Chlorothalonil

Proposed Interim Registration Review Decision
Case Number 0097

September 2023

Approved by: _____

Mary Elissa Reaves, Ph.D.
Director
Pesticide Re-evaluation Division

Date: 09/29/2023

Approved by: _____

Anita Pease
Director
Antimicrobials Division

Date: 09/29/2023

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for chlorothalonil (PC Code 081901, case 0097). During registration review under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard.[1]

FIFRA[2] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program. EPA was tasked with reviewing each registered pesticide every 15 years.[3] Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

Where appropriate, the Agency may issue an interim registration review decision (ID) before completing a final registration review decision.[4] However, issuance of an ID is not a decision on whether a pesticide's registrations continue to satisfy the FIFRA standard for registration.[5] Rather, the ID may determine, among other things, that new risk mitigation measures are necessary, lay out interim risk mitigation measures, 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.[6]

The Agency is issuing a PID for chlorothalonil to identify proposed interim risk mitigation (see Appendices A, B, C, and E). EPA has not yet fully evaluated chlorothalonil's risks to federally listed species. However, consistent with its obligations under the Endangered Species Act (ESA)[7], EPA expects to complete effects determinations and any necessary consultation with the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS)

---

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[3] Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022) extended the deadline for initial registration review, which includes chlorothalonil, until Oct. 1, 2026.
[4] 40 C.F.R. §§ 155.56, 155.58.
[5] At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration." 40 C.F.R. §§ 155.40(a), 155.57; FIFRA § 3(g), 7 U.S.C. § 136a(g); *see also* FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5) (FIFRA registration standard); FIFRA § 2(bb), 7 U.S.C. § 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]").
[6] 40 C.F.R. § 155.56.
[7] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.

(collectively, the Services) before completing the chlorothalonil registration review and issuing a final registration review decision. For more information on the listed-species assessment for the chlorothalonil registration review, see Appendix D.

EPA continues to work with the Services to improve the consultation process for pesticides in registration review. In April 2022, EPA released its ESA Workplan, which outlines strategies and actions for the Agency to meet its ESA obligations for FIFRA actions.[8] Consistent with the ESA Workplan, EPA is focused on steps it will take during registration review to reduce exposure for listed species as it moves toward fulfilling its ESA obligations and making final registration review decisions. In November 2022, EPA released its first ESA Workplan Update.[9] As part of this update, EPA announced that, going forward, EPA may include a variety of FIFRA Interim Ecological Mitigation (IEM) measures in its registration review decisions that seek to reduce exposures for nontarget organisms based on its FIFRA ecological risk assessment(s). EPA expects that this mitigation may also reduce pesticide exposures for listed species.

As part of this PID, EPA has considered a variety of FIFRA IEM measures based on the risks and benefits of chlorothalonil to reduce exposures to nontarget organisms, including listed species, while the Agency works toward a final registration review decision. While these mitigation measures do not satisfy EPA's ESA obligations, EPA believes that early mitigation may improve protections for listed species from currently registered pesticide products. The FIFRA IEM measures that EPA is proposing for chlorothalonil are discussed in Section IV of this document. EPA intends these proposed measures would also fulfill EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Among other things, Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the *Federal Register* between December 29, 2022 and October 1, 2026 for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]."

Before completing registration review, EPA will also address its obligations for chlorothalonil under the endocrine disruptor screening program at section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA). For more information on the endocrine disruptor screening for the chlorothalonil registration review, see Appendix F.

Chlorothalonil is a fungicide active ingredient (a.i.) with end-use products registered for use on numerous conventional and antimicrobial sites. Registered conventional use sites include both food (including potatoes, peanuts, tomatoes, herbs, berries, wheat, and fruit and nut trees) and non-food (including residential and non-residential turf, sod, golf courses, ornamental plants and shrubs, and Christmas trees) use sites. Registered antimicrobial use sites include building products, adhesives, concrete blocks and surfaces, paints, plaster, metals, and lumber. Chlorothalonil was first registered in 1966, and there are currently approximately 150 actively

[8] *Balancing Wildlife Protections and Responsible Pesticide Use* (Apr. 2022), https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf

[9] *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions* (Nov. 2022), https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

registered products containing chlorothalonil. Chlorothalonil end-use products come in a variety of physical forms, such as ready-to-use solutions, soluble, emulsifiable, and flowable concentrates, impregnated materials, water-dispersable granules, and granules. They are applied using aircraft, groundbooms, airblast sprayers, and handheld equipment, among other methods. There are 13 registrants of technical grade chlorothalonil products: Adama Makhteshim Ltd., AMVAC Chemical Corporation, Argite, LLC, CAC Chemical Americas LLC, Drexel Chemical Company, IBC Manufacturing Co, Koppers Performance Chemicals, Inc., Lanxess Corporation, Sipcam Agro Usa, Inc, Syngenta Crop Protection, LLC, Troy Chemical Corporation, Troy Technology II, and UPL Delaware, Inc. Technical grade products are used to formulate end-use products. Chlorothalonil was subject to reregistration and the Reregistration Eligibility Decision (RED) was signed in 1999.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how chlorothalonil can legally be used and where chlorothalonil is actually 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, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete registration review).

A. Summary of Chlorothalonil Registration Review

On March 28, 2012, the Agency formally initiated registration review for chlorothalonil with the opening of the registration review docket (EPA-HQ-OPP-2011-0840) for the case.[10] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of chlorothalonil:

- March 2012 – EPA posted the *Chlorothalonil Summary Document for Registration Review: Initial Docket*, which included the Preliminary Work Plan (PWP) (March 22, 2012); *Chlorothalonil. Human-Health Assessment Scoping Document in Support of Registration Review* (March 14, 2012); and *Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment and Drinking Water Exposure Assessment of Chlorothalonil* (March 22, 2012) to the chlorothalonil public docket for a 60-day public comment period. Additionally, EPA posted the following documents to the chlorothalonil docket:
    - *PRD Appendix A: Food/Feed & Non-Food/Non-Feed Uses Considered in Registration Review Work Planning*
    - *BEAD Chemical Profile for Registration Review: Chlorothalonil (PC #081901)*
    - *Chlorothalonil (081901) California DPR Usage Data*
    - *Chlorothalonil (081901) Screening Level Usage Analysis (SLUA)*

[10] 40 C.F.R. § 155.50.

  - *Summary of Registered Antimicrobial Uses of Chlorothalonil in Support of the Registration Review Summary Document (Case 0097, PC Code 081901)*

- September 2012 – EPA posted the *Chlorothalonil Registration Review Final Work Plan* (FWP) (September 19, 2012) to the chlorothalonil public docket. The Agency received 11 comments on the PWP. Comments were submitted by several concerned citizens, several California water quality control groups, the California Rural Legal Assistance Foundation (CRLAF), FIFRA Endangered Species Task Force, Pesticide Action Network of North America (PANNA), as well as two registrants, Sipcam Agro USA, and Syngenta Crop Protection. The comments did not address the timeline described in the PWP, but they did address the planned ecological and human health risk assessments and data requirements, as well as general concern over the effects of chlorothalonil. In the FWP, EPA noted additional data were needed for the chlorothalonil registration review of conventional and antimicrobial uses, including several ecological studies. Additionally, EPA posted the following documents to the chlorothalonil docket:
  - *Chlorothalonil: Response to Comments on the Human Health Assessment Scoping Document and Preliminary Workplace.*
  - *Chlorothalonil Registration Review Problem Formulation—Office of Pesticide Program's Response to Public Comments*
  - *Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment*

- March 2013 – EPA issued a generic data call-in (GDCI) for chlorothalonil to obtain data needed to conduct the registration review risk assessments (DCI GDCI-081901-1301). The registrants submitted all required data except a soil column leaching study (GLN 835.1240). Accordingly, all data requirements have not been satisfied. For more information, see Sections III.A.4 and III.B.3.

- July 2013 – EPA posted *Chlorothalonil-Environmental Fate and Effects Division's Response to Public Comments on the Registration Review Problem Formulation* to the chlorothalonil public docket.

- June 2015 – The Agency completed its weight of evidence review of the Tier I assays required under the Endocrine Disruptor Screening Program (EDSP)[11]. No further data for human estrogen, androgen, and thyroid endpoints were recommended. An additional EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) study was recommended for chlorothalonil.

- May 2021 – EPA posted *Chlorothalonil: Revised Human Health Draft Risk Assessment for Registration Review* (2021 HH DRA) and *Chlorothalonil: Draft Ecological Risk Assessment for Registration Review* (2020 Eco DRA) for a 60-day public comment period, which was extended by an additional 60 days. The Agency received 42 comments from 35 commenters. The Agency has summarized and responded to these comments in Section I.B., below. The comments did change the risk assessments and registration

[11] Available in EPA's public docket: https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0028

review timeline for chlorothalonil. The comments and new data submitted lead to a re-evaluation of the existing toxicity database, which ultimately impacted dietary risk conclusions. For details of these changes, see Sections I.B. and III.A. of this document. Additionally, EPA posted the following documents to the public docket:

- *Chlorothalonil: Human Health Draft Risk Assessment for Registration Review.*
- *Chlorothalonil. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Risk Assessment.*
- *Chlorothalonil. Occupational and Residential Exposure Assessment for Registration Review*
- *Chlorothalonil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment*
- *Chlorothalonil Drinking Water Assessment for Registration Review*
- *Chlorothalonil Preliminary Evaluation of the Potential Exposure from Volatilization*
- *Registration Review Draft Risk Assessment (DRA) for the Antimicrobial Uses of Chlorothalonil*

- September 2023 – EPA completed the PID for chlorothalonil 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 chlorothalonil public docket:
  - Chlorothalonil: Response to Comments on the Draft Human Health Risk Assessment for Registration Review, and Risk Assessment Addendum to Include Updated Dietary Risk Estimates (September 27, 2023)
  - Chlorothalonil. Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Risk Assessment (September 27, 2023)
  - Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment (September 27, 2023)
  - 2020 Chlorothalonil (081901) Screening Level Usage Analysis (SLUA) (October 21, 2020)
  - Response to Public Comments on the Chlorothalonil Draft Risk Assessment for Antimicrobial Uses (September 29, 2023)
  - Chlorothalonil (PC Code 081901) Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites (September 29, 2023)
  - Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals (September 14, 2023)

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

In response to requests from conventional and antimicrobial registrants and stakeholders, EPA extended the public comment period for an additional 60 days. During the 120-day public-comment period (May 21, 2021 to September 20, 2021), the Agency received comments on the conventional and antimicrobial uses of chlorothalonil.

1. Comments on Chlorothalonil's Conventional Uses

The Agency received 42 public comments on the conventional uses of chlorothalonil, including comments from the following entities:

- the conventional technical registrants Syngenta Crop Protection, LLC (Syngenta) and Makhteshim Agan of North America, Inc. (d/b/a ADAMA) and Control Solutions, Inc. submitted comments on the conventional draft risk assessments;

- the IR-4 Project, Northwest Horticultural Council, California Specialty Crop Council, Washington State Potato Commission, AmericanHort, Arizona Pest Management Center, Austin Hagan, Dan Anco, Arizona Farm Bureau Federation, Dr. Lina Quesada-Ocampo (North Carolina State University), Erik Guinter, John Cates (Addis Cates Company), Greg Bird (Michigan Vegetable Council), Florida Fruit and Vegetable Association (FFVA), Ginseng Board of Wisconsin, Mt. Olive Pickle Company, Dr. Pamela D. Roberts (University of Florida IFAS Southwest Florida Research and Education Center), Makhteshim Agan of North America, Inc. (d/b/a ADAMA) and Control Solutions, Inc. (CSI), National Potato Council, Golf Course Superintendents Association of America, the United States Department of Agriculture Office of Pest Management Policy (USDA OPMP), and the American Sugarbeet Growers Association submitted comments on the benefits and usage of chlorothalonil;

- the People for the Ethical Treatment of Animals (PETA), Physicians Committee for Responsible Medicine, Syngenta, USDA OPMP, Humane Society of the United States (HSUS), and Humane Society Legislative Fund (HSLF) submitted comments on the new approach methodology (NAM) for the inhalation assessment;

- Syngenta, USDA OPMP, FFVA, and National Potato Council submitted comments on tolerance harmonization;

- the Environmental Working Group (EWG) submitted a comment on the risk assessments and the European Union's chlorothalonil ban;

- the Center for Biological Diversity (CBD) submitted a comment addressing pollinator data, risks to invertebrates, impacts on soil health, pesticide mixtures, and ESA;

- Dr. Quesado-Ocampo (North Carolina State University), John Cates (Addis Cates Company), and Mt. Olive Pickle Company submitted comments about the restricted entry interval (REI);

- the National Agricultural Aviation Association (NAAA) submitted a comment on AgDRIFT; and

- California Stormwater Quality Association (CASQA) commented on the ecological and drinking water risks.

Substantive comments, comments of a broader regulatory nature, and the Agency's responses to those comments are summarized below. The Agency thanks all commenters for participating and has considered all comments in developing this PID. The Agency encourages future comments that specifically address the risk mitigation measures proposed herein.

Comment Submitted by Syngenta Crop Protection, LLC (EPA-HQ-OPP-2011-0840-0123)
Comment: Syngenta submitted comments on the 2021 HH DRA and the 2020 Eco DRA, which includes the 2020 Drinking Water Assessment (DWA). Regarding the 2021 HH DRA, Syngenta provided comments on the adjustment factors in the Dietary Exposure Evaluation Model (DEEM) model, the use of personal protective equipment (PPE) in the residential use scenario, and the toxicity of chlorothalonil metabolites and degradates. For the 2021 HH DRA and 2020 DWA, Syngenta provided additional data on the residues of concern/chlorothalonil metabolites. These data address the toxicological relevance of metabolites/degradates, leading Syngenta to suggest removing two degradates (R417888 and R613636) from the residues of concern for drinking water. Syngenta also commented on the modeling approach for estimating chlorothalonil and its major metabolite SDS-3701 in drinking water. For the 2020 Eco DRA and DWA, Syngenta noted EPA's publication *Analysis of Subsurface Metabolism in Groundwater Modeling* and updated groundwater concentrations with 2-meter subsurface degradation and asked the Agency to consider this as a possible refinement to the DWA. Additionally, Syngenta commented on the need for additional characterization for groundwater monitoring data as well as the availability of targeted monitoring studies. For the 2020 Eco DRA, Syngenta commented on aquatic toxicity and the avian chronic reproduction endpoints as well as the risk estimates for mammals and birds. Syngenta also commented on a few inconsistencies between the text and tables and several editorial errors in the ecological risk assessment.

EPA Response: The Agency's detailed responses to these concerns can be found in the memoranda *Chlorothalonil: Response to Comments on the Draft Human Health Risk Assessment for Registration Review and Risk Assessment Addendum to Include Updated Dietary Risk Estimates* (September 27, 2023) and *Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment* (September 27, 2023) issuing simultaneously with this PID.

For the 2021 HH DRA and the 2020 DWA, the Agency reviewed both the new and existing toxicity databases and concluded that the data do not support changes to the residues of concern for drinking water. The registrant submitted a 90-day oral rat study for the R611965 degradate (used to assess the R613636 degradate), which was reviewed for relative toxicity comparison, but this compound was not included as a residue of concern in the previous risk assessment because it does not have an intact cyano group. Degradates with an intact cyano group are considered to have toxicity profiles similar to that of chlorothalonil on the basis of the structural similarities. EPA re-evaluated two 90-day oral toxicity studies in rats for chlorothalonil and updated data evaluation records (DERs) for those studies. Based on the updates to the 90-day studies for chlorothalonil and the review of the studies submitted by the registrant, there is no clear difference, including R417888, in relative toxicity between chlorothalonil and the metabolites/degradates. Additionally, EPA reviewed the existing toxicity database of the SDS-3701 metabolite and selected an acute dietary endpoint for SDS-3701 specific to females 13-49

years of age. The acute dietary risk assessment for SDS-3701, and chronic dietary risk assessment for chlorothalonil were updated to reflect this new acute endpoint and changes to estimated drinking water concentrations (EDWCs) with the updated version of DEEM (*Chlorothalonil. Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Risk Assessment.* G. Kramer, September 27, 2023). The new EDWCs modeled with 2-meter subsurface degradation (as described in the *Analysis of Subsurface Metabolism in Groundwater Modeling*) replaced the EDWCs previously reported in the 2020 DWA. For the 2020 Eco DRA, EPA appreciates Syngenta's comments on endpoint selection and reviewed the selections, which did not result in any changes to the overall risk conclusions. Additionally, the monitoring data noted by Syngenta could not be used quantitatively but rather was used in a weight-of-evidence analysis and additional characterization to assess groundwater concentrations. While the targeted monitoring studies are informative, they do not provide enough data temporally or spatially to allow EPA to use the data in place of modeling.

Regarding the use of PPE in the residential use scenario, EPA conducted the residential exposure assessment assuming that the residential handler was not wearing any PPE.

Comment Submitted by the United States Department of Agriculture (USDA; EPA-HQ-OPP-2011-0840-0125)

Comment: USDA submitted comments on the 2021 HH DRA and the 2020 Eco DRA and DWA. USDA also provided information on the uses and benefits of chlorothalonil for ornamentals, potatoes, peanuts, cranberries, and forestry. For the 2020 Eco DRA, USDA commented on the use of a 35-day foliar dissipation half-life for SDS-3701 as opposed to a reported mean foliar dissipation half-life for chlorothalonil of 5.02 days. USDA noted that modeled maximum labeled application rates were higher than average application rates as reported by USDA National Agricultural Statistics Service (NASS). Furthermore, assumptions in the Pesticide in Flooded Agriculture Model (PFAM), which estimates concentrations in water based on the use of a pesticide applied continually year after year, are inconsistent with cranberry disease resistance management practices.

For the 2020 DWA, USDA also noted updated groundwater concentrations with 2-meter subsurface degradation and soil organic matter and use refinements for in-field and container ornamental production, flower bed, and turf use sites. USDA provided rate information for ornamental and potato uses, which differed from the modeled rates in chronic dietary exposure via drinking water. USDA also proposed mitigation measures such as well setbacks for EPA's consideration for vulnerable soils.

EPA Response: EPA appreciates the comments to the draft human health and ecological risk assessments. The Agency's detailed responses to these concerns can be found in the memoranda *Chlorothalonil: Response to Comments on the Draft Human Health Risk Assessment for Registration Review* (September 27, 2023) and *Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment* (September 27, 2023) issuing simultaneously with this PID.

For the 2020 Eco DRA, EPA maintained the foliar dissipation half-life of 35 days for SDS-3701 in the TREX model of exposure to birds and mammals. For applications to cranberries, EPA acknowledges that PFAM-estimated exposures are conservative for modeling annual applications and EPA does not have a validated conceptual model for a receiving water body. For estimation of chlorothalonil concentrations in ground water, EPA updated the depth of metabolism from 1-meter to 2-meters in PRZM-GW, and the new EDWCs modeled with 2-meter subsurface degradation replaced the previously reported EDWCs in the 2020 DWA. The refined concentrations were incorporated into the 2023 Revised Dietary Assessment, which is summarized in Section III.A. and available in the public docket (*Chlorothalonil. Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Risk Assessment*).

EPA thanks USDA and its university and extension partners for their insight to the usage and benefits of chlorothalonil products. EPA has considered the information provided in USDA's comment such as typical rates, number of applications, and general usage information when developing the proposed mitigation. EPA encourages comments to provide additional feedback on this PID, particularly regarding the rate reductions and regional- and soil-specific mitigation proposed.

Comments Submitted by IR-4 Project (EPA-HQ-OPP-2011-0840-0089), Northwest Horticultural Council (EPA-HQ-OPP-2011-0840-0090), California Specialty Crop Council (EPA-HQ-OPP-2011-0840-0091), Washington State Potato Commission (EPA-HQ-OPP-2011-0840-0092 and -0099), AmericanHort (EPA-HQ-OPP-2011-0840-0094), Arizona Pest Management Center (EPA-HQ-OPP-2011-0840-0095), Austin Hagan (EPA-HQ-OPP-2011-0840-0096), Dan Anco (EPA-HQ-OPP-2011-0840-0097), Arizona Farm Bureau Federation (EPA-HQ-OPP-2011-0840-0100), Dr. Lina Quesada-Ocampo (North Carolina State University; EPA-HQ-OPP-2011-0840-0101), Erik Guinter (EPA-HQ-OPP-2011-0840-0108), John Cates (Addis Cates Company; EPA-HQ-OPP-2011-0840-0109), Greg Bird (Michigan Vegetable Council; EPA-HQ-OPP-2011-0840-0110), Florida Fruit and Vegetable Association (FFVA; EPA-HQ-OPP-2011-0840-0111), Ginseng Board of Wisconsin (EPA-HQ-OPP-2011-0840-0112), Mt. Olive Pickle Company (EPA-HQ-OPP-2011-0840-0113), Dr. Pamela D. Roberts (University of Florida IFAS Southwest Florida Research and Education Center; EPA-HQ-OPP-2011-0840-0118), Makhteshim Agan of North America, Inc. (d/b/a ADAMA) and Control Solutions, Inc (CSI) (EPA-HQ-OPP-2011-0840-0120), National Potato Council (EPA-HQ-OPP-2011-0840-0122), Golf Course Superintendents Association of America (EPA-HQ-OPP-2011-0840-0124), the United States Department of Agriculture Office of Pest Management Policy (USDA OPMP; EPA-HQ-OPP-2011-0840-0125), and the American Sugarbeet Growers Association (EPA-HQ-OPP-2011-0840-0128)

Comment: The comments provided information on the use, usage, and benefits of chlorothalonil. Benefits of chlorothalonil included the multisite activity of chlorothalonil and its importance for resistance management, the many use sites that use chlorothalonil and diseases controlled by chlorothalonil, its use in both preventative and curative application scenarios, and the option for tank mixes. The comments highlighted its safety record, long history of use, and cost effectiveness. Chlorothalonil is particularly important for farms in wet climates or during periods of high rainfall and moisture. The comments described the usage of chlorothalonil with

information on application frequency, single application rates, number of applications per year, tank mixes, and regional and climatic variations in use.

EPA Response: EPA thanks these commenters for their expertise and insight to the use, usage and benefits of chlorothalonil products. EPA has considered these comments as sources of reliable information to add to what the scientific and extension literature says about the pest management benefits provided by chlorothalonil. EPA has incorporated information from these comments pertinent to evaluating the disease management role of chlorothalonil into benefits assessments that were used to inform this PID. Benefits assessments will be issued simultaneously with this PID to the chlorothalonil docket (*Chlorothalonil (PC Code 081901) Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites (*September 29, 2023 *) Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals (September 14, 2023*). EPA appreciates commenters' descriptions of use along with frequency of applications and application rates. EPA encourages comments to provide additional feedback on this PID, particularly regarding the proposed rate reductions and regional- and soil-specific mitigation.

Comments submitted by the People for the Ethical Treatment of Animals (PETA; EPA-HQ-OPP-2011-0840-0087), United States Department of Agriculture (USDA; EPA-HQ-OPP-2011-0840-0125), Physicians Committee for Responsible Medicine (EPA-HQ-OPP-2011-0840-0129), Syngenta (EPA-HQ-OPP-2011-0840-0107, EPA-HQ-OPP-2011-0840-0123), Humane Society of the United States (HSUS; EPA-HQ-OPP-2011-0840-0119), and Humane Society Legislative Fund (HSLF; EPA-HQ-OPP-2011-0840-0119)

Comment: The commenters supported EPA's use of the NAM to refine the inhalation risk and use of non-animal technology for risk assessment.

EPA Response: EPA thanks the commenters for their feedback on and support of the NAM used to refine the inhalation risk for chlorothalonil. The NAM is further discussed in this document in Section III.A.

Comments submitted by Syngenta Crop Protection, LLC (EPA-HQ-OPP-2011-0840-0123), the United States Department of Agriculture Office of Pest Management Policy (USDA OPMP; EPA-HQ-OPP-2011-0840-0125), Florida Fruit and Vegetable Association (FFVA; EPA-HQ-OPP-2011-0840-0111), and National Potato Council (EPA-HQ-OPP-2011-0840-0122)

Comment: The commenters addressed tolerance actions and maximum residue limit (MRL) harmonization in the 2021 HH DRA. USDA OPMP commented on tolerance actions and MRL harmonization, generally supporting the EPA's proposals, but also recommending clarifications for the recommended tolerance levels for several commodities. USDA OPMP also requested that the agency consider harmonization for soybean, banana, and peach. Syngenta commented on tolerance levels for celery and potato requesting that the US tolerances be maintained for trade purposes. The National Potato Council also noted that harmonization on potato tolerances could create a potential trade barrier with Canada. FFVA expressed concerns about differences in MRLs/tolerances across countries and supports harmonization.

EPA Response: For tolerance actions and MRL harmonization, EPA listed established tolerances and recommended changes only to commodities summarized in the risk assessment tolerance revisions section (see Table 2.1.2 of the 2021 HH DRA). Regarding the potential for harmonization with Codex MRLs, EPA identified opportunities to harmonize existing U.S. tolerances with Codex MRLs where feasible. However, harmonization is not possible in some cases due to a difference in tolerance expression (*e.g.*, a difference in metabolites covered), a difference in commodity definition (*e.g.,* livestock meat versus livestock fat), or a difference in use pattern (*e.g.*, in season versus post-harvest). The Agency may identify tolerance actions that are necessary and appropriate during registration review, and those actions could include new tolerances or exemptions that are needed to cover residues or modifications, such as crop group updates or changes in tolerance levels, or revocations of existing tolerances or exemptions. Any petition to establish a new tolerance should be sent to the Registration Division Product Manager for chlorothalonil.

Comment Submitted by Dr. Quesado-Ocampo (North Carolina State University; EPA-HQ-OPP-2011-0840-0101), Addis Cates Company (EPA-HQ-OPP-2011-0840-0109), and Mt. Olive Pickle Company (EPA-HQ-OPP-2011-0840-0113)

Comment: The commenters requested EPA keep the current 12-hour restricted entry interval (REI) for cucurbit crops rather than increase the REI to 48 hours. The 48-hour REI would disrupt the hand-harvest timing for these crops, and chlorothalonil would not be usable for Downy mildew control.

EPA Response: EPA thanks the commenters for their feedback on increasing the REI for crop applications. The 48-hour REI is based on chlorothalonil's classification in the acute toxicity categories (Toxicity Category I for primary eye irritation). For all registrations subject to the Worker Protection Standard (WPS), labels must include an REI of at least 48 hours, unless labels include the Special Eye Irritation Provisions below, which would allow a lower REI of 12 hours on labels:

"Special Eye Irritation Provisions: This product is a severe eye irritant. Do not enter or allow workers to enter a treated area within 7 days of application, unless the following safety measures have been taken:

(1) At least one container designed specifically for flushing eyes must be available in operating condition at the WPS-required decontamination site intended for workers entering the treated area.

(2) Workers must be informed in a manner they can understand:

- that residues in the treated area may be highly irritating to their eyes,
- that they should take precautions, such as refraining from rubbing their eyes, to keep the residues out of their eyes,

- that if they do get residues in their eyes, they should immediately flush their eyes using the eye flush container that is located at the decontamination site or using other readily available clean water"

See the memorandum *Chlorothalonil: Response to Comments on the Draft Human Health Risk Assessment for Registration Review* (September 27, 2023) and Section III.A for the Agency's detailed response.

Comment Submitted by the Environmental Working Group (EWG; EPA-HQ-OPP-2011-0840-0121)

Comment: The EWG comment provided a rationale for prohibiting the use of chlorothalonil, including dietary exposure for sensitive groups, carcinogenic and endocrine-disrupting properties, inhalation toxicity, reduction of the FQPA children's health safety factor to 1X (including in connection with neurotoxic effects), incomplete assessment of chlorothalonil's breakdown products and drinking water contamination, and risks to terrestrial and aquatic taxa based on concentration estimates in the environment. The EWG also highlighted that the European Union did not reapprove chlorothalonil for registration with all uses of the fungicide ending in 2020, citing the potential for chlorothalonil breakdown products to cause DNA damage, which may be linked to increased cancer risk, and the capacity of both the parent and breakdown compounds to contaminate drinking water.

EPA Response: EPA thanks EWG for their comments. The Agency is proposing mitigation in this PID to address the risks of concern, in particular those due to exposure through drinking water. The 2021 HH DRA accounted for potential carcinogenic and endocrine-related properties of chlorothalonil. A NAM was developed and used to evaluate inhalation toxicity and yielded a refined inhalation risk assessment due to challenges and animal welfare concerns associated with conducting repeat dose testing for respiratory irritants like chlorothalonil. Several studies reported evidence of primary DNA damage or chromosomal aberrations *in vitro*. However, the same endpoints were evaluated for chlorothalonil *in vivo* and were negative for inducing DNA strand breaks (comet assay) and were also negative in the *in vivo* guideline micronucleus assay. *In vivo* studies in mammals are given more weight compared to in vitro studies, when determining if a chemical has genotoxic risk to humans. Therefore, EPA does not think there is convincing evidence in the recent literature to impact its current approach to evaluating carcinogenic risk from chlorothalonil. The chlorothalonil toxicology database is complete and there is no evidence of neurotoxicity. The Agency concluded that the default 10X FQPA SF can be reduced to 1X. The mitigation proposed in this PID is expected to address drinking water risks of concern as well as ecological risks of concern. EPA encourages comments to provide additional feedback on the mitigation proposed in this PID.

Comment Submitted by the Center for Biological Diversity (CBD; EPA-HQ-OPP-2011-0840-0114)

Comment: CBD's comment focused on EPA's duty to consult with the Services on the registration review of chlorothalonil in accordance with ESA. The CBD comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, considering additional real-world scenarios, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their

designated critical habitat. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, impacts on soil health, environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide. CBD also commented on EPA's exposure modeling and not accounting for spills or illegal uses of pesticides.

EPA Response: The 2020 Eco DRA addressed EPA's current understanding of the risks to terrestrial invertebrates, including pollinators, based on available data. EPA has acknowledged data gaps in this area and anticipates conducting a full pollinator assessment when data are available. Additionally, EPA is proposing updated pollinator advisory statements for chlorothalonil labels and welcomes comments on the mitigation proposals aimed at the ecological risks of concern. For more on the Agency's ecological risk assessments and approach to soil health, please see *Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment* (September 27, 2023) issuing simultaneously with this PID. Regarding misuse of pesticides, EPA evaluates risk based on label instructions. Additionally, EPA monitors incident reports, and these are summarized in Sections III.A.2 and III.B.

EPA has reviewed CBD's comments and will address many of the concerns regarding listed species as part of its ongoing collaborative work with the Services and USDA to improve the consultation process for listed species for pesticides in accordance with the ESA § 7. See Listed Species Assessment in Appendix D of this document for more information. EPA has not completed an assessment of potential effects to listed species or their designated critical habitat from current uses of chlorothalonil. However, consistent with the ESA Workplan Update, EPA is proposing several FIFRA Interim Ecological Measures for chlorothalonil, as detailed in Section IV. While these mitigation measures do not satisfy EPA's ESA obligations, EPA believes that early mitigation and including Bulletins Live Two (BLT) reference language may improve protections for listed species from currently registered pesticide products. EPA will address concerns specific to chlorothalonil particularly regarding pollinators, ESA, and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See Endocrine Disruptor Screening Program in Appendix F of this document for more information regarding endocrine disruption. EPA is currently developing an Agency policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, EPA released an interim process for public comment, available at www.regulations.gov in docket EPA-HQ-OPP-2017-0433. Once that policy has been finalized, EPA intends to consider its implications on the Agency's final decision for chlorothalonil.

Although EPA has not yet completed a nationwide listed species assessment for chlorothalonil, the Agency is in the process of implementing the 2011 *National Marine Fisheries Service Endangered Species Act Section 7 Consultation. Biological Opinion. Environmental Protection Agency Registration of Pesticides 2,4-D, Triclopyr BEE, Linuron, Captan, and Chlorothalonil* on the impacts of chlorothalonil on listed Pacific salmonids (2011 NMFS Salmonid BiOp; https://www3.epa.gov/pesticides/endanger/litstatus/final-4th-biop.pdf). For more information, see Sections III and IV of this document.

Comment Submitted by the National Agricultural Aviation Association (NAAA; EPA-HQ-OPP-2011-0840-0098)

Comment: The NAAA provided comments regarding the spray drift analysis conducted in the draft risk assessments, particularly concerning the spray drift model, AgDRIFT, the inputs used in the model (e.g., drift fraction, application rates, droplet sizes), and argued that the Tier 1 AgDRIFT model is overly conservative for assessing the risk of drift from aerial applications. NAAA recommended the use of a refined assessment with a higher tiered (Tier 3) model previously provided to the Office of Pesticide Programs in a June 2020 letter. NAAA recommended that a medium or larger droplet size be required for aerial applications on all chlorothalonil labels and that a medium droplet size be used in all risk assessments. NAAA also recommended that 150-foot buffers around marine/estuarine water bodies be wind directional, citing 2,4-D/Enlist labels with wind directional based buffer zones. Finally, NAAA proposed banning the use of human flaggers for aerial applications of chlorothalonil since most aerial applicators use a high-tech navigational GPS to ensure a targeted application.

EPA Response: The Agency acknowledges and thanks NAAA for their comments. AgDRIFT is the currently approved model for evaluating potential spray drift from a pesticide application. The Agency appreciates the additional suggestions provided by NAAA for revising the AgDRIFT modeling inputs and continues to work with industry to update and improve modeling methods to better reflect typical application practices. At the December 2020 Center of Excellence in Regulatory Science in Agriculture (CERSA) workshop, EPA, NAAA, and other stakeholders discussed these potential refinements for AgDRIFT modeling. However, modeling for a national-level assessment is first conducted using maximum application rates, while also considering limitations and instructions listed on chlorothalonil labels. In the absence of specific use directions and application restrictions implemented across all product labels, default assumptions (based on empirical data) are used. In this PID, EPA is proposing medium or coarser droplet sizes for any remaining conventional liquid spray applications and welcomes comments on the updated spray drift language.

EPA is proposing updated spray drift management language and wind directional buffers in the FIFRA IEM section of this PID.

According to a 2012 NAAA survey, human flaggers are used for aerial pesticide applications about 1% of the time. EPA did not identify risks of concern for human flaggers and the risk estimates for human flaggers are presented in the chlorothalonil HH DRA. The Agency welcomes comments that can provide additional information on human flaggers for aerial applications of chlorothalonil.

Comment Submitted by California Stormwater Quality Association (CASQA; EPA-HQ-OPP-2011-0840-0127)

Comment: CASQA commented on the 2020 Eco DRA, recommending that EPA use available Pesticide in Water Calculator (PWC) scenarios to model the common conventional outdoor urban uses of chlorothalonil prior to publishing a final risk assessment. CASQA requested that EPA develop a comprehensive program of mitigation to reduce the potential for negative impacts to aquatic organisms from non-agricultural uses of chlorothalonil. CASQA requested that EPA prioritize mitigation measures that reduce the transport of chlorothalonil to urban runoff.

EPA Response: EPA thanks CASQA for their comment. The Agency is proposing mitigation in this PID, such as rate reductions, buffers to all aquatic areas, and drift mitigation, to address risks of concern. The mitigation is expected to reduce the concentrations of chlorothalonil in urban run-off. EPA encourages comments to provide additional feedback on the mitigation proposed in this PID.

2. Comments on Chlorothalonil's Antimicrobial Uses

Comment Submitted by Lanxess Corporation (EPA-HQ-OPP-2011-0840-0116):
Comment: The registrant Lanxess Corporation indicated that their chlorothalonil product used in the papermaking process is only used on the dry-end and would not result in exposure or risks to aquatic taxa as indicated by the 2021 *Registration Review Draft Risk Assessment (DRA) for the Antimicrobial Uses of Chlorothalonil*.

EPA Response: The "dry-end" of the papermaking process deals with finished or semi-finished paper products. This is opposed to the "wet-end," where large amounts of water are used to create a papermaking slurry. As the registrant indicates, if chlorothalonil products are only applied in the dry-end of the papermaking process as a protective coating to finished materials, there would be minimal exposure to aquatic taxa. For this reason, the Agency is proposing a label amendment to clarify that chlorothalonil products may only be applied in the dry-end of the papermaking process. See "Proposed Risk Mitigation Measures for Antimicrobial Uses" for more details.

Comment Submitted by Sipcam Agro (EPA-HQ-OPP-2011-0840-0115)
Comment: The chlorothalonil registrant Sipcam Agro USA, Inc. commented that they agree with the human health risk findings of the 2021 *Registration Review Draft Risk Assessment (DRA) for the Antimicrobial Uses of Chlorothalonil*, including the finding that inhalation exposures to occupational handlers manufacturing preserved materials may result in risks of concern. The registrant suggested that this risk could be mitigated by using a PF10 respirator.

Similar to the public comment submitted by Lanxess Corporation, Sipcam Agro also shared that their products are only used in the dry-end of the papermaking process and explained how that use pattern would not result in exposures to aquatic organisms.

Finally, the registrant raised concerns over the conservative nature of the ecological assessment for exterior paints and coatings.

EPA Response: Although the Agency generally prefers engineering controls for reducing risk, PPE such as PF10 respirators also serves to reduce the exposure to occupational handlers and results in a passing margin of exposure (MOE). In this PID, the Agency is proposing to require that all personnel present during the application via open pour open of chlorothalonil products in the manufacture of preserved materials (e.g., paints, coatings, adhesives, paper products, etc.) must wear a PF-10 respirator.

The "dry-end" of the papermaking process deals with finished or semi-finished paper products. This is opposed to the "wet-end," where large amounts of water are used to create a papermaking slurry. As the registrant indicates, if chlorothalonil products are only applied in the dry-end of the papermaking process as a protective coating to finished materials, there would be minimal exposure to aquatic taxa. For this reason, the Agency is proposing a label amendment to clarify that chlorothalonil products may only be applied in the dry-end of the papermaking process. See section IV.A.4. *Proposed Risk Mitigation Measures for Antimicrobial Uses* for more details.

The portion of the comment related to exterior paints and coatings is similar in content to the comment submitted by IBC Manufacturing Company and has been addressed in the document *DP 463821 Response to Public Comments on the Chlorothalonil Draft Risk Assessment for Antimicrobial Uses*, which is being posted to the public docket simultaneously with this PID.

Comment Submitted by the United States Department of Agriculture (USDA; EPA-HQ-OPP-2011-0840-0125)

Comment: In addition to providing information on chlorothalonil's conventional uses, the comment from USDA also provided background on chlorothalonil's antimicrobial use as a treatment for wood products, including a history of chlorothalonil registrations and usage as well as various benefits of the active ingredient.

EPA Response: The Agency thanks USDA for providing this information regarding chlorothalonil's use, usage, and benefits in the forestry sector. This information was used in the benefits assessment for the antimicrobial uses of chlorothalonil, which can be found in Section III of this document.

Comment Submitted by California Stormwater Quality Association (CASQA) (EPA-HQ-OPP-2011-0840-0127)

Comment: CASQA expressed concerns about potential for risk to aquatic organisms resulting from the use of exterior paints and encouraged EPA to implement mitigation measures for those potential risks.

EPA Response: The Agency appreciates this feedback from CASQA. A more detailed comment summary and the Agency's response can be found in the document *Response to Public Comments on the Chlorothalonil Draft Risk Assessment for Antimicrobial Uses (DP 463821)*, which is being issued simultaneously with this PID.

Comment Submitted by IBC Manufacturing Company (EPA-HQ-OPP-2011-0840-0117)

Comment: The registrant IBC recommended the use of PF10 respirators to address inhalation risks of concern for paint manufacturers. IBC also raised concerns over the conservative nature of the ecological assessment for exterior paints and coatings.

EPA Response: As discussed in the response to the comment submitted by Sipcam Agro, the Agency is proposing to require PF10 respirators to address the inhalation risks of concern for preserved-materials manufacturers.

A more detailed comment summary and the Agency's response to concerns about the conservative nature of the exterior paint assessment can be found in the document *Response to Public Comments on the Chlorothalonil Draft Risk Assessment for antimicrobial uses (DP 463821)*, which is being issued simultaneously with this PID.

Comment Submitted by Koppers Performance Chemicals, Inc. (EPA-HQ-OPP-2011-0840-0126)

Comment: The chlorothalonil registrant Koppers Performance Chemicals, Inc. raised concerns about the assessment of chlorothalonil's wood treatment uses, including the application rates and leaching rates that were used in the human health and ecological portions of the antimicrobial assessment.

EPA Response: The Agency confirms that the application rates used in the risk assessment reflect rates that are found on product labels. Additionally, the Agency notes that though the leaching study used to assess human health and environmental risks resulting from the pressure treatment of wood was valid, the use rates used in the study are lower than the highest application rates found on product labels. A more detailed comment summary and the Agency's response can be found in the document *Response to Public Comments on the Chlorothalonil Draft Risk Assessment for antimicrobial uses (DP 463821)*, which is being issued simultaneously with this PID.

II. USE AND USAGE

A. Conventional Use and Usage

Chlorothalonil is registered for use on many fruit, vegetable, legume, and tree nut crops. Additional food uses include mint and mushrooms. Chlorothalonil is also registered for use on several crops grown for seed. Non-food uses include nursery and greenhouse grown ornamentals, Christmas trees, grasses grown for seed, and residential and non-residential grass and turf (including sod farms, athletic fields, and golf courses).

Chlorothalonil end-use products are formulated as emulsifiable, flowable, and soluble concentrates, water dispersible granules, granules, impregnated materials, and ready-to-use liquids. Products are registered with chlorothalonil as the single active ingredient as well as co-formulated with other fungicide active ingredients. Chlorothalonil products can be applied as a broadcast, banded, or directed application with ground equipment, aerial equipment, hand-held spray bottle, or by chemigation. Applications can also be made as a spray drench or dip treatment. Most registered sites allow for multiple applications of chlorothalonil per year and are restricted by an annual maximum application rate (for more details on current labeled rates, see the docketed memos listed below).

Nationally, surveys of agricultural sites reported an average annual application of approximately 8.7 million lbs a.i. applied to approximately 7.9 million total acres treated (TAT) between 2016

and 2020.[12,13] Peanuts and potatoes were the highest usage agricultural sites; these two sites combined comprised the majority of usage across all agricultural sites in terms of both lbs a.i. applied and TAT. Peanuts and potatoes were also among those sites with the highest reported percent crop treated (PCT) (peanuts 66 PCT, potatoes 60 PCT).[14] Available chlorothalonil usage data also indicates appreciable usage, in terms of PCT, on dozens of other registered crops.

Surveys of pesticide usage on golf course turf, sod production, and ornamental plants in 2021 indicate that chlorothalonil is a market leading fungicide in each of these segments, in terms of pounds of active ingredient applied.[15] Usage of chlorothalonil is particularly high in golf course turf, with about 5.8 million pounds of active ingredient (lbs a.i.) applied, and over $47 million in product sales, in 2021 for disease management in this market segment.[15] Chlorothalonil pounds applied represent nearly 75% of the total market for fungicides applied to golf courses, and chlorothalonil is the top active ingredient in sales, comprising nearly 29% of the market. [15] In addition, nearly 1.1 million and 1.5 million lbs a.i. of chlorothalonil were applied to residential ornamentals in 2016 and 2019, respectively.[16,17]

For more details on the use and usage for conventional uses of chlorothalonil, see the following documents in the chlorothalonil registration review docket (EPA-HQ-OPP-2011-0840):

- Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals
- Chlorothalonil (PC Code 081901) Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites

B. Antimicrobial Use and Usage

The antimicrobial uses of chlorothalonil include wood preservation, mold control and material preservation. The wood preservation uses include surface treatment, pressure treatment and sapstain applications. The mold control uses include surface treatment of interior walls, surfaces and framing in buildings. The material preservative uses include non-food uses in caulks and sealants, paper, paperboard, paper coatings and paperboard coatings and uses on adhesives, grouts, joint compounds, paints, stains, and coatings. Chlorothalonil is used as a dry-film fungicide in paints and coatings and is mainly used in white paints. Market research indicates that chlorothalonil is seldom used in colored paint formulations as it tends to cause chalking (i.e.,

[12] Kynetec USA, Inc. 2021a "The AgroTrak® Study from Kynetec USA, Inc." iMap Software. Database Subset: 2016-2020. [Accessed March 2022].
[13] United States Department of Agriculture, National Agricultural Statistics Service (USDA NASS). 2022a. Agricultural Chemical Usage Program. Data years: 2017, 2019, 2021. https://www nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Chemical_Use/. [Accessed April 2022]
[14] Kynetec USA, Inc. 2021b. "The AgroTrak® Study from Kynetec USA, Inc." Microsoft Access Database. Database Subset: 2016-2020. [Accessed March 2022].
[15] Nonagricultural Market Research Data (NMRD). 2022. Study on production animal health in 2021. [Accessed February 2023].
[16] Kline and Company. 2017a. Consumer Markets for Pesticides and Fertilizers 2016: U.S. Market Analysis and Opportunities - Volume 2. September 2021. [Accessed September 2021]
[17] Nonagricultural Market Research Data (NMRD). 2020. Study on consumer markets for pesticides and fertilizers. September 2021.

development of a superficial white film) of the paint on exposure to light for long periods. About $5.2 million of paint coatings containing chlorothalonil were sold in the United States in 2016, accounting for less than 4% of total sales in the dry-film mildewcides market. Additionally, in the anti-sapstain market for treated lumber, about 70% of hardwood (as a measure of dollar sales) is treated with a blend of idopropynyl butylcarbamate (IPBC) and propiconazole, while the remaining 30% is treated with 2-mercaptobenzothiazole (MBT), 2-thiocyanomethylthiobenzothiazole (TCMTB), and chlorothalonil.[18]

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized its human health risk assessments below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of chlorothalonil. Along with this PID, EPA is releasing the 2023 Revised Dietary Assessment. The 2023 Revised Dietary Assessment updates the dietary risk conclusions of the 2021 HH DRA. Following release of the 2021 HH DRA, EPA finalized updates to its exposure modeling[19, 20] and identified a new acute dietary toxicity endpoint for chlorothalonil. For additional details on the 2021 HH DRA, see *Chlorothalonil: Revised Human Health Draft Risk Assessment for Registration Review*. For additional details on the 2023 Revised Dietary Assessment, see the *Chlorothalonil. Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration Review Risk Assessment*. All documents can be found in EPA's public docket (EPA-HQ-OPP-2011-0840).

A new approach methodology (NAM) to refine the inhalation risk assessment for direct contact irritants was utilized to calculate human equivalent concentrations (HECs) and human-equivalent doses for chlorothalonil. NAMs are any non-animal technology or approach that can be used to provide information on chemical hazard and risk assessment. Efforts to develop NAMs for hazard identification and characterization have been supported by the Agency. These efforts are consistent with the recommendations presented in the National Research Council's vision of toxicity testing in the 21st century,[21] as well as the National Academy of Science's report on how to integrate and use data from emerging techniques to improve risk-related evaluations.[22]

The Agency worked with one of the chlorothalonil registrants, Syngenta, to develop a NAM to refine the inhalation risk assessment. In December 2018, the proposed approach was presented to

[18] Kline and Company. 2017b. Specialty Biocides 2016: United States Market Analysis. [Accessed September 2021].
[19] https://www.epa.gov/pesticides/epa-transitions-using-updated-dietary-exposure-model; https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/deem-fcidcalendex-software-installer
[20] *Analysis of Subsurface Metabolism in Groundwater Modeling* (EPA-HQ-OPP-2021-0241); https://www.epa.gov/pesticides/epa-releases-final-analysis-model-used-estimate-pesticide-concentrations-groundwater
[21] https://www.nap.edu/catalog/11970/toxicity-testing-in-the-21st-century-a-vision-and-a
[22] https://www.nationalacademies.org/our-work/incorporating-21st-century-science-into-risk-based-evaluations

a FIFRA Science Advisory Panel (SAP),[23] and the final SAP report was published in April 2019. Inhalation points of departure (PODs) were derived from *in vitro* data using cultured human airway cells. A computational fluid dynamic (CFD) model estimated aerosol deposition results of the upper human respiratory tract, and site-specific HECs were calculated for three distinct particle size distributions. The trachea provided the most health protective values for inhalation risk assessment. Since the CFD model directly predicts the deposition of aerosols in the human respiratory tract (toxicokinetics) and the *in vitro* study directly measured endpoints in a system derived from human cells (toxicodynamics), EPA determined that the interspecies uncertainty factor (UF) can be reduced to 1X. Furthermore, since chlorothalonil is a direct-acting irritant with toxicity occurring at the point of contact in the respiratory tract, the absorption, distribution, metabolism, and excretion characteristics are not likely to have a significant impact on the response among the human population. Therefore, EPA determined the toxicokinetic portion of the intraspecies UF may be reduced to 3X. As a result, the level of concern (LOC) for inhalation exposure is 3 (1X interspecies, 3X intraspecies).

1. Risk Summary and Characterization

a) Dietary (Food + Water) Risks

Conventional Uses:

The 2021 HH DRA assessed human health risks, including dietary risks, associated with registered conventional uses of chlorothalonil. Toxicity endpoints were identified on an acute exposure basis for females of reproductive age and on a chronic exposure basis for the general population. These were compared to estimates of dietary exposure to determine if potential risks of concern may result. The 2021 HH DRA did not identify any potential acute dietary risks of concern. It did identify potential chronic dietary risks of concern for all subpopulations. The all infants (<1-year-old) subpopulation had the highest exposure estimate.

After publication of the 2021 HH DRA, changes to environmental fate and exposure modeling resulted in overall reductions to exposure estimates. Additionally, a review of the existing toxicity database revealed that the SDS-3701 metabolite appears to be much more acutely toxic than chlorothalonil; thus, an acute dietary endpoint for the metabolite was selected for females 13-49 years of age. As a result of these updates, the Agency has identified potential acute dietary risks of concern for the female aged 13-49 subpopulation. Additionally, EPA has updated its chronic dietary analyses.

In all instances where potential risks of concern were identified, drinking water exposure resulting from groundwater contamination was the major source of exposure. Table 1 summarizes the revisions to the dietary risk conclusions between 2021 and 2023. For full details of the Agency's updated dietary risk conclusions, see the 2023 Revised Dietary Assessment in EPA's public docket (EPA-HQ-OPP-2011-0840).

[23] Evaluation of a Proposed Approach to Refine the Inhalation Risk Assessment for Point of Contact Toxicity: A Case Study Using a New Approach Methodology (NAM). Docket # EPA-HQ-OPP-2018-0517, https://www.epa.gov/sap/fifra-scientific-advisory-panel-meetings

Table 1: Summary of Revisions to Dietary Risk Conclusions

Exposure	Subpopulation	2021 HH DRA Risk Estimates	2023 Revised Dietary Assessment Risk Estimates	Summary of changes
Acute	General Population	Not calculated; no endpoint identified	Not calculated; no endpoint identified	No change
	Females Aged 13-49	Chlorothalonil: 18% of aPAD[1]	Chlorothalonil: 11% of aPAD	Risk estimate decreased
		SDS-3701 (degradate): not assessed	SDS-3701 (degradate): **130% of aPAD**	New risk of concern identified
Chronic	General Population	Chlorothalonil: **260% of cPAD[2]**	Chlorothalonil: **150% of cPAD**	Risk estimate decreased
	All Infants (<1-year-old)	Chlorothalonil: **650% of cPAD**	Chlorothalonil: **520% of cPAD**	Risk estimate decreased

[1] Acute population-adjusted dose
[2] Chronic population-adjusted dose
Bold indicates a potential risk of concern; risk estimates greater than 100% of the PAD are considered potential risks of concern.

The 2021 HH DRA identified an acute toxicity endpoint for chlorothalonil exposure for the female aged 13-49 subpopulation. In a developmental study with rats, an increase in the number of fetal resorptions per dam (mostly early; with a related increase in post-implantation loss) was observed at 400 mg/kg/day. The no-observed adverse-effect level (NOAEL) was 100 mg/kg/day. Application of the appropriate uncertainty factors yielded an acute reference dose (aRfD) of 1.0 mg/kg/day. The respective acute population-adjusted dose (aPAD) was also 1.0 mg/kg/day. EPA's 2021 exposure estimate for the female 13–49-year-old subpopulation was 18% of the aPAD. Exposure estimates of less than 100% of the aPAD are not of concern; therefore, EPA's 2021 HH DRA did not identify any potential acute dietary risks of concern to the female 13–49-year-old subpopulation from registered uses of chlorothalonil. Risks of concern were not assessed for other subpopulations because no relevant toxic effects endpoints were identified.

Following the 2021 HH DRA, EPA updated its assumptions for groundwater modeling to assume that aerobic soil metabolism of pesticide residues occurs to a depth of two meters, from a previously assumed depth of one meter.[24, 25] This resulted in lower estimates of drinking water contamination and overall dietary exposure for chlorothalonil. EPA also updated its exposure modeling to account for dietary exposure to infants from drinking water consumed in baby formula.[26, 27] This led to an increase in the dietary exposure estimates for the infants <1-year-old subpopulation. This increase was counteracted by the decrease in overall dietary exposure estimates resulting from the changes to aerobic soil metabolism modeling.

The 2023 Revised Dietary Assessment describes the changes to the Agency's modeling and dietary risk conclusions for chlorothalonil. The acute exposure assessment also assumed 100

[24] *Analysis of Subsurface Metabolism in Groundwater Modeling* (EPA-HQ-OPP-2021-0241)
[25] https://www.epa.gov/pesticides/epa-releases-final-analysis-model-used-estimate-pesticide-concentrations-groundwater

PCT (i.e., applications were made to 100% of acres of crops for which chlorothalonil is registered) and that residues in most food commodities reflected the tolerance levels for those commodities (in some cases, EPA assumed maximum field trial residues). EPA's updated estimate of acute dietary exposure to chlorothalonil for the female 13–49-year-old subpopulation is 11% of the aPAD (lowered from 18% of the aPAD, as presented in the 2021 HH DRA) and is not of concern.

In response to comments submitted on the 2021 HH DRA, EPA reevaluated the toxicity database and identified an acute toxicity endpoint for females 13-49 years old for the SDS-3701 metabolite, which is lower (*i.e.*, more toxic) than the acute dietary POD for females 13-49 years old for chlorothalonil. In a prenatal rat study with SDS-3701, increased early fetal resorptions were observed at 15 mg/kg/day. The corresponding NOAEL for SDS-3701 was 5 mg/kg/day (compared with the NOAEL of 100 mg/kg/day for chlorothalonil). With application of the appropriate uncertainty factors, the acute dietary aPAD and RfD for females 13-49 for SDS-3701 is 0.05 mg/kg/day (compared to 1.0 mg/kg/day for chlorothalonil).

EPA's 2023 revised SDS-3701 exposure estimate for the female 13–49-year-old subpopulation was 130% of the aPAD. When considering drinking water exposure only, the SDS-3701 exposure estimate was 120% of the aPAD (i.e., exposure from residues in food accounted for a minority of overall exposure). Exposure estimates greater than 100% of the aPAD are of concern; therefore, EPA concludes there are potential acute dietary risks of concern to the female 13–49-year-old subpopulation from registered uses of chlorothalonil.

The 2021 HH DRA identified potential chronic dietary risks of concern for all subpopulations from registered conventional uses of chlorothalonil products. Chronic risk estimates greater than 100% of the chronic population-adjusted dose (cPAD) are of concern. The chronic dietary risk for the general population was 260% of the cPAD. The chronic dietary risk for the highest exposed subpopulation, all infants (<1-year-old), was 650% of the cPAD. EPA's 2023 Revised Dietary Assessment also identified chronic dietary risks of concern for all assessed subpopulations; however, the 2023 risk estimates were lower than those in the 2021 assessment, reflecting the updates to EPA's exposure modeling discussed above. The revised 2023 risk estimate for the general population was 150% of the cPAD. For the subpopulation with the highest exposure, all infants (<1-year-old), the revised risk estimate was 520% of the cPAD. EPA's chronic dietary risk conclusions were based on toxicity of chlorothalonil and residues of concern. The chronic dietary endpoint for chlorothalonil is protective of chronic toxicity from the SDS-3701 metabolite; therefore, EPA did not conduct a separate chronic dietary assessment for SDS-3701. For the all infants (<1-year-old), drinking water alone accounted for 99% of the chronic risk estimate. EPA identified cPAD exceedances for all assessed subpopulations.

For the 2021 HH DRA and the 2023 Revised Dietary Assessment, EPA established a cPAD of 0.02 mg/kg/day for chlorothalonil. EPA based the cPAD on a chronic toxicity study in rats in which kidney effects (epithelial hyperplasia in the renal proximal convoluted tubules of female rats) were observed at a dose of 4 mg/kg/day. The NOAEL for this study was 2 mg/kg/day. Application of the appropriate uncertainty factors yielded a chronic reference dose (cRfD) of 0.02 mg/kg/day. In the 2023 chronic exposure assessment, food residues levels were refined using U.S. Department of Agriculture (USDA) Pesticide Data Program (PDP) monitoring data,

though tolerance-level residues were assumed for some foods. EPA also refined its assessment with PCT data. For complete PCT data used to refine the 2023 Revised Dietary Assessment, see the Agency's 2020 *Screening Level Usage Analysis of Chlorothalonil* (SLUA), available in the public docket. EPA applied default processing factors and tolerance-level residues for some commodities. Drinking water was incorporated directly into the dietary assessment and used the post-breakthrough average for groundwater concentrations updated with 2-meter subsurface degradation.

For drinking water exposure modeling estimates, EPA included both chlorothalonil and chlorothalonil transformation products with an intact cyano group as the residues of concern, using the total toxic residue (TTR) method. Degradates with an intact cyano group are considered to have toxicity profiles similar to that of chlorothalonil on the basis of the structural similarities. EPA modeled exposure to pesticide residues resulting from both groundwater and surface water contamination. Modeling of registered uses of chlorothalonil indicated that residues in groundwater are greater than those in surface water. None of the modeled surface water Estimated Drinking Water Concentrations (EDWCs) were of concern. Nearly all modeled groundwater EDWCs were of concern. To quantify groundwater contamination, the Agency models applications on several soil types that are vulnerable to leaching.

EPA also models applications to a variety of use sites. Modeling of ornamental crop and turf uses yielded the highest EDWCs. For agricultural crops, higher acreage crops with the highest EDWCs were potatoes, cucurbits, and tomatoes. Other modeled crops resulted in higher EDWCs than those listed here, but these are not widely grown across the U.S. (e.g., pistachios, almonds, mangos) or are low acreage (e.g., celery, horseradish). Modeled EDWCs were scaled with application rates, and the highest EDWCs were seen in use sites with the highest maximum annual application rates. Lower annual application rates produced lower EDWCs.

EPA also reviewed the available data from studies that monitor for the presence of residues in water. While modeling is based on total residues, monitoring data were available only for the parent chlorothalonil molecule and the SDS-3701 transformation product. In the available surface water monitoring studies, both chlorothalonil and SDS-3701 concentrations generally did not exceed 1 µg/L. Groundwater monitoring measured concentrations of chlorothalonil as high as 2.1 µg/L. The highest measured concentration of SDS-3701 was 368 µg/L. For context, the aPAD used for acute dietary risk assessment was 1.0 mg/kg/day for chlorothalonil and 0.05 mg/kg/day for SDS-3701. The cPAD was 0.02 mg/kg/day (chlorothalonil only).

EPA did not assess cancer risks associated with dietary exposure to chlorothalonil from registered conventional uses. Chlorothalonil is classified as "likely to be a human carcinogen by all routes of exposure;" however, a Science Advisory Panel (SAP) decision from June 30, 1998[28] supports the use of a threshold approach for the chlorothalonil risk assessment. A threshold approach for cancer risk assessment is appropriate because available data suggest that there is a threshold dose at and above which tumors result. In a threshold model, the instances of tumors increase with the dose (i.e., dose-response). In contrast, a stochastic or probabilistic model of carcinogenicity assumes that the probability of tumor development increases with every

[28] https://archive.epa.gov/scipoly/sap/meetings/web/html/finaljul html

exposure. This is because the mechanism of carcinogenicity is thought to involve genetic mutations, which occur with any exposure and accumulate with successive exposures. In a probabilistic model, there is no dose below which there is no probability of a tumor occurring.

The point of departure for chlorothalonil dietary cancer assessment was based on a study with rats in which there was increased cell proliferation in proximal convoluted tubules in the kidney and stomach tissue as well as tumors observed at doses ≥15 mg/kg/day. The 2 mg/kg/day point of departure used for chronic dietary assessment is thus protective of potential carcinogenicity. Therefore, quantification of cancer risk was not warranted.

Antimicrobial Uses:
There are no expected dietary exposures from residues in food that result from the antimicrobial uses of chlorothalonil. Additionally, conventional agricultural uses of chlorothalonil are expected to result in higher drinking water residues than antimicrobial uses and are expected to be protective of antimicrobial uses Therefore, neither dietary nor drinking water assessments are required for the antimicrobial uses of chlorothalonil.[29]

b) Residential Handler Risks

Conventional Uses:
EPA did not identify any residential handler risks of concern from registered uses of chlorothalonil. The short-term inhalation LOC is 3; resulting MOEs ranged from 22,000 to 350,000, which are above the LOC and are therefore not of concern. No dermal endpoint was selected, because no systemic effects were observed in the subchronic dermal toxicity studies in rats and rabbits, and there was no concern for increased susceptibility to the developing fetus or offspring. Therefore, potential residential handler dermal exposures were not assessed.

Antimicrobial Uses:
Residential handler inhalation exposures were assessed for the use of paints that are preserved with chlorothalonil. The inhalation MOEs, which ranged from 650 to 1,500,000, are not of concern because they are greater than the LOC of 3.

A quantitative residential handler assessment was not conducted for dermal exposures as a dermal point of departure (POD) was not selected for chlorothalonil.[30]

c) Residential Post-Application Risks

Conventional Uses:
No dermal endpoint was selected, so potential residential post-application dermal exposures were not assessed. Young children (those who would be expected to engage in behaviors such as hand-to-mouth oral exposures) are not expected to enter or play in the types of areas treated with

[29] U.S. EPA. 2021. Registration Review Draft Risk Assessment (DRA) for the Antimicrobial Uses of Chlorothalonil. D459727, April 9, 2021
[30] U.S. EPA. 2020a. Chlorothalonil: Draft Ecological Risk Assessment for Registration Review. D457662, December 30, 2020

chlorothalonil (golf courses, home gardens); therefore, incidental oral post-application exposure for children ages one to two is not anticipated and was not assessed.

Antimicrobial Uses:
Residential post application incidental oral exposures were assessed for the use of wood pressure treated with chlorothalonil. These exposures were assessed using a dislodgeable residue study, where treated wood was wipe tested 14 to 180 days after treatment. The incidental oral MOE is 1,200 based on the highest residue measured and is not of concern because it is greater than the LOC of 100.

A quantitative residential handler assessment was not conducted for dermal exposures as a dermal point of departure (POD) was not selected for chlorothalonil.[31]

d) Bystander Risks

Conventional Uses:
EPA did not identify any potential bystander risks of concern from registered uses of chlorothalonil. Bystanders living and working near application sites may be exposed to pesticide residues that travel off-site via spray drift. Spray drift can occur during or following application. Pesticide residues that travel offsite during application can lead to bystander exposure via direct inhalation or dermal contact. Residues can also deposit on surfaces that bystanders may later contact. Exposure may also occur after application when residues on the field volatilize and travel offsite. Bystander exposure is determined by many factors, including application practices, the volume of residues that travels offsite, and weather conditions. EPA modeled bystander exposure risks with application-specific data and reviewed available monitoring data when available.

The Agency assessed potential indirect incidental oral exposure to children (one- to two-years-old) resulting from spray drift. EPA did not identify risks of concern from indirect incidental oral exposure to children resulting from spray drift. EPA did not assess dermal exposures from spray drift during application, because a dermal POD was not selected.

To assess inhalation post-application, near-field, point source exposures, EPA used the Probabilistic Exposure and Risk Model for FUMigants (PERFUM). PERFUM estimates the concentration of volatilized residues in air following a single application as a function of distance from the application site. None of the modeling scenarios yielded exposures above the level of concern, and risks of concern were not identified for bystanders at the field edge following chlorothalonil application.

To assess inhalation post-application, ambient, non-point source exposures, EPA reviewed air monitoring data collected from areas in which multiple chlorothalonil applications might take place. These data characterize the amount of background pesticide residues in the air in a given area over a given timeframe. None of the measured air concentrations of chlorothalonil exceeded

[31] U.S. EPA. 2020a. Chlorothalonil: Draft Ecological Risk Assessment for Registration Review. D457662, December 30, 2020

the level of concern, and risks were not identified for bystanders from ambient chlorothalonil exposure.

e) Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency sums 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.

Because the dietary exposures to SDS-3701 (on an acute basis) and chlorothalonil (on a chronic basis) alone are above the dietary acute and chronic LOCs, aggregate risks of concern are also identified. Aggregate acute and chronic MOEs for chlorothalonil are equal to the dietary MOEs for the exposures associated the conventional uses because a dermal endpoint was not selected. EPA aggregated the dietary exposures associated with conventional uses of chlorothalonil with the incidental oral exposures associated with antimicrobial uses of chlorothalonil in pressure-treated wood. The incidental oral exposures associated with antimicrobial uses are not of concern (MOE = 370 > LOC = 100; MOEs greater than LOCs are not of concern). Residential exposures from conventional-use products are not aggregated with dietary exposures because the endpoints for oral and inhalation are based on different effects.

f) Cumulative Risks

EPA has not made a common-mechanism-of-toxicity-to-humans finding for chlorothalonil and any other substance. Chlorothalonil does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has premised this PID and the underlying risk assessments on the belief that chlorothalonil does not have a common mechanism of toxicity with other substances.

g) Occupational Handler Risks

Conventional Uses:
EPA did not identify any occupational handler risks of concern from registered conventional uses of chlorothalonil. Occupational handler exposure is expected from registered conventional uses of chlorothalonil, but all the MOEs for the assessed scenarios were above the LOCs and were not of concern. Only inhalation exposures were quantitatively assessed. Dermal exposures were not assessed as a dermal endpoint was not selected. The short- and intermediate-term inhalation MOEs range from 5 to 660,000, assuming baseline clothing (i.e., no respirator) and are not of concern (LOC = 3).

Antimicrobial Uses:
Occupational handler exposures are anticipated when chlorothalonil is used to preserve materials such as paints, caulks, sealants, paper, paperboard, paper coatings, paperboard coatings, adhesives, grouts, joint compounds, stains, and coatings. Exposures are also anticipated when using materials that are preserved with chlorothalonil. The inhalation MOE of 1.8 for open pouring of powder at the application rate of 9,800 ppm for the manufacture of preserved

materials is of concern because it yields an MOE less than the LOC of 3. The remaining MOEs for occupational handlers are not of concern, including for the application of preserved paints as well as the use of chlorothalonil as a pressure treatment or sapstain treatment of wood products.

A quantitative occupational post-application assessment was not conducted for dermal exposures as a dermal point of departure (POD) was not selected for chlorothalonil.[32]

h) Occupational Post-Application Risks

Conventional Uses:
The Agency did not quantitatively assess occupational post-application risks resulting from registered conventional uses of chlorothalonil. Risks to workers resulting from dermal exposures following application were not assessed because a dermal endpoint was not selected. Post-application exposure also may occur through inhalation, including via volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. Though EPA did not assess occupational post-application inhalation exposures, the Agency did assess risks to occupational handlers during application. Handler exposure during application is likely to be higher than post-application exposure; therefore, the handler assessment is considered to be protective of worker post-application risks. EPA did not identify any risks of concern to occupational handlers during application of conventional use chlorothalonil products (see *Occupational Handler Risks*, above), thus risks to post-application workers also are not of concern.

The regulations at 40 CFR §156.208(c)(2) describe the appropriate restricted entry interval (REI) for pesticide product active ingredients, based on their Acute Toxicity Categories (I-V) for acute dermal, eye irritation and primary skin irritation. EPA did not identify a systemic dermal exposure endpoint for chlorothalonil, and, as described above, post-application worker risks for chlorothalonil are not considered to be of concern. Chlorothalonil is classified as Toxicity Category I for eye irritation. If a product contains only one active ingredient and it is in Toxicity Category I, then the prescribed REI is 48 hours. However, since eye irritation is the determining factor for chlorothalonil products, the REI can be reduced to 12 hours when special eye protection language is included on product labels. Available chlorothalonil incident data indicate that a 48-hour REI does not necessarily protect workers (i.e., irritation to workers' eyes has been reported beyond the 48-hour REI); additionally, residue dissipation data show that residues may not dissipate significantly within 48 hours of application. Because the 48-hour REI may not be sufficiently protective, specific label language to address eye irritation already is included on labels, and the appropriate REI is 12 hours. For more details, including the Special Eye Irritation Provisions, see the *Chlorothalonil: Response to Comments on the Draft Human Health Risk Assessment for Registration Review*, available in the public docket with this PID.

Antimicrobial Uses

[32] U.S. EPA. 2020a. Chlorothalonil: Draft Ecological Risk Assessment for Registration Review. D457662, December 30, 2020

A quantitative occupational post-application assessment was not conducted for dermal exposures as a dermal point of departure (POD) was not selected for chlorothalonil.[33]

i) Endocrine Disrupter Screening Program (EDSP)

As required by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic, and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints that may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental, and reproductive effects in different taxonomic groups. As part of its most recent registration decision for chlorothalonil, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database.

In addition, FFDCA § 408(p)(1) requires EPA to develop an Endocrine Disruptor Screening Program (EDSP) 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." FFDCA § 408(p)(3) requires the Agency to "provide for the testing of all pesticide chemicals." Under FFDCA § 408(p)(4), EPA may, by order, exempt the pesticide from the testing requirements if EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." Finally, if EPA finds that the pesticide is found to have an endocrine 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."

The EDSP screening program developed by EPA includes data sets to address human and wildlife testing for estrogen, androgen, and thyroid (E, A, and T) 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 E, A, or T hormonal systems. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any E, A, or T effect.

Between October 2009 and February 2010, EPA issued Tier 1 data call-ins (DCIs) for a group of 67 chemicals, which contained 58 pesticide active ingredients and nine inert ingredients. EPA scientists (composed of experts within the Office of Chemical Safety and Pollution Prevention (OCSPP) with consultations with experts in the Office of Research and Development) performed Weight of Evidence (WoE) analyses of the potential interaction with the E, A, and/or T signaling pathways for humans, fish, and wildlife using results of the Tier 1 battery and other scientifically

[33] U.S. EPA. 2020a. Chlorothalonil: Draft Ecological Risk Assessment for Registration Review. D457662, December 30, 2020

relevant information (OSRI) and the conclusions of those initial reviews are available in the chemical-specific public dockets. Tier 1 data were submitted for chlorothalonil.

In 2015, EPA published the EDSP WoE Conclusions on the Tier 1 Screening Assays for chlorothalonil, which stated that there was no convincing evidence for potential interaction with the E, A, and T. Thus, EPA concludes that no further data are needed to assess chlorothalonil for potential interaction with the human E, A, and T pathways and, based on the data available, no further action is need under FFDCA section 408(p)(6) to ensure protection of human health.

There was also no convincing evidence of interaction with the E, A, and T pathways in mammals, fish, and birds for chlorothalonil and thus no EDSP Tier 2 testing is recommended for chlorothalonil for these endpoints and species. The results of the Amphibian Metamorphosis Assay (AMA) suggested a potential interaction with the thyroid pathway in amphibians at a concentration of 5.0 ug a.i./L. An EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) was recommended. This recommendation will be further addressed in subsequent updates on implementation of the EDSP under FFDCA section 408(p).

Additional information may be found in Appendix F and in the *Chlorothalonil Data Evaluation Records (DERs) for EDSP Tier 1 Assays*.[34]

2. Human Incidents and Epidemiology

EPA reviewed chlorothalonil incidents reported to both the Main and Aggregate Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR). As of EPA's latest search on August 4, 2020, the Main IDS showed 10 chlorothalonil incidents involving a single active ingredient and six chlorothalonil incidents involving multiple active ingredients, dated from 2015 to 2020. There were 53 chlorothalonil incidents reported in Aggregate IDS (the Aggregate IDS typically includes incidents of lesser severity, and details about the incidents may not be available). SENSOR identified 41 cases involving chlorothalonil from 2010-2017. However, both IDS and SENSOR-Pesticides identified several moderate severity and one high severity chlorothalonil incidents (27 in total). These more severe incidents primarily involved individuals who were applying the product and accidentally got it on their face and into their eyes. Overall, the incidents were mostly low in severity (73% in SENSOR and 77% in IDS). Chlorothalonil is included in the Agricultural Health Study (AHS), and there is insufficient evidence to conclude that a clear associative or causal relationship exists between chlorothalonil exposure and the carcinogenic and non-carcinogenic health outcomes assessed in the 44 AHS publications. No incidents were attributed to the use of chlorothalonil as an antimicrobial pesticide. The Agency intends to monitor human incidents for chlorothalonil and will conduct additional analyses if necessary.

[34] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0029

For additional details, see the memorandum *Chlorothalonil: Tier I Update Review of Human Incidents and Epidemiology for Draft Risk Assessment* (dated December 9, 2020) available in chlorothalonil public docket (EPA-HQ-OPP-2011-0840-0040).

3. Tolerances

Chlorothalonil is registered for conventional uses that result in residues in or on food. Generally, a tolerance or tolerance exemption must cover the residues or the affected food is considered adulterated.[35] EPA has determined that most of the necessary tolerances are in place to cover residues resulting from chlorothalonil's legal use.

The Agency has established tolerances for chlorothalonil under 40 C.F.R. § 180.275.

During the risk assessment process, EPA determined that revisions to the tolerance expression and tolerance revisions are necessary or appropriate to cover residues in or on food from uses of chlorothalonil. For more information, see Section IV.C.

EPA has not established tolerances or tolerance exemptions for residues for the antimicrobial uses of chlorothalonil because antimicrobial uses are non-food uses. Chlorothalonil has not been cleared as a food additive by the U.S. Food and Drug Administration (US FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 409.

4. Human Health Data Needs

The human health database for chlorothalonil is considered complete. An EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) was recommended. This recommendation will be further addressed in subsequent updates on implementation of the EDSP under FFDCA section 408(p).

B. Ecological Risks

The Agency has summarized the ecological DRAs for the conventional and antimicrobial uses of chlorothalonil below. The Agency used the most current science policies and risk assessment methodologies to prepare these risk assessments in support of the registration review of chlorothalonil. For additional details on the 2020 conventional Eco DRA, see *Chlorothalonil: Draft Ecological Risk Assessment for Registration Review* and *Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment*. For additional details on the 2021 antimicrobial DRA, see *Registration Review Draft Risk Assessment (DRA) for Antimicrobial Uses of Chlorothalonil.* Both documents are available in EPA's public docket (EPA-HQ-OPP-2011-0840).

Although EPA has not yet conducted a nationwide listed species assessment for chlorothalonil as part of this registration review, in 2003, the Agency conducted a focused biological evaluation (BE) for Pacific salmonids and initiated a formal consultation with NMFS in response to

[35] 21 U.S.C. §§ 342, 346(a).

litigation. In its 2011 salmonid Biological Opinion (BiOp), NMFS concluded that chlorothalonil is not likely to jeopardize the continued existence of any listed salmonid but is likely to adversely modify the designated critical habitat of some listed salmonids. The 2011 salmonid BiOp describes reasonable and prudent alternatives to avoid adverse modification or destruction of designated critical habitat from the use of chlorothalonil and reasonable and prudent measures to minimize take (e.g., unintentional harm or death) that could result from the legal use of chlorothalonil to individuals of these listed species and their critical habitats. Certain aspects of the 2011 BiOp are discussed further in Section IV.

1. Risk Summary and Characterization

Potential risks to non-target, non-listed species generally are described below.

a) Conventional Uses

For conventional uses of chlorothalonil, EPA compared risk quotients (RQ) against the Agency's LOCs to estimate potential risks. The RQ is the ratio of the exposure estimates to the toxicity endpoint. RQs above the LOC represent potential risks of concern. EPA uses LOC exceedances as one line of evidence to describe the potential risks posed by a pesticide to non-target organisms. For chlorothalonil's conventional uses, the Agency identified potential risks of concern to aquatic non-vascular plants and terrestrial invertebrates (although available data is limited). Acute and chronic risks of concern were also identified for mammals, birds, reptiles and terrestrial-phase amphibians from foliar applications, and chronic risks of concern from granular applications, as well as freshwater fish, aquatic- phase amphibians, estuarine/ marine fish, and freshwater invertebrates. Uses resulting in risks of concern include agricultural and non-agriculture uses.

Terrestrial Risks

Mammals

Chlorothalonil (the parent) is classified as "practically non-toxic" to mammals on an acute exposure basis, while the major transformation product, SDS-3701 is more toxic than chlorothalonil based on both acute (mortality) and sublethal effects (such as reproduction and growth). SDS-3701 is classified as "moderately toxic" to small mammals. A laboratory study in rats demonstrated an acute LD_{50} (the dose lethal to 50% of the test subjects) of 242 mg SDS-3701 per kg rat bodyweight (mg/kg-bw) for rats exposed orally to SDS-3701. The chronic toxicity endpoint for mammals was based on a study in which the pups of rats exposed to SDS-3701 experienced reductions in bodyweight at 6 mg/kg-bw. Moreover, the chronic toxicity endpoint for mammals was based on the lowest dose at which toxic effects were observed (i.e., the LOAEL or lowest observed adverse effects level) rather than on a lower dose at which no affects were observed (i.e., the NOAEL, or no observed adverse effects level).

Terrestrial vertebrates (including mammals and birds, reptiles and terrestrial-phase amphibians; see below) may be exposed to chlorothalonil when feeding in treated areas following foliar applications. Dietary EECs for terrestrial vertebrates are based on application rates, number of applications, and application intervals. Because it is more toxic to terrestrial vertebrates and is

more mobile and persistent in the environment, the Agency used exposure to the SDS-3701 metabolite to assess the potential risks to terrestrial vertebrates from chlorothalonil foliar applications. The maximum application rates were adjusted to 34% of the label maximum, reflecting the percentage of SDS-3701 formed from chlorothalonil. EPA notes that various studies report percentages of SDS-3701 formation lower than 34%— To account for this range, EPA has reported RQs based on both upper bounded and mean EECs.

The Agency identified potential acute and chronic risks of concern to mammals from foliar applications of registered conventional use chlorothalonil products. The acute RQs exceed the LOC of 0.5 for many of the use sites for terrestrial mammals. Acute RQs for the modeled foliar applications ranged from 0.01 to 7.94 when considering upper-bounded EECs, and less than 0.01 to 2.81 when considering mean EECs. The highest foliar application acute RQs resulted from modeling of non-agricultural uses (e.g., ornamentals and golf courses). The highest modeled agricultural-use RQs were for mangos (mean-bounded RQ = 0.74), Christmas trees (mean-bounded RQ = 0.71), almonds (mean-bounded RQ = 0.68), and cranberries (mean-bounded RQ = 0.68).

The chronic RQs exceed the LOC of 1.0 for all uses and a majority of dietary items for terrestrial mammals. Chronic RQs for the modeled foliar applications of chlorothalonil ranged up to 320 for the upper-bound EECs and up to 113 for the mean EECs. The highest foliar application chronic RQs resulted from modeling of non-agricultural uses (e.g., ornamentals and golf courses). The highest modeled agricultural-use chronic RQs were for mangos (mean-bounded RQ = 29.92), Christmas trees (mean-bounded RQ = 28.65), almonds (mean-bounded RQ = 27.35), and cranberries (mean-bounded RQ = 27.35).

The Agency also assessed potential risks to terrestrial mammals resulting from applications of granular formulations of chlorothalonil to turf. EPA did not identify any acute risks of concern for terrestrial mammals from granular-formulation turf applications. To reach the NOAEL from the chronic toxicity studies, mammals would have to ingest 89 granules, which is likely excessive. Additionally, the length of time to elicit adverse effects to mammals from granular ingestion is uncertain. The length of time the granules remain on the soil surface available for consumption and how much of the degradate (SDS-3701) versus the parent is in the intact granules is uncertain. EPA identified potential chronic risks of concern from indirect consumption of SDS-3701 in the form of contaminated soil invertebrates. Chronic risks were identified at the maximum application rate only, and risks were not identified when a single application was modeled. With respect to the exposure to the degradate (SDS-3701) via granule dissolution into the soil and uptake via soil-dwelling invertebrates, there are dietary exceedances (for sublethal effects) for mammals (RQ=1.4 at LOC=1.0) under the maximum use pattern on turf greens and tees mainly.

The Agency also assessed risks to terrestrial mammals from bioaccumulation of residues in aquatic food webs using the KABAM (the K_{OW} (based) Aquatic BioAccumulation Model). None of the modeled RQs for bioaccumulation exceeded the LOCs for terrestrial mammals and no risks of concern were identified.

The Agency has concluded that the acute and chronic risk to mammals may occur from registered uses of chlorothalonil.

Birds, Reptiles, and Terrestrial-Phase Amphibians

EPA does not routinely assess risks to reptiles and terrestrial-phase amphibians. It instead uses birds as a surrogate taxon to assess risks to these taxa. Thus, the conclusions for birds summarized below also apply to reptiles and terrestrial-phase amphibians.

Chlorothalonil (the parent) is classified as "practically non-toxic" to birds on an acute exposure basis, while the major transformation product, SDS-3701 is classified as "slightly toxic" to "moderately toxic" to birds on an acute basis. A laboratory study with mallard ducks demonstrated an acute LD_{50} of 158 mg/kg-bw. The chronic toxicity endpoint selected for birds was 50 mg/kg-diet, based on reductions to eggshell thickness observed in an avian reproductive study performed on mallards. Importantly, serious reproductive effects were seen at a dose of 250 mg/kg-diet. These effects included reductions to eggs laid, impairments to chick development and survival, and effects to adult bodyweight, food consumption, and gonad development. EPA's analysis showed many scenarios in which modeled EECs were greater than 250 mg/kg-diet. SDS-3701 is generally more toxic to terrestrial vertebrates, including birds; however, the toxicity of chlorothalonil is closer to that of SDS-3701 on a chronic basis for birds. Risk estimates for foliar applications based on exposure to chlorothalonil are similar to those for SDS-3701. Chronic toxicity in birds is based on a study in which reductions in eggshell thickness were seen at 100 mg/kg-diet.

The Agency identified potential acute and chronic risks of concern to birds from foliar applications of registered conventional use chlorothalonil products. The acute RQs for birds exceed the LOC of 0.5 for many of the animal size and dietary classes across the modeled uses. For birds, acute RQs for the modeled foliar applications ranged from 0.03 to 61.46 (upper-bound EECs) and from less than 0.02 to 21.77 (mean EECs). The highest RQs resulted from modeling of non-agricultural uses (e.g., ornamentals and golf courses). The highest modeled agricultural-use RQs were for mangos (mean-bounded RQ = 16.22), Christmas trees (mean-bounded RQ = 15.53), almonds (mean-bounded RQ = 14.83), and cranberries (mean-bounded RQ = 14.83).

The chronic RQs exceed to LOC of 1.0 for many uses using both the upper bound and mean EECs. Chronic RQs for the modeled foliar applications ranged from 1.91 to 88.54 (upper-bound EECs) and from 0.54 to 31.36 (mean EECs). The highest foliar application chronic RQs resulted from modeling of non-agricultural uses (e.g., ornamentals and golf courses). The highest modeled agricultural-use chronic RQs were for mangos (mean-bounded RQ = 5.74), Christmas trees (mean-bounded RQ = 5.50), cranberries (mean-bounded RQ = 7.57, and almonds (mean-bounded RQ = 7.56).

In assessing the risks to birds from foliar applications, EPA reviewed one incident involving birds exposed to chlorothalonil. In the incident, young chickens were exposed to chlorothalonil via spray drift and experienced dermal irritation and feather loss. EPA lacks methods for assessing dermal exposure risks to birds (and reptiles and terrestrial-phase amphibians), but

given the calculated risk exceedances, this incident is an additional line of evidence to support the risk conclusions.

The Agency also assessed potential risks to birds (and reptiles and terrestrial-phase amphibians) resulting from applications of granular formulations of chlorothalonil to turf. The Agency assessed the acute risks to birds from granular formulations using LD_{50}-per-square-foot (LD_{50}/ft^2) RQs. Only the LD_{50}/ft^2 for a small (20 g) birds exceeded the LOC ($LD_{50}/ft^2 = 2.44$; LOC=0.5). A small bird would need to eat 3,105 granules to receive a dose equivalent to the acute LD_{50} for chlorothalonil. Larger birds would need to eat even more. To reach the sublethal effects (chronic risk) dose, a small bird would need to eat 19 granules, while larger birds would need to eat more. Given this context and the limited nature of the identified risk of concern, EPA considered the potential for risks of concern for birds from granular formulations to be low.

EPA identified potential chronic risks of concern to birds resulting from applications of granular formulations of chlorothalonil to turf. On an acute exposure basis, the likelihood of mortality to birds via exposure to intact granules is considered low. To reach the NOAEL from the chronic toxicity studies, birds would need to consume 19 granules. A single exposure is considered to be sufficient, but there is uncertainty regarding the likelihood of adverse effects to small birds. The same uncertainties outlined in the previous section on terrestrial mammals concerning the granular formulations applies to birds (amount of parent versus degradate in the granule and length of time granules sit on the soil surface). EPA identified potential chronic risks of concern from indirect consumption of SDS-3701 in the form of contaminated soil invertebrates. Chronic risks were identified at the maximum application rate only, and risks were not identified when a single application was modeled. With respect to the exposure to the degradate (SDS-3701) via granule dissolution into the soil and uptake via soil-dwelling invertebrates, there are dietary exceedances (for sublethal effects) for birds (RQ=3.3 at LOC=1.0) under the maximum use pattern on turf greens and tees mainly.

As it did for terrestrial mammals, the Agency also assessed bioaccumulation risks from registered uses of chlorothalonil to birds, reptiles, and terrestrial-phase amphibians. EPA did not identify any potential risks of concern to terrestrial mammals because of bioaccumulation of residues in aquatic food webs.

Finally, the Agency evaluated risks to birds (and reptiles and terrestrial-phase amphibians) from inhalation exposure to chlorothalonil residues resulting from registered uses. The 2012 *Chlorothalonil Ecological Problem Formulation* suggested that inhalation exposure may lead to risks of concern for birds. An avian acute inhalation toxicity study was submitted to the Agency following the problem formulation. In the study, no mortality was observed in any doses, up to solubility limit of chlorothalonil. Because of this, RQs could not be calculated; however, since no toxic effects were observed at the highest possible dose of chlorothalonil (i.e., the solubility limit) the potential for risk of concern is low. For more details, see the 2020 Eco DRA.

The Agency has concluded that the acute and chronic risk to birds, reptiles, and terrestrial phase amphibians may occur from the registered uses of chlorothalonil.

Terrestrial Invertebrates

EPA relies on data about honey bees as a surrogate for terrestrial invertebrate species. There are limited data available to assess risks for honey bees and terrestrial invertebrates from registered uses of chlorothalonil, but based on the available data, the Agency has determined that chlorothalonil uses may present risks of concern to honey bees. RQs were not calculated. The available evidence does not suggest that bees are being exposed at toxic levels from the single exposure pathway. However, non-guideline data with other bee lifestages and other exposure pathways suggest bees may be exposed to toxic levels of chlorothalonil in the environment. Generally, the lack of data severely limits the Agency's ability to draw conclusions about the potential risks of concern for honey bees.

Despite the overall sparseness of pollinator data for chlorothalonil, the open literature demonstrates that chlorothalonil is frequently found in pollen and wax samples taken from hives in the field. Moreover, chlorothalonil is applied to numerous pollinator-attractive plants/crops.

Chlorothalonil is classified as "practically non-toxic" to honey bees on an acute contact exposure basis. EPA lacks guideline studies assessing acute oral adult honey bee toxicity. The Agency also lacks studies of acute and chronic oral toxicity for larval honey bees (since they do not forage, the contact exposure route is not considered a relevant exposure pathway for larval bees). Several open literature toxicity studies were also considered. Collectively, the data suggest that chlorothalonil exposure results in toxic effects to bees and other terrestrial invertebrates.

EPA reviewed two open literature studies with honey bees. A study on larval oral toxicity generally followed the guideline protocols for acute and chronic toxicity tests. It demonstrated higher rates of acute mortality in larva fed on chlorothalonil (as compared with control groups) after 24 and 48 hours, though these differences were not seen after 72 hours. It also established a chronic oral NOAEL of 0.35 µg a.i./bee/day, based on mortality rates observed in the 30 and 100 mg/bee treatment groups. The second study showed significant larval toxicity at a dose of 1.18 µg a.i./bee/day.

EPA reviewed an acute oral contact guideline honey bee study conducted with a formulated pesticide product that includes chlorothalonil and other active ingredients. For chlorothalonil, this study demonstrated a 48-hr acute oral LC_{50} greater than 28.08 µg/bee and a 48-hr acute oral contact LC_{50} greater than 22.8 µg/bee (LC_{50} = the concentration lethal to 50% of the test subjects). The Agency does not typically use studies with multiple active ingredients for risk assessment.

The Agency also reviewed an open literature study performed on bumble bees at the colony level. Colonies that foraged on crops treated with a registered chlorothalonil product showed reductions in the number of workers produced, bee biomass, and queen body mass (as compared to control colonies). EPA also reviewed studies that associate bumble bee prevalence and range declines with chlorothalonil use. These studies also associate chlorothalonil use with an increased prevalence of bumble bee parasites.

Finally, EPA reviewed studies with other terrestrial invertebrates, including earthworms, wasps, and beneficial insects. These data suggest that other terrestrial invertebrates are sensitive to chlorothalonil toxicity, but not at levels reflecting maximum label application rates.

Given the lack of toxicity data, EPA could not calculate RQs to quantify honey bee and terrestrial invertebrate risks. The only guideline toxicity data available yielded a non-definitive LC_{50} of greater than 181 µg/bee. The Agency does not calculate RQs from non-definitive endpoints. EPA's contact exposure estimate was 2.7 µg/bee, below the LC_{50} of greater than 181 µg/bee. EPA also considered non-guideline, open literature studies of chlorothalonil toxicity. These studies produced toxicity estimates below the respective exposure estimates, suggesting that risks of concern may result. In conclusion, the available data do not preclude the possibility of risk to honey bees and terrestrial invertebrates. Therefore, the Agency has determined that registered conventional uses of chlorothalonil may present risks of concern to honey bees. More data are needed to fully quantify the potential risks of concern for these taxa from registered conventional uses of chlorothalonil.

Terrestrial Plants

The Agency did not identify risks of concern for terrestrial plants. There are no LOC exceedances for terrestrial plants and risk to plants is generally low, although there have been some plant incidents reported. Reported incidents generally resulted from direct applications of chlorothalonil to a plant or plants, and the certainty index is generally low (i.e., "possible"). Many incidents occurred in lawn grass, though some involved other ornamental or food crops.

The Agency has concluded that the likelihood of adverse effects to terrestrial plants from the registered uses of chlorothalonil is considered low.

Aquatic Risks

Freshwater Fish and Aquatic-Phase Amphibians

On an acute exposure basis, chlorothalonil is classified as "very highly toxic" to freshwater (FW) fish (LC_{50} of 18 and 23 µg a.i./L) and amphibians (LC_{50}= 8.2 µg a.i./L).

The Agency identified potential acute and chronic risks to FW fish. The acute RQs exceed the LOC of 0.5 for all uses except cranberry (RQs up to 6). The highest acute RQs resulted from modeling of non-agricultural uses on turf, while the highest modeled agricultural-use RQs were for cucurbits (RQ = 2.7). For chlorothalonil (parent only) acute risk, the EECs for a variety of agricultural and non-agricultural uses exceed or approach test concentrations that resulted in 90 and 100% mortality for the freshwater rainbow trout (36 µg a.i./L).

On a chronic exposure basis, all uses exceed the LOC of 1.0. The FW fish chronic RQs range from 1.3 to 46 (based on 78% reductions in fecundity). The highest chronic RQs resulted from modeling of non-agricultural uses on ornamentals (RQ=46), while the highest modeled agricultural-use RQs were for almond/pistachio (RQ = 20.3). On a chronic exposure basis, fathead minnow fecundity was affected in both the short-term reproduction study (78% reduction in fecundity at the highest concentration of 7 µg a.i./L; NOAEC: 0.77 µg a.i./L) and the early life stage (ELS) study (NOAEC 1.3 µg a.i./L). If using the LOAEC from the ELS study (LOAEC=3.0 µg/L), rather than the value from the short-term reproduction assay used for risk

assessment, the EECs exceed the concentrations where reductions in fecundity occurred for most uses. This study (MRID 00030391) is classified as Supplemental due to replicate size and solvent control mortality (microbial buildup in one replicate). The calculated acute-to-chronic ratio (ACR) for fathead minnow, (*i.e.*, 23/1.3=17.7) results in an estimated NOAEC of 1.0 µg a.i./L for rainbow trout. Therefore, even though rainbow trout are the more sensitive species, given the similarity, the chronic NOAEC value of 1.3 µg a.i./L for the fathead minnow is considered representative without using the ACR factor.

The Agency identified potential acute and chronic risks to aquatic-phase amphibians. Based on the available data, there are LOC exceedances (acute RQs=0.9-13.2), and EECs also exceed the 100% mortality concentration (24 µg a.i./L). The highest acute RQ was for turf (RQ=13.2), and the highest agricultural use site RQ was for cucurbits (RQ=6).

The chronic RQs exceed the LOC of 1.0 for all use sites for amphibians. The chronic RQs range from 1.7 to 58 (based on growth effects of 23% reduction in weight at days 7 and 21). The highest chronic RQs resulted from modeling of non-agricultural uses on ornamentals (RQ= 58), while the highest modeled agricultural-use RQs were for almond/pistachio (RQ= 25.6). On a chronic exposure basis, amphibians have an endpoint of 0.6 µg a.i./L resulting from the 21-day amphibian metamorphosis assay (with the African clawed frog) based on significant decreases in growth (42 and 23% reduction in weight at days 7 and 21, respectively) at the highest dose of 4.0 µg a.i./L.

Based on available monitoring data, chlorothalonil is frequently detected in the environment with a 24% detection rate out of 35,000 samples from non-targeted monitoring data and values up to 56 µg ai/L from a golf course. Overall, the monitoring data confirms a complete exposure pathway that could impact non-target aquatic organisms.

The Agency has concluded that the acute and chronic risk to freshwater fish and aquatic-phase amphibians may occur from registered uses of chlorothalonil.

Estuarine/Marine Fish

Chlorothalonil labels prohibit applications within 150 feet (aerial and airblast applications) or 25 feet (ground applications) of estuarine and marine waterbodies, which is accounted for in the risk estimates for estuarine/marine (E/M) taxa.

On an acute exposure basis, chlorothalonil is classified as "very highly toxic" to fish (LC_{50} of 23 µg a.i./L). In chronic testing, sheepshead minnow exhibited reductions in weight and length, with a resulting NOAEC/LOAEC of 10.9/23.8 µg a.i./L.

The Agency identified potential acute and chronic risks to estuarine/marine fish. The acute RQs exceed the LOC (LOC=0.5) for many uses for E/M fish (RQs=0.1-2.26). For acute risk in estuarine/marine fish, EECs for chlorothalonil (parent only) exceed or approach test concentrations associated with 90 and 100% mortality in sheepshead minnow for a variety of agricultural and non-agricultural uses (39 µg a.i./L). The highest acute RQ was for ornamentals (RQ=2.26), and the highest agricultural use site RQ was for cucurbits (RQ=1.54). For E/M fish,

the only use that exceeds the chronic LOC of 1.0 is ornamentals (RQ=1.68), with the endpoint based on 16% reduction in wet weight and a 6% reduction in length.

The Agency has concluded that the acute and chronic risk to estuarine/marine fish and aquatic-phase amphibians may occur from registered uses of chlorothalonil.

Freshwater Invertebrates

Chlorothalonil is classified as "very highly toxic" to aquatic invertebrates on an acute basis. The freshwater (FW) water flea 48-hour EC_{50} is 54 µg a.i./L. On a chronic exposure basis, the life-cycle toxicity study with the FW daphnid resulted in a NOAEC/LOAEC of 0.6/1.8 µg a.i./L based on reduced survival.

The Agency identified potential acute and chronic risks to FW invertebrates. There are acute LOC (LOC=0.5) exceedances for FW invertebrates exposed in the water column with RQs ranging between 0.1- 2.01. The highest acute RQ was for turf (RQ=2.01), and the highest agricultural use site RQ was for cucurbits (RQ=0.91). There is also a potential for acute risk for benthic dwelling FW invertebrates using pore water EECs and water column toxicity data as a proxy. The only potential acute risk of concern identified for FW benthic invertebrates is from the cranberry with an acute RQ of 11.22. Therefore, based on the available data, there is a potential acute risk concern for water column and benthic dwelling invertebrates, especially from the use on cranberry (a crop associated with both FW and E/M environments when considering the discharge).

For FW invertebrates in the water column, all uses are noted to exceed the chronic LOC of 1.0 with RQs up to 88.92 (based on reductions in survival). The highest chronic RQ was for turf, and the highest agricultural use site RQ was for almond/ pistachio (RQ=40.62). For FW benthic invertebrates, the only chronic RQ that exceeds the LOC is for the cranberry use (porewater RQ=3.7 and sediment RQ=3.29).

The Agency has concluded that the acute and chronic risk to freshwater invertebrates may occur from registered uses of chlorothalonil.

Estuarine/Marine Invertebrates

Chlorothalonil is classified as "very highly toxic" to aquatic invertebrates on an acute basis. The most acutely sensitive species tested is the Eastern oyster (96-hour IC_{50} = 3.6 µg a.i./L based on a reduction in shell deposition). The 28-day study with the E/M mysid resulted in a NOAEC/LOAEC of 0.38/0.83 µg ai/L, based on reduced offspring/female.

As with estuarine/marine (E/M) fish, the Agency included the 150 foot aerial buffer and 25 foot ground buffer from E/M waterbodies in the modeling. The Agency identified potential acute and chronic risks for E/M invertebrates. There are acute LOC (LOC=0.5) exceedances for E/M invertebrates exposed in the water column (RQs=0.9-17.57). The highest acute RQ was for ornamentals, and the highest agricultural use site RQ was for cucurbits (RQ=12.01). There is

also a potential for acute risk for benthic dwelling invertebrates using pore water EECs and water column toxicity data as a proxy, with RQ exceedances ranging from 0.56 to 168. The highest acute RQ was for cranberry use.

For E/M invertebrates in the water column, all conventional uses exceeded the chronic LOC (LOC=1) with RQs up to 84.63 (based on a 22% reduction in offspring/female). The highest chronic RQ was for ornamentals, and the highest agricultural use site RQ was for berry and small fruit (RQ=41.11). There were no chronic LOC exceedances for benthic dwelling invertebrates.

The Agency has concluded that the acute and chronic risk to estuarine/ marine invertebrates may occur from registered uses of chlorothalonil.

Aquatic Vascular and Non-Vascular Plants

The Agency did not identify risks of concern to aquatic vascular plants but did so for aquatic non-vascular plants (RQs 0.6-9, LOC = 1.0). The highest RQ was for turf, and the highest agricultural use site RQ was for cucurbits (RQ=4.1). The most sensitive non-vascular plants were the freshwater alga (*Navicula pelliculosa*) and marine diatom (*Skeletonema costatum*) with similar EC_{50} values of 12 µg a.i./L and 14 µg a.i./L, respectively.

The Agency has concluded that the likelihood of adverse effects to aquatic vascular plants from the registered uses of chlorothalonil is considered low, while the potential risks of concern are likely to occur for non- vascular plants.

b) Antimicrobial Uses

Terrestrial Risks

Risks of concern to terrestrial taxa (including pollinators) are not expected from the currently registered antimicrobial uses of chlorothalonil due to low exposure potential.

Aquatic Risks

Of the current uses, the material preservatives in products used in wet-end processes of paper manufacturing (i.e., in the process water), exterior paint/coatings, and pressure treated woods are expected to result in the highest aquatic exposures. Other chlorothalonil uses such as material preservation of paper coatings applied to finished paper products on the dry-end of paper processing, building materials (e.g., caulks, grouts), and sapstain control uses may have the potential for environmental exposure, but wet-end paper use, exterior paints/coatings, and pressure treated wood use directly discharge or leach into aquatic areas and are considered to be protective of the other uses.

When chlorothalonil is used in pulp and paper mills as a material preservative in the papermaking slurry or wet-end of the paper production process, there are risks of concern for all

aquatic taxa assessed. For low-flow streams receiving facility effluent, concentrations of concern (COCs) were exceeded for 29-360 days. For average-flow streams, the COCs were exceeded 3-295 days. Based on the high application rates of chlorothalonil and the sensitivity of both freshwater and estuarine/marine aquatic organisms to parent chlorothalonil, risks from the use of chlorothalonil in the material preservation of paper products are expected for all aquatic receptor groups modeled for this use pattern.

For exterior paints/coatings, a screening-level risk assessment assuming a leach rate of 100% (the Agency assumes 100% when use-specific leaching data are not available to support a more refined leach rate) found risk to freshwater fish (acute and chronic), freshwater invertebrates (acute and chronic), and non-vascular plants assessed when one house adjacent to a waterbody is painted with chlorothalonil preserved paint. Based on the most sensitive species (freshwater invertebrates, chronic risk), and 100% leaching, the Agency estimated that up to 76 ft^2 (latex paint) and 65 ft^2 (oil-based paint) or less than one house could be treated without exceeding a concentration that would result in a LOC exceedance. Based on the least sensitive species (vascular plants), 80,868 ft^2 (latex paint) and 69,200 ft^2 (oil-based paint) or 24 to 29 houses could be treated without exceeding levels of concern. For exterior paints/coatings, exposure is expected for freshwater and estuarine/marine organisms but may be reduced by sorption to soil and sediment with an average chemical absorption coefficient (Kf) value of 56 L/kg which reduces aqueous concentrations.

For wood preservative use, modeling demonstrates that >90 docks with a total surface area of >7,020 ft^2 could be put into an aquatic habitat before there would be risks of concern for the most sensitive taxa – freshwater invertebrates. When used as a preservative in pressure-treated wood, no risks to freshwater and estuarine species are expected from chlorothalonil based on data that demonstrate limited leaching from wood and limited water solubility (<1 mg/L) without considering the potential for sorption to soil and sediment.

Ecotoxicity data indicate that chlorothalonil is less toxic to benthic invertebrates than it is to invertebrates living in the water column. However, based on the sorption and persistence of chlorothalonil in soil and sediment, as well as some toxicity to benthic dwelling organisms, risk to these organisms is expected when used as a material preservative in exterior paints/coatings and pulp and paper use.

2. Ecological Incidents

EPA reviewed chlorothalonil incidents reported to the Incident Data System (IDS). As of EPA's latest search on September 25, 2020, IDS showed 36 incidents reported from 1998 to 2020 for conventional uses of chlorothalonil and no incidents attributed to antimicrobial uses. Since 2012, there were several incidents classified as "possible" for plants, fish, and bees. An incident rated as probable from 2006 (I017726-017) reports feather loss and dermal irritation to 113 of 125 young chickens that were exposed from spray drift. The product applied was reported to be a liquid mixture ground spray application of fluazifop-p-butyl (Fusiland Dx) and chlorothalonil (Bravo Ultrex) that accidentally drifted to the residential area where the chickens were exposed. Most bee incidents included other pesticides in addition to chlorothalonil, so it is difficult to determine causation with the information available.

There is a 2021 reported incident that is currently in review. The incident reports fish mortality in Chartiers Creek near a golf course in PA. While causation is still being determined, the incident is consistent with the risk assessment findings. The Agency intends to monitor ecological incidents for chlorothalonil and will conduct additional analyses if necessary.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for chlorothalonil is not considered complete. Given the uncertainties surrounding potential risks to terrestrial invertebrates for conventional uses of chlorothalonil, EPA has determined that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although EPA identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for chlorothalonil, the problem formulation and registration review DCI for chlorothalonil were both issued prior to the EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*[36]. This 2014 guidance lists pollinator studies that were not included in the chlorothalonil registration review DCI. If the Agency determines that additional pollinator exposure and effects data are necessary for chlorothalonil, then EPA will issue a DCI to obtain these data. The pollinator studies that could be required are listed in Table 2 below.

Table 2: Potential Pollinator Data Requirements

OCSPP Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honey bees
850.3030	Honey bee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity
Non-Guideline	Honey bee adult chronic oral toxicity
Non-Guideline	Honey bee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

As part of the EDSP WoE review of EDSP Tier 1 assays, an EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) was recommended for chlorothalonil. This recommendation will be further addressed in subsequent updates on implementation of the EDSP under FFDCA section 408(p).

[36] Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Additionally, soil column leaching study (GLN 835.1240) was not submitted. This study could be used to further refine risk to aquatic taxa. The soil column leaching study was called in through the GDCI as described in Section I.A. and is still considered outstanding.

C. Benefits Assessment

Chlorothalonil is a fungicide registered for both conventional and antimicrobial uses. A discussion of the benefits of each of these use types follows.

1. Conventional Use Benefits: Agricultural Use Sites

Chlorothalonil is important in the production of a broad variety of crops, including peanut, potato, cucurbit vegetables, fruiting vegetables, stone fruit, celery, asparagus, cole crops, bulb crops, fresh beans, cranberry, blueberry, and ginseng. Chlorothalonil is used as a foliar-applied protectant fungicide to prevent economically important diseases caused by a broad spectrum of pathogens, including those caused by fungi and oomycetes, and to delay the development of fungicide resistance to highly efficacious single-site fungicides. Chlorothalonil is important for the management of a broad spectrum of diseases, including peanut leaf spot diseases, early blight and late blight of potato and tomato, cherry leaf spot in tart cherries, and gummy stem blight and downy mildew in cucurbits. If these diseases are not managed effectively, they can quickly spread within and between fields, causing widespread yield and quality losses.

Multisite fungicides such as chlorothalonil inhibit multiple biological processes in target pathogens. These fungicides have a broad spectrum of activity and are considered very low-risk for fungicide resistance development. Growers use chlorothalonil not only to manage an array of fungal and oomycete diseases but also to prevent or reduce development of resistance to single-site fungicides. Without chlorothalonil, growers would need to use alternative multisite fungicide(s), if available. Alternative multisite fungicides may be inferior to chlorothalonil with regard to label requirements (e.g., longer pre-harvest intervals preventing late-season applications), efficacy, or plant safety. If an adequate alternative multisite fungicide is not available, growers would need to use more single-site fungicides, drastically increasing the risk of fungicide resistance development, which could further reduce the pool of available efficacious fungicides, especially for resistance-prone pathogens such as *Botrytis* spp. and *Colletotrichum* spp.

For more information about the agricultural benefits of chlorothalonil, please see *Chlorothalonil (PC Code 081901) Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites* available in the chlorothalonil docket.

2. Conventional Use Benefits: Non-Crop Use Sites

In turf and ornamentals, the benefits of chlorothalonil are its effective control of a wide range of fungal diseases, utility in disease resistance management, flexible number of allowable applications and retreatment intervals, and its cost-effectiveness relative to available alternatives. While there are no exact replacements for chlorothalonil in turf and ornamental sites, potential chemical alternatives which display the most similar characteristics and benefits are those

fungicides with multisite modes of action (MOAs). These include mancozeb, captan, and copper-based compounds.[37] Potential alternatives that have a single site MOA which target a narrower spectrum of pests can effectively control individual diseases but not the full suite of diseases targeted by chlorothalonil. Additionally, these potential single-site MOA alternatives do not offer any of the resistance management benefits conferred by chlorothalonil, and plant pathogens are at a much higher risk of developing resistance. There is currently documented resistance for several potential alternative active ingredients and fungicide chemical groups against key diseases currently controlled with chlorothalonil. If users were forced to replace chlorothalonil, they would most likely need to apply more than one active ingredient in order to achieve the same level of control as with chlorothalonil (given the broad range of diseases controlled by chlorothalonil) and manage for resistance, which would increase fungicide costs.

For more information about the benefits of chlorothalonil in turf and ornamentals, please see *Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals* in the chlorothalonil docket.

3. Antimicrobial Use Benefits

Antimicrobial uses of chlorothalonil include wood preservation, mold control and material preservation. The wood preservation uses include surface treatment, pressure treatment and anti-sapstain applications. The mold control uses include surface treatment of interior walls, surfaces and framing in buildings. The material preservative uses include non-food uses in caulks and sealants, paper, paperboard, paper coatings and paperboard coatings and uses in adhesives, grouts, joint compounds, paints, stains, and coatings.

Wood Preservation

Chlorothalonil was first registered as a wood preservative and anti-sapstain in the late 1970s. Wood preservative products are those that claim to control wood degradation problems due to fungal rot or decay, sapstain, molds, or wood-destroying insects.[38] Though information from the US Department of Agriculture (USDA) suggests that chlorothalonil is not a key active ingredient in the antisapstain market, chlorothalonil has several of the qualities of an effective wood preservative, including: good solubility and ability to penetrate the wood, and efficacy against the fungi that cause sapstain in freshly sawn lumber.[39,40]

Sapstain is the discoloration of freshly sawn timber due to fungal growth. The discoloration can range from blue to grayish-black and can make the sawn wood unsuitable for certain uses.[41]

---

[37] Thiram and ziram would also be considered potential multisite fungicide alternatives. As of the publication of this PID, a final decision on these uses has not been issued. However, in February 2022, the Agency proposed cancellation of all conventional use sites, including turf and ornamentals.

[38] EPA. 2017. *Overview of wood preservative chemicals*. Available online: https://www.epa.gov/ingredients-used-pesticide-products/overview-wood-preservative-chemicals

[39] "USDA Comments on the Draft Human Health and Ecological Risk Assessments for Chlorothalonil for Registration Review; EPA-HQ-OPP-2011-0840." (https://www.regulations.gov/comment/EPA-HQ-OPP-2011-0840-0125)

[40] Ibid

[41] Wolman Wood and Fire Protection. *Sapstain/Blue Stain Fungi*. https://www.wolman.de/en/infocenter-wood/about-wood-pests/sapstain

Antisapstain treatments such as chlorothalonil are applied to debarked logs or rough sawn lumber at the wood mill.[42] This treated layer of wood is removed during the final milling process and thus, exposure to end users and the environment is not likely to result from this use. Alternative anti-sapstain active ingredients include Iodopropynyl Butyl Carbamate (IPBC) and propiconazole, which, together, account for almost 70% of hard wood anti-sapstain treatments, in terms of dollar sales.[43] Other alternatives include methylene bisthiocyanate (MBT), 2-(Thiocyanomethylthio)-benzothiazole (TCMTB) and copper 8-quinolinolate.

Mold Control

Mold control products containing chlorothalonil are surface treatments that are intended to be applied to interior walls and surfaces in order to kill mold and mildew as well as inhibit future growth. Mold control products are useful in moist and humid environments where mold and mildew grow easily. EPA reviewed market research data for chlorothalonil usage in mold control. Data specific to chlorothalonil was unavailable, suggesting that chlorothalonil products make up a small portion of the mold control market.[44]

Material Preservation: Paints and Coatings

Chlorothalonil is used as a materials preservative in various materials including paints and coatings, paper products, and adhesives. Among these use sites, chlorothalonil is most widely used as a dry-film mildewcide preservative for paints. Paints are pigments suspended in either oil, acrylic polymer, or water. Between these three media, water is especially susceptible to microbial contamination by bacteria and fungi. A dry-film preservative is used to combat these effects after the paint is applied. This is in contrast with in-can preservatives which are used to combat these effects prior to the paint being applied. Microbial breakdown of dry-film paints is caused by high levels of moisture (e.g., condensation or rainfall), high microbial activity, and the presence of nutrients necessary to support microbial growth.[45]

Dry-film preservation systems for coatings require a specific set of characteristics to be considered efficacious: broad spectrum fungicidal efficacy, strong initial and long-term coverage protection, and chemical stability in both wet and dry-film stages. Each characteristic of the treated paint is necessary for dry-film preservation while also simultaneously not impacting the finished paint color or drying time.[46]

Chlorothalonil is an efficacious and widely used fungicide but has efficacy gaps against *Aspergillus niger* and *Penicillium* species. Additionally, chlorothalonil has good long-term coverage due to leaching resistance and low water solubility. Finally, chlorothalonil is generally stable in both the wet (in-can) phase and dry-film phase, with temperature stability above 100

[42] Sidhu, Avtar. *Anitsapstain Industry in North America*. 2011. Wood Preservation Canada (CWPA) Annual Meeting. Available online: https://woodpreservation.ca/wp-content/uploads/2021/09/sidhu32.pdf
[43] Kline and Company. 2017b. Specialty Biocides 2016: United States Market Analysis. Accessed September 2021
[44] Ibid
[45] "Extending the Life of Dry-Film Coatings by Selecting the Right Preservative Systems." McGough, 2019. (https://www.coatingsworld.com)
[46] Ibid

degrees Celsius and stability in neutral, as well as acidic conditions, however chlorothalonil may be prone to hydrolysis in the pH range above 9.[47]

In 2016, chlorothalonil ranked fourth (by weight; representing about 4% of total volume applied) among active ingredients used for dry-film paint preservation, following IPBC, zinc pyrithione and octhilinone (OIT). Other active ingredients used in dry-film paint preservation include carbendazim, diuron and Dowicil-75.[48]

Materials Preservative: Paper Products

Chlorothalonil is also used to prevent the growth of mold and mildew in paper products such as paper labels and soap packaging. Chlorothalonil is generally applied to finished paper products and is subsequently dried and rolled before shipment.[49] This is known as a "dry-end" application as opposed to "wet-end" applications, where the antimicrobial active ingredient is incorporated into the papermaking slurry. Because chlorothalonil is used primarily as a dry-end preservative, this greatly reduces the potential for environmental exposure resulting from the papermaking use pattern.[50]

Materials Preservative: Adhesives

Finally, chlorothalonil is registered for incorporation into adhesives, including sealants, caulks, and plasters. Adhesives are susceptible to microbial degradation during manufacturing, shipping, and storage due to the presence of biodegradable emulsifiers, stabilizers, and cellulosic thickeners present within the adhesive formulation. In-can preservative systems require waterborne biocides to protect latex-based adhesive products, while dry-film adhesives are preserved using biocides with low water solubility applied in both aqueous and solvent adhesive systems. Biocides are added to the formulation to prevent the growth of mold, mildew, algae, and other microbes that cause premature failure. Premature failure results from the breakdown of the adhesive film and formation of pores in the film. Biocides with low leachability and broad fungicidal and algicidal activity are selected for greater long-term efficacy, and combinations of biocides are common to provide broader efficacy against target organisms.[51]

Though chlorothalonil does have traits that would make it an effective adhesive preservative, a review of market research data showed no additional information for chlorothalonil's use in the preservation of adhesives, [44] suggesting that it is used minimally in that use site.

[47] Ibid
[48] Kline and Company. 2017b. Specialty Biocides 2016: United States Market Analysis. Accessed September 2021
[49] "Public Comment for the Registration Review Draft Antimicrobial Risk Assessment posted on May 21, 2021 to the Chlorothalonil Registration Review Docket EPA-HQ-OPP2011-0840." Sipcam Agro USA, Inc. (https://www regulations.gov/comment/EPA-HQ-OPP-2011-0840-0084)
[50] Ibid
[51] Adhesives and Sealants Industry (ASI): Biocides. 2004. The necessary evil of protecting and preserving adhesives and sealants. https://www.adhesivesmag.com/articles/85555-biocides

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Risk Mitigation and Regulatory Rationale

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 chlorothalonil at this time in the registration review process, EPA is proposing in this PID certain changes to the affected registrations and their labeling. EPA proposes that the mitigation measures identified in Section IV and Appendices A, B, C, and E would address specific risks of concern identified at this point in the ongoing registration review process.

At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[52] However, what is proposed in this PID may not be sufficient for EPA to determine that chlorothalonil registrations continue to satisfy the FIFRA standard for registration. EPA may determine that additional mitigation or other measures are necessary in its final registration review decision. The Agency has reviewed the risks and benefits associated with the registered uses of chlorothalonil in developing this PID and has identified proposed interim risk mitigation to address the risks discussed in Section III of this document.

For conventional uses of chlorothalonil, EPA identified human health risks of concern from dietary (food + drinking water) exposure. Drinking water via groundwater exposure was the major contributor to dietary exposure. EPA proposes that these human health dietary risks of concern from registered uses of chlorothalonil are inconsistent with the FFDCA safety standard. Taking into consideration the available information on toxicity and exposure, EPA found risks exceeding the Agency's levels of concern. Based on currently available information, EPA proposes that it cannot conclude that residues of chlorothalonil in or on food are safe without the proposed mitigations identified below. No other conventional use human health risks of concern were identified. EPA also identified acute and chronic risks of concern for birds, mammals, fish, amphibians, aquatic invertebrates, and aquatic non-vascular plants resulting from registered conventional uses. Risks for terrestrial invertebrates could not be fully assessed due to lack of data.

For antimicrobial uses of chlorothalonil, EPA identified human health risks of concern from occupational exposures to workers preserving materials (such as paints) with products containing chlorothalonil. EPA also identified acute and chronic risks of concern for aquatic taxa resulting from chlorothalonil's use as a materials preservative in the wet-end of the papermaking process and from the use of chlorothalonil-treated exterior paints and coatings.

EPA also evaluated the benefits of chlorothalonil's conventional and antimicrobial uses. The Agency found that chlorothalonil provides high benefits to users and is a unique active ingredient

[52] 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]").

with efficacy against a broad range of economically important diseases. More information is available in Section III.C. of this document and, for conventional uses, in the following documents which will be issued to the docket simultaneously with this PID: *Chlorothalonil (PC Code 081901) Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites* (September 29, 2023) and *Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals* (September 14, 2023).

The Agency is proposing several mitigation measures, such as reductions to maximum annual application rates, and buffers to all aquatic areas. EPA is also proposing FIFRA IEM measures to reduce exposure to nontarget species, including listed species, at this time based on the use patterns of chlorothalonil. EPA is proposing to require incident reporting language, Bulletins Live Two (BLT) reference language, pollinator advisory language, spray drift mitigation, and wind-directional drift buffers to conservation areas. In addition, EPA is in the process of implementing the 2011 NMFS Salmonid BiOp for chlorothalonil and is proposing certain nationwide restrictions on the general pesticide product labeling and other restrictions on a geographic-specific basis in Endangered Species Protection Bulletins (Bulletins) that are accessed through the BLT website and made enforceable through directions to access and follow them on pesticide labeling.[53] Finally, EPA proposes label changes to address general labeling requirements for all chlorothalonil products and uses. For the antimicrobial uses of chlorothalonil, EPA is also proposing to require PF10 respirators for occupational handlers and to limit the use of chlorothalonil to the dry-end of the papermaking process. The registrants are aware of the proposed mitigations in this PID.

EPA encourages submission of comments about these proposed mitigations and their possible impacts to the public docket for this PID (EPA-HQ-OPP-2011-0840).

1. Proposed Risk Mitigations for Conventional Uses

a) Proposed Mitigation: Reductions to Maximum Annual Application Rates

EPA proposes changes to maximum annual application rates to address both the dietary risks of concern and the ecological risks of concern for chlorothalonil. These proposed annual application rate reductions described below partially mitigate the ecological risks identified. To further mitigate the ecological risks, EPA is proposing additional measures listed in subsequent mitigation measure sections. EPA relied on historical chlorothalonil usage data to assist in identifying annual application rates that balance reducing risk and minimizing user impacts. In some cases, the proposed annual rates are derived from usage data indicating that a lower maximum annual application rate is not likely to unduly impact users.

EPA proposes that there are human health dietary risks of concern from registered uses of chlorothalonil that are inconsistent with the FFDCA safety standard. Based on currently available information, EPA proposes that it cannot conclude that residues of chlorothalonil in or on food are safe without the proposed mitigation. EPA is therefore proposing rate reductions to

[53] https://www.epa.gov/endangered-species/bulletins-live-two-view-bulletins

reduce the amount of chlorothalonil entering drinking water thus reducing dietary exposure and risk in vulnerable soils. “Vulnerable soils” are defined as sandy or coarse-textured soils with less than 2% organic matter content and occur where the water table is 30 feet or less from the surface. All other soils are designated as “non-vulnerable.”

EPA is not proposing any rate changes to indoor uses of chlorothalonil (mushrooms and ornamentals grown indoors) as the potential for chlorothalonil to enter groundwater sources is greatly reduced.

EPA has limited usage data for select sites, such as mangoes and persimmons, and welcomes any additional usage data from chlorothalonil users and stakeholders.

Maximum Annual Application Rate Reductions

To address ecological risks of concern, the Agency is proposing reductions to maximum annual application rates (in lbs a.i./acre/year). For sites for which usage data were available and sufficiently robust, EPA relied on historical chlorothalonil usage data to assist in identifying annual application rates that balance reducing risk and minimizing user impacts. In some cases, the proposed annual rates are derived from usage data indicating that a lower maximum annual application rate is not likely to unduly impact users. Tables 3 and 4 list the proposed annual rates by use site.

Table 3: Proposed maximum annual application rates by use site (agricultural food uses) for non-vulnerable soils

Use Sites- Ag	**Annual application rate (lbs a.i. /A/yr)**
Almond, Filbert (Hazelnut), Pistachio; Beans, Dried; Lentils; Lupine; Parsnip; Sugar beet (grown for seed)	6.0
Asparagus	7.5
Beans (Snap)	7.2
Blueberry; Grass (Forage, Hay, Seed); Soybean; Strawberry (nursery seedlings for pre-transplant; non-food)	4.5
Brassica/Cole (Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	3.75
Cabbage	7.5
Carrot	7.5
Celery	5.5
Conifer (i.e., Christmas tree plantations)	16.5
Corn, Field (grown for seed); Mint	3.0
Corn, Sweet	7.5
Cranberry	10.0
Cucurbits	9.0
Fruiting Vegetables except Tomato	6.75

Use Sites- Ag	Annual application rate (lbs a.i. /A/yr)
Fruiting Vegetables except Tomato in Florida, Georgia, North Carolina, and South Carolina	7.9
Ginseng	12.0
Grass Grown for Seed*	4.5
Horseradish	18.0
Onion (Dry Bulb); Garlic	9.0
Onion (Green Bunching); Leek; Shallots; Onion and Garlic (Grown for Seed)	6.7
Papaya*	6.75
Passion Fruit*	7.5
Peach	12.4
Peanut	6.75
Persimmon	4.7**
Potato	8.0
Rhubarb*	13.5
Apricot, Nectarine, Plum, Prune, and Sweet cherry,	6.5
Tart cherries*	15.4
Tomato	6.5
Tomato in Florida, Georgia, North Carolina, and South Carolina	10.5
Turf – Sod	12.6
Yam	8.0
Mango	4.7**
Mushrooms (Indoor)*	8.25***

*no proposed rate change
** EPA is seeking input on usage and rates
***rate in fl oz/1000 sq ft of bed; rate based on cropping cycles not annual applications

For mushrooms grown indoors, the potential for chlorothalonil to enter groundwater sources is greatly reduced; therefore, EPA is not proposing any changes to the indoor mushroom maximum application rates.

Table 4: Proposed maximum annual application rates by use site (non-agricultural uses) for non-vulnerable soils

Use Sites Non-Ag	Annual application rate (lbs ai /A/yr)
Conifers* (i.e., nursery beds, seed orchards, and landscape ornamentals)	16.5
Ornamentals – Field Grown	18.75
Ornamentals – Root/Bulb Dip	18.75
Ornamentals – Spot Treatment (outdoor)	18.75
Ornamentals – Greenhouse/Indoors/Containers*	36.4

Turf – Golf Course Fairways	22.6
Turf – Golf Course Tees	33.9
Turf – Golf Course Greens	45.2
Turf – Industrial, Athletic Fields	22.6

*no proposed rate change

For ornamentals grown in containers or indoors (greenhouse), the potential for chlorothalonil to enter groundwater sources is greatly reduced; therefore, for ornamentals grown in containers or indoors, EPA is proposing no changes to current maximum annual application rates.

For each outdoor use site, EPA proposes the following label language:

> "Do not apply more than [XX] lbs chlorothalonil per acre per year."

Maximum Annual Application Rate Vulnerable Soils Restrictions

To address potential groundwater contamination and drinking water risks, EPA is proposing the maximum annual application rate restrictions listed in Table 5 for all outdoor use sites where plants are grown in vulnerable soils, defined as having all three of the following characteristics:

- sandy or coarse-textured soils, based on USDA's soil classification system (see USDA's Web Soil Survey tool to determine soil texture): https://websoilsurvey.nrcs.usda.gov/app/HomePage.htm);
- less than 2% organic matter content; and
- the water table occurs at a depth of 30 feet or less from the surface.

These restrictions are based on groundwater modeling. To help prevent chlorothalonil and its residues of concern from leaching into groundwater, EPA is proposing yearly maximum application rates, listed by use site in Table 5 below, for soils with sandy or coarse textures, low organic matter, and shallow depth to groundwater. Water movement through the soil profile is faster through sandy soils than through clay soils; therefore, a sandy soil texture restriction is important for mitigating potential groundwater contamination. Soils with low organic matter content have greater leaching potential because organic matter binds some chemicals and keeps them from moving through the soil profile. Organic matter also aids in water retention. EPA expects that rate reductions for vulnerable soils will reduce the potential for dietary exposure.

If a use site's current annual rate limit or the annual rate proposed in Tables 3 or 4 is less than 6.5 lbs a.i./acre/year, then that lower rate is maintained for vulnerable soils and no further changes are proposed. Table 5 lists the proposed annual rates by use site for vulnerable soils.

Table 5: Proposed maximum annual application rates by use site for vulnerable soils

Use Sites	**Annual application rate (lbs ai /A/yr)**
Corn, Field (grown for seed); Mint*	3.0

Brassica/Cole (Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	3.75
Blueberry; Grass (Forage, Hay, Seed); Grass Grown for Seed*; Soybean*; Strawberry (nursery seedlings for pre-transplant; non-food)	4.5
Mango and Persimmon	4.7
Celery	5.5
Almond, Filbert (Hazelnut), Pistachio; Beans, Dried*; Lentils; Parsnip*; Sugar beet (grown for seed)	6.0
Turf (Sod, Industrial, Athletic Fields; Golf Courses)	6.2
All other use sites	6.5

*no proposed rate change

For each outdoor use site, EPA proposes the following label language for vulnerable soils:

> "For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than [XX] lbs chlorothalonil per acre per year."

These proposed annual application rate reductions mitigate the human health risks identified and partially mitigate the ecological risks identified. To further mitigate the ecological risks, EPA is proposing additional measures listed in the following mitigation measure sections.

Proposed Restrictions and Advisory Statements for Residential Users with On-Site Drinking Wells

The Agency is proposing to limit residential user applications, who obtain their drinking water from an on-site well, to the vulnerable soils rates proposed in Table 5 with additional advisory language warning applicators to not apply within 30 feet of wells. EPA proposes the following language:

> "For residential users who obtain their drinking water from an on-site well, do not apply more than [XX] pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 feet of drinking water wells will further reduce the risk of drinking water contamination."

EPA encourages stakeholders to provide information on the potential impacts of this proposed mitigation during the public comment period.

Impacts of Annual Maximum Application Rate Reduction for Crops on Vulnerable and Non-Vulnerable Soils

An annual application rate reduction of chlorothalonil will affect some growers more than others. Some growers currently utilize multiple applications of chlorothalonil to control/prevent disease on their crop/site. A reduced maximum annual application rate means that growers who currently utilize a higher annual application rate than the proposed maximum allowed annual application rate will need to make fewer applications over the course of the year or incorporate an alternative

fungicide(s) in place of one or more chlorothalonil application(s). Growers most likely to be affected are those located where disease pressure is high and those operating on vulnerable soils. Disease is favored in areas where it is cool, wet and/or humid. The Agency found that areas that face higher disease pressure for diseases targeted by chlorothalonil tend to occur in the Southeast, Northeast, and upper Midwest regions of the United States.

Specifically, the Agency found that limiting the maximum allowed annual application rate on vulnerable soils to 6.5 lb a.i./acre/year is most likely to impact tart cherry, potatoes, and carrot production in the upper Midwest, tomatoes in the Southeast, and cranberries in the Northeast. Ginseng production may also be affected. Potential impacts include yield and quality losses from reductions in disease management and increased risk of fungicide resistance if growers needed to use more single-site fungicides to maintain disease control.

The Agency expects that the potential reductions of annual application rates for crops on non-vulnerable soils listed in Table 3 will have little to no impacts to growers, depending on the use site. For more details, see *Chlorothalonil [PC Code 081901] Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites*.

Based on the proposed mitigation, the dietary risks of concern would be resolved and would no longer be of concern.

EPA encourages stakeholders to provide information on the potential impacts of this proposed mitigation during the public comment period. In addition, the Agency seeks input on the use and usage of chlorothalonil on persimmon and mangoes.

Impacts of Maximum Annual Application Rate Reductions on Turf and Ornamentals

EPA expects impacts from this mitigation especially in golf course use sites, where usage information indicates that users apply the currently labeled maximum single application rate of 12.6 lb a.i./acre up to eight times per year. Reducing annual maximum application rates could limit the control of target diseases, in which case users might stop using chlorothalonil and switch to alternative fungicide(s), while also leaving them with a limited number of multi-site MOA fungicides which are not as effective against the same suite of diseases as chlorothalonil. Additionally, if chlorothalonil cannot effectively control target diseases within the reduced annual application rates, users are likely to increase their reliance on a greater number of single-site MOA fungicides, along with an increased number of applications to control those diseases currently treated with chlorothalonil. This increased incorporation on less effective multi-site MOA fungicides, and increased reliance and application of single-site MOA fungicides, could lead to sub-optimal control of diseases targeted by chlorothalonil and an overall increase in disease pressure due to efficacy and/or disease resistance development. Users would also have to potentially adopt additional cultural and mechanical control methods to provide added disease control and/or suppression, increasing operational costs and reducing management flexibility. Therefore, a reduction in maximum annual application rates in turf and ornamental sites could hinder resistance management efforts, increase single-site MOA fungicide applications, and promote a sub-optimal control of target diseases, ultimately being reflected in higher operational costs, decreased product quality, and/or the discontinuation of products (e.g., specific ornamental

and turf varieties) due to unfeasible production/operational costs or unacceptable product quality within the market. For more details, please see *Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals* in the public docket for this PID, EPA-HQ-OPP-2011-0840.

Based on the proposed mitigation, the dietary risks of concern would be resolved and would no longer be of concern. Without the proposed mitigation for the vulnerable soils, registered uses of chlorothalonil would be inconsistent with the FFDCA safety standard. Based on currently available information, EPA proposes that it cannot conclude that residues of chlorothalonil in or on food are safe without this proposed mitigation. EPA relied on historical chlorothalonil usage data to assist in identifying annual application rates in non-vulnerable soils to mitigate the ecological risks and balance reducing risk and minimizing user impacts. EPA encourages stakeholders to provide information on the potential impacts of this proposed mitigation during the public comment period.

b) Proposed Mitigation: Buffers to All Aquatic Areas

The Agency is proposing extending buffers to all aquatic areas. Buffers are currently only required for estuarine/marine habitats. This proposal extends buffers to freshwater habitats. These restrictions are expected to help mitigate aquatic risks from spray drift and runoff. The following label language is proposed under Use Restrictions:

"This product must not be applied within 150 feet (for aerial and airblast applications) or 25 feet (for ground applications) of water bodies (estuarine/marine and freshwater) unless there is an untreated buffer area of that width between the area to be treated and the water body."

The Agency expects impacts from this proposed requirement. Imposing buffer zones adjacent to freshwater habitats would likely result in affected users switching to alternate fungicides if the treatment use area falls within the established buffer area. Disease management practices specific to each use site could also be impacted in such instances where additional fungicide applications could be necessary. Additional fungicide applications also impose additional labor costs on users. Therefore, buffers adjacent to aquatic areas are anticipated to cause substantial localized impacts in terms of disease management practices, resistance management, and potential economic costs to current chlorothalonil users in use sites with or next to surface water bodies, where smaller acreage use sites are expected to be more impacted than those with large footprints, as a larger share of the total productive area may be affected by a buffer. EPA encourages stakeholders to provide information on the potential impacts of this proposed mitigation during the public comment period.

c) Proposed Label Mitigation: Soil Saturation Statement

Runoff was identified as a potential exposure route of concern for aquatic risks of chlorothalonil. In order to reduce the potential for surface water runoff and protect non-target organisms, EPA is proposing the following soil saturation statement for chlorothalonil products delivered via liquid spray or granules to crops that do not require production in flooded fields or streams:

"Do not apply when soil in the area to be treated is saturated (if there is standing water on the field or if water can be squeezed from soil)."

The Agency expects minor negative impacts from a prohibition on applying chlorothalonil when soils are saturated, as this would limit the available window users have to make time sensitive applications. Users may have to resort to an alternative fungicide without such saturated soil restrictions.

d) Proposed Label Mitigation: Update and Standardize Environmental Hazard, Groundwater and Surface Water Advisory Statements

While chlorothalonil end-use labels already have environmental hazard statements listed, EPA proposes updating these statements to provide clearer guidance to users on protecting surface water and aquatic organisms. Updated language is provided in EPA's Label Review Manual. Chlorothalonil has been detected in groundwater and may pose a risk to groundwater from the labeled conventional uses. EPA proposes updated groundwater and surface water advisory language that will increase awareness among users and promote improved practices to protect water sources. EPA proposes updating and standardizing the following environmental hazard, groundwater and surface water advisory statements:

- *Non-Target Organism Advisory Statement*: "This product is toxic to fish, aquatic-phase amphibians, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."

- *For outdoor terrestrial uses only*: "For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

- *Updated Surface Water Advisory Statement*: "This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow groundwater. This product is classified as having a medium potential for reaching both surface water and aquatic sediment via runoff for several months or more after application."

    - *For labels not intended for residential uses*: "A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of chlorothalonil from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours. Sound erosion control practices will reduce this product's potential to reach aquatic sediment via runoff."

- *Updated Outdoor Terrestrial Use Statement for products intended for homeowner use formulated as liquids*: "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that

wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid runoff to water bodies or drainage systems."

- *Updated outdoor terrestrial use statement for products intended for homeowner use formulated as granules for broadcast application*: "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent runoff to water bodies or drainage systems."

- *Updated outdoor terrestrial use statement for products intended for homeowner use formulated as ready to use products*: "To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area."

- *Groundwater Advisory Statement*: "Chlorothalonil and chlorothalonil degradates are known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow."

    - *For labels intended for homeowner use*: "Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."

e) Proposed Label Update: 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. Based on the results of the 2019 AHETF data, to ensure that all mixers and loaders of liquid formulations are protected from direct exposure to liquid concentrate, the following label language is proposed 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."

f) Proposed Label Update: Glove Statement

The Agency proposes updating the gloves statements on chlorothalonil labels, consistent with Chapter 10 of the Label Review Manual[54]. In particular, EPA proposes removing any references to specific categories in EPA's chemical-resistance category selection chart and specifying the appropriate types of gloves. For specific label language, see Appendix B. The proposed clarification does not fundamentally change the PPE that workers must use.

g) Proposed Label Update: Respirator Statement

The Agency proposes updating the respirator statement on chlorothalonil labels. For specific label language, see Appendix B. The proposed clarification does not fundamentally change the PPE that workers currently must use.

h) Proposed Label Update: PPE for Residential Uses

Any PPE statements on chlorothalonil labels registered for residential uses should be removed. The agency did not identify risks of concern for residential handers in the HHDRA. Further, PPE is not considered a mitigation option for residential handlers because users are not trained, and compliance would not be expected.

i) Proposed Label Update: Resistance Management

The Agency proposes adding resistance-management language to chlorothalonil labels[55] to address pesticide resistance.[56] Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management,[57] EPA intends to propose pesticide resistance measures for existing chemicals during registration review and for new chemicals and new uses at the time of registration. To combat pesticide resistance, resistance management experts recommend using pesticides with different chemical modes (or mechanisms) of action against the same target pest population as part of integrated pest management (IPM) programs. This approach may prevent or delay target pest populations from developing resistance to a particular mode (or mechanism) of

[54] https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm_2-22-21.pdf
[55] For specific label language, see Appendix B.
[56] Pesticide resistance is the ability of portions of a pest population to tolerate or survive otherwise lethal doses of a pesticide through genetic or behavioral changes. EPA considers increased pesticide resistance an adverse effect that can drive increased use of pesticides. For more details, see PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.
[57] PRN 2017-1, "Guidance for Pesticide Registrants on Pesticide Management Labeling" (Aug. 24, 2017), available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

Adding this language will provide pesticide users with easy access to important information on maintaining the effectiveness of pesticides—including chlorothalonil—thereby preserving the benefits of chlorothalonil and other useful pesticides.[58] EPA does not expect this language to affect the risks or benefits of chlorothalonil.

2. FIFRA Interim Ecological Mitigation Measures for Conventional Uses

EPA developed the proposed FIFRA Interim Ecological Mitigation measures in this section to reduce exposure to nontarget species, including listed species, based on the risks and benefits of chlorothalonil.[59] The proposed FIFRA Interim Ecological Mitigation measures for chlorothalonil are as follows:

- Pollinator stewardship advisory language
- Ecological incident reporting label language
- Bulletins Live! Two (BLT) labeling
- Spray drift mitigation
- Wind-directional drift buffers for conservation areas

The proposed FIFRA Interim Ecological Mitigation measures in this PID are not designed to fully address ESA obligations for chlorothalonil during registration review. Rather, they are initial steps under FIFRA that are designed to reduce exposure to all non-target organisms, including listed species, while EPA continues to work towards meeting its ESA obligations and completing a final registration review decision under FIFRA. EPA may propose additional mitigation measures as part of its various ESA initiatives.[60]Additional measures may also be necessary when EPA conducts effects determinations and, if necessary, consults with the Service(s) on chlorothalonil.

The ESA Workplan Update Appendix includes a FIFRA Interim Ecological Mitigation measures, some of which are included in this PID. From November 16, 2022 to February 14, 2023, EPA sought public comment on the full suite of FIFRA Interim Ecological Mitigation measures, which is available in docket EPA-HQ-OPP-2022-0908 at www.regulations.gov.[61] The FIFRA Interim Ecological Mitigation in this PID have been updated based on the public comments submitted during the comment period.

---

[58] For a detailed discussion of chlorothalonil's benefits, see Section III.C, above. Resistance-management language is already on many chlorothalonil labels, but the language is most effective when all product labels reflect resistance-management best practices.

[59] *See ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions* (Nov. 2022), https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

[60] *Id.*

[61] https://www.regulations.gov/document/EPA-HQ-OPP-2022-0908-0002. EPA particularly sought feedback on issues relating to feasibility, user impacts, efficacy, appropriateness, compliance or enforcement issues, and suggested improvements to the proposed labeling.

The FIFRA Interim Ecological Mitigation (IEM) measures not proposed for chlorothalonil include the runoff and erosion mitigation menu, wind-directional drift buffers for aquatic areas, the 48-hour rain application prohibition statement from the runoff mitigation label language, and treated seed label language updates. The mitigation measures proposed in the previous section (rate reductions and buffers to all aquatic areas) aim to mitigate the ecological risks of concern identified for chlorothalonil and, therefore, the runoff and erosion conservation mitigation menu and aquatic area drift buffers in addition to those mitigation measures would not provide additional protections to address the ecological risks of concern. The complete 48-hour runoff statement, which includes a soil saturation statement and a rainfall application timing statement, is not being proposed for chlorothalonil to account for the rainfastness of foliar-applied chlorothalonil products and the importance of applying fungicides before rain events. In the previous section, the Agency proposes a soil saturation statement for chlorothalonil products and in the following section, proposes rain event language in a geographic-specific Bulletin as part of the mitigation to implement the 2011 Salmonid BiOp. Chlorothalonil is not used as a seed treatment, therefore the treated seed label language does not apply.

EPA is proposing updated spray drift language and wind-directional conservation area buffers in the FIFRA IEM section of this PID. These spray drift updates include updates to mandatory and advisory spray drift language to reduce the extent of environmental exposure and risks to non-target plants and animals. These updates include a proposed requirement to measure wind speed and direction prior to application, as well as best management practices for measuring windspeed and direction. EPA is also proposing wind-directional buffers to conservation areas as part of the FIFRA IEM (buffers to aquatic areas are proposed in the previous mitigation section). These additional mitigation measures designed to reduce exposure to all non-target organisms, including listed species.

Impact of Risk Mitigation
The Agency proposed rate reductions and buffers to all aquatic areas in order to mitigate ecological risks of concern, including runoff and erosion risks, and is not proposing any additional mitigation measures for such. The impacts of those mitigation proposal are discussed in their respective sections. Hence, the menu of mitigation measures for runoff and erosion control will not impact growers using chlorothalonil.

a) Advisory Pollinator Stewardship Language

Chlorothalonil is registered for foliar use during bloom on numerous bee attractive crops. Risks to pollinators were not assessed due to lack of data. The high frequency of residue detections in pollen and wax and the toxicity data available from the open literature suggest that exposure to pollinators is likely and that risks of concern may result.

EPA is proposing to include advisory language for insect pollinators. This advisory language distills the most important information growers need to know to voluntarily reduce risk to insect pollinators. The language is intended to raise awareness of potential hazard to bees and other insect pollinators. Although this language is advisory, the goal is to promote use best management practices that applicators may consider to reduce exposures to bees, particularly

managed pollinators. This language is consistent with EPA's pollinator protection strategic plan.[62]

The pollinator hazard statement below is being proposed because there is potential risk to insect pollinators from agricultural crop uses of chlorothalonil. Additionally, the Agency is proposing a statement outlining best management practices for pollinator protection. EPA is proposing this statement because the ecological risk suggests potential risks to insect pollinators from agricultural crop uses of chlorothalonil. The proposed pollinator hazard and best management practices language is as follows:

- **Pollinator Hazard Statement:** "This product may be toxic to bees and other pollinating non-target insects exposed to direct treatment on blooming crops or weeds."
- **Advisory Best Management Practices for Pollinator Protection:** The following best management practices (BMPs) can help reduce risk to pollinators:
    - Develop and maintaining clear communication with local beekeepers to help protect bees. To the extent possible, advise beekeepers within a 1-mile radius 48-hours in advance of the application, and confirm hive locations before spraying.
    - Avoid applications when bees are actively foraging.
    - Avoid applying pesticides to plants in bloom, including flowering weeds.
    - Apply pesticides in the evening or at night when fewer bees are foraging.
    - Use Pollinator Protection Plans when they are available. These plans may be available from state lead agencies and promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees and other pollinators to pesticides.
    - Use integrated pest management to prevent or mitigate potential negative effects to pollinators and consider multiple pest management options before resorting to a pesticide application.
    - Mowing understory weeds or cover crops in orchards and vineyards before blooming can prevent flowering of weeds and reduce exposure to bees where and when pesticides are applied.

  The following BMPs can help promote the health and habitat of ground-nesting bees:
    - For uncultivated land, leaving large undisturbed patches of land un-mowed and untilled can provide nesting and forage sites.
    - For uncultivated land, mowing at the highest cutting height possible (minimum of 8-10 inches if possible) can increase and diversify food sources.

  For additional resources on pollinator BMPs and Pollinator Protection Plans, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators"

[62] https://www.epa.gov/pollinator-protection/pollinator-protection-strategic-plan

b) Ecological Incident Reporting Label Language

EPA has proposed and subsequently required ecological incident reporting language on some pesticide product labels in the past, and ecological incident reporting has been included as a reasonable and prudent measure and/or alternative in biological opinions issued by the Services, including the 2011 BiOp for chlorothalonil. The Agency anticipates the need to add incident reporting labeling as part of any necessary ESA consultation. EPA is proposing incident reporting labeling to provide consistent information to pesticide users on how to report ecological incidents and to expedite any necessary ESA consultation.

EPA has recently revised the ecological incident reporting language based on stakeholder comments received on the Appendix to the ESA Workplan Update. The proposed incident reporting language is as follows:

> "**REPORTING ECOLOGICAL INCIDENTS**: For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target insects, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticide-incidents or call (registrant phone number)."

Requiring reporting of fish mortality (as required for specific areas per the 2011 BiOp) and bee kill incidents (required nationally) is not expected to have large impacts on applicators of chlorothalonil as a registrant phone number will be listed on the label for applicators to call.

c) Bulletins Live! Two Labeling

ESA mitigation can take the form of nationwide restrictions on the general pesticide product labeling or geographic-specific restrictions located in Endangered Species Protection Bulletins (hereafter referred to as Bulletins), which are made enforceable through directions to access and follow them on pesticide labeling. EPA is using a web-based system, Bulletins Live! Two (BLT), to provide timely protections for listed species and to minimize pesticide product labeling changes.

EPA uses BLT when mitigation applies in a particular geographic region where listed species are present and, in some cases, during only certain times of the year. BLT simplifies compliance by offering a tool for users to identify where and when they are subject to the mitigation. When directed by product labeling, pesticide applicators are required to visit the BLT online database, and follow any mitigation specified in a Bulletin for the application area.

Chlorothalonil does not currently have any listed species bulletins. However, the Agency is proposing the following Bulletins language be added to all chlorothalonil product labels to implement the 2011 NMFS BiOp. This language instructs users to check the BLT website to understand listed species use restrictions that may apply to them, if available. In addition to facilitating implementation of the 2011 NMFS BiOp, including this language on product labels will help streamline implementation of any additional risk reduction measures that may be identified during any necessary ESA consultation.

EPA has recently revised the BLT reference language based on stakeholder comments received on the Appendix to the ESA Workplan Update. The proposed BLT language is as follows:

> "**ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS**: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov."

Although the BLT system has been in place for many years, there may be applicators who are unfamiliar with this system. Using the online tool to determine if mitigation is required for a particular treatment area may be a new step that many users will need to take prior to an application. Requiring the use of BLT is likely to have initial impacts in the form of added complexity when planning and performing applications, which may hinder operational procedures and increase training requirements, resulting in potential reduction in productivity and a rise in costs. However, the Agency anticipates that over time and with wider implementation, BLT will become a familiar tool that is integrated into a user's planning process for pesticide applications. In February 2022, EPA released an improved version of BLT[63], which allows users to more easily find the information they need for a particular pesticide product. The Agency has also developed a tutorial[64] that explains how to use the online system. In addition, the general label language referring users to BLT provides a phone number and email address for those needing technical assistance.

d) Spray Drift Mitigation

The Agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all chlorothalonil products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the Agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of chlorothalonil.

The Agency is proposing the following spray drift mitigation language to be included on all chlorothalonil product labels for products applied by liquid spray application. The proposed spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The Agency is also providing recommendations which allow chlorothalonil product

[63] https://www.epa.gov/endangered-species/endangered-species-protection-bulletins
[64] https://www.epa.gov/endangered-species/bulletins-live-two-blt-tutorial

registrants to standardize all advisory language on chlorothalonil product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this PID, once effective.

- Applicators must not spray during temperature inversions.

- For aerial applications, do not apply when wind speeds exceed 10 miles per hour at the application site. The boom length must not exceed 75% of the wingspan for airplanes or 90% of the rotor blade diameter for helicopters.

- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.

- For ground boom applications, apply with the release height no more than 3 feet above the ground or crop canopy (2 feet for turf).

- For ground applications, do not apply when wind speeds exceed 10 miles per hour at the application site.

- For ground and aerial applications, applicators must select nozzle and pressure that deliver medium or coarser droplets as indicated in accordance with American Society of Agricultural & Biological Engineers Standard 572 and Standard 641 (ASABE S572 for ground application and ASABE S641 for aerial applications).

- For airblast applications, nozzles directed out of the orchard must be turned off in the outer row.

- For airblast applications, applications must be directed into the canopy foliage.

EPA proposes label language that addresses wind speed and direction measurements for aerial, ground, and airblast applications:

- Sustained Wind Speed, as defined by the National Weather Services.
- Wind speed and direction must be measured on location using a windsock, an anemometer, or an aircraft smoke system.
- Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.

EPA is also proposing advisory 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, in 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. The windsock should be pointed in the opposite direction of the windbreak and the conservation area.
  - 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.

In addition to including the spray drift restrictions on chlorothalonil labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed for removal from all chlorothalonil labels where such information currently appears. The proposed new language above, which cites ASABE S572.3, eliminates the need for VMD information.

The Agency is proposing a restriction on droplet size because coarser droplets have been demonstrated to decrease spray drift and, therefore, reduce potential risks to non-target species. Even though a medium droplet size has shown to deposit efficiently and provide good coverage on stems and narrow vertical leaves as required by a protectant fungicide such as chlorothalonil, EPA does not know the effect this requirement will have on the performance of chlorothalonil across various use patterns. In general, potential negative impacts to growers from requiring larger droplets could include reductions in efficacy, increased selection pressure for the evolution of fungicide resistance due to a decrease in lethal dose delivered to target fungi, increased application rates used by growers, increased costs associated with reduced yield, more fungicide applications, purchase of alternative products, or an inability to use tank mix or premix products. EPA encourages comments on any potential impacts to growers from specifying a mandatory minimum droplet size on product labels.

Prohibiting applications during inversions could result in delays to intended applications and, more generally, reduce the amount of time users have to apply chlorothalonil. Management of production activities would be more complex.

e) Wind-directional Drift Buffers for Conservation Areas

Risks of concern were identified for terrestrial organisms such as birds, mammals, reptiles, terrestrial-phase amphibians and potentially for terrestrial invertebrates from applications of chlorothalonil. In order to reduce risks to organisms that reside in conservation areas, the Agency is proposing spray drift buffers between the edge of the field and conservation areas (e.g., public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands). A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets certain criteria. The proposed spray drift buffers and windbreak reduction are as follows for aerial, ground, and airblast applications near conservation areas:

- For aerial applications: "Do not apply within 100 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area."

- For ground applications: "Do not apply within 25 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area."

- For airblast applications: "Do not apply within 100 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area."

- Conservation Area Windbreak Language for all Application Methods Above: A 50% reduction in the wind-directional buffer distance required above can be made if a

windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria:

- The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area.
- The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage sufficient to intercept drift at the time of application.
- The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side.
- The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application.
- The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted.
- The windbreak or shelterbelt must be maintained such that their functionality is not compromised.

A manmade structure (e.g., curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application.

The aerial buffer requirements of 100 and 150 feet next to conservation lands and freshwater areas respectively may impact growers that are reliant on aerial applications, including potato growers in several regions, and cucurbits, tomatoes, other vegetable crops growers in California and Washington. Impacts include not being able to apply chlorothalonil on certain sections of productive land, forcing users to apply additional fungicides to obtain the same levels of disease and resistance control afforded by chlorothalonil. Additionally, some users could be forced to put productive land out of production. These scenarios would increase overall costs for users by complicating and reducing the efficacy of resistance management programs, increasing the amount of fungicide applications and/or reducing yield amounts. Buffers adjacent to conservation areas are anticipated to cause substantial localized impacts in terms of disease management practices, resistance management, and potential economic costs to current chlorothalonil users in use sites near conservation areas, where smaller acreage use sites are expected to be more impacted than those with large footprints, as a larger share of the total productive area may be affected by a buffer. The Agency welcomes stakeholder comment on the level of impacts that growers are expected to experience.

3. Endangered Species: Proposed Risk Mitigation to Implement the 2011 NMFS Salmonid BiOp for Conventional Uses

The ESA workplan noted EPA's intention to implement the terms of existing NMFS biological opinions (see Appendix A of ESA workplan). In 2011, NMFS released a partial Biological Opinion (BiOp) specific to listed Pacific salmon and steelhead species for various pesticides, including chlorothalonil. The Agency is proposing modifications to the Reasonable and Prudent Alternatives (RPAs) described in the 2011 NMFS BiOp for two reasons: 1) to account for the nationwide mitigation measures already negotiated with registrants as part of FIFRA registration

review and 2) to align mitigation measures with NMFS' current approach for reducing pesticide loading in aquatic environments (*i.e.*, point system), as described in the most current BiOp to the Agency.[65] See Appendix E for additional information.

The proposed FIFRA mitigations, including IEM, largely address the potential effects from the use of chlorothalonil to Pacific salmon and steelhead species and designated critical habitat. However, EPA is proposing additional mitigation to implement NMFS' salmonid BiOp.

EPA proposes that applications of chlorothalonil may not be made to saturated soil, or if NOAA/National Weather Service predicts a total rainfall of 1 inch or greater over the 48 hours following the day of application, only considering a 48-hour period when, at any point during the 48-hour period, the precipitation potential is 50% or greater following application in or near salmonid habitat. EPA proposes that the 48-hour rain restriction for chlorothalonil be implemented on a geographic-specific basis in Bulletins. See Appendix C for the proposed Bulletins mitigation for chlorothalonil.

EPA proposes general label language limiting chlorothalonil applications to conifers to the following use sites: (i) conifer nursery beds; (ii) Christmas tree and bough production plantations; (iii) tree seed orchards; and (iv) landscape situations (ornamental or specimen trees in a residential or commercial landscape). In the 2011 NMFS BiOp, Syngenta indicated that though current chlorothalonil labels allow use on forest stands of conifers, in practice chlorothalonil is not used for general forestry management. The proposed label amendments clarify that conifer uses include nursery beds, Christmas tree and bough production, tree seed orchards, and landscaping but not applications to forests. See Appendix B for the proposed label language for this chlorothalonil mitigation measure.

The windspeed restrictions, Bulletins Live! Two reference language, and ecological incident reporting language, described above, address other terms of the 2011 NMFS BiOp. NMFS generally requires BLT reference language and language to improve the reporting of ecological incidents in its pesticide biological opinions, as it did in its 2011 salmonid BiOp for chlorothalonil (although this BiOp contained an older version of this label language). The language presented above reflects NMFS' most recent approach to BLT reference language and ecological incident label language, as well as EPA updates to this language based on stakeholder comments received on the Appendix to the ESA Workplan Update. The Agency is coordinating with NMFS on this updated language and on other aspects of the 2011 BiOp.

The 48-hour rain restriction near designated salmonid critical habitats in California, Idaho, Oregon, and Washington, required as part of the mitigation measures presented in the 2011 Biological Opinion issued by the NMFS, may have high impacts on growers near salmonid habitats (i.e., within 1000 feet of certain water bodies) that require a chlorothalonil application. Potato, tomato, celery, onion, and cabbage growers in those areas that require time-sensitive applications to ensure protection from disease ahead of a rain event may have to resort to an alternative chemistry or combination of chemistries that are more expensive. Carrot growers have no other available effective multisite fungicides and would need to resort to single site

[65] https://www.fisheries noaa.gov/resource/document/biological-opinion-chlorpyrifos-diazinon-and-malathion

fungicides for time sensitive applications ahead of rain events which may lead to yield losses and less effective resistance management.

A 48-hour restriction on applications prior to rainfall will have moderate impacts on conifer and ornamental plant users, as periods of wet weather are when plants are most vulnerable to foliar diseases and coating plants with a protective fungicide such as chlorothalonil prior to rain events helps in preventing the initiation and spread of disease. Restricting chlorothalonil applications 48 hours before a rain event near salmonid habitat in California, Idaho, Oregon, and Washington would limit users' flexibility in using chlorothalonil to protect turf and ornamentals against fungal diseases during vulnerable periods with wet weather, which could lead to suboptimal disease control and/or prompt users to switch to an alternative fungicide.

4. Proposed Risk Mitigation Measures for Antimicrobial Uses

In the *Registration Review Draft Risk Assessment (DRA) for the Antimicrobial Uses of Chlorothalonil*, human health risks of concern were identified for the inhalation route of exposure. These risks result when occupational handlers pour powdered chlorothalonil products during the manufacture of preserved materials. The EPA proposes to require that occupational handlers use PF10 respirators in this scenario.

Ecological risks of concern were also identified resulting from the discharge of chlorothalonil-treated water from pulp/paper mills. The Agency is proposing to restrict chlorothalonil's use to the dry-end of the papermaking process, thereby preventing chlorothalonil from reaching waterbodies through this route.

Ecological risks of concern were also identified resulting from the use of exterior paints and coatings. The model that was used to assess exterior paints and coatings is a high-end, screening-level approach that used many conservative assumptions that may not be representative of real-world conditions. Due to chlorothalonil's position as an important paint preservative in a niche sector of the paint market (i.e., dry film mildewcides) and the conservatism of the ecological risk assessment, the Agency is not currently proposing any additional mitigation for the paint and coatings uses of chlorothalonil. The Agency is, however, proposing to include ecological incident reporting instructions on chlorothalonil product labels. The Agency will continue to monitor the IDS for ecological incidents resulting from the use of paints containing chlorothalonil. If incident data suggest a potential concern with this use, the Agency may initiate further risk assessment or risk mitigation, as appropriate to determine whether poses unreasonable risks.

a) Proposed Mitigation for Chlorothalonil Products Used in the Manufacture of Preserved Materials

To mitigate the inhalation risks of concern for occupational handlers, the Agency is proposing to require the use of respirators when open-pouring powdered chlorothalonil products. Occupational handlers would be required to wear a NIOSH approved air-purifying half-face mask elastomeric respirator (PF10) with any R or P filter during use. By requiring a PF10

respirator, the MOE for this scenario will increase to 18, which is above the LOC of 3 and no longer of concern. For more information, see Appendices A and B.

When inhalation risk is identified, EPA may require fit testing, training, and medical evaluations for all pesticide handlers who are required to wear respirators per guidance in the Label Review Manual.[66] If a chlorothalonil handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler's employer.

Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Based on available information, the average cost of an elastomeric half mask respirator is $45, with replacement cartridges averaging around $40.[67] The impact of the respirator requirement would be lower for a chlorothalonil handler who is already required to use a respirator as part of the personal protective equipment for their job (i.e., the handler or employer will only incur the cost of purchasing filters for the respirator on a more frequent basis).

b) Proposed Mitigation for Chlorothalonil Products Used in Pulp and Paper Mills

To mitigate the ecological risks of concern for aquatic organisms, the Agency is proposing to prohibit chlorothalonil from use in the wet-end of the papermaking process. By restricting the use of chlorothalonil to the dry-end of the process, EPA anticipates that chlorothalonil would not be released via paper mill effluent and thus minimal aquatic exposure would be expected. Registrants have indicated that chlorothalonil is already only used in dry-end processes, so this requirement would serve to clarify chlorothalonil's use. For more information, see Appendices A and B.

c) Proposed Ecological Incident Reporting Language

The Agency is proposing to add incident reporting labeling as part of chlorothalonil's registration review. Incident reporting labeling is intended to provide consistent information to pesticide users on how to report ecological incidents.

The proposed incident reporting language is as follows:

> "**REPORTING ECOLOGICAL INCIDENTS**: For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target insects, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticide-incidents or call (registrant phone number)."

[66] The Revised Respirator Section of the Label Review Manual Chapter 10 is available at https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment

[67] Gempler's. Commercial-Grade Outdoor Work Gear Online Catalogue. Accessed online on September 28, 2023, at http://www.gemplers.com/respirators

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 chlorothalonil.

A community which may experience disproportionate exposure to pesticides is agricultural farmworkers. EPA has conducted assessments of risks to farmworkers who handle chlorothalonil or may be exposed to chlorothalonil when mixing, loading, or applying chlorothalonil and has not found risks of concern for chlorothalonil. 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 chlorothalonil. EPA has also evaluated risk to adults/children that may be exposed to residues after pesticide application and has not found risks of concern.

According to labor force data by the Bureau of Labor Statistics, a segment of workers who may experience disproportionate exposure to antimicrobial pesticides are those who work with preserved materials (i.e., paints, coatings, joint compounds, adhesives, among other materials) such as occupational painters or construction workers.[68] This data indicates that for painters, those identifying as Hispanic or Latino in the 2022 Current Population Survey represented 59.1% of painters and 50.7% of construction laborers, compared to around 19.1% of the general U.S. population identifying as these subpopulations.[69,70] The Agency evaluated risk to those who may use treated materials after manufacturing and did not find 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 chlorothalonil compared to the general population or who may otherwise be disproportionately affected by the use of chlorothalonil 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 chlorothalonil and to specify the residues

[68] Bureau of Labor Statistics, 2022. Labor Force Statistics from the Current Population Survey: Table 11 – Employed persons by detailed occupation, sex, race, and Hispanic or Latino ethnicity. Accessible at: https://www.bls.gov/cps/cpsaat11.pdf.
[69] Ibid.
[70] United States Census Bureau, 2022. Vintage 2022 Population Estimates. Accessible at: https://www.census.gov/quickfacts/fact/table/US/PST045222.

to be measured for each commodity for enforcement purposes. To reflect current Agency policy, EPA anticipates amending the tolerance expression to read as follows:

> 40 CFR §180.275(a)(1): "Tolerances are established for residues of chlorothalonil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only chlorothalonil (2,4,5,6-tetrachloro-1,3-benzenedicarbonitrile) and its metabolite 4-hydroxy-2,5,6-trichloro-1,3-benzenedicarbonitrile, calculated as the stoichiometric equivalent of chlorothalonil, in or on the commodity," 40 CFR §180.275(a)(2): "Tolerances are established for residues of chlorothalonil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only 4-hydroxy-2,5,6-trichloro-1,3-benzenedicarbonitrile in or on the commodity."

The Agency also proposes certain tolerance revisions are necessary to harmonize with Codex, align with the current rounding class practice, update crop groups, and revise commodity definitions. Additionally, the Agency recommends several additional tolerances that were previously recommended. For more information see Appendix G.

D. Proposed Interim Registration Review Decision

The Agency is issuing this PID in accordance with 40 C.F.R. §§ 155.56 and 155.58. The Agency has made the following proposed interim decision: (1) EPA proposes that other than Tier 1 pollinator data needed to evaluate risks to bees and a soil column leaching study, no additional data are required at this time; and (2) EPA proposes that chlorothalonil does not meet the registration standard without changes to the affected registrations and their labeling. EPA proposes that the mitigation specified in Sections IV and Appendices A, B, C, and F are sufficient to address certain concerns.

The Agency conducted a detailed draft HHRA and eco DRA. In these risk assessments, EPA identified human health dietary and non-target organism risks of concern. EPA identified potential dietary risks of concern resulting from drinking water exposure to residues in groundwater. EPA also identified potential risks of concern to non-target terrestrial vertebrates and aquatic vertebrates, aquatic invertebrates, and aquatic non-vascular plants. Furthermore, EPA identified potential exposure to terrestrial invertebrates, but could not quantify the potential risks of concern, resulting from registered uses of chlorothalonil. The proposed rate reductions will reduce the amount of chlorothalonil entering drinking water sources and the environment more broadly. The proposed buffer zones and spray drift management language will limit movement of residues to non-target organism habitat.

In the draft risk assessment of chlorothalonil's antimicrobial uses, EPA identified human health risks of concern from occupational exposures to workers manufacturing materials that are preserved with chlorothalonil. EPA also identified acute and chronic risks of concern for aquatic taxa. The Agency's proposal to require occupational handlers to wear respirators and restrict chlorothalonil's use to the dry-end of the papermaking process will address both of these risks.

EPA has determined that continuing to register chlorothalonil provides benefits to users. Chlorothalonil protects treated sites from a wide variety of fungal pests, many of which can result in widespread and economically damaging losses for affected growers. As a group M05 multisite fungicide, chlorothalonil targets a wide spectrum of diseases and presents a low risk of resistance development. As a result, chlorothalonil is frequently used in combination or rotation with other fungicides to provide increased crop protection and resistance management.

Chlorothalonil's antimicrobial uses also provide benefits to users, primarily as a fungicide used to preserve wood and other materials such as paints, coatings, adhesives, and paper products. Chlorothalonil's use extends the lifespans of these preserved materials and reduces the frequency for replacement and associated costs.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[71] Here, EPA proposes that chlorothalonil does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A and Appendices A, B, C, and E. EPA identified human health dietary and environmental non-target organisms risks of concern for registered uses of chlorothalonil. Where appropriate, EPA considered the benefits of chlorothalonil and is proposing product labeling changes that aim to preserve these benefits while mitigating the identified risks of concern. EPA invites comments on the mitigation proposals.

The proposed mitigation described in Section IV.A. for conventional uses is also intended to meet EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the *Federal Register* between December 29, 2022, and October 1, 2026, for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]."

The proposed mitigations identified in this PID would reduce chlorothalonil's effects on listed species or any designated critical habitat, because exposures to aquatic environments would be reduced.

Section 711 also requires EPA to "take into account the input" of the Secretary of Agriculture and other members of the interagency working group, established under FIFRA Section 3(c)(11), in developing such measures. EPA plans to obtain input on various types of mitigation measures, including those described in this PID, consistent with section 711, prior to issuing the Interim Decision for chlorothalonil. EPA will take any input provided on the measures detailed above into account during the development of the Interim Decision for chlorothalonil.

[71] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 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]"). In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

EPA proposes that there are human health dietary risks of concern from registered uses of chlorothalonil that is inconsistent with the FFDCA safety standard. Taking into consideration the available information on toxicity and exposure, EPA assessed chlorothalonil's potential aggregate risks, including dietary (food and water) and non-occupational residential exposures, and found risks exceeding the Agency's levels of concern.[72] EPA identified acute dietary risks of concern for the females aged 13-49 subpopulation and chronic dietary risks of concern for all subpopulations. These risks are driven by exposure to residues resulting from contamination of groundwater drinking water sources.

Based on currently available information, EPA proposes that it cannot conclude that residues of chlorothalonil in or on food are safe without the proposed mitigation. EPA is proposing rate reductions to reduce the amount of chlorothalonil entering drinking water thus reducing dietary exposure and risk. Therefore, chlorothalonil's residues would not present human health dietary risk if the risk mitigation measures described above are implemented.

During the risk assessment process, EPA determined that additional tolerances, an update to the tolerance expression, and tolerance revisions are needed to cover residues in or on food from uses of chlorothalonil. For more information, see Section IV.C, above.

In 2015, EPA published the EDSP WoE Conclusions on the Tier 1 Screening Assays for chlorothalonil, which stated that there was no convincing evidence for potential interaction with the estrogen, androgen, and thyroid pathways in humans. Consistent with that review, EPA concludes in this PID that no further data are needed to assess chlorothalonil for potential interaction with the human estrogen, androgen, and thyroid pathways and, based on the data available, no further action is need under FFDCA section 408(p)(6) to ensure protection of human health. That same review also stated that mammalian,fish, and bird data were sufficient, but because the results of the Amphibian Metamorphosis Assay (AMA) suggested a potential interaction with the thyroid pathway in amphibians the reviewers recommended an EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA). This recommendation will be further addressed in subsequent updates on implementation of the EDSP under FFDCA section 408(p).

The Agency is not making effects determinations for listed species, though the proposed mitigation is expected to reduce the extent of environmental exposure to listed species whose range or designated critical habitat co-occur with the use of chlorothalonil. In addition, the Agency is proposing mitigation to implement the NMFS 2011 BiOP on the effects of chlorothalonil on Pacific salmonids. The Agency will complete a nationwide effects determinations and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services before issuing a final registration review decision for chlorothalonil. For more information, see Appendices D and F.

[72] *Chlorothalonil: Revised Human Health Draft Risk Assessment for Registration Review* (2021)

E. Data Requirements

Other than pollinator studies described in Section III.B. of this PID and the recommendation for an EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) which will be further addressed in the subsequent updates on implementation of the EDSP under FFDCA section 408(p), EPA does not anticipate calling in additional data for chlorothalonil's registration review at this time.

V. NEXT STEPS AND TIMELINE

In addition to considering public comment, the Agency still must (1) complete nationwide effects determinations and (2) meet EPA's ESA section 7 obligations (*e.g.*, initiate any necessary consultation with the Services, consistent with ESA § 7(a)(2)). As part of the EDSP WoE review of EDSP Tier 1 assays, an EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) was recommended for chlorothalonil. This recommendation will be further addressed in subsequent updates on implementation of the EDSP under FFDCA section 408(p).

If appropriate, EPA may issue an Interim Registration Review Decision (ID) for chlorothalonil after taking comment on the chlorothalonil PID. The Agency may also instead move on to a proposed and final registration review decision for chlorothalonil, without previously issuing an ID. If EPA moves forward with an ID or a final registration review decision, the chlorothalonil registrants will be expected to submit requests for amendment of registration(s), including the label changes described in Appendices A, B, C, and E, within 60 days after publication of the ID or final registration review decision.

Appendix A: Summary of Proposed Actions for Chlorothalonil

Registration Review Case #: EPA-HQ-OPP-2011-0840
PC Code: 081901
Chemical Type: fungicide
Chemical Family: chloronitrile
Mechanism of Action: unspecified (multi-site)

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions
Conventional Uses					
• Women 13-49 years of age	• Dietary	• Ingestion of drinking water sourced from groundwater	• Acute	• Acute toxicity	• Reduction to the maximum annual application rate to sandy/coarse-textured soils with less than 2% organic matter content and a depth to water table of 30 feet or less
• General population	• Dietary	• Ingestion of drinking water sourced from groundwater	• Chronic	• Chronic toxicity	
• Birds and mammals	• Residues at/on site of treatment	• Consumption of residues on food items following foliar spray applications • Consumption of contaminated soil invertebrates following applications of granular products	• Acute • Chronic	• Mortality • Acute toxicity • Mammals: reductions in pup weight • Birds: reductions in eggshell thickness	• Use-site-specific reductions to the maximum annual application rate • Buffers to aquatic habitats • Mandatory spray drift language • Wind-directional buffers to conservation areas • Soil saturation language
• Aquatic organisms	• Offsite movement of residues via runoff, spray drift, and atmospheric transport	• Immersion in contaminated water	• Acute • Chronic	• Mortality • Reductions in growth, reproduction, and survival	
• Non-vascular aquatic plants			• N/A	• Growth inhibition	

• Endangered Species (Pacific Salmonids in CA, OR, WA, and ID)	• Residues in surface water from runoff and spray drift	• Contact and reduced diet	• Acute • Chronic	• Adverse effects to prey and habitat	• Implement 2011 NMFS salmonid BiOp
Antimicrobial Uses					
• Occupational Handlers	• Inhalation	• Inhalation of powders during manufacture of preserved materials	• Short • Intermediate	• Short-term toxicity • Intermediate-term toxicity	• Require occupational handler to use PF10 respirators
• Aquatic Organisms	• Pulp and Papermill effluent	• Immersion in contaminated water	• Acute • Chronic	• Acute toxicity • Chronic toxicity	• Prohibit chlorothalonil from being used in the wet-end of the papermaking process
• Aquatic Organisms	• Exterior Paints and Coatings	• Immersion in contaminated water	• Acute • Chronic	• Acute Toxicity • Chronic Toxicity	• N/A
• All taxa	• All uses	• All ecological exposures	• All ecological exposures	• N/A	• Require ecological incident reporting language on labels

Appendix B: Proposed Labeling Changes for Chlorothalonil Products

<table>
<tr><th>Description</th><th>Proposed Label Language for Chlorothalonil Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>Conventional 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 (FUNGICIDE) in the fourth column.

CHLOROTHALONIL | GROUP | M05 | FUNGICIDE</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>Updated Respirator Language for PF10</td><td>[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 and particulates (or aerosols), use the following language:]</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements</td></tr>
</table>

	"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.	
Updated Non-Target Organism Advisory Statement	"This product is toxic to fish, aquatic-phase amphibians, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."	Environmental Hazards
Updated Surface Water Label Advisory	"**Surface Water Advisory** This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having a medium potential for reaching both surface water and aquatic sediment via runoff for several months or more after application." [Note to registrants. Include the following language on product labels with agricultural use sites:] "A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of chlorothalonil from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours. Sound erosion control practices will reduce this product's potential to reach aquatic sediment via runoff."	Environmental Hazards
Updated Outdoor, Terrestrial Use Statement (Required for products not intended only for homeowner use)	"For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."	Environmental Hazards – Surface Water Advisory
Updated Outdoor Terrestrial Use Statement	"To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems."	Environmental Hazards – Surface Water Advisory

(Required for products intended for homeowner use formulated as liquid concentrates)		
Updated Outdoor Terrestrial Use Statement (Required for products intended for homeowner use formulated as granules for broadcast application)	"To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems."	Environmental Hazards – Surface Water Advisory
Updated Outdoor Terrestrial Use Statement (Required for products intended for homeowner use formulated as ready to use (RTU) products)	"To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area."	Environmental Hazards – Surface Water Advisory
Updated Groundwater Advisory (Required for products not intended only for homeowner use)	"**Groundwater Advisory** Chlorothalonil and chlorothalonil degradates are known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow."	Environmental Hazards
Updated Groundwater Advisory (Required for products intended for homeowner use)	"**Groundwater Advisory** Chlorothalonil and chlorothalonil degradates are known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Environmental Hazards

Pollinator Hazard Statement For all products applied to agricultural crops. Only for pesticides classified as moderately to highly toxic via acute oral or acute contact toxicity.	"This product may be toxic to bees and other pollinating non-target insects exposed to direct treatment on blooming crops or weeds."	Environmental Hazards under the Heading "POLLINATOR HAZARD STATEMENT"
Soil Saturation Statement For all products delivered via liquid spray applications to crops that do not require production in flooded fields or streams.	"Do not apply when soil in the area to be treated is saturated (if there is standing water on the field or if water can be squeezed from soil)."	Directions for Use –Under the Restriction or Use Restriction Section
Resistance-management for fungicides [Does not apply to labels for product intended only for homeowner use.]	Include resistance management label language for fungicides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year). See section 3 (Scope) of the PRN to determine whether the resistance management measures outlined in the PRN apply to your product.	Directions for Use, prior to directions for specific crops
Advisory Best Management Practices for Pollinator Protection For all products delivered via liquid	"**Advisory Best Management Practices for Pollinator Protection** The following best management practices (BMPs) can help reduce risk to pollinators: • Develop and maintaining clear communication with local beekeepers to help protect bees. To the extent possible, advise beekeepers within a 1-mile radius 48-hrs in advance of the application, and confirm hive locations before spraying. • Avoid applications when bees are actively foraging.	Directions for Use – Under the Advisory Best Management Practices header after Resistance Management section

spray applications to agricultural crops	• Avoid applying pesticides to plants in bloom, including flowering weeds. • Apply pesticides in the evening or at night when fewer bees are foraging. • Use Pollinator Protection Plans when they are available. These plans may be available from state lead agencies and promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees and other pollinators to pesticides. • Use integrated pest management to prevent or mitigate potential negative effects to pollinators and consider multiple pest management options before resorting to a pesticide application. • [*If applicable*:] Mowing understory weeds or cover crops in orchards and vineyards before blooming can prevent flowering of weeds and reduce exposure to bees where and when pesticides are applied. The following BMPs can help promote the health and habitat of ground-nesting bees: • For uncultivated land, leaving large undisturbed patches of land un-mowed and untilled can provide nesting and forage sites. • For uncultivated land, mowing at the highest cutting height possible (minimum of 8-10 inches if possible) can increase and diversify food sources. For additional resources on pollinator BMPs and Pollinator Protection Plans, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators .”	
Endangered Species Protection Requirements For all products, excluding those labeled/ registered solely for residential use; or where exposure is negligible or there are no toxic effects expected across uses included on a label (e.g., cattle ear tag, fly baits)	“**ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS:** Before using this product, you must obtain any applicable Endangered Species Protection Bulletins (‘Bulletins’) within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov.”	Directions for Use, at the beginning under the heading “ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS”
Ecological Incidents Statement For all products	“**REPORTING ECOLOGICAL INCIDENTS**: For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target insects, see EPA’s Pesticide Incident Reporting website: https://www.epa.gov/pesticide-incidents or call (registrant phone number)”.	Directions for Use, under the heading “REPORTING

		ECOLOGICAL INCIDENTS"
Maximum Annual Application Rate Reductions for Almond, Filbert (Hazelnut), Pistachio; Beans, Dried; Lentils; Parsnip; Sugar beet (grown for seed)	"Do not apply more than 6.0 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Brassica/Cole (Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	"Do not apply more than 3.75 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Blueberry; Grass (Forage, Hay, Seed); Grass Grown for Seed; Soybean; Strawberry (nursery seedlings for pre-transplant; non-food)	"Do not apply more than 4.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Mango and Persimmon	"Do not apply more than 4.7 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Celery	"Do not apply more than 5.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Corn,	"Do not apply more than 3.0 pounds of chlorothalonil per acre per year."	Directions for Use

Field (grown for seed); Mint		
Maximum Annual Application Rate Reductions for Tomato	"Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Apricot, Nectarine, Plum, Prune, and Sweet Cherry	"Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Asparagus	"Do not apply more than 7.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Beans (Snap)	"Do not apply more than 7.2 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Cabbage	"Do not apply more than 7.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Carrot	"Do not apply more than 7.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate	"Do not apply more than 7.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a	Directions for Use

Reductions and Vulnerable Soil Restriction for Corn, Sweet	depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Cranberry	"Do not apply more than 10.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Cucurbits	"Do not apply more than 9.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Tomato in Florida, Georgia, North Carolina, South Carolina	"Do not apply more than 10.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Fruiting Vegetables except Tomato	"Do not apply more than 6.75 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Fruiting Vegetables	"Do not apply more than 7.9 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use

except Tomato in Florida, Georgia, North Carolina, South Carolina		
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Ginseng	"Do not apply more than 12.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Horseradish	"Do not apply more than 18.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Onion (Dry Bulb); Garlic	"Do not apply more than 9.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Onion (Green Bunching); Leek; Shallots; Onion and Garlic (Grown for Seed)	"Do not apply more than 6.7 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Papaya	"Do not apply more than 6.75 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use

Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Passion Fruit	"Do not apply more than 7.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Peach	"Do not apply more than 12.4 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Peanut	"Do not apply more than 6.75 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Potato	"Do not apply more than 8.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Rhubarb	"Do not apply more than 13.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Tart cherries	"Do not apply more than 15.4 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and	"Do not apply more than 8.0 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use

Vulnerable Soil Restriction for Yam		
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Conifers	"Do not apply more than 16.5 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Ornamentals – Field Grown	"Do not apply more than 18.75 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Ornamentals – Root/Bulb Dip	"Do not apply more than 18.75 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Ornamentals – Spot Treatment	"Do not apply more than 18.75 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.5 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Turf – Sod	"Do not apply more than 12.6 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.2 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and	"Do not apply more than 22.6 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a	Directions for Use

Vulnerable Soil Restriction for Turf – Industrial, Athletic Fields; Turf – Golf Course Fairways	depth of 30 feet or less from the surface: Do not apply more than 6.2 pounds of chlorothalonil per acre per year."	
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Turf – Golf Course Tees	"Do not apply more than 33.9 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.2 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Turf – Golf Course Greens	"Do not apply more than 45.2 pounds of chlorothalonil per acre per year. For sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 2% organic matter content, where the water table occurs at a depth of 30 feet or less from the surface: Do not apply more than 6.2 pounds of chlorothalonil per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Residential Uses for Almond, Filbert (Hazelnut), Pistachio; Beans, Dried; Lentils; Parsnip; Sugar beet (grown for seed)	"For residential users who obtain their drinking water from an on-site well, do not apply more than 6.0 pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Directions for Use
Maximum Annual Application Rate Reductions for Residential Uses for Brassica/Cole (Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	"For residential users who obtain their drinking water from an on-site well, do not apply more than 3.75 pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Directions for Use
Maximum Annual Application Rate Reductions for Residential Uses for	"For residential users who obtain their drinking water from an on-site well, do not apply more than 4.5 pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Directions for Use

Blueberry; Grass (Forage, Hay, Seed); Grass Grown for Seed; Soybean; Strawberry (nursery seedlings for pre-transplant; non-food)		
Maximum Annual Application Rate Reductions for Residential Uses for Celery	"For residential users who obtain their drinking water from an on-site well, do not apply more than 5.5 pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Directions for Use
Maximum Annual Application Rate Reductions for Residential Uses for Corn, Field (grown for seed); Mint	"For residential users who obtain their drinking water from an on-site well, do not apply more than 3.0 pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Directions for Use
Maximum Annual Application Rate Reductions for Residential Uses for all other use sites including ornamentals	"For residential users who obtain their drinking water from an on-site well, do not apply more than 6.5 pounds of chlorothalonil per year. Avoiding application of chlorothalonil within 30 ft of drinking water wells will further reduce the risk of drinking water contamination."	Directions for Use
Additional Required Labelling Action Applies to all products delivered via liquid spray applications	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
For all liquid products where there are mixers and loaders involved in mixing concentrate	"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
Spray Drift Management Application	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**:	Directions for Use, in a box titled "Mandatory Spray Drift Management"

Restrictions for products that are applied as liquid with aerial equipment	• Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 641 (ASABE S641). • During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes) must register between 3 and 10 miles per hour. • Wind speed and direction must be measured on location using a windsock, an anemometer on the ground or application equipment, or an aircraft smoke system. • Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment. • If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. • The boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • Do not apply during temperature inversions."	under the heading "Aerial Applications" Placement for these statements should be in general directions for use, before and use-specific directions for use.
Spray Drift Management Application Restrictions for products that are applied as liquid with airblast equipment	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Airblast applications:** • Sprays must be directed into the canopy. • During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 10 miles per hour. • Winds speed and direction must be measured on location using a windsock or anemometer on the ground or application equipment. • Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment • User must turn off outward pointing nozzles at row ends and when spraying outer row. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Airblast Applications"
Spray Drift Management Application Restrictions for products that are applied as liquid with ground boom equipment	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Ground Boom Applications:** • During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 10 miles per hour. • Wind speed and direction must be measured on location using a windsock or anemometer on the ground or application equipment. • Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment • Do not release spray at a height greater than 3 feet above the ground or crop canopy, except for applications to turf. • For golf course, sod, and turf (except residential lawns) applications, do not release spray at a height greater than 2 feet above the ground.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"

	• Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572). • Do not apply when wind speeds exceed 10 mph at the application site. • Do not apply during temperature inversions."	
Spray Drift Management Application Restrictions for products that are applied as liquid with boomless ground sprayer equipment	**"MANDATORY SPRAY DRIFT MANAGEMENT** **<u>Boomless Ground Applications:</u>** • Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572). • 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"
Spray Drift Buffer to Aquatic Habitats	"This product must not be applied within 150 ft (for aerial and airblast applications) or 25 ft (for other ground applications) of water bodies (freshwater and estuarine/marine) unless there is an untreated buffer area of that width between the area to be treated and the water body."	Directions for use – Under the Restriction or Use Restriction Section
Spray Drift Buffer to Wildlife Conservation Areas For products that are applied as liquid with aerial (except Ultra Low Volume/ULV applications for mosquitocides), groundboom, or airblast equipment	Aerial (non-ULV): "Do not apply within 100 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area. A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria: o The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area. o The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage sufficient to intercept drift at the time of application. o The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side. o The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application. o The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted.	Directions for use – Under the Restriction or Use Restriction Section

	○ The windbreak or shelterbelt must be maintained such that their functionality is not compromised. A manmade structure (e.g., curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application." Ground: "Do not apply within 25 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area. A 50% reduction in buffer distance can be made if ○ the application is made with a hooded sprayer; or, ○ if a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria: ○ The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area. ○ The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage sufficient to intercept drift at the time of application. ○ The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side. ○ The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application. ○ The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted. ○ The windbreak or shelterbelt must be maintained such that their functionality is not compromised. A manmade structure (e.g., curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application. A 75% reduction in buffer distance can be made if a hooded sprayer is used and a downwind windbreak is present and higher than the release height."	

	Airblast: • "Do not apply within 100 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area. A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria: o The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area. o The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage sufficient to intercept drift at the time of application. o The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side. o The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application. o The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted. o The windbreak or shelterbelt must be maintained such that their functionality is not compromised. A manmade structure (e.g., curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application."	
Advisory Spray Drift Management Language for all products applied as liquid spray	**"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.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

	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)* 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. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded 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. **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: o Relying on equipment on the application equipment that measures wind speed (e.g., aerial equipment). o 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 mins 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. o 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. The windsock should be pointed in the opposite direction of the windbreak and the conservation area. o 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** **<u>Boomless Ground Applications:</u>** • 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	**"SPRAY DRIFT ADVISORIES** **<u>Handheld Technology Applications:</u>** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

applied as liquid with handheld equipment		
Use Restriction for Conifers	"Use on conifers is restricted to the following use sites: nursery beds, Christman tree and bough production plantations, tree seed orchards, and landscaping. Do not apply on forest stands of conifers."	Directions for Use
Antimicrobial End Use Products		
Requirement of PF10 Respirator for Occupational Handlers During the Manufacture of Preserved Materials	"All personnel present during the application via open pour open of chlorothalonil products in the manufacture of preserved materials (ex. paints, coatings, adhesives, paper products, etc.) are required to wear a NIOSH-approved, properly fitting elastomeric half mask respirator (PF10) with organic vapor (OV) cartridges and combination 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"	Directions for Use
Respirator Fit Testing, Medical Qualification, and Training	"Using a program that conforms to Occupational Safety and Health Administration's (OSHA) 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 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 of 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."	Directions for Use
Restricting Chlorothalonil's Use to the Dry End of the Papermaking Process	"Chlorothalonil products may only be used in the dry-end of the papermaking process."	Directions for Use
Ecological Incidents Statement For all products	"**REPORTING ECOLOGICAL INCIDENTS**: For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target insects, see EPA's Pesticide Incident Reporting website: https://www.epa.gov/pesticide-incidents or call (registrant phone number)".	Directions for Use, under the heading "REPORTING ECOLOGICAL INCIDENTS"

Appendix C: Proposed "Bulletins Live! Two" Mitigation for Chlorothalonil Products to Implement NMFS Salmonid Biological Opinion

Species	Description	Proposed Label Language for Chlorothalonil Products	Spatial Extent of Mitigation
Listed Pacific salmon and steelhead species (Implementation of NMFS 2011 BiOp)	Soil and rain restrictions	"Do not apply when soil in the area to be treated is saturated (if there is standing water on the field or if water can be squeezed from soil) or if NOAA/National Weather Service predicts a total rainfall of 1 inch or greater over the 48 hours following the day of application, only considering a 48-hour period when, at any point during the 48-hour period, the precipitation potential is 50% or greater. Detailed National Weather Service forecasts for local weather conditions should be obtained on-line at: www.weather.gov or by contacting your local National Weather Service Forecasting Office."	Mitigation measures are proposed within 985 feet (300 meters) of aquatic habitat within the listed salmonid and steelhead ranges and designated critical habitat. For more detailed information on species range and distribution, visit: https://www.fisheries.noaa.gov/species-directory/threatened-endangered

Appendix D: 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 chlorothalonil appears in Appendix E.

Developing Approaches for ESA Assessments and Consultation for FIFRA Actions

In 2015, EPA, along with the Services—the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[73] 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.[74]

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.[75]

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 biological opinion 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 biological opinion. EPA received a final malathion biological opinion[76] from FWS in February 2022 and a final biological opinion from

[73] https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report.
[74] https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional.
[75] https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act.
[76] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.

NMFS on malathion, chlorpyrifos and diazinon in June 2022.[77] The Agency plans to implement both biological opinions according to the 18-month timeframes specified in the biological opinions.

In 2020, EPA released draft BEs for the first two chemicals conducted using the 2020 Revised Method—carbaryl and methomyl. Subsequently, EPA has used the Revised Method to complete final BEs for carbaryl, methomyl, atrazine, simazine, glyphosate, clothianidin, imidacloprid, and thiamethoxam. EPA is currently in consultation with the Services on these active ingredients.

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy[78] to evaluate potential effects of new conventional pesticide active ingredients to listed species and their designated critical habitat and initiate consultation with the Services, as appropriate, before registering these new pesticides. Before the Agency registers new uses of pesticides for use on pesticide-tolerant crops, EPA will also continue to make effects determinations. If these determinations are likely to adversely affect determinations, the Agency will not register the use unless it can predict that registering the new use would not have a likelihood of jeopardizing listed species or adversely modifying their designated critical habitats. EPA will also initiate consultation with the Services as appropriate.

In April 2022, EPA released a comprehensive, long-term approach to meeting its ESA obligations, which is outlined in *Balancing Wildlife Protections and Responsible Pesticide Use*.[79] This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

On November 16, 2022, EPA released the *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions*.[80] As part of this update, EPA announced its plan to consider and include, as appropriate, a menu of FIFRA Interim Ecological Risk Mitigation intended to reduce off-target movement of pesticides through spray drift and runoff in its registration review and other FIFRA actions. These measures are intended to reduce risks to nontarget organisms efficiently and consistently across pesticides with similar levels of risks and benefits. EPA expects that these mitigation measures may also reduce pesticide exposures to listed species.

[77] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.
[78] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides.
[79] https://www.epa.gov/endangered-species.
[80] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

Appendix E: Proposed Alternative Mitigation to Implement NMFS Salmonid Biological Opinion for Chlorothalonil

Background

In 2011, NMFS released a Biological Opinion (BiOp) specific to listed Pacific salmon and steelhead species for various pesticides, including chlorothalonil. In this BiOp, NMFS concluded that chlorothalonil is not likely to jeopardize the continued existence of any listed salmonid but is likely to adversely modify the designated critical habitat of some listed salmonids. EPA is implementing this BiOp as part of its registration review process. The Agency is proposing modifications to the Reasonable and Prudent Alternatives (RPAs) described in the 2011 NMFS BiOp for two reasons: 1) to account for the nationwide mitigation measures already negotiated with registrants as part of FIFRA registration review and 2) to align mitigation measures with NMFS' current approach for reducing pesticide loading in aquatic environments (hereafter referred to as 'NMFS point system'), as described in its most current biological opinion to the Agency.[81] As noted in the Services' Consultation Handbook,[82] action agencies (in this case, EPA) may choose to develop modified RPAs, based on what they perceive is the best available scientific and commercial data. In addition, the action agencies (not the Services) are responsible for determining the validity of the alternative measures.

Estimated points needed to reduce environmental exposure to chlorothalonil

According to the NMFS point system, the magnitude by which the EECs exceed the selected aquatic toxicity endpoints is an approximation of the amount of mitigation needed to reduce harmful exposure in the environment. NMFS assigns a pesticide an overall number of target points for runoff and drift reduction. Identified risk reduction options are given point values based on their effectiveness in reducing environmental loading from drift and runoff/drainage.

For the purpose of developing modified RPAs for chlorothalonil, the Agency relied on the modeling that supports the 2020 Eco DRA for chlorothalonil. EPA compared the average 1-in-15 year daily average EECs in surface water with the chlorothalonil toxicity endpoints specific to salmon species. The 2020 Eco DRA incorporates all current label uses and restrictions, including a 150-foot aerial and 25-foot ground buffer to estuarine/marine habitats; the current labels do not include buffers to freshwater areas.

Single maximum application rates for agricultural uses of chlorothalonil range from 1.2 to 16.5 lbs a.i./A. Based on the current labels, these rates can be applied multiple times in a year. Modeled chlorothalonil EECs (without proposed freshwater buffers) were greater than the selected acute aquatic toxicity endpoints[83] by a factor of up to 9 for several chlorothalonil use scenarios. Given that the magnitude by which the EECs exceed the aquatic toxicity endpoints is minimal, additional mitigation does not appear to be warranted to avoid adverse modification of

[81] See p. 131 at https://www fisheries.noaa.gov/resource/document/biological-opinion-chlorpyrifos-diazinon-and-malathion
[82] See pp. 47-48, https://www fws.gov/sites/default/files/documents/endangered-species-consultation-handbook.pdf
[83] Aquatic algae is most sensitive: *Navicula pelliculosa* EC_{50} = 12 ppb.

salmonid designated critical habitat. However, EPA is proposing mitigation that will further reduce environmental loading into salmonid habitat as described below.

Proposed mitigation to reduce exposure to listed salmon and steelhead species

Mitigation measures proposed in this PID for chlorothalonil were not accounted for in the 2011 NMFS BiOp. The Agency is proposing a variety of FIFRA mitigation measures (see Section IV), including rate reductions for both vulnerable and non-vulnerable soils, buffers to freshwater areas (in addition to the estuarine/marine buffers already on labels), spray drift mitigation, and runoff reduction label language (i.e., statements prohibiting application to saturated soils or when rainfall is forecasted within 48 hours). When the proposed FIFRA mitigations from the PID are considered, EPA concludes that no additional mitigation is needed to address the adverse modification finding for chlorothalonil in the 2011 NMFS salmonid BiOp.

EPA concludes that with the proposed mitigation for chlorothalonil outlined in Section IV, the Agency is able to predict that there is not a likelihood of adverse modification of listed Pacific salmon and steelhead designated critical habitat.

Appendix F: Endocrine Disruptor Screening Program

As required by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic, and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints that may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental, and reproductive effects in different taxonomic groups. As part of its most recent registration decision for chlorothalonil, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database.

In addition, FFDCA § 408(p)(1) requires EPA to develop an Endocrine Disruptor Screening Program (EDSP) 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." FFDCA § 408(p)(3) requires the Agency to "provide for the testing of all pesticide chemicals." Under FFDCA § 408(p)(4), EPA may, by order, exempt the pesticide from the testing requirements if EPA "determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen." Finally, if EPA finds that the pesticide is found to have an endocrine 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.

The EDSP screening program developed by EPA includes data sets to address human and wildlife testing for estrogen, androgen, and thyroid (E, A, and T) 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 E, A, or T hormonal systems. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any E, A, or T effect.

Between October 2009 and February 2010, EPA issued Tier 1 data call-ins (DCIs) for a group of 67 chemicals, which contained 58 pesticide active ingredients and nine inert ingredients. EPA scientists (composed of experts within the Office of Chemical Safety and Pollution Prevention (OCSPP) with consultations with experts in the Office of Research and Development) performed Weight of Evidence (WoE) analyses of the potential interaction with the E, A, and/or T signaling pathways for humans, fish, and wildlife using results of the Tier 1 battery and other scientifically relevant information (OSRI) and the conclusions of those initial reviews are available in the chemical-specific public dockets. Tier 1 data were submitted for chlorothalonil. For further information, visit the EPA website.[84]

[84] https://www.epa.gov/endocrine-disruption

In 2015, EPA published the EDSP WoE Conclusions on the Tier 1 Screening Assays for chlorothalonil, which stated that there was no convincing evidence for potential interaction with the estrogen, androgen, and thyroid pathways in humans. Consistent with that review, EPA concludes that no further data are needed to assess chlorothalonil for potential interaction with the human E, A, and T pathways. Thus, based on the data available, no further action is need under FFDCA section 408(p)(6) to ensure protection of human health.

That review also stated that there was no convincing evidence of interaction with the E, A, and T pathways in mammals, fish, and birds for chlorothalonil and thus no EDSP Tier 2 testing is recommended for chlorothalonil for these endpoints and species. The results of the Amphibian Metamorphosis Assay (AMA) suggested a potential interaction with the thyroid pathway in amphibians at a concentration of 5.0 ug a.i./L. As a result, an EDSP Tier 2 Larval Amphibian Growth and Development Assay (LAGDA) was recommended. This recommendation will be further addressed in subsequent updates on implementation of the EDSP under FFDCA section 408(p).

Additional information may be found in Appendix F and in the Chlorothalonil Data Evaluation Records (DERs) for EDSP Tier 1 Assays (https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0029).

Appendix G: Summary of Tolerance Revisions

Table G. Summary of Tolerance Revisions for Chlorothalonil (40 CFR §180.275)[1].			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
40 CFR 180.275(a)(1)			
Apricot	0.5	1.5	Harmonization with Codex.
Almond, hulls	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Banana	-	0.5	Commodity term revision.
Banana (NMT 0.05 ppm in edible pulp)	0.5	remove	
Bean, snap, edible podded	-	5	Commodity term revision.
Bean, snap, succulent	5	remove	
Blueberry	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Broccoli, chinese	-	5	Crop group conversion/revision.[2,3]
Brussels sprouts	-	6	Harmonization with Codex.
Cacao, dried bean	-	0.05	Commodity term revision.
Cocoa bean, dried bean	0.05	remove	
Celery	15	20[4]	Harmonization with Codex.
Coffee, green bean	-	0.2	Commodity term revision. Corrected value to be consistent with OECD Rounding Class Practice.
Coffee, bean, green	0.20	remove	
Corn, sweet, forage	-	65	Recommended for previously[5].
Corn, sweet, stover	-	50	
Cranberry	5.0	5	Corrected values to be consistent with OECD Rounding Class Practice.
Fungi, edible, group 21	-	1	Commodity term revision. Corrected values to be consistent with OECD Rounding Class Practice.
Mushroom	1.0	remove	
Ginseng	4.0	4	Corrected values to be consistent with OECD Rounding Class Practice.
Horseradish	4.0	4	
Kohlrabi	-	5	Crop group conversion/revision.[2,3]
Lentil, dry seed	-	0.1	Commodity term revision.

Table G. Summary of Tolerance Revisions for Chlorothalonil (40 CFR §180.275)[1].			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Lentil	0.10	remove	Corrected value to be consistent with OECD Rounding Class Practice.
Mango	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Nectarine	0.5	remove	Covered by Peach (§180.1(g))
Okra	6.0	remove	Member of Vegetable, fruiting, group 8-10
Onion, bulb	0.5	1.5	Harmonization with Codex.
Onion, green	5	10	
Papaya	15	20	
Peanut, hay	-	20	Recommended for previously[5].
Plum, prune, fresh	-	0.2	Commodity term revision.
Plum, prune	0.2	remove	
Potato	0.1	0.3[4]	Harmonization with Codex.
Rhubarb	4.0	7	
Soybean, seed	-	0.2	Commodity term revision.
Soybean	0.2	remove	
Starfruit	3.0	3	Corrected values to be consistent with OECD Rounding Class Practice.
Vegetable, cucurbit, group 9	5.0	5	
Vegetable, fruiting, group 8-10, except tomato	-	7	Crop group conversion/revision. Harmonization with Codex.
Vegetable, fruiting, group 8, except tomato	6.0	remove	
Yam, true, tuber	-	0.3	Commodity term revision. Harmonization with Codex.
Yam, true	0.10	remove	
Vegetable, *brassica* head and stem, group 5-16, except Brussels sprouts	-	5	Corrected value to be consistent with OECD Rounding Class Practice. Crop group conversion/revision.[2]
Brassica, head and stem, subgroup 5A	5.0	remove	
Vegetable, legume, pea, edible podded, subgroup 6-22B	-	5	Commodity term revision.
Pea, edible podded	5	remove	
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E	-	0.1	Commodity term revision.
Bean, dry, seed	0.1	remove	

Table G. Summary of Tolerance Revisions for Chlorothalonil (40 CFR §180.275)[1].			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
40 CFR 180.275(a)(2)			
Cattle, meat byproducts, except kidney	0.05	0.2	Harmonization with Codex.
Goat, meat byproducts, except kidney	0.05	0.2	
Hog, meat byproducts, except kidney	0.05	0.2	
Horse, meat byproducts, except kidney	0.05	0.2	
Sheep, meat byproducts, except kidney	0.05	0.2	
40 CFR 180.275(c) Tolerances with regional registrations.			
Peppermint, fresh leaves	-	2	Commodity term revision.
Peppermint, tops	2	remove	
Persimmon, american	-	1.5	Commodity term revision.
Persimmon, black	-	1.5	
Persimmon, japanese	-	1.5	
Persimmon	1.5	remove	
Spearmint, fresh leaves	-	2	Commodity term revision.
Spearmint, tops	2	remove	

[1] For complete list of established/recommended tolerances see the International Residue Limit Status Sheet in Appendix D of the draft human health risk assessment for Registration Review (DP# 457661).

[2] The recommended conversion of existing tolerance in/on crop subgroup 5A to crop group 5-16 (vegetable, *Brassica*, head and stem), kohlrabi, and Chinese broccoli are consistent with the document titled, "Attachment - Crop Group Conversion Plan for Existing Tolerances as a Result of Creation of New Crop Groups under Phase IV (4-16, 5-16, and 22)" dated 03-OCT-2015.

[3] HED is recommending for individual tolerances at a level of 5 ppm for Broccoli, Chinese and Kohlrabi based on the currently established tolerance for these commodities as part of crop group 5A.

[4] Syngenta has requested that the US tolerance levels for these crops be maintained in order to facilitate trade with Canada (R. Louden *et al.*, September 27, 2023; D463742).

[5] The Revised HED Chapter of the Reregistration Eligibility Decision (RED) Document for Chlorothalonil, 07-JAN-1998.

OECD = Organization for Economic Cooperation and Development.