefoil, hay	135	135	
Turnip, roots	8	8	
Vegetable, brassica, head and stem, group 5-16	--	8	Crop group conversion/revision
Vegetable, brassica, leafy, group 5	8	remove	
Vegetable, leafy, group 4-16	--	8	Crop group conversion/revision
Vegetable, leafy, except brassica, group 4	8	remove	
Turnip, greens	8	remove	
Vegetable, legume, pea, edible podded, subgroup 6-22B	--	8	Commodity definition revision based on 180.1(g)
Vegetable, legume, pea, succulent shelled, subgroup 6-22D			Commodity definition revision based on 180.1(g)
Pea	8	remove	
Vegetable, legume, bean, succulent shelled, subgroup 6-22C	--	8	Commodity definition revision based on 180.1(g)
Bean, succulent shelled	8	remove	
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E	--	8	Commodity definition revision based on 180.1(g)
Bean, dry, seed	8	remove	
Vegetable, stalk, stem, and leaf petiole group 22	--	8	Crop group conversion/revision *Celtuce, Florence fennel and kohlrabi can be listed on the label under the use directions for asparagus. There are also data for celery (subgroup 22B) at the same tolerance level as 22A so*
Asparagus	8	remove	

Table 2. Tolerance Summary for Malathion (40 CFR §180.111)			
Commodity/Correct Commodity Definition	**Established Tolerance (ppm)**	**HED-Recommended Tolerance (ppm)**	**Comments**
			the group 22 tolerance can be established.
Vetch, forage	135	135	
Vetch, hay	135	135	
Walnut, black	--	8	Crop group conversion/revision
Walnut, English	--	8	
Walnut	8	remove	
Watercress	0.2	0.2	
Wheat, forage	4.0	4	Corrected value to be consistent with HED Rounding Class Practice
Wheat, grain	8	8	
Wheat, hay[1]	50	30	
Wheat, straw	50	50	

[1] 2016 RED (S. Shelat, D414107, 06/09/2016) recommended tolerances for these commodities based on data call-ins (DCIs) and Response to Deficiency: Magnitude of Residues in grain sorghum and stover; Magnitude of Residues on Wheat Hay; Magnitude of Residues on Cotton Gin-Byproducts, M. Sahafeyan, D406369, 07/15/2014).

[2] Fungi, edible group 21 only consists of mushroom; therefore, we are granting the crop group use.

D. Data Requirements

EPA proposes that no additional data are required at this time.

E. Reference Standards Statements

The analytical reference standard for malathion is out of stock and must be submitted to EPA's National Pesticide Standards Repository (https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository). An analytical reference standard for malathion's metabolite, malaoxon, is available at EPA's National Pesticide Standards Repository (NPSR) (https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository), but expires 8/25/2025.

V. NEXT STEPS AND TIMELINE

A. Comment on this Proposed Interim Decision

A Federal Register Notice will announce the availability of the malathion PID and open a 60-day comment period for the PID, the 2024 HH DRA, and the 2024 Eco DRA. The Agency may issue an ID after the close of this comment period if appropriate.

Appendix A: Summary of Proposed Actions for Malathion

Registration Review Case #: 0248 PC Code: 057701 Chemical Type: insecticide Chemical Family: organophosphate Mode of Action: acetylcholinesterase inhibitors						
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Proposed Actions**	**Comment**
• Fish, Aquatic invertebrates, Birds, and Mammals	• Spray Drift • Runoff	• Ingestion	• Acute • Steady-State	• Survival • Growth • Reproduction	• Require enforceable spray drift reduction • 96-hour water holding time after application for rice	

Appendix B: Proposed Labeling Changes for Malathion Products

<table>
<tr><th>Description</th><th>Proposed Label Language for Malathion Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>End Use Products</td><td></td></tr>
<tr><td>Mode of Action Group Number</td><td>Note to registrant:
Include the name of the ACTIVE INGREDIENT in the first column
Include the word “GROUP” in the second column
Include the MODE/MECHANISM/SITE OF ACTION CODE in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is MODE OF ACTION)
Include the type of pesticide (i.e., INSECTICIDE) in the fourth column.
<table><tr><td>Malathion</td><td>GROUP</td><td>1B</td><td>INSECTICIDE</td></tr></table></td><td>Front Panel, upper right quadrant.
All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.</td></tr>
<tr><td>Updated Gloves Statement</td><td>Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</td></tr>
<tr><td>Personal Protective Equipment Clarification (not on residential use labels)</td><td>For labels with residential uses and PPE: Remove requirement for specific clothing and/or PPE if the product is intended for residential use only.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements</td></tr>
</table>

Updated Respirator Language for PF10	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products. [**Note to registrant:** For respiratory protection from organic vapor a**nd** particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Respirator Fit Testing Requirements for Non-WPS Uses	**"Respirator fit testing, medical qualification, and training** Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements."	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Separation of mosquito adulticide	Create separate mosquito adulticide use, federal, and state programs labels so they are not part of other labels per PRN 2005-1.	Sublabel

use, and state and federal programs into sublabels from other uses		
For all liquid formulations; for mixers and loaders	"Removable chemical extraction probes (also known as "stingers") used in suction/extraction systems must be rinsed within the pesticide container prior to removal."	Directions for Use
Label Clarification for Cotton	The minimum application retreatment interval for non-Boll Weevil Eradication Program (BWEP) cotton is 7 days. For the BWEP use on cotton, the minimum application retreatment interval for cotton is 3 days.	Directions for Use, Specific Use Directions
Restriction for Rice Use	"A 96-hour holding time is required before floodwaters may be released after treatment to rice."	Directions for Use for Rice
Directions for mixing/loading products packaged in water soluble bags	Instructions for Introducing Water Soluble Packages Directly into Spray tanks: "Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 C.F.R. 170.607(d)]. Handling Instructions Follow these steps when handling pesticide products in WSPs. 1. Mix in spray tank only. 2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 3. Keep the WSP in outer packaging until just before use. 4. Keep the WSP dry prior to adding to the spray tank. 5. Handle with dry gloves and according to the label instructions for PPE. 6. Keep the WSP intact. Do not cut or puncture the WSP. 7. Reseal the WSP outer packaging to protect any unused WSP(s). Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions.	Directions for Use

	1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 3. Stop adding water and stop any agitation. 4. Place intact/unopened WSP into the tank. 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP. 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label." For Toxicity Category I and II products: "ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down." For Toxicity Category III and IV products: "ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in	

	intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."	
Spray Drift Management Application Restrictions for products that are applied as liquid with boomless ground sprayer equipment	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Boomless Ground Applications:** • Do not apply when wind speeds exceed 10 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Boomless Applications"
Advisory Spray Drift Management Language for all products applied as liquid spray (except Ultra Low Volume/ULV applications for mosquitocides)	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. Be aware of nearby Non-Target sites and environmental conditions. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. Controlling Droplet Size – Ground Boom (note to registrants: remove if ground boom is prohibited on product labels) • Volume – Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure – Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle – Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. Controlling Droplet Size – Aircraft (note to registrants: remove if aerial application is prohibited on product labels) • Adjust Nozzles – Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom (note to registrants: remove if ground boom is prohibited on product labels)**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

	For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT – Aircraft (note to registrants: remove if aerial application is prohibited on product labels)** Higher release heights increase the potential for spray drift. **HOODED (OR SHIELDED) SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using hooded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift. **MEASURING WIND SPEED AND WIND DIRECTION** **Best Management Practices for measuring wind speed and direction of wind:** • Applicators should check and acquire the predicted wind speed and direction for the application site within 12 hours prior to conducting applications to determine the time periods wind speed is likely to fall outside the applicable thresholds.	

	• Applicators should reassess wind speed and direction at the application site every 15 minutes while applications are in progress.
	• Measuring wind speed and direction can be done by:
	  ○ Relying on equipment on the application equipment that measures wind speed (e.g., aerial equipment).
	  ○ Using a tower anemometer with telemetry or handheld anemometer. Users should read user manual on how to calibrate, operate and interpret the output from an anemometer. Ground applicators should stop every 15 minutes to take a reading with a tower anemometer with telemetry or handheld anemometer. Some anemometers may have software that would allow users to view wind measurements in real time while making an application, and, those cases, applicators would not have to stop to take measurements.
	  ○ Using a windsock. Wind can be estimated with a windsock using the strips on a windsock. The applicator should consult the user manual for the windsock on wind speed estimation and direction of wind. Applicators should look at the sock at least every 15 minutes to estimate wind speed and direction. [If there is a conservation area or aquatic habitat, buffer, include "The windsock should be pointed in the opposite direction of the windbreak and [CONSERVATION AREA/AQUATIC HABITAT]"].
	  ○ Using an aircraft smoke system. Laying down several puffs of smoke along different lines using an aircraft smoke system can provide an accurate view of what the wind speed and direction for the application.
	Checking behind the spray rig at least every 15 minutes to see if the spray has changed direction from when the application started."	

Advisory Spray Drift Management Language for products that are applied as liquid with boomless ground sprayer equipment	**"SPRAY DRIFT ADVISORIES** **Boomless Ground Applications:** Setting nozzles at the lowest effective height will help to reduce the potential for spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Advisory Spray Drift Management Language for products that are applied as liquid with handheld equipment	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Appendix C: Listed-Species Assessment

This Appendix provides general background about the Agency's assessment of the effects of pesticides on listed species and designated critical habitats under the Endangered Species Act (ESA). Additional background specific to malathion appears at the conclusion of this Appendix.

Developing Approaches for ESA Assessments and Consultation for FIFRA Actions

In 2015, EPA, along with the Services—the U.S. FWS and the NMFS—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[35] for assessing the effects of pesticides to listed species. The agencies jointly developed these Interim Approaches in response to the 2013 National Academy of Sciences' recommendations that discussed specific scientific and technical issues related to the development of assessments of pesticides' effects to listed species. Since that time, the agencies have been continuing to work to improve the approaches for assessing effects to listed species. After receiving input from the Services and USDA on proposed revisions to the interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* ("Revised Method") in March 2020.[36]

The agencies also continue to work collaboratively through a FIFRA Interagency Working Group (IWG). The IWG was created under the 2018 Farm Bill to recommend improvements to the ESA section 7 consultation process for FIFRA actions and to increase opportunities for stakeholder input. This group is led by EPA and includes representatives from NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). The IWG outlines its recommendations and progress on implementing those recommendations in reports to Congress.[37]

Consultation on Chemicals in Registration Review

EPA initially conducted biological evaluations (BEs) using the interim method on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned as the start of an iterative process. Later that year, NMFS issued a final BiOp for these three pesticides. In 2019, EPA requested to reinitiate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 BiOp. FWS and NMFS published their BiOps in February and June 2022, respectively. The label implementation required by both BiOps was completed

[35] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report.
[36] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional.
[37] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act.

in August 2023. Bulletins required by the FWS and NMFS BiOps were completed in August 2023 and April 2024, respectively.

Appendix D: Endocrine Disruptor Screening Program

The Federal Food Drug and Cosmetic Act (FFDCA) § 408(p) requires EPA to develop a screening program to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." (21 U.S.C. 346a(p)). In carrying out the Endocrine Disruptor Screening Program (EDSP), FFDCA section 408(p)(3) requires that EPA "provide for the testing of all pesticide chemicals," which includes "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including all active and pesticide inert ingredients of such pesticide." (21 U.S.C. 231(q)(1) and 346a(p)(3)). However, FFDCA section 408(p)(4) authorizes EPA to, by order, exempt a substance from the EDSP if the EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." (21 U.S.C. 346a(p)(4)).

The EDSP initiatives developed by EPA in 1998 includes human and wildlife testing for estrogen, androgen, and thyroid pathway activity and employs a two-tiered approach. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid pathways. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any estrogen, androgen, or thyroid effect. If EPA finds, based on that data, that the pesticide has an adverse endocrine-related effect on humans, FFDCA § 408(p)(6) also requires EPA, "…as appropriate, [to] take action under such statutory authority as is available to the Administrator … as is necessary to ensure the protection of public health." (21 U.S.C. 346a(p)(6)).[38]

Between October 2009 and February 2010, EPA issued Tier 1 test orders/data call-ins (DCIs) for its first list of chemicals ("List 1 chemicals") for EDSP screening and subsequently required submission of EDSP Tier 1 data for a refined list of these chemicals. EPA received data for 52 List 1 chemicals (50 pesticide active ingredients and 2 inert ingredients). EPA scientists performed weight-of-evidence (WoE) analyses of the submitted EDSP Tier 1 data and other scientifically relevant information (OSRI) for potential interaction with the estrogen, androgen, and/or thyroid signaling pathways for humans and wildlife. [39]

In addition, for FIFRA registration, registration review, and tolerance-related purposes, EPA collects and reviews numerous studies to assess potential adverse outcomes, including potential outcomes to endocrine systems, from exposure to pesticide active ingredients. Although EPA has been collecting and reviewing such data, EPA has not been explicit about how its review of required and submitted data for these purposes also informs EPA's obligations and

[38] For additional details of the EDSP, please visit https://www.epa.gov/endocrine-disruption.
[39] Summarized in *Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions*; EPA-HQ-OPP-2023-0474-0001; https://www.regulations.gov/document/EPA-HQ-OPP-2023-0474-0001

commitments under FFDCA section 408(p). Consequently, on October 27, 2023, EPA issued a Federal Register Notice (FRN) providing clarity on the applicability of these data to FFDCA section 408(p) requirements and near-term strategies for EPA to further its compliance with FFDCA section 408(p). This FRN, entitled *Endocrine Disruptor Screening Program (EDSP): Near-Term Strategies for Implementation' Notice of Availability and Request for Comment* (88 FR 73841) is referred to here as EPA's EDSP Strategies Notice. EPA also published three documents supporting the strategies described in the Notice:

- *Use of Existing Mammalian Data to Address Data Needs and Decisions for Endocrine Disruptor Screening Program (EDSP) for Humans under FFDCA Section 408(p);*
- *List of Conventional Registration Review Chemicals for Which an FFDCA Section 408(p)(6) Determination is Needed; and,*
- *Status of Endocrine Disruptor Screening Program (EDSP) List 1 Screening Conclusions* (referred to here as List 1 Screening Conclusions).

The EDSP Strategies Notice and the support documents are available on www.regulations.gov in docket number EPA-HQ-OPP-2023-0474. As explained in these documents, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans, focusing first on conventional active ingredients. Although EPA voluntarily expanded the scope of the EDSP to screening for potential impacts to the estrogen, androgen, and thyroid systems in wildlife, EPA announced that it is not addressing this discretionary component of the EDSP at this time, considering its current focus on a comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan[40] and November 2022 ESA Workplan Update[41]). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE[42] memoranda indicate that available data were sufficient for FFDCA section 408(p) assessment and review for potential effects to the estrogen, androgen, or thyroid pathways for wildlife. For the remaining 17 List 1 chemicals, Tier 1 WoE memoranda made recommendations for additional testing. EPA expects to further address these issues taking into account additional work being done in concert with researchers within the EPA's Office of Research and Development (ORD).

As discussed in EPA's EDSP Strategies Notice and supporting documents, EPA will be using all available data to determine whether additional data are needed to meet EPA's obligations and discretionary commitments under FFDCA section 408(p). For some conventional pesticide active ingredients, the toxicological databases may already provide sufficient evaluation of the chemical's potential to interact with estrogen, androgen, and/or thyroid pathways and EPA will generally not need to obtain any additional data to reevaluate those pathways, if in registration review, or to provide an initial evaluation for new active ingredient applications. For instance,

[40] https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf
[41] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf
[42] https://www.epa.gov/endocrine-disruption/endocrine-disruptor-screening-program-tier-1-screening-determinations-and

EPA has endocrine-related data for numerous conventional pesticide active ingredients through either an acceptable two-generation reproduction toxicity study performed in accordance with the current guideline (referred to here as the updated two-generation reproduction study; OCSPP 870.3800 - Reproduction and Fertility Effects) or an extended one-generation reproductive toxicity (EOGRT) study (OECD Test Guideline 443 - Extended One-Generation Reproductive Toxicity Study). In these cases, EPA expects to make FFDCA 408(p)(6) decisions for humans without seeking further estrogen or androgen data. However, as also explained in the EPA's EDSP Strategies Notice, where these data do not exist, EPA will reevaluate the available data for the conventional active ingredient during registration review to determine what additional data, if any, might be needed to confirm EPA's assessment of the potential for impacts to estrogen, androgen, and/or thyroid pathways in humans. For more details on EPA's approach for assessing these endpoints, see EPA's EDSP Strategies Notice and related support documents.

Also described in the EPA's EDSP Strategies Notice is a framework that represents an initial approach by EPA to organize and prioritize the large number of conventional pesticides in registration review. For conventional pesticides with a two-generation reproduction toxicity study performed under a previous guideline (i.e., an updated two-generation reproduction toxicity study or an EOGRT are not available), EPA has used data from the Estrogen Receptor Pathway and/or Androgen Receptor Pathway Models to identify a group of chemicals with the highest priority for potential data collection (described in EPA's EDSP Strategies Notice as Group 1 active ingredients). For these cases, although EPA has not reevaluated the existing endocrine-related data, EPA has sought additional data and information in response to issuance of EPA's EDSP Strategies Notice to better understand the positive findings in the ToxCast™ data for the Pathway Models and committed to issuing DCIs to require additional EDSP Tier 1 data to confirm the sufficiency of data to support EPA's assessment of potential adverse effects to the estrogen, androgen, and/or thyroid pathways in humans and to inform FFDCA 408(p) data decisions. For the remaining conventional pesticides (described in EPA's EDSP Strategies Notice as Group 2 and 3 conventional active ingredients), EPA committed to assessing the available data to determine what additional studies, if any, might be needed to confirm EPA's assessment of the potential for impacts to endocrine pathways in humans.

Malathion is on List 1. In 2015, EPA published the Tier 1 WoE analyses for malathion and that evaluation determined that no further data to assess the potential for impacts on the estrogen, androgen, or thyroid pathways are needed for humans or wildlife.[43] There was no evidence of interaction with the estrogen, androgen, or thyroid hormone pathways for malathion. Based on that evaluation, EPA has concluded at this time that the points of departure for human health risk assessment to evaluate the EPA-registered uses and established tolerances of malathion are protective of potential estrogen, androgen, and thyroid effects in humans. Therefore, EPA has completed its FFDCA section 408(p)(6)-related commitments and obligations "to ensure the

[43] See https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0027 on the EPA-HQ-OPP-2009-0317 malathion docket.

protection of public health" at this time. For additional information, please see the List 1 Screening Conclusions.