OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

Chlorothalonil

Interim Registration Review Decision
Case Number 0097

December 2024

Approved by: Jean Overstreet

Jean Overstreet
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Date: 12/26/2024

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Date: 12/20/2024

Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for chlorothalonil (PC Code 081901, case 0097). The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)[1] mandates a periodic review of existing pesticide registrations every 15 years, referred to as registration review.[2] During registration review, the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard.[3] 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 include mitigation measures and changes to labeling that EPA has identified that would address risks of concern, identified 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 this ID for chlorothalonil to identify risk mitigations that would address risks of concern for chlorothalonil, as presented in Section IV and Appendices A and B.

Chlorothalonil is a fungicide active ingredient (a.i.) first registered for use in the United States in 1966. There are 17 technical grade products and 137 end-use products containing chlorothalonil. 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.

End-use products are registered for use on numerous conventional food, non-food, 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 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 end-use products are formulated as

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136w-8.
[2] For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.
[3] FIFRA § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57; *see also* FIFRA § 3(c)(5).
[4] 40 C.F.R. §§ 155.56, 155.58. Consistent with 40 C.F.R. § 155.58, EPA must first issue and take comment on a PID before issuing an ID.
[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]"). This document is not a "registration review decision" within the meaning of FIFRA Section 3(g) and 40 C.F.R. § 155.57.
[6] 40 C.F.R. § 155.56.

ready-to-use solutions, soluble, emulsifiable, and flowable concentrates, impregnated materials, water-dispersible granules, and granules. Chlorothalonil products are applied using aircraft, ground equipment, airblast sprayers, handheld equipment, chemigation equipment, and dip tanks. Chlorothalonil was subject to reregistration and the Reregistration Eligibility Decision (RED) was signed in 1999.

EPA has not yet fully evaluated chlorothalonil's effects on federally threatened and endangered (listed) species or designated critical habitats. 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 and the National Marine Fisheries Service (the Services) before completing the chlorothalonil registration review and issuing a final registration review decision. For more information on EPA's ESA obligations during 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 ID, EPA has considered a variety of FIFRA IEM measures and ecological mitigation measures based on the risks and benefits of chlorothalonil to reduce exposures to nontarget organisms, including listed species, while EPA works toward a final registration review decision. While these mitigation measures do not satisfy EPA's ESA obligations, EPA identified early mitigation measures that may shorten the consultation process and improve protections for listed species from currently registered pesticide products. EPA also interpreted that the FIFRA IEM measures and ecological risk mitigation measures that the Agency has identified for chlorothalonil in this ID (Section IV.A.2) 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)]."

[7] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[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

In 2015, EPA determined that no further data were needed to assess the potential for impacts on the estrogen, androgen, or thyroid pathways in humans[10]. EPA thus concluded that points of departure used for human health risk assessment to evaluate the EPA-registered uses and established tolerances of chlorothalonil are protective of potential adverse estrogen, androgen, and thyroid effects in humans. Given the absence of evidence of an interaction with the estrogen, androgen, or thyroid hormone pathways for chlorothalonil, EPA has determined that it has met its obligations for chlorothalonil under the endocrine screening program at section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA).[11] For more information on the endocrine screening for the chlorothalonil registration review, see Appendix F.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments);
- *Use and Usage* (discussing how chlorothalonil may legally be used and how it is actually used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Interim Registration Review Decision* (presenting EPA's interim 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. Updates Since the Proposed Interim Decision

In October 2023, EPA published the Proposed Interim Decision (PID) for registration review of chlorothalonil. Since the PID, EPA has identified the need for minor changes to the maximum annual application rates for non-vulnerable soils for some crops, clarified and updated vulnerable soil language to exclude most cranberry bogs and turf putting greens, and included the option to use a vegetative filter strip for turf instead of the ground buffer to aquatic areas as a result of comments received on the PID. EPA also identified an update to the necessary respirator language for antimicrobial chlorothalonil products. This change follows suggestions made by the Occupational Safety and Health Administration (OSHA). For more details on how public comments influenced these changes, see Section I.C. EPA has not updated the draft Human Health Risk Assessment or the draft Ecological Risk Assessment. This ID finalizes the Agency's interim decision and draft supporting documents (*Chlorothalonil: Revised Human Health Draft Risk Assessment for Registration Review* and *Chlorothalonil: Draft Ecological Risk Assessment for Registration Review*), which are available in EPA's public docket (EPA-HQ-OPP-2011-0840) on www.regulations.gov.

[10] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0028
[11] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

B. 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 for the case.[12] 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)*
    - *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 Work Plan.*
    - *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*

[12] 40 C.F.R. § 155.50

- 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). However, this study requirement was deemed satisfied[13,14] by the absorption/desorption studies (OECD 106 (2000)) submitted in 2014 (MRID 49342703, 49342704, 49342705, 49342706). 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.

- 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. In response to the comments received, EPA changed the registration 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 posted the PID for chlorothalonil for a 60-day public comment period. EPA received a request from a chlorothalonil technical registrant, Syngenta Crop Protection, LLC, to extend the public comment period for 90 additional days. After careful consideration of the request, EPA extended the comment period for an additional 30 days.[15] During the 90-day comment period, the Agency received 195

[13] *Chlorothalonil – Response to Public Comments Received on the Registration Review Proposed Interim Decision* (December 19, 2024)
[14] *Data Evaluation Report on the leaching of chlorothalonil in unaged and aged soil columns* (October 5, 2006)
[15] EPA-HQ-OPP-2011-0840-0159 on www.regulations.gov

comments. In response to the comments received, EPA changed the registration review timeline for chlorothalonil to ensure all comments were considered and addressed. 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)

- December 2024 – EPA published the ID for chlorothalonil. Along with the ID, EPA posted the following documents to the chlorothalonil public docket:
  - *CHLOROTHALONIL: Response to Comments on the Proposed Interim Registration Review Decision (PID)* (June 3, 2024)
  - *Chlorothalonil – Response to Public Comments Received on the Registration Review Proposed Interim Decision* (December 19, 2024)
  - *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024)
  - *Meeting Notes: Florida Tropical Fruit Takeaways with USDA Office of Pest Management Policy* (July 17, 2024)
  - *Meeting Notes: Turf Grass Discussion with University of Wisconsin Extension Specialists* (August 27, 2024)
  - *Meeting Notes: EPA and Canada's Pest Management Regulatory Agency (PMRA)* (September 3, 2024)
  - *Meeting Notes: EPA and Syngenta Crop Protection, LLC* (September 5, 2024)
  - *Data Evaluation Report on the leaching of chlorothalonil in unaged and aged soil columns* (October 5, 2006).

C. Summary of Public Comments on the PID

In response to a request from a chlorothalonil technical registrant, EPA extended the public comment period for the PID for an additional 30 days. During the 90-day public-comment

period for the chlorothalonil PID, the Agency received 195 unique comments. Comments were submitted by:

- the conventional technical registrants Syngenta Crop Protection, LLC (Syngenta) and Makhteshim Agan of North America, Inc. (d/b/a ADAMA)
- United State Department of Agriculture Office of Pest Management Policy (USDA OPMP)
- National Agricultural Aviation Association (NAAA)
- IR-4 Project
- Center for Biological Diversity (CBD)
- CropLife America (CLA)
- PETA Science Consortium International e.V.
- Sacramento Rivers Source Water Protection Program (SRSWPP)
- California Stormwater Quality Association (CASQA)
- crop associations, crop groups, and companies that use chlorothalonil including:
    - North Carolina Pickle Packers Association (NCPPA),
    - National Watermelon Association (NWA),
    - Sanoca Farms, Kenny Inc,
    - Swanson Pickle Co., Inc., McClure Farms / West Coast Tomato,
    - Michigan Seedling Growers Association,
    - Wisconsin Potato & Vegetable Growers Association (WPVGA),
    - Cranberry Institute,
    - Lipman Family Farms,
    - Cherry Marketing Institute, Inc. (CMI),
    - Pickle Packers International (PPI),
    - Michigan Blueberry Commission,
    - Hartung Brothers Inc.,
    - Florida Fruit and Vegetable Association (FFVA),
    - National Potato Council (NPC),
    - Washington State Potato Commission,
    - Southern Forest Nursery Management Cooperative,
    - National Christmas Tree Association (NCTA),
    - Northwest Horticultural Council (NHC),
    - Michigan Farm Bureau,
    - California Tomato Research Institute (CTRI),
    - California Prune Board (CPB),
    - North American Blueberry Council (NABC),
    - National Alliance of Independent Crop Consultants (NAICC)
  - 14 individuals who use or have used chlorothalonil
- 137 golf course superintendents, country club representatives and other turf professionals,
- research and extension professionals including:
    - James Adaskaveg, University of California- Riverside,

  - Dave Norman, University of Florida,
  - A comment authored by nine turfgrass pathologists and extension specialists at land-grant universities and reviewed and endorsed by 11 additional professionals (Paul Koch, University of Wisconsin – Madison; James Baird, University of California – Riverside; Ming-Yi Chou, Rutgers University; Travis Gannon, North Carolina State University; John Inguagiato, University of Connecticut; Jim Kerns, North Carolina State University; Alec Kowalewski, Oregon State University; Lee Miller, Purdue University; Joseph Roberts, Clemson University; Michael Fidanza, Penn State University; Phil Harmon, University of Florida; Brandon Horvath, University of Tennessee; Wendell Hutchens, University of Arkansas; Young-Ki Jo, Texas A&M University; Geunhwa Jung, University of Massachusetts – Amherst; John Kaminski, Penn State University; David McCall, Virginia Tech University; Fereshteh Shahoveisi, University of Maryland; Joseph Vargas, Michigan State University; Nathan Walker, Oklahoma State University),
  - American Phytopathological Society,
  - Arizona Pest Management Center (APMC),
  - Utah State University ("Utah Pests"), and
  - Gary Vallad, University of Florida
- several anonymous public commenters.

The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. The Agency thanks all commenters for participating and has considered all comments in developing this ID.

Comment submitted by Syngenta Crop Protection LLC (EPA-HQ-OPP-2011-0840-0316)
Comment: Syngenta Crop Protection LLC. (henceforth referred to as 'Syngenta'), a technical registrant of chlorothalonil, noted areas of the PID where clarification or revisions were necessary, including absent or incorrect citations, and updates to the outstanding data needs. Syngenta suggested that the maximum single application rate for turf use sites should be clarified from 12.6 lb a.i./acre to 11.3 lb a.i./acre and that any reference to chlorothalonil use on residential lawns is not consistent with labeled use. Syngenta provided feedback and proposed updates for both the human health and ecological risk assessment and conclusions that were included in the PID.

Comments on the human health assessment and risks:
Regarding the human health risks, Syngenta proposed that EPA adjust the acute toxicity point of departure (POD) for SDS-3701, metabolite of chlorothalonil, using a benchmark dose assessment (BMD) approach because there is no statistically significant difference between the response (early resorptions) at the lowest observed adverse effect level (LOAEL) compared to the control group. Based on Syngenta's BMD modeling, the dietary exposure estimates for females aged 13 to 49 are 48% of the acute population-adjusted dose (aPAD), and therefore not

of concern. Additionally, Syngenta raised concerns with EPA's use of the (Dietary Exposure Evaluation Model) DEEM (Food Commodity Intake Database) FCID version 4.02 model for the estimated dietary exposure. Syngenta suggested that using the newer DEEM-FCID model in the first round of registration review is inconsistent with EPA statements that ensured first round re implementing registration review cases would be considered using the same data.

Syngenta noted that tolerance changes were proposed in the PID for celery and potato to harmonize with Codex. However, Syngenta had previously requested that the tolerances for these crops be maintained to facilitate trade with Canada. Syngenta cited *Chlorothalonil Response to Comments on the Draft Human Health Risk Assessment for Registration Review and Risk Assessment Addendum to Include Updated Dietary Risk Estimates* (Sept. 27,2023), in which EPA agreed with this request.

Comments on the ecological assessment, drinking water assessment and risks:
In response to the risks described in the PID, Syngenta requested that EPA refine the turf groundwater scenarios for chlorothalonil using an approach similar to the provisional modeling scenario used previously by EPA for oxadiazon. Syngenta suggested that this refinement would reduce chlorothalonil estimated groundwater concentrations by fifty percent.

Additionally, Syngenta requested that EPA consider a recent population modeling study, when evaluating risks to freshwater fish and aquatic-phase amphibians. Syngenta proposed that EPA's recommendation to conduct a Larval Amphibian Growth and Development Assay (LAGDA) may be premature, given EPA's updated approach to the EDSP and the ongoing research efforts to develop test methods for thyroid effects in wildlife. Syngenta also responded to EPA's *Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment* (Sept. 27, 2023). With regards to EPA's 2023 response to comments, Syngenta noted that they disagree with EPA's rationale that the NOAEC selection does not impact the overall risk determination because individual crop uses are the units of the risk assessment and mitigation measures and estimated environmental concentrations (EECs) can vary drastically between crop uses which translates to significant impact on the risk outcome. Syngenta also disagrees with EPA's use of the fish short term reproductive assay (FSTRA) for the chronic fish endpoint because the FSTRA study is designed to assess endocrine responses, rather than growth, reproduction, and survival. Further, Syngenta notes that the dose spacing of the FSTRA study is not effective for determining effect thresholds for fish growth, reproduction, and survival endpoints. Syngenta suggested that establishing the chronic avian NOAEC and LOAEC based solely on eggshell thinning, is overly protective because eggshell thinning was the only study endpoint with significant effects detected at the 100 mg/kg-diet treatment level.

Comments on proposed mitigations:
Syngenta included feedback and suggested updates on the mitigation measures proposed by EPA in the PID. Specifically, Syngenta requested a more detailed description of the methodology applicators should use to determine soil vulnerability, that golf courses and

professional/collegiate athletic fields use sites should not be considered vulnerable soils, and that the advisory best management practices for pollinator protection statements not apply to turf uses and sod farms. Syngenta proposed that the 25-foot aquatic buffer for turf use should be changed to a 10-foot vegetative filter strip and noted that this change would have negligible impacts on risk reduction and estimated exposure. Finally, Syngenta suggested that describing the annual application rate for the ornamental root/bulb dip use pattern in lbs a.i./acre/year is not consistent with the use pattern.

EPA Response: EPA thanks Syngenta for making the Agency aware of the citation errors and has revised these discrepancies in this ID. The Agency appreciates Syngenta's feedback on the maximum single application rate for turf. However, EPA notes that while the maximum single application rate for turf use sites for Syngenta end use products containing chlorothalonil is 11.3 lb ai/acre, this is not the maximum single application rate for turf across all EPA registered end use products containing chlorothalonil. EPA recognizes that there are no residential lawn uses of registered chlorothalonil products and clarified this in this ID, however there are turf uses registered for use on golf courses and on home gardens that can result in residential post-application exposure. EPA thanks Syngenta for providing clarification regarding the need for the soil column leaching study (GLN 835.1240) and agrees that this data requirement has been satisfied with the absorption/desorption studies that were submitted in 2014. While clarifications have been made to this ID, the Agency's risk assessments and conclusions remain unchanged.

Response to comments on the human health assessment and risks:
The Agency's detailed responses to Syngenta's comments related to human health risks can be found in the memorandum *CHLOROTHALONIL: Response to Comments on the Proposed Interim Registration Review Decision (PID)* (June 3, 2024), issuing to the public docket simultaneously with this ID. EPA thanks Syngenta for providing their BMD assessment for SDS-3701. The Agency has conducted a preliminary analysis of the submitted BMD assessment. However, EPA is not conducting a full review of the registrant's BMD analysis or revisiting a potential update to the SDS-3701 acute dietary POD for females 13-49 years of age because the mitigation measures intended to reduce chronic exposures and risks will also alleviate the acute dietary risks. Therefore, updating the acute dietary POD for SDS-3701 will not impact the mitigation strategy for addressing dietary risks.

EPA appreciates Syngenta's feedback on the use of the DEEM 4.02 model in the first round of registration review. The Agency used the DEEM 4.02 model for the revised chlorothalonil dietary assessment (and the assessments for other active ingredients) because the DEEM 3.16 model version does not accurately capture drinking water consumption of all infants due to a coding error. As a result of the coding error, DEEM 3.16 excluded infant water consumption when drinking water is mixed with infant formula. Updating the dietary assessment to DEEM version 4.02 is therefore consistent with the Agency's focus on using the best available science to inform decisions.

EPA thanks Syngenta for their proposal to maintain tolerance levels for celery and potato to facilitate trade with Canada. EPA removed these tolerance revisions that were proposed in the PID from this ID, so that the current tolerances (15 ppm for celery and 0.1 ppm for potato) will not be changed.

Response to comments on the ecological assessment and drinking water assessment and risks: The Agency's detailed responses to Syngenta's comments related to ecological risks can be found in the memorandum *Chlorothalonil – Response to Public Comments Received on the Registration Review Preliminary Interim Decision* (December 19, 2024), issuing to the public docket simultaneously with this ID.

EPA acknowledges that chemical-specific provisional scenarios were used to refine groundwater concentrations for oxadiazon. While this approach was appropriate for oxadiazon, the Agency is not confident that these refinements are appropriate for modeling groundwater concentrations from chlorothalonil use because the provisional scenario assumes no irrigation, which does not reflect turf growing conditions.

EPA appreciates Syngenta's suggested use of the population modeling-based approach as part of the risk picture for freshwater fish and aquatic phase amphibians. However, this approach is not within the Agency's standardized methods, and requires further review before use in regulatory decision making. EPA agrees with Syngenta's perspective on the need for the LAGDA study. As noted in Appendix F, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans. Simultaneously, EPA is developing a comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan[16] and November 2022 ESA Workplan Update[17]) and is therefore not yet addressing the discretionary wildlife component of EDSP.

With regards to Syngenta's comments on EPA's previous response to comments on the draft risk assessment[18] that described endpoint selection and its impacts on overall risk determination, EPA agrees that individual crop uses are the units of the risk assessment and mitigation measures. Crop-specific risk quotients (RQs) are considered when developing mitigation measures. There is a robust discussion of the risk characterization and comparison of the NOAEC (1.3 µg a.i./L) and the LOAEC (3.0 µg a.i./L) as the endpoint in section III.B.1.C of this ID.

In response to Syngenta's concerns with use of the FSTRA study for the chronic fish endpoint, EPA agrees that there is uncertainty with the available chronic data for fish and that the FSTRA

[16] https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf
[17] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf
[18] *Chlorothalonil – Response to Public Comments Received on the Registration Review Draft Ecological Risk Assessment and Drinking Water Assessment* (September 27, 2023)

study is designed to detect endocrine responses, rather than effect thresholds. EPA will continue to characterize the uncertainty of the risks with the available studies and use both NOAECs together in the absence of an acceptable full life cycle study. With regards to Syngenta's concerns with the use of eggshell thinning endpoint to establish the chronic avian effect levels, eggshell thinning is a chronic endpoint for establishing risk for this study design and is therefore used to establish the chronic effect levels.

Response to comments on the proposed mitigation measures:
EPA appreciates Syngenta's feedback on the vulnerable soil application rate restriction and the methods by which applicators should use to determine soil vulnerability. In this ID, EPA has amended the criteria describing where vulnerable soil mitigation measures are necessary for chlorothalonil and clarified the mitigation language to reference USDA's soil classification system and include supplemental instruction for quantifying soil organic matter content and texture based on feedback received during the public comment period. See Appendix B for updated label language. EPA also adapted vulnerable soil maximum annual application rate language based on feedback from both Syngenta and comments from other turfgrass stakeholders to be better suited for golf courses and professional/collegiate athletic field use sites.

EPA agrees with Syngenta's assertion that there is less than 0.1 ppb difference in EECs from a 25-foot aquatic buffer for ground application and a 10-foot vegetative filter strip. The Agency agrees that vegetative filter strips are a viable mitigation option for turf and has adapted the mitigation in this ID to reflect Syngenta's proposal. See Section IV.A.1 and Appendix B for updated label language for ground applications to turf.

In response to Syngenta's concerns with the annual application rate for the ornamental root/bulb dip use, the maximum annual application rate listed in Appendix B refers to the ground application rate of chlorothalonil in the spent root/bulb fluid, not the root/bulb dip treatment application rate. This has been clarified in Appendix B of this ID.

EPA considered Syngenta's suggestion to exempt golf course use sites and professional/collegiate athletic fields from the vulnerable soil definition and annual application rate. The Agency recognizes that the soil and organic matter profile of turf and other fields with modified/engineered rootzones are unique and given their manufactured nature, may not be representative of the native soils. EPA also recognizes that organic matter readily accumulates in established turfgrass stands. While the Agency is not exempting all turf use sites from the vulnerable soil annual application rate, based on public comments and engagement with stakeholders, EPA identified that it is not necessary for the vulnerable soil annual application rate to apply to putting greens constructed according to the U.S. Golf Association (USGA) or California green specifications or constructed as push up greens,[19] and that applications to

[19] Term originating from the technique of using bulldozers or similar equipment to "push up" the native soil (rather than imported soil or other material) to form the contours of the putting green. Push up greens, unlike USGA and

these types of greens can follow the maximum annual application rate for non-vulnerable soils. Based on consultation with research and extension specialists at the University of Wisconsin, Madison, EPA identified that putting greens constructed according to these specifications do not have the same vulnerability to groundwater leaching as soils considered in the Agency's model for vulnerable soils,[20] and therefore the non-vulnerable soil maximum annual application rate is more appropriate for these style greens (see Table 4 in Section IV.A.1 and Appendix B). EPA has also updated the vulnerable soil language for turf use sites other than sod farms based on feedback from Syngenta and other turfgrass stakeholders to provide more clarity to turf users. Specifically, in the vulnerable soil label language for turf, EPA specified that that thatch/mat may be included in the organic matter content for turfgrass. EPA also included instructions to users with advisory language for measuring organic matter and determining soil texture.

EPA appreciates Syngenta's feedback and proposed addition of the Pollinator Hazard Statement to labels. The Agency agrees that turf is not considered pollinator attractive when weeds are actively managed and that some products have agricultural and non-agricultural uses. However, the Agency disagrees that the Pollinator Hazard Statement is misleading. The intention of the statement is to make users aware of the hazard of the active ingredient to bees and other pollinating non-target insects and the statement specifically mentions exposure via "direct treatment on blooming crops or weeds." For these reasons, the Agency continues to find the Pollinator Hazard Statement necessary for turf uses and sod farms.

Comment Submitted by Makhteshim Agan of North America, Inc. (d/b/a ADAMA) and Control Solutions, Inc. (CSI) (EPA-HQ-OPP-2011-0840-0337)

Comment: Makhteshim Agan of North America, Inc. (hence force referred to as ADAMA) and Control Solutions, Inc. (CSI) provided joint comment on the PID. ADAMA and CSI emphasized the importance of chlorothalonil as a tool in fungicide disease control and the important role that multisite fungicides play in resistance management strategies. ADAMA and CSI suggested that there are no alternatives to chlorothalonil that can provide adequate disease control with a similar toxicity. Their comment suggested that the mitigations proposed in the PID will limit growers significantly, leading to fungicide resistance and disease epidemics.

EPA Response: EPA thanks ADAMA and CSI for their feedback on the rate reduction mitigation measures included in the PID. EPA has considered these comments in the development of this ID. However, because EPA identified human health dietary risks that exceed the Agency's level of concern as a result of chlorothalonil use, the Agency cannot conclude that dietary residues of chlorothalonil are safe without the mitigation measures included in this ID. Drinking water exposure via groundwater was the major contributor to dietary exposure of chlorothalonil. The Agency has identified that the annual rate reductions are necessary to reduce groundwater

California greens, rely on surface drainage as the primary method for draining excess water from the green. Push up greens may be topped with 4 or more inches of sand to improve smoothness and water drainage.

[20] Meeting Notes: Turf Grass Discussion with University of Wisconsin Extension Specialists (August 27, 2024) available on the public docket EPA-HQ-OPP-2011-0840 on www.regulations.gov

exposure and dietary risk. Additionally, for the ecological risks, EPA considered the risks and benefits when identifying the necessary mitigation to reduce exposure to non-target species.

Comment submitted by United States Department of Agriculture (USDA) (EPA-HQ-OPP-2011-0840-0345)

Comment: USDA provided benefits information and described concerns with the potential impacts of the proposed mitigation measures on disease control and fungicide resistance for potatoes, ginseng, tomatoes, cucurbits, cherries, mangoes, blueberries, and turfgrass.

For potatoes, USDA suggested that the proposed annual rate reductions may cause economic loss because of both yield and quality losses when there is heavy disease pressure and that growers will likely need to rely on single site fungicides. Under low disease pressure, the typical annual chlorothalonil is lower than the proposed application rate for vulnerable soils. However, USDA noted that in some growing regions where disease pressure is greater, higher application rates are needed to maintain quality and yield.

For ginseng, USDA noted that chlorothalonil alternatives (captan and mancozeb) face regulatory pressure, which increases the need for chlorothalonil to provide broad spectrum disease control throughout the growing season and limit the development of resistance. The proposed annual application rate reduction may pressure growers to use less efficacious single site fungicides for ginseng that are at higher risk to developing resistance.

USDA highlighted that chlorothalonil is a critical piece of disease management and control of late blight in tomatoes and is the primary means for controlling target spot fungal pathogen on tomato caused by *Corynespora cassiicola* in Florida. USDA suggested that the proposed rate reductions will have long term implications on the ability to control these diseases.

USDA emphasized that chlorothalonil is the primary preventative fungicide for cucurbit disease control programs nationally and is more effective than some alternative multi-site fungicides (copper and sulfur compounds). If chlorothalonil were to become unusable for cucurbits, the only alternative would be to use combinations of single-site fungicides, which are known to be at risk of developing resistance. If use of chlorothalonil is limited, growers will need to consider timing of chlorothalonil applications in the season based on disease pressure and strain/variety of the disease.

USDA described the importance of chlorothalonil to cherry growers, who are reliant on broad spectrum, contact, multi-site fungicides because of cherry leaf spot resistance to demethylation inhibitor (DMI) and succinate dehydrogenase inhibitor (SDHI) fungicides. Chlorothalonil is beneficial to growers because alternative multisite fungicides (such as captan and copper compounds) have phototoxicity effects. Based on the proposed rate reductions, growers would be limited to two applications per year in areas with vulnerable soils. Based on feedback USDA received from Michigan, cherry leaf spot is worsening in wet years, which are becoming more common, for sweet cherry growers. Because of phototoxicity concerns, sweet cherry growers

have limited fungicide options. Therefore, limiting the annual application rate to 6.5 b a.i./acre/ year is of concern for sweet cherry growers, and all stone fruit grown in Michigan.

USDA noted that the annual applications rate reductions proposed in the PID would jeopardize season-long control of anthracnose in mangos. Growers apply chlorothalonil 7 times per year at the highest labeled rate per application. Tropical fruits, such as mango, have long growing seasons and require multiple applications. With the proposed mitigation measures, growers would be limited to 1 application per year, providing inadequate control of the disease, and reduced fruit yield, fruit quality, and marketability. The reduced rate could cause a rise in disease rate and increased resistance to single-site fungicides.

Chlorothalonil is critical for disease control in blueberries. Ziram, an alternative, provides good control of some diseases but cancelation of the use has been proposed. Without ziram, growers are limited to chlorothalonil and captan, which only provides fair control of disease. Higher rates would allow growers to better manage disease control and prevent and manage fungicide resistance.

USDA described the benefits of chlorothalonil use for turfgrass disease management and fungicide resistance management and the notable cost difference per acre of turfgrass between chlorothalonil products and other commonly used fungicides for control the same diseases. USDA shared insight from turf pathologists, who agreed that the application rate reductions proposed in the PID will maintain adequate use opportunities for golf course superintendents. However, these pathologists suggested that engineered golf course rootzones in putting greens should be exempted from EPA's vulnerable soil definition because of its difficulty with implementation and enforcement. They suggested that, if an exemption can't be made, EPA provide clearer instructions for defining vulnerable soils and measuring organic matter content, that determination of organic matter content should include the thatch, and that EPA provide a one-year exemption for newly established turf grass because organic matter is artificially low in the first year while the mat/thatch layer develops.

USDA quantified the crop acreage that corresponds to areas of vulnerable soil for potatoes, melons, tomatoes, cherries, peaches, and onions, to determine the crops with the greatest impacts from the annual application rate reduction for areas with vulnerable soils. USDA determined that the largest impacts would be to potatoes and cherries, but there was also notable overlap of vulnerable soils with melon acreage in some states.

With regards to the proposed mitigation measures, USDA suggested that EPA better define the characteristics of vulnerable soils and noted that some growers test organic matter content regularly. Additionally, USDA suggested that the maximum annual application rate for vulnerable soils not apply to cranberry bogs, where water does not infiltrate groundwater by design. USDA suggested that EPA modify the proposed label language for aquatic buffers to be consistent with buffers proposed under FIFRA IEM. USDA also expressed concerns about the soil saturation statement, particularly for potato growers, the additional burden to check the

Bulletins Live! Two website, and wind-directional buffers to conservation areas. USDA also noted that a coarser droplet size could reduce the efficacy of chlorothalonil as a preventative fungicide.

EPA Response: EPA appreciates USDA's comments and insight on the use of chlorothalonil and the impacts of the proposed mitigation measures. The Agency's crop-specific responses to the crops discussed in this comment can be found in the *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024), issuing to the public docket simultaneously with this ID.

With regards to USDA's comments on the annual application rate reductions for potatoes, EPA recognizes that the reduced annual application rates will have some impacts on growers, especially in growing regions and years with higher disease pressure. EPA agrees that mancozeb is the most likely alternative to chlorothalonil in potatoes and that reduced annual application rates for chlorothalonil will likely result in increased reliance on mancozeb. In July 2024, EPA released the PID for mancozeb and did not propose any rate reductions for foliar applications to potatoes, which means this multi-site fungicide will likely remain available for growers to use in rotation with chlorothalonil.[21]

EPA appreciates USDA's feedback on disease management pressures for ginseng. Mancozeb is still at the PID stage of registration review, however, in the mancozeb PID EPA did not propose rate reductions for use on ginseng.[22] Therefore, this multiuse fungicide will likely still be available to growers to use in rotation with chlorothalonil.

EPA appreciates USDA's feedback on the annual application rate reductions proposed for tomatoes in the PID. EPA agrees that chlorothalonil is an important tool for tomato disease control and that the loss of chlorothalonil to growers would have long term pest management consequences. In this ID, EPA has identified that the maximum annual application rate for tomato should be reduced to address the ecological and human health risks associated with this use pattern. EPA agrees that the conditions in Florida can result in higher disease pressure and has allowed a higher rate (10.5 lbs a.i./acre/year) in Florida, Georgia, North Carolina, and South Carolina. While this rate is lower than what is currently available to growers (15.0 lbs a.i./acre/year), it will allow for several applications of chlorothalonil and maintain its use as a rotational partner in resistance management.

The Agency thanks USDA for its feedback on cucurbit disease control and impacts of the annual application rate reductions included in the PID. EPA notes that based on the mitigation measures outlined in this ID, growers on non-vulnerable soils will be able to apply 9.0 lbs a.i./acre/year while growers in vulnerable soils will only be able to apply 6.5 lbs a.i./acre/year. Based on usage data, nearly all use of chlorothalonil on representative melon cucurbits (cantaloupe, watermelon) and vegetable cucurbits (cucumber, pumpkin, squash) was less than

[21] EPA-HQ-OPP-2015-0291-0092 on www.regulations.gov
[22] EPA-HQ-OPP-2015-0291-0092 on www.regulations.gov

9.0 lb a.i./acre/year in recent years.[23] Furthermore, nationally, a majority of surveyed cucurbit acres treated with chlorothalonil reported an annual rate less than 6.5 lbs a.i./acre/year. However, state-level information indicates that growers in the Southeast and Northeast may be more impacted than in other growing regions due to greater pest pressures and may utilize an annual rate greater than 6.5 lb ai/acre/year. Growers needing to apply more chlorothalonil than these annual rate limits would likely be able to replace an early season application of chlorothalonil with mancozeb. Therefore, EPA expects impacts of these annual rate reductions to be limited for cucurbit production. Growers who require additional applications beyond the maximum annual application rates may need to replace applications with mancozeb and may need to consider seasonal timing of applications, and the Agency recognizes this additional burden.

EPA appreciates the cherry benefits information that USDA provided and the insight on worsening pathogen conditions. The Agency understands that the maximum annual application rate for cherries in vulnerable soils included in this ID (6.5 lbs a.i./A/year) limits growers to two applications per year at the maximum single application rate, which may be insufficient for growers east of the Rocky Mountains (Upper Midwest and other eastern production areas). While the maximum annual application rate for cherries in vulnerable soils has not changed since this PID, EPA has updated the maximum annual application rate limits for cherries on non-vulnerable soils in this ID. In the PID, the Agency proposed different maximum annual application rates for sweet cherries (6.5 lbs a.i./acre/year) and tart cherries (15.4 lbs a.i./acre/year) in non-vulnerable soils. In this ID, EPA has regrouped cherries as one crop and has included a higher maximum annual application rate (15.4 lbs a.i./acre/year on non-vulnerable soils) for cherry growers east of the Rocky Mountains, where disease pressure is higher, and maintained the lower rate (6.5 lbs a.i./acre/year on non-vulnerable soils) for cherry growers west of the Rocky Mountains where chlorothalonil usage, in terms of annual application rate, is low. For more specific benefit and usage information on sweet and tart cherries, see *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024).

EPA appreciates the benefit and usage information USDA provided for mangos. At the time of the PID, the Agency did not have usage information for this crop to consider as part of a risk benefit analysis. Based on USDA's comments and additional usage and benefit feedback USDA provided from southern Florida tropical fruit growers,[24] EPA has changed the maximum annual application rate for mangos in this ID from 4.7 a.i./acre/year to 6.5 a.i./acre/year, allowing growers to make two to three applications of chlorothalonil per year.

EPA appreciates USDA's feedback on disease management control for chlorothalonil used on blueberries. USDA suggested that captan, when used as an alternative to chlorothalonil, may only provide fair control for some diseases. However, EPA notes that extension

[23] Chlorothalonil Use, Usage Pest Management Benefits and Impacts of Potential Mitigation for Agricultural Use Sites (September 29, 2023)
[24] Meeting Notes: Florida Tropical Fruit Takeaways with USDA Office of Pest Management Policy (July 17, 2024)

recommendations suggest the use of captan for in-season fungicide resistance management in blueberry. [25] Growers could use captan in season and limit their chlorothalonil applications to the post-harvest period. In response to USDA and other commenters, EPA has identified a need for the rate to be no higher than 6.5 lbs a.i./acre/year for blueberries in order to reduce dietary exposure to chlorothalonil in drinking water.

EPA thanks USDA for their feedback on turfgrass disease management and fungicide resistance management. EPA understands that there is a cost differential associated with the use of different fungicides if chlorothalonil use is limited and appreciates USDA's assertion that the mitigation measures proposed in the PID will maintain adequate use of chlorothalonil on fairways and tees. In this ID, EPA has updated where restrictions apply to vulnerable soils and has updated instructions for measuring organic matter and determining soil type for users based on feedback from USDA and other commenters.

EPA considered USDA's suggestion to exempt putting greens with engineered rootzones from the vulnerable soil definition and annual application rate and EPA did not concur with USDA's proposed alternatives. While the Agency is not exempting all turf use sites from the vulnerable soil annual application rate, based on public comments and engagement with stakeholders, EPA identified that it is not necessary for the vulnerable soil annual application rate to apply to putting greens constructed according to the US Golf Association (USGA) or California green specifications or constructed as push up greens,[26] and that applications to these types of greens can follow the maximum annual application rate for non-vulnerable soils (See Table 4 in Section IV.A.1 and Appendix B). Based on consultation with research and extension specialists at the University of Wisconsin, Madison, EPA identified that putting greens constructed according to these specifications do not have the same vulnerability to groundwater leaching as soils considered in the Agency's model for vulnerable soils,[27] and therefore the non-vulnerable soil maximum annual application rate is more appropriate for these style putting greens.

Additionally, EPA updated the vulnerable soil language for turf use sites other than sod farms based on feedback from USDA and turfgrass stakeholders to provide more clarity to turf users. Specifically, in the vulnerable soil label language for turf, EPA specified that thatch/mat may be included in the organic matter content for turfgrass. EPA also included instructions to users with advisory language for measuring organic matter and determining soil texture.
The Agency disagrees that newly established turf should not be subject to the vulnerable soil restrictions. If the turf is established in soil that has less than 2% organic matter, is sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive

[25] *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024).
[26] Term originating from the technique of using bulldozers or similar equipment to "push up" the native soil (rather than imported soil or other material) to form the contours of the putting green. Push up greens, unlike USGA and California greens, rely on surface drainage as the primary method for draining excess water from the green. Push up greens may be topped with 4 or more inches of sand to improve smoothness and water drainage.
[27] Meeting Notes: Turf Grass Discussion with University of Wisconsin Extension Specialists (August 27, 2024) available on the public docket EPA-HQ-OPP-2011-0840 on www.regulations.gov

layer that impedes the movement of water through soil,[28] and the water table occurs at a depth of 30 feet or less from the surface, then the soil is vulnerable to leaching, and the vulnerable soil rate is necessary to mitigate groundwater contamination leading to drinking water exposure to chlorothalonil.

EPA appreciates USDA's analysis of crop specific impacts of the vulnerable soil mitigation measures. EPA identified that the vulnerable soil mitigation measures are necessary to limit chlorothalonil residues in drinking water because the Agency identified human health dietary risks (for residues in/on food and drinking water) of concern from registered uses of chlorothalonil. Therefore, EPA cannot conclude that dietary consumption of residues of chlorothalonil is safe without the vulnerable soil mitigation measures.

EPA agrees with USDA's assertion that most cranberry bogs should not be subject to the vulnerable soil annual application rate because most cranberry beds are built on substrate that holds a flood and completely isolates flood water from ground water. The Agency has updated the vulnerable soil mitigation language to reflect this. See Section IV.A.1 and Appendix B for updated label language.

EPA acknowledges the impacts to both potato growers and the turf industry that may result from the buffers to aquatic areas and appreciates USDA's proposed clarification to make these buffers wind directional. However, the Agency has not made these buffers wind directional because the buffers to aquatic areas are intended to reduce ecological risks from both runoff and spray drift. EPA addresses this in *Chlorothalonil – Response to Public Comments Received on the Registration Review Proposed Interim Decision* (December 19, 2024).

EPA appreciates USDA's feedback on potential impacts of the soil saturation statement on potato growers. The Agency agrees that prohibiting applications of chlorothalonil to saturated soil and during temperature inversions will restrict the times that growers can apply chlorothalonil. However, EPA maintains that these mitigation measures are necessary to address the risk associated with chlorothalonil use.

EPA appreciates USDA's feedback on the use of the Bulletins Live! Two (BLT) interface for communicating geographic-specific pesticide mitigation measures to users. EPA recognizes that there are barriers and burdens associated with grower adoption of this technology.

The Agency agrees that the use of coarser droplets may reduce efficacy of contact fungicides, such as chlorothalonil, but notes that, in general, a medium droplet size is recommended for

[28] USDA's Web Soil Survey tool can be used to determine soil texture, which may be found here: https://websoilsurvey.nrcs.usda.gov/app/

contact fungicides.[29,30] In this ID, EPA indicates that "medium or coarser" droplets are necessary to address ecological risks. The Agency acknowledges that the buffers to conservation areas may cause growers to not apply to areas of their fields, eliminate aerial application as an option, or to have to use alternative fungicides. However, EPA maintains that these mitigation measures are necessary to address the risk associated with chlorothalonil use.

Comment submitted by National Agricultural Aviation Association (NAAA) (EPA-HQ-OPP-2011-0840-0173)

Comment: NAAA appreciated EPA's consideration of their comments on the chlorothalonil draft risk assessments. NAAA emphasized their support of wind-directional buffers to conservation areas and suggested that the 150-foot buffer to aquatic areas be revised to be wind-directional. NAAA proposed that if the buffer to aquatic areas is intended to mitigate both drift and runoff, then the buffer distances should be the same for both ground and aerial application. NAAA is supportive the measures proposed to mitigate drift from aerial applications of chlorothalonil except the 10 mile per hour (mph) wind speed restriction, citing that wind speeds commonly exceed 10 mph during critical application periods and that several other registration review cases where 15 mph wind speed restrictions were proposed.

EPA Response: EPA thanks NAAA for their comments. NAAA is correct in concluding that the buffer to aquatic areas is intended to mitigate both drift and runoff concerns. However, EPA does not agree the ground and aerial buffer distances should be equivalent because spray drift from ground and aerial applications is not equivalent. EPA maintains that the 10-mph wind speed restrictions is necessary to address risks, and that the existing language on most chlorothalonil labels already includes a 10-mph maximum wind speed restriction.

Comment submitted by IR-4 Project (EPA-HQ-OPP-2011-0840-0313)

Comment: IR-4 described the crucial role that chlorothalonil plays in fungicide programs for specialty crops and emphasized the importance of chlorothalonil as a tool for effective disease control for these crops. IR-4 suggested that the annual application rate reductions proposed in the PID would result in growers being unable to adequately protect crops and would result in substantial economic losses. Specifically, the annual rates proposed for almonds, pistachios, stone fruits, mangoes, brassicas, carrots, celery, horseradish, and tomatoes are less than half of the current labeled annual rate and that the maximum annual application rates proposed in the PID would cause significant impact to growers. They highlight that maintaining chlorothalonil is essential to secure the continued protection of specialty crops.

EPA Response: EPA thanks IR-4 project for their comment and has considered the benefits of chlorothalonil use and the potential impacts of the mitigation measures included in this ID.

[29] Crop Protection Network. 2021. Fungicide Use in Field Crops Web Book: Section 3.1: Foliar Fungicide. https://cropprotectionnetwork.org/web-books/fungicide-use-in-field-crops?section=31-foliar-fungicide [Accessed August 2024]

[30] Virginia Cooperative Extension. 2009. Droplet Chart/Selection Guide. Hipkins, P., Grisso, R., Wolf, B., Reed, T. https://bae.k-state.edu/faculty/wolf/PDF/442-031_DropletChart-SelectionGuide.pdf

Since the PID, EPA has increased the maximum annual application rate mitigation measures for some of the crops noted by IR-4 project including mangos, celery, and some stone fruits (nectarines and cherries) based on feedback and information from stakeholders. For the uses noted by IR-4 where EPA did not increase the maximum annual application rate mitigation since the PID (almonds, pistachios, brassicas, carrots, horseradish, and tomatoes), EPA cannot conclude that dietary residues of chlorothalonil without changes to the registrations to include the necessary mitigations identified in this ID.

Comment submitted by Center for Biological Diversity (EPA-HQ-OPP-2011-0840-0346)
Comment: CBD's comment focused on EPA's duty under the ESA to consult with the Services on the registration review of chlorothalonil and on EPA's implementation of the 2011 NMFS salmonid BiOp for chlorothalonil. CBD's comments mention various aspects of the risk assessment process (*e.g.*, use of the best available data), including necessary data and studies (*e.g.*, those necessary to develop listed-species risk assessments) and evaluation of effects on listed species and their designated critical habitat. CBD expressed concern about the rigor of EPA's preliminary determinations for this registration review regarding the effects of chlorothalonil on listed species and their designated critical habitat. CBD also expressed concern about the effects of chlorothalonil on pollinators and other beneficial insects, possible endocrine disruption effects on human health and environmental safety, and any additive, cumulative and synergistic effects from the use of chlorothalonil.

CBD suggested that the alternative mitigation measures that EPA included in the PID to address the 2011 NMFS salmonid BiOp do not fully comply with the reasonable and prudent alternatives (RPAs) and reasonable and prudent measures (RPMs) described in the 2011 NMFS salmonid BiOp. To rectify this, CBD urged EPA:

- to prohibit applications when the windspeed is less than two mile per hour (i.e., inversion mitigation),
- to make advisory windspeed re-checks enforceable and require recordkeeping of windspeed measurements,
- to adapt the rain restriction language as written in the 2011 NMFS salmonid BiOp to reference high-end estimates,
- to include NMFS-approved runoff reduction measures, and
- to improve the incident reporting process.

Further, CBD emphasized EPA's duty to commit to environmental monitoring as part of the RPMs outlined in the NMFS 2011 salmonid BiOp.

CBD also described their concerns with the FIFRA IEM measures proposed in the PID, and suggested that the pollinator advisory language, buffers to conservation areas, and runoff mitigation measures are insufficient. With regards to the IEM runoff mitigation, CBD suggested that EPA require larger buffers, functional riparian systems and vegetative filter strips. CBD emphasized the incidence and impact of misuse and accidental spills. CBD urged EPA to

consider these non-labeled routes of exposure in their risk assessments. CBD described the potential impacts of pesticide mixtures and urged EPA to take action to address pesticide mixtures.

CBD further discussed EPA's duty under the Endangered Species Act (ESA) to consult with the Services on the registration review of chlorothalonil. CBD's comments mention various aspects of the endangered species assessment (*e.g.*, "Not Likely to Adversely Affect" and "Likely to Adversely Affect" determinations for listed species and their designated critical habitat), the consultation process with The Services, and the implementation of BiOps into end-use labels.

EPA Response: EPA thanks CBD for their feedback on the implementation of the 2011 NMFS salmonid BiOp and the FIFRA IEM measures that were proposed in the PID. Regarding temperature inversion mitigation, in the PID the Agency proposed a minimum windspeed of three miles per hour (mph) for most application types on product labels as part of the mandatory spray drift management label language. Specifically, for aerial, airblast, and ground boom applications, the Agency included the following statement be added to labels under the heading "MANDATORY SPRAY DRIFT MANAGEMENT" establishing a minimum windspeed of three miles per hour:

> "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."

EPA maintains that the 10-mph wind speed restriction is necessary to address risks to non-listed species and to implement the 2011 salmonid BiOp for Pacific salmon and steelhead species. See Section IV.D. and Appendix B and Appendix C of this document for more information.

EPA appreciates CBD's support for proposed mandatory drift mitigation language instructing applicators to measure windspeed and direction with a windsock, an anemometer, or an aircraft smoke system. EPA notes CBD's suggestion to convert the best practices language describing periodic rechecking of wind conditions from advisory to mandatory and to require recordkeeping of windspeed and direction measurements for enforcement purposes. The Agency has not determined the recordkeeping of windspeed and other wind conditions is necessary.

EPA considered CBD's suggestion to include additional language in the rain restriction mitigation that notes that the National Weather Service's 1 inch rainfall prediction should be the *"*high-end estimate*."* The Agency appreciates CBD's proposal but has not adopted this language due to compliance concerns.

EPA maintains that the mitigation measures identified in this ID address RPA 6 of the 2011 BiOp and avoid adverse modification of salmonid habitat. Additional mitigations may be necessary once a nationwide consultation is completed with NMFS and FWS.

The Agency appreciates CBD's support of the updated incident reporting language and suggestions for additional improvements and anonymous submissions. EPA acknowledges that the incident reporting website needs improvement and is actively working to improve this interface. With regards to the incident reporting statement, EPA notes that the language included in Appendix B, which is intended to implement the 2011 Salmonid BiOp, aligns with incident reporting language included in recent NMFS BiOp decisions.

EPA appreciates CBD's feedback on the effectiveness monitoring RPM. EPA and NMFS continue to have conversations about effectiveness monitoring as it relates to pesticide BiOps.

EPA considered CBD's comments and concerns with the FIFRA IEM measures, the incidence and impact of misuse and accidental spills, and the impacts of pesticide mixtures. The mitigation measures included in this ID are consistent with EPA's current FIFRA IEM approach. With regards to misuse and accidental spills, under FIFRA, EPA reviews pesticides to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration and requires that a pesticide generally will not cause unreasonable adverse effects on the environment.[31] While the Agency does consider incidents as a line of evidence in its risk evaluations, during registration review EPA is evaluating the registration and therefore legal (labeled) uses and routes of exposure of a pesticide. Because use of a pesticide product that is inconsistent with the labeling is illegal, and EPA believes that users follow the label, the registration review analysis generally does not include assumptions of misuse.

EPA has reviewed CBD's comments and is addressing many of the concerns about listed species. The Agency continues to coordinate with the Services and USDA to improve the consultation process for listed species and pesticides.[32] In addition, the Agency is planning to develop a draft fungicide strategy to address risks to listed species from fungicides, which will be released for a public comment period. For more information on this ongoing work, see Appendix D. EPA intends to address listed species concerns specific to chlorothalonil when developing its final registration review decision.

As discussed above and in Appendix F, in the absence of convincing evidence of an interaction with the estrogen, androgen, or thyroid hormone pathways for chlorothalonil, EPA determined that it has met its obligations "to ensure the protection of public health" under FFDCA section 408(p).[33] For more information on EPA's review of chlorothalonil under this FFDCA provision, see Appendix F. EPA is currently developing a policy on how to consider synergy claims made by registrants in their patents and patent applications. For more information on this policy, see the interim process posted for public comment on September 9, 2019 to EPA's public docket (EPA-HQ-OPP-2017-0433).

[31] 40 CFR 155.40
[32] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[33] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

Comment submitted by CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) (EPA-HQ-OPP-2011-0840-0344)

Comment: CLA and RISE expressed their support of the comments submitted by Syngenta in response to the both the chlorothalonil PID and draft risk assessments. Specifically, CLA emphasized their support of the use of the fish early life stage study (MRID: 00030391) for determining the NOAEC for fish. CLA echoed Syngenta's comment that the early life stage study is designed to detect growth, reproduction, and survival, unlike the EDSP FSTRA study which detects endocrine-related effects.

EPA Response: EPA thanks CLA for their comments and agrees that there is uncertainty with the available chronic data for fish and that the FSTRA study is designed to detect endocrine responses, rather than effect thresholds. EPA will continue to characterize the uncertainty of the risks with the available studies and use both NOAECs together in the absence of an acceptable full life cycle study.

Comment submitted by PETA Science Consortium International e.V. (EPA-HQ-OPP-2011-0840-0174)

Comment: PETA Science Consortium International e.V. shared their support for EPA's use of human-relevant *in vitro* and *in silico* models for the risk assessment of inhaled chemicals and noted that use of these technologies can enhance the quality of risk assessments and protections.

EPA Response: EPA thanks PETA Science Consortium International e.V. for their feedback and support.

Comments submitted by Sacramento River Source Water Protection Program (SRSWPP) (EPA-HQ-OPP-2011-0840-0334) and California Stormwater Quality Association (CASQA) (EPA-HQ-OPP-2011-0840-0335)

Comment: SRSWPP and CASQA expressed concerns with pesticide contamination, including chlorothalonil, in water bodies and drinking water and the potential impacts on humans and aquatic life from exposure to chlorothalonil. Both comments were supportive of EPA's approach to mitigating risks from chlorothalonil exposure proposed in the PID. CASQA suggested that the label language for non-agricultural products be modified to be more appropriate for consumer use. Specifically, they suggested describing conventional use application rates in terms of fluid ounces per square foot instead of pounds per acre. Finally, CASQA suggested that EPA revise the proposed rainfall statement for runoff prevention to prohibit application for 48 hours prior to rain, rather than 24 hours, which is consistent with other pesticide labels.

EPA Response: EPA thanks SRSWPP and CASQA for their support of the mitigation measures proposed in the PID. EPA appreciates CASQA's feedback on the annual application rate for non-agricultural/ consumer products containing chlorothalonil. EPA agrees that lbs a.i./acre is not a meaningful unit of measure for residential non-commercial agriculture products. However, the

Agency notes that the application rates are not listed in lbs a.i./ acre on these types of products, and that products intended for residential use express the application rate in smaller units, such as ounces, teaspoons/gallon, or pounds/square foot.

EPA appreciates CASQA's proposal to extend the period prior to rainfall where application is prohibited from 24 hours to 48 hours and acknowledges that 24-hour rainfall statement included in this ID for chlorothalonil is inconsistent with the 48-hour rainfall statements included in registration review decisions for other active ingredients. Rainfall statements, like other mitigation measures, are developed on a case-by-case basis by considering the risks and benefits of the pesticide. EPA identified that a 24-hour interval was appropriate for chlorothalonil. Fungicides, including chlorothalonil, are often used as protectants and require applications be made immediately prior to anticipated rain events to prevent disease from occurring or worsening due to wet conditions. The rainfastness, or the interval between a fungicide application and a rain event for which a pesticide product maintains effectiveness, for most fungicides varies from 15 minutes to 24 hours.[34,35] For this reason, EPA modified the interval from the standard 48 hours to 24 hours for chlorothalonil to maintain fungicidal effectiveness while also providing protection against runoff.

Comments submitted by crop groups and associations and grower/packaging groups (Florida Fruit and Vegetable Association (FFVA) (EPA-HQ-OPP-2011-0840-0329), North Carolina Pickle Packers Association (NCPPA) (EPA-HQ-OPP-2011-0840-0175), National Watermelon Association (NWA) (EPA-HQ-OPP-2011-0840-0176), Swanson Pickle Co., Inc. (EPA-HQ-OPP-2011-0840-0185), Michigan Seedling Growers Association (EPA-HQ-OPP-2011-0840-0195), Cranberry Institute et al. (EPA-HQ-OPP-2011-0840-0208), Wisconsin Potato & Vegetable Growers Association (WPVGA) (EPA-HQ-OPP-2011-0840-0199), Pickle Packers International (PPI) (EPA-HQ-OPP-2011-0840-0283), Michigan Blueberry Commission (EPA-HQ-OPP-2011-0840-0284), Cherry Marketing Institute, Inc. (CMI) (EPA-HQ-OPP-2011-0840-0266), National Potato Council (NPC) (**EPA-HQ-OPP-2011-0840-0330), Washington State Potato Commission (EPA-HQ-OPP-2011-0840-0332), Southern Forest Nursery Management Cooperative (EPA-HQ-OPP-2011-0840-0333), Northwest Horticultural Council (NHC) (EPA-HQ-OPP-2011-0840-0341), National Christmas Tree Association (EPA-HQ-OPP-2011-0840-0339), Michigan Farm Bureau (EPA-HQ-OPP-2011-0840-0343), California Prune Board (CPB) (EPA-HQ-OPP-2011-0840-0350), North American Blueberry Council (NABC) (EPA-HQ-OPP-2011-0840-0351), Arizona Pest Management Center (EPA-HQ-OPP-2011-0840-0352), National Alliance of Independent Crop Consultants (NAICC) (EPA-HQ-OPP-2011-0840-0359))**

Comment: Commenters emphasized the importance of chlorothalonil for managing foliar diseases in brassica crops, celery, cucurbits, tomato, onion, peppers, potato, snap beans, peanuts, conifers, cranberries, cherries, blueberries, mango, prune, ginseng, turf and sod, and expressed concern with reduced annual application rates. Commenters cited the effective

[34] Paul, P. 2016. Rainfastness of fungicides in wheat. The Ohio State University. https://agcrops.osu.edu/newsletter/corn-newsletter/2016-11/rainfastness-fungicides-wheat/

[35] Wells, L. 2017. How long does your fungicide need to be on before the rain? University of Georgia. https://site.extension.uga.edu/pecan/2017/06/how-long-does-your-fungicide-need-to-be-on-before-the-rain/

disease control provided by chlorothalonil, the cost-effectiveness of chlorothalonil products, the ease of handling and storage, the short restricted-entry and preharvest intervals, and the lack of chemical alternatives. Commenters raised concerns for potential resistance development if they have to rely on single-site fungicide alternatives. Some commenters provided insight on application rates and number of applications made, and described how the maximum annual applications rates proposed in the PID would impact fungicide treatment programs. Some commenters provided insight on disease pressure in their region and whether their crops are typically grown on vulnerable soils. Commenters also requested clarification on buffers to aquatic and conservation areas and whether they were wind directional. Some commenters suggested that the proposed mitigation measures are reasonable and can be easily adopted for their operations. Finally, commenters raised concerns with the use of BLT system, and requested clarity on whether growers would be able to provide comment on mitigation measures before they are included in BLT.

Grower and crop group associations raised concerns for diseases specific to their crops and growing regions. FFVA highlighted that Florida's environmental conditions are conducive to fungal proliferation, and that the vulnerable soil classification will encompass most of Florida's fruiting vegetable production areas. FFVA described Florida's unique environmental conditions that allows for multiple growing seasons per year. Given that the application rate reductions are for annual rates and multiple crops cycles may be grown on the same soil in the same year, growers in Florida are more limited than growers in other states because the total annual chlorothalonil load for one field must be divided between multiple crop cycles. Therefore, FFVA suggested that annual application rates should be described on a 'per season' basis. FFVA encouraged EPA to consult groups such as the South Florida Water Management District, the Florida Department of Environmental Protection, and the U.S. Geological Survey, which collect and maintain water monitoring data that demonstrate low concentrations of chlorothalonil in ground water. FFVA provided specific use information for chlorothalonil on crops in Florida and emphasized that the annual application rates proposed in the PID will result in significant reductions (30-85%) in allowable chlorothalonil use for crops such as tomatoes, celery, cucurbits, potatoes, snap beans, brassica crops, and mango.

FFVA provided application rates for celery, noting that chlorothalonil is applied to 98-100% of celery produced in Florida. They highlighted the short growing season for celery and Florida's unique environment that allows for multiple growing seasons per year. FFVA emphasized the difference in the current labeled annual rate (18.0 lbs a.i. /acre per year) and the annual application rate proposed in the PID (5.5 lbs a.i./acre per year).

Potato stakeholders noted the Special Local Needs (SLN) label allowing midwestern potato growers to apply higher rates of chlorothalonil because of high disease pressure and fungicide resistance. They emphasized that the reduced annual application rates will particularly impact these potato growers. Other stakeholders discussed the reduced annual application rates and suggested that growers only apply less than 6.5 lbs chlorothalonil a.i./acre/year when late blight is not present, and that higher rates are needed when late blight occurs. Potato

stakeholders also raised concerns with the soil saturation statement, noting that disease pressure is high when soil is saturated. Commenters discussed the impacts of the buffers to aquatic areas, citing the disproportionate effects on smaller farms and the potential the risks of rot and potato greening from the use of ground equipment.

The Cranberry Institute noted that most cranberry beds are peat-bottomed with thick organic matter. However, some newer beds do not have a natural peat bottom and are constructed with man-made layer to prevent leaching. With both peat-bottom and man-made, in order for a cranberry bed to retain water, it must be constructed in a way that provides isolation from ground water. For this reason, cranberry growers requested that the vulnerable soil language be modified to acknowledge cranberry bogs as an exception.

Cherry growers and stakeholders emphasized chlorothalonil's role in controlling cherry leaf spot (*Blumeriella jaapii*) and brown rot (*Monilinia fructicola*) due to the development of resistance to several single site fungicides. Commenters prefer chlorothalonil to other multisite fungicides because of lower phytotoxicity and sometimes higher efficacy. Sweet cherry growers in the Northwest, represented by the Northwest Horticultural Council, felt that the annual application rate reductions could be adopted in their region. Tart and sweet cherry grower groups in the Upper Mid-West expressed concerns with the annual application rate reductions and the rainfall restriction mitigation language.

The Michigan Blueberry Commission and the Michigan Farm Bureau highlighted that blueberries are primarily grown in sandy soils and most crops in Michigan are in vulnerable soil and would therefore need to apply chlorothalonil at the vulnerable soil application rate. The North American Blueberry Council noted that the annual application rate for blueberries is below the current labeled rate (9.0 lb a.i./acre/year) but suggested that the proposed rate (4.5 lb a.i./acre/year) is insufficient for Michigan growers.

EPA Response: EPA appreciates the commenter's feedback on the proposed mitigation measures, the benefits and typical use information, and the impacts of the mitigation measures on Brassica crops, celery, cucurbits, tomato, onion, peppers, potato, snap beans, peanuts, conifers, cranberries, cherries, blueberries, mango, prune, ginseng, turf and sod. EPA has considered these comments in the development of this ID. EPA thanks commenters for their feedback on the vulnerable soil language. EPA has updated and clarified the vulnerable soil language in this ID based on commenter feedback.

With regards to the commenters' concerns with the buffer mitigation measures, EPA clarifies that the buffers to aquatic areas are not wind directional because they are intended to address both spray drift and runoff, but the buffers to conservation areas are wind directional. However, the ground buffer to aquatic areas mitigation has been updated in this ID to provide ground applicators to turf the option to use a 10-foot vegetative filter strip as an alternative to 25-foot buffer. The Agency thanks the commenters for their feedback on the use of BLT to provide users with geographic-specific mitigation measures and confirms that EPA would

provide a public comment period when it proposes new measures in registration review (e.g., in a proposed final decision after completion of ESA section 7(a)(2) consultation with the Services where additional mitigation is identified).

The Agency's detailed crop-specific responses to public comments can be found in the memorandum *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024), issuing to the public docket simultaneously with this ID.

The Agency thanks FFVA for their feedback on the annual application rate reductions for celery. While the Agency maintains application rate reductions that are on an annual basis, and not based on crop cycle, EPA has updated the annual application rate reduction for celery to 7.5 lb a.i. /acre/ year (and 6.5 lb a.i./acre/year for vulnerable soils) in this ID based on usage information and feedback provided by commenters. See Appendix B for updated label language.

EPA appreciates the feedback provided by The Cranberry Institute on the vulnerable soil definition. EPA has updated the vulnerable soil language to exclude cranberry bogs that hold a flood and fully isolate flood water from ground water because the intention of the vulnerable soil mitigation is to address drinking water exposure via groundwater. See Appendix B for updated label language.

EPA thanks cherry stakeholders for their feedback on the proposed mitigation. The Agency agrees that 6.5 lb a.i./acre/year may be insufficient for both sweet and tart cherry growers east of the Rocky Mountains (Upper Midwest and other eastern production areas). While the maximum annual application rate for cherries in vulnerable soils (6.5 lb a.i./acre/year) has not changed since this PID, the maximum annual application rate for cherries in non-vulnerable soils has been updated in this ID. In the PID, the Agency proposed different annual application rates for sweet cherries (6.5 lbs a.i./acre/year) and tart cherries (15.4 lbs a.i./acre/year) grown on non-vulnerable soils. In this ID, EPA has regrouped cherries as one crop and has included the tart cherry rate (15.4 lbs a.i./acre/year on non-vulnerable soils) for all cherry growers east of the Rocky Mountains, where disease pressure is higher, and maintained lower sweet cherry rate (6.5 lbs a.i./acre/year on non-vulnerable soils) for cherry growers west of the Rocky Mountains where chlorothalonil usage, in terms of annual application rate, is low. For more specific benefit and usage information on sweet and tart cherries, see *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024). See Appendix B for updated label language.

The Agency agrees that some blueberry growers would be impacted by the proposed 4.5 lb a.i./acre maximum annual application rate, based on usage information and feedback provided by commenters. EPA has revised the maximum annual application rate for all soils to 6.5 lb a.i./acre.

Comments submitted by research and extension specialists (University of California, Riverside (EPA-HQ-OPP-2011-0840-0177), University of Florida (UF) Institute of Food and Agricultural Science (EPA-HQ-OPP-2011-0840-0193), American Phytopathological Society (APS) (EPA-HQ-OPP-2011-0840-0331), Arizona Pest Management Center (EPA-HQ-OPP-2011-0840-0352), Utah State University ("Utah Pests") (EPA-HQ-OPP-2011-0840-0357), UF Gulf Coast Research and Education Center (EPA-HQ-OPP-2011-0840-0360) + other turfgrass pathologists and land-grant university extension specialists (EPA-HQ-OPP-2011-0840-0318))

Comment: Research and extension specialist emphasized the benefits of chlorothalonil and its role in various industries, including golf course turfgrass, ornamental plants, stone fruits, onions, almonds, and potatoes. Commenters highlighted chlorothalonil's cost effectiveness, short post-harvest and worker restricted entry intervals, low abrasiveness of formulated products, effectiveness against many pathogens, role as a resistance management rotational partner, and long history of use without development of resistance. Commenters noted that the toxicological profile of chlorothalonil had not changed, but the risk outcomes have been updated based on modeling updates made by the Agency. Further, commenters noted that the Agency's groundwater modeling outputs are conservative when compared to California Department of Pesticide Regulation (DPR) groundwater monitoring data for chlorothalonil. Commenters also highlighted the disproportionate impacts that mitigation measures may have on specialty crop growers who have limited alternatives. Some commenters were opposed the 25-foot buffers to water bodies for ground applications proposed in the PID, while other commenters suggested that this mitigation measure was reasonable.

Several research and extension commenters described the importance of chlorothalonil for turfgrass management and the potential impacts on the golf course industry from the proposed mitigations. Commenters were concerned with the 25-foot buffer from water bodies because water bodies are common attributes of golf courses. The buffer from water bodies would effectively ban the use of chlorothalonil on larger portions of golf courses, causing uneven management and course conditions. Commenters cited published research that suggests that golf course turf/putting greens limit distribution and leaching of chlorothalonil and other pesticide active ingredients. Many commenters suggested that golf courses should be exempt from the vulnerable soil maximum annual application rate mitigation measure. Commenters cited that the vulnerable soil definition provided in the PID is more appropriate for agricultural fields than golf course greens and noted the difficulty with implementation and enforcement. Commenters noted that water table depth could vary across the golf course, and it is unclear where the water table depth should be measured to establish whether soils are vulnerable. Further, commenters described a variety of complications with quantifying organic matter content that are specific to golf course turf. Arizona Pest Management Center noted that many golf course greens are engineered with a layer of sand in the top 18-24 inches of soil and the "native" soil sits below the low-organic matter sand, making the organic matter of the topsoil artificially low. If engineered soils were not exempt from the vulnerable soil definition, research and extension specialists made the following suggestions to EPA: (1) provide clear instructions on defining vulnerable soils in golf course environment (2) determination of organic matter in turfgrass should include thatch/mat component and (3) provide exemptions for newly

established turfgrass sites within the first year of seeding. Turfgrass professionals requested a higher annual application rate for putting greens because they are the smallest acreage and highest value area on golf courses and face unique challenges. Turfgrass professionals did not foresee any significant challenges on fairways or tees from the proposed mitigations.

Commenters provided regional-specific comments based on the crops and pathogens present in their areas. University of Florida commenters noted that nearly all of Florida soils will be considered vulnerable under the proposed definition and the proposed rate reductions would severely impact the vegetable and specialty crop production in Florida. University of California, Riverdale supported some of the proposed mitigation but suggested that the proposed rate reductions will severely limit usefulness of chlorothalonil on fruit and nut crops in California to two applications and emphasized that a minimum of three applications is needed for chlorothalonil to be effective. Alternatively, Arizona Pest Management Center suggested that, based on their data, all known uses of chlorothalonil in Arizona and Southeastern California (onion, broccoli, cauliflower, cabbage, celery, potato) are well within EPA's proposed annual application rates.

Utah Pests surveyed crop experts in Utah, Wyoming, Colorado, and Montana on the mitigation measures proposed in the PID. Most growers using chlorothalonil in these states are treating tree fruit (most commonly tart cherry). Other common use sites for chlorothalonil in this region are peaches, apricot, nectarine, plum, prune, and sweet cherry. Although significant annual application rate reductions are proposed for these use sites, surveyed growers and experts did not express any specific concerns to Utah Pests. Further, Utah Pests noted that the majority of chlorothalonil applications in this region are not made within 30 feet of drinking water, and no applications of chlorothalonil are made within the specified distances of either fresh or saltwater bodies or when soil is saturated. Utah Pests conveyed that most individuals surveyed did not think their crops were grown on vulnerable soils, but some growers are unsure what portion of their soil would qualify as vulnerable. Finally, all stakeholders surveyed were unfamiliar with Bulletins Live! Two, and Utah Pests suggested that more outreach and education may be necessary.

EPA Response: EPA thanks the commenters for their valuable feedback on the proposed mitigation measures, benefits information, and impacts information. EPA has considered this feedback in the development of this ID.

For detailed crop-specific responses to relevant public comments, see the memorandum *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024), issuing to the public docket simultaneously with this ID.

EPA agrees that the toxicological profile of chlorothalonil did not change when the dietary risks were updated. However, the update was necessary because prior modeling did not accurately capture risks due to a coding error.

The Agency intends to continue providing outreach and educational opportunities (e.g., webinars) and training resources for the BLT system. The Agency will also continue to communicate and work with stakeholders to address any concerns about the wider use of Bulletins and the BLT system.

EPA thanks stakeholders for providing and citing drinking water monitoring programs and data for chlorothalonil. However, because the Agency identified human health dietary risks of concern from registered uses of chlorothalonil that are inconsistent with the FFDCA safety standard, EPA cannot conclude that dietary residues of chlorothalonil are safe without the mitigations identified in this ID.

EPA appreciates the commenter's feedback emphasizing that specialty crop growers are more likely to be impacted by mitigation measures because they have more limited alternative options.

EPA acknowledges that some stakeholders and industries may be more impacted by the buffers to aquatic areas than others. For ground applications, EPA has included an option to use a 10-foot vegetative filter strip for turf users instead of the buffer in this ID based on feedback received on the PID.

EPA appreciates the feedback received from turf research and extension specialists. As noted previously, the Agency has included an option to use a 10-foot vegetative filter strip for turf users in lieu of the 25-foot ground buffer because the EECs from the two measures are very similar (within 0.06 ppb). EPA considered the commenter's suggestion to exempt putting greens with engineered rootzones from the vulnerable soil definition and annual application rate and the proposed alternatives if an exemption could not be granted. While the Agency is not exempting all turf use sites from the vulnerable soil annual application rate, based on public comments and engagement with stakeholders, EPA identified that it is not necessary for the vulnerable soil annual application rate to apply to putting greens constructed according to the US Golf Association (USGA) or California green specifications or constructed as push up greens,[36] and that applications to these types of greens can follow the maximum annual application rate for non-vulnerable soils (See Table 4 in Section IV.A.1 and Appendix B). Based on consultation with research and extension specialists at the University of Wisconsin, Madison, EPA identified that putting greens constructed according to these specifications are do not have the same vulnerability to groundwater leaching as soils considered in the Agency's model for vulnerable soils.[37] Therefore, the non-vulnerable soil maximum annual application rate is more appropriate for these style greens. EPA also updated the vulnerable soil language

[36] Term originating from the technique of using bulldozers or similar equipment to "push up" the native soil (rather than imported soil or other material) to form the contours of the putting green. Push up greens, unlike USGA and California greens, rely on surface drainage as the primary method for draining excess water from the green. Push up greens may be topped with 4 or more inches of sand to improve smoothness and water drainage.
[37] Meeting Notes: Turf Grass Discussion with University of Wisconsin Extension Specialists (August 27, 2024) available on the public docket EPA-HQ-OPP-2011-0840 on www.regulations.gov

for turf use sites other than sod farms based on feedback from turfgrass stakeholders to provide more clarity to turf users. Specifically, in the vulnerable soil label language for turf, EPA specified that that thatch/mat may be included in the organic matter content for turfgrass. EPA also included instructions to users with advisory language for measuring organic matter and determining soil texture.

The Agency disagrees that newly established turf should be exempt from the vulnerable soil definition. If the turf is established in soil that has less than 2% organic matter, is sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil,[38] and the water table occurs at a depth of 30 feet or less from the surface, then the soil is vulnerable, and the vulnerable soil rate should be followed.

The Agency agrees that the majority of Florida will fall within the 'vulnerable soil' category and that this may have some impacts on some of the fruit and vegetable industries.

Comments submitted by 137 turf and golf course professionals

Comment: Turf grass and golf course stakeholders provided comments on the benefits of chlorothalonil, described the importance of chlorothalonil for their golf course and turf disease management programs, described chlorothalonil's history of use and benefits as a multisite fungicide, requested adjustment of the annual application rate for turf, requested updates to the vulnerable soil definition, and noted the cost difference between chlorothalonil and alternative fungicides. Some commenters suggested that they would be unable to provide adequate conditions for golfers without the use of chlorothalonil at the current labeled application rates. Some commenters noted that turf grass thatch helps to minimize runoff of pesticides applied to turf. A few of the comments described typical application rates of chlorothalonil on their golf courses and suggested that their courses would fall in the vulnerable soil category. Several commenters expressed concerns with the 25-foot buffer to aquatic areas for ground applications of chlorothalonil.

EPA Response: EPA thanks the commenters for their feedback on the chlorothalonil PID and the mitigation measures. These comments have been considered in the development of this PID. EPA notes that the vulnerable soil language has been clarified in this ID based on commenter feedback. Additionally, EPA has added the option for turf users to implement a 10-foot vegetative filter strip instead of the 25-foot buffer to aquatic areas.

Comments on Antimicrobial Uses

Comment from the California Stormwater Quality Association (CASQA) (EPA-HQ-OPP-2011-0840-0335): The California Stormwater Quality Association (CASQA) raised concerns about chlorothalonil's use as a materials preservative in building materials and paints. Specifically,

[38] USDA's Web Soil Survey tool can be used to determine soil texture, which may be found here: https://websoilsurvey.nrcs.usda.gov/app/

CASQA mentioned the potential for chlorothalonil to leach from treated materials during a rainfall event and to result in risks of concerns in nearby aquatic environments. As a result, CASQA recommended that EPA require the following language on chlorothalonil-treated products that may be exposed to rain:

- Advisory Statement: "This product is toxic to fish, aquatic-phase amphibians, and aquatic invertebrates."
- Surface Water Advisory Statement: "Surface Water Advisory. This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having a [medium/large] potential for reaching both surface water and aquatic sediment via runoff for several months or more after application."
- Ecological Incidents Statement: "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)."

Additionally, CASQA recommended that EPA revise antimicrobial labels to units that are more intelligible for consumers. For example, CASQA recommends communicating application rates in ounces rather than pounds.

EPA Response: EPA thanks CASQA for their comment on the PID. Due to chlorothalonil's niche use as one of the few remaining preservatives for solvent-based paints, low risks to human health and the extremely conservative nature of the ecological risk assessment for chlorothalonil treated products, EPA did not identify a need to include additional mitigation language on labels for chlorothalonil-treated products.[39]

Additionally, EPA does not regulate language on product labels for exempt pesticide-treated products, including chlorothalonil-treated paints or building materials. These products fall under the "treated article exemption" as long as the inclusion of the pesticide active ingredient is only intended to preserve the material itself and not objects that may be painted with or otherwise come into contact with the treated articles.[40] However, EPA has solicited comments on the issue of including label language on treated paint cans in a recent Advanced Notice of Proposed Rulemaking (ANPRM) that was released for public comment.[41] The Office of Pesticide Programs (OPP) continues to look into this issue.

[39] Regulations.gov - https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0081
[40] EPA Website – Consumer Products Treated with Pesticides: https://www.epa.gov/safepestcontrol/consumer-products-treated-pesticides#:~:text=The%20treated%20articles%20exemption%20is,than%20other%20described%20product%20features.
[41] EPA website - EPA Issues Advanced Notice of Proposed Rulemaking for Public Comment to Seek Additional Information on Use of Pesticide Treated Seed and Paint: https://www.epa.gov/pesticides/epa-issues-advanced-notice-proposed-rulemaking-public-comment-seek-additional

Finally, EPA does not require registrants to use specific units when describing application rates of antimicrobial pesticide products. As these products are often being used in the manufacture of chlorothalonil-treated products, EPA defers to product registrants who are more familiar with the manufacturing settings to choose how application rates should be communicated. That being said, EPA converts all application rates to parts per million (PPM) for the purposes of assessing risk, so product application rates may be compared to one another.

D. Summary of Public Comments Submitted to the ESA Workplan Docket (EPA-HQ-OPP-2022-0908) on the FIFRA IEM Measures

Advisory Pollinator Label Language

Comments submitted by Center for Biological Diversity, Natural Resources Defense Council and Center for Food Safety (EPA-HQ-OPP-2022-0908-0061), Northwest Horticultural Council (NHC) and Minor Crop Farmer Alliance (MCFA) (EPA-HQ-OPP-2022-0908-0062), Bayer Crop Science (EPA-HQ-OPP-2022-0908-0086), Center for Food Safety (CFS) (EPA-HQ-OPP-2022-0908-0052), Audubon Delta (EPA-HQ-OPP-2022-0908-0099), Pollinator Stewardship Council (EPA-HQ-OPP-2022-0908-0046), Growing Matters Coalition (EPA-HQ-OPP-2022-0908-0043), Illinois Farm Bureau (IFB) (EPA-HQ-OPP-2022-0908-0095), Oregon Department of Agriculture (ODA) (EPA-HQ-OPP-2022-0908-0109), Tina Harvey of Weld County Government (EPA-HQ-OPP-2022-0908-0026)

Comments: Commenters highlighted the need to distinguish between advisory and mandatory language on labels. Several commenters suggested the Best Management Practices (BMPs) language should become mandatory and others commented that growers are familiar with the proposed BMPs. Commenters suggested that advisory language may cause confusion with growers and users.

EPA Response: EPA appreciates the feedback on the pollinator advisory language from the commenters. To clarify that the BMPs are advisory, “advisory” has been added to the heading for the BMPs (“Advisory Best Management Practices for Pollinator Protection”). This is consistent with other advisory statements on labels such as for spray drift.

Comments submitted by Crop Life America (EPA-HQ-OPP-2022-0908-0071), National Cotton Council (EPA-HQ-OPP-2022-0908-0091), Syngenta Crop Protection, LLC (EPA-HQ-OPP-2022-0908-0051), American Sugarbeet Growers Association (ASGA) (EPA-HQ-OPP-2022-0908-0060), American Bird Conservancy et al. (EPA-HQ-OPP-2022-0908-0053), Growing Matters Coalition (EPA-HQ-OPP-2022-0908-0043)

Comments: Commenters proposed replacing the generalized term “pollinator” with other terms to designate non-target pollinating species. Commenters provided suggestions to clarify that pollinators are not just insects but also include vertebrates. Additionally, within pollinators, commenters noted there are many different potential routes of exposure and diverse feeding

patterns and behaviors for different crops. In several instances, commenters suggested "bee" rather than "pollinator" for specificity and consistency.

EPA Response: EPA thanks the commenters for providing feedback on the language and pollinator designation. For consistency with incident reporting language, in the pollinator hazard statement, the language has been updated to "bees and other pollinating non-target insects." In the advisory BMPs, language has been updated and proposed to include "bees" and "bees and other pollinators." The Agency also added new language to address concerns specifically for ground-nesting bees in the BMPs.

Comments submitted by Center for Biological Diversity, Natural Resources Defense Council and Center for Food Safety (EPA-HQ-OPP-2022-0908-0061), National Cotton Council (EPA-HQ-OPP-2022-0908-0091), Northwest Horticultural Council (NHC) and Minor Crop Farmer Alliance (MCFA) (EPA-HQ-OPP-2022-0908-0062), United States Department of Agriculture (USDA) (EPA-HQ-OPP-2022-0908-0104), American Bird Conservancy et al. (EPA-HQ-OPP-2022-0908-0053), Minnesota Corn Growers Association (MCGA) (EPA-HQ-OPP-2022-0908-0045), Audubon Delta (EPA-HQ-OPP-2022-0908-0099), National Corn Growers Association (NCGA) (EPA-HQ-OPP-2022-0908-0107), National Sorghum Producers (NSP) (EPA-HQ-OPP-2022-0908-0087), U.S. Beet Sugar Association (USBSA), and the Beet Sugar Development Foundation (BSDF) (EPA-HQ-OPP-2022-0908-0060), Wyoming Department of Agriculture (WDA) (EPA-HQ-OPP-2022-0908-0101), Growing Matters Coalition (EPA-HQ-OPP-2022-0908-0043), American Mosquito Control Association (AMCA) (EPA-HQ-OPP-2022-0908-0093), U.S. Canola Association (USAC) (EPA-HQ-OPP-2022-0908-0037), NAPPC Imperiled Bombus Taskforce (EPA-HQ-OPP-2022-0908-0022)

Comments: Commenters suggested edits to proposed BMPs and provided new BMPs for EPA's consideration. Commenters requested that BMP updates and additions include bloom and temperature restrictions, buffers, low toxicity pesticide selections, alternatives to pesticides, nighttime applications, beekeeper notifications of application, integrated pest management (IPM) practices, mowing understory weeds and cover crops prior to applications, and measures for ground nesting bees. Commenters also requested EPA update information about pollinator protection plans and information on pollinators from state lead agencies. In addition, pollinator protection plans and state-level information should be easily accessible to growers and users.

EPA Response: EPA thanks all commenters for their feedback on the proposed BMPs and for providing suggested BMPs to add to the pollinator advisory language. As a result of the comments, EPA is modifying existing BMPs and adding BMPs to address applications during bloom, nighttime applications, IPM, mowing practices and ground-nesting bees. The BMP addressing Pollinator Protection Plans has been updated to provide information on labels about the plans and their availability to users through state lead agencies. EPA also removed the incident reporting statement from the BMPs since it is a duplicate of mandatory language in another section of labels.

Comments from American Farm Bureau Federation (AFBF) (EPA-HQ-OPP-2022-0908-0048) and National Alliance of Independent Crop Consultants (NAICC) (EPA-HQ-OPP-2022-0908-0055)

Comments: AFBF and NAICC commented with their general support for the pollinator language.

EPA Response: EPA thanks the commenters for taking time to review the pollinator advisory language and to provide comments. EPA has considered all the comments and updated the pollinator label language, especially the BMPs, to address these comments.

Comments from Minnesota Department of Agriculture (MDA) (EPA-HQ-OPP-2022-0908-0103), North Dakota Grain Growers Association (NDGGA) (EPA-HQ-OPP-2022-0908-0034), Vermont Agency of Agriculture, Food and Markets, Division of Public Health and Agricultural Resource Management (VAA, EPA-HQ-OPP-2022-0908-0094), National Cotton Council (NCC) (EPA-HQ-OPP-2022-0908-0091), American Mosquito Control Association (AMCA) (EPA-HQ-OPP-2022-0908-0093), Minnesota Corn Growers Association (MCGA) (EPA-HQ-OPP-2022-0908-0045), National Corn Growers Association (NCGA) (EPA-HQ-OPP-2022-0908-0107), Bayer Crop Science (EPA-HQ-OPP-2022-0908-0086),
Pollinator Stewardship Council (EPA-HQ-OPP-2022-0908-0046), Pollinator Stewardship Council (EPA-HQ-OPP-2022-0908-0046), Agribusiness Association of Iowa (AAI) (EPA-HQ-OPP-2022-0908-0102)

Comments: Commenters provided feedback on a variety of topics including pollinator language for all labels, pollinator boxes on labels, pollinator stewardship, pollinator risk assessments, communication with growers, and pollinator Endangered Species Act (ESA) language as well as general support and concerns for the pollinator advisory language. This included comments from MDA on the need for additional pollinator protection language on labels, NDGGA on the potential for regulatory overreach by the Agency when enacting endangered species protections, VAA, on the appropriateness of proposed pollinator protection language, NCC on the limitations of current risk assessments, and AMCA on the pollinator hazard statement. MCGA and NCGA also commented on the need for communication with growers. Bayer commented on pollinator stewardship and educational outreach. The Pollinator Stewardship Council noted their concern about the length of time between registration review periods and protections for systemic insecticides. AAI commented on the relationships between tenant farmers and landowners and how it may impact conservation practices.

EPA Response: EPA thanks all the commenters for taking time to review the pollinator advisory language and to provide comments. The Agency reviewed the comments and determined that comments could not be addressed with current efforts to develop advisory best management practices for labels as the current measures are advisory in nature and these comments suggested changes that would require mandatory label language.

Incident Reporting Label Language

Comment*:* The Agency solicited comments on the proposed label language for ecological incident reporting as well as any challenges with reporting incidents. The Agency received 13 substantive comments regarding the ecological incident reporting language from federal and state partners, conservation groups, and registrants. Commenters expressed concern regarding the definition of ecological incidents, the deletion of the registrant phone number, the organization of the Agency incident reporting website, and the overall quality of incident reporting.

EPA Response*:* The Agency appreciates the feedback from stakeholders on the Interim Ecological Mitigation and acknowledges the importance of high quality and thorough ecological incident reporting. EPA is adapting the scope of ecological incidents to be more inclusive of all incidents, including plants, animals, and other non-target insects, instead of solely stating "bee kills." The registrant phone number will be added back to the reporting statement on product labels for increased flexibility in reporting incidents. Additionally, the Agency acknowledges the need for a more user-friendly website platform for reporting incidents and is revising EPA's Pesticide Incident Reporting website, which will likely result in more thorough ecological incident reporting.

Bulletins Live! Two Label Language

Comments Summary: EPA sought specific stakeholder feedback on proposed revisions to the BLT reference language for pesticide product labels (e.g., the clarity of the language and whether the 6-month timeframe to access Bulletins was adequate for planning purposes). The Agency received approximately 70 comments from federal and state partners, grower and mosquito control groups, certified crop advisors, conservation organizations, universities, and registrants. In response to the question about the overall clarity of the BLT reference language, commenters suggested improvements to both the label language and the functionality of the BLT online system. In response to the timeframe to access Bulletins, five of the 36 stakeholders who commented on this matter indicated that 6 months was adequate time for planning pesticide applications. However, most stakeholders requested more lead time (9 – 12 months) to access BLT given the complexity of pest management and the time to establish structural mitigation measures (e.g., vegetative filter strips). Commenters also identified a variety of other issues, including smartphone/tablet accessibility, use of a QR code, accessibility for those without internet, and the need for more education and outreach to familiarize pesticide applicators with the BLT system.

Response: EPA has updated the BLT reference language in response to feedback from stakeholders on the ESA Workplan Update and other actions containing this language. Specifically, in response to stakeholder feedback on the clarity of the BLT reference language, EPA has made the following changes to the language: (1) updated the name of the BLT link and redirected it to send users directly to the BLT website (https://www.epa.gov/pesticides/bulletins); (2) included the name of the BLT website in the reference language; (3) reordered the language to start with the important instructions to go to

the BLT website before using a pesticide; and (4) simplified the language. While EPA considered the additional information that users provided about the time to plan pesticide applications, the Agency did not alter the timeframe to access Bulletins for at least the following reasons: (1) more time to access Bulletins will not address the larger issue of the time needed to implement structural mitigation measures that are not already in place (e.g., a vegetative filter strip can take two years to establish), and (2) timeframe concerns appeared to be grounded in misconceptions about the BLT system (e.g., concerns that Bulletins are frequently updated and may take users by surprise).

EPA also recognizes the need for education and outreach on Bulletins and the BLT system and is planning to provide additional educational opportunities (e.g., webinars) and training resources. The Agency will also continue to communicate and work with stakeholders to address any concerns about the wider use of Bulletins and the BLT system. EPA also appreciated stakeholder suggestions to improve the functionality and accessibility of the BLT system and will take those ideas into consideration in future updates to the BLT reference language and website.

II. USE AND USAGE

A. Conventional Use and Usage

Conventional Uses

Chlorothalonil is registered for many food and non-food uses. Chlorothalonil is registered as a fungicide for use on the following food uses: almonds, apricots, asparagus, bananas, beans (succulent/snap), beans (dry, except soybean; Crop Subgroup 6C), blueberries, brassica head and stem vegetables (Crop Subgroup 5A), carrots, celery, cherries (sweet and tart), corn (sweet and grown for seed), cranberries, cucurbit vegetables (Crop Group 9), filberts (hazelnuts), fruiting vegetables (Crop Group 8), garlic, ginseng, horseradish, leeks, lentils, lupine, mangos, mint, mushrooms, nectarines, okra, onions (dry bulb, green, and grown for seed), papayas, parsnips, passion fruit, peaches, peanuts, persimmons, pistachios, plums (prunes), potatoes, rhubarb, shallots, soybeans, spinach grown for seed (OR only)[42], strawberry (non-bearing nursery grown), sugar beets grown for seed (OR only), Swiss chard grown for seed (OR only), tomatoes, and yams.

Chlorothalonil products for agricultural food use can be applied as a broadcast, banded, or directed foliar application with ground equipment, aerial equipment, hand-held spray bottle, or by chemigation. Applications as a spray drench are allowed on mushrooms and as a dip treatment on non-bearing nursery strawberries. Products are formulated as emulsifiable, flowable, and soluble concentrates, water dispersible granules, and ready-to-use liquids. Products are available with chlorothalonil as the single active ingredient as well as co-

[42] Site only found on Section 24c registrations for Oregon.

formulated with other fungicide active ingredients including cymoxanil, oxathiapiprolin, fludioxonil, metalaxyl-m, propiconazole, sulfur, and tebuconazole.

Conventional non-food uses of chlorothalonil are field and greenhouse grown ornamentals, landscape ornamentals (including deciduous and conifer trees, including Christmas trees), grasses grown for seed, interior plantscapes, and non-residential grass and turf (including sod farms, industrial turf, professional and collegiate athletic fields, and golf courses). Chlorothalonil end-use products for turfgrass and ornamental use are formulated as granules, water dispersible granules, emulsifiable concentrates, liquid flowable concentrates, soluble concentrates, 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, including fludioxonil, iprodione, fluoxastrobin, and propiconazole.

Most conventional use sites may be treated with multiple applications of chlorothalonil per year and are restricted by a maximum application rate per year, crop cycle, or growing season (for more details on current labeled rates, see the docketed memos listed below).

Conventional Usage

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.[43,44] Peanuts and potatoes were the highest usage agricultural sites; these two sites combined comprised about 65% of lbs a.i. applied and 75% of TAT across all agricultural sites during this period. These two crops were also among those sites with the highest reported annual average percent crop treated (PCT) from 2016 to 2020: cucumbers (77 PCT), peanuts (66 PCT), celery (65 PCT), watermelons (62 PCT), and potatoes (60 PCT).[45] Survey data also indicates appreciable usage on many other surveyed crops from 2016 to 2020.

Additionally, chlorothalonil was reported in a recent survey of pesticide usage in turf and ornamentals. Though it is difficult to compare market share across active ingredients based on pounds of active ingredient applied, given different application rates, registered uses, and use restrictions, 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.[46] Usage of chlorothalonil was particularly high in golf course turf, with about 5.8 million lbs a.i. applied, and over $47 million in product sales in 2021 for disease management in this market segment.[43] Chlorothalonil pounds applied represent nearly 75% of the total market

[43] Kynetec USA, Inc. 2021a "The AgroTrak® Study from Kynetec USA, Inc." iMap Software. Database Subset: 2016-2020. [Accessed March 2022].
[44] 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]
[45] Kynetec USA, Inc. 2021b. "The AgroTrak® Study from Kynetec USA, Inc." Microsoft Access Database. Database Subset: 2016-2020. [Accessed March 2022].
[46] Nonagricultural Market Research Data (NMRD). 2022. Study of turf and ornamental usage in 2021. [Accessed February, 2023].

for fungicides applied to golf courses, and chlorothalonil is the top active ingredient in sales, comprising nearly 29% of the market at the time.[46] Additionally, surveys of consumer pesticide usage report that chlorothalonil was among the two most frequently applied fungicides in the consumer market, second to neem oil.[44] Because chlorothalonil use is prohibited on residential turfgrass, this usage is most likely associated with applications to residential ornamental plants. In 2016, with approximately 1.1 million pounds applied, and in 2019 with approximately 1.5 million pounds applied, chlorothalonil accounted for about 30% of fungicide pounds applied in the consumer market during these years.**Error! Bookmark not defined.**,**Error! Bookmark not defined.**

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 on www.regulations.gov):

- *Chlorothalonil (PC Code 081901) Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Turfgrass and Ornamentals* (September 14, 2023)
- *Chlorothalonil (PC Code 081901) Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites* (September 29, 2023)
- *BEAD Crop-by-Crop Response to Public Comment on the Chlorothalonil Proposed Registration Review Interim Decision (PID)* (September 19, 2024)

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., development of a superficial white film) of the paint on exposure to light for long periods.[47] 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.[47]

[47] Kline and Company. 2017b. Specialty Biocides 2016: United States Market Analysis. [Accessed September 2021].

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 the PID, EPA released the 2023 Revised Dietary Assessment. The 2023 Revised Dietary Assessment updated the dietary risk conclusions of the 2021 HH DRA. Following release of the 2021 HH DRA, EPA finalized updates to its exposure modeling[48, 49] and identified a new acute dietary (females 13-49 years of age) toxicity endpoint for a chlorothalonil metabolite (SDS-3701). 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,[50] 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.[51]

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 a FIFRA Science Advisory Panel (SAP),[52] 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

[48] 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
[49] *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
[50] https://www.nap.edu/catalog/11970/toxicity-testing-in-the-21st-century-a-vision-and-a
[51] https://www.nationalacademies.org/our-work/incorporating-21st-century-science-into-risk-based-evaluations
[52] 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

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).

No dermal endpoint was selected because there were no systemic effects observed in the subchronic dermal toxicity studies in rats and rabbits for chlorothalonil. Because there was no POD selected, no dermal routes of exposure could be assessed for chlorothalonil. Therefore, the human health risk assessment for chlorothalonil is based on risks established through dietary and inhalation routes of exposure.

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 drinking water 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 identified potential acute dietary risks of concern for the female aged 13-49 subpopulation. Additionally, EPA updated its chronic dietary analyses using the updated DEEM 4.02.

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).

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 (10X for interspecies extrapolation, 10X for intraspecies variability, and a 1X Food Quality and Protection Act (FQPA) safety factor) yielded an acute reference dose (aRfD) of 1.0 mg/kg/day. The respective 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.[53, 54] This resulted in lower estimates of drinking water contamination and lower overall dietary exposure for chlorothalonil. EPA also updated its DEEM to account for dietary exposure to infants who consume drinking water when mixed with baby formula.[55,56] The model update led to an increase in the dietary exposure estimates for the

[53] *Analysis of Subsurface Metabolism in Groundwater Modeling* (EPA-HQ-OPP-2021-0241)
[54] https://www.epa.gov/pesticides/epa-releases-final-analysis-model-used-estimate-pesticide-concentrations-groundwater
[55] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/deem-fcidcalendex-software-installer
[56] *Chlorothalonil. Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Registration review Risk Assessment.* (Sept. 27, 2023)

infants <1-year-old subpopulation. The increase in dietary exposure from updated dietary exposure modeling was counteracted by the decrease in dietary exposure estimates that resulted from the changes to aerobic soil metabolism modeling.

The 2023 Revised Dietary Assessment described the changes to the Agency's modeling and dietary risk conclusions for chlorothalonil. The acute exposure assessment also assumed 100 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 still 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 (10X for interspecies extrapolation, 10X for intraspecies variability, and a 1X FQPA safety factor), 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).

After revision, EPA's 2023 SDS-3701 exposure estimate for the female 13–49-year-old subpopulation was 130% of the aPAD assuming tolerance level residues and 100 PCT. 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 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. The 2023 risk estimates were lower than those in the 2021 assessment, reflecting the updates to EPA's exposure modeling discussed above, but nevertheless of concern. 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) group, 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 (10X for interspecies extrapolation, 10X for intraspecies variability, and a 1X FQPA safety factor) 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 presumed 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 potential 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 EDWC used for the acute dietary risk assessment was 1556 µg/L and the EDWC used for the chronic dietary assessment was 1370 µg/L.

EPA did not quantitively 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[57] 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 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 any exposure that may occur from antimicrobial uses. Therefore, neither dietary nor drinking water assessments are required for the antimicrobial uses of chlorothalonil.[58]

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 margins of exposure (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

[57] https://archive.epa.gov/scipoly/sap/meetings/web/html/finaljul.html
[58] *Chlorothalonil: Revised Human Health Draft Risk Assessment for Registration Review* (Apr. 9, 2021)

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.

c) Residential Post-Application Risks

Conventional Uses:
No dermal endpoint was selected because there were no systemic effects observed in the subchronic dermal toxicity studies in rats and rabbits. Therefore, 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 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.

d) Bystander Risks

Conventional Uses:
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. EPA did not identify any potential bystander risks of concern from registered uses of chlorothalonil.

EPA 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 quantitatively 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 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 (food, drinking water, and residential exposure) 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, and the route-specific inhalation study is not relevant for aggregation with dietary exposures due to the different toxicological effects observed. 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).

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 ID 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.

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-IV) 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. 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 ID.

Antimicrobial Uses

A quantitative occupational post-application assessment was not conducted for dermal exposures as a dermal point of departure (POD) was not selected for chlorothalonil. Overall, although chlorothalonil appears to be a sensitizer based on several of the evaluated studies, it is challenging to properly characterize its potency and quantify the dermal sensitization effect for human health risk assessment. AD is not quantifying the dermal route of exposure at this time and will continue to evaluate these studies in more detail and will determine if additional information is needed to sufficiently evaluate the dermal route of exposure.

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.

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.[59] 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.

B. Ecological Risks

EPA 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).

[59] 21 U.S.C. §§ 342, 346(a).

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 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 RQs 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.

b) Terrestrial Risks

<u>Mammals</u>

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 most 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, small 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 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, instead the Agency 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.

EPA 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 the 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 (surrogates for 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 birds 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.

EPA has concluded that acute and chronic risks 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. Based on the available guideline acute contact study with adult honey bees, chlorothalonil is classified as "practically non-toxic" to honey bees on an acute contact exposure basis. The EECs for chlorothalonil are well below the highest test concentration used in the adult acute contact study, and there was no mortality or sublethal effects observed, which suggests risk is low on an adult contact exposure basis. EPA lacks guideline or non-guideline studies assessing acute or chronic oral toxicity for adult or larval honey bees. In addition to the guideline adult acute contact study with chlorothalonil technical grade active ingredient (TGAI), EPA reviewed additional open-literature and guideline pollinator studies: two open literature non-guideline studies with larval honey bees,[60,61] a guideline study with formulated pesticide end use product, an open literature study performed on bumble bees at the colony level, [62] and an open literature study describing pesticide residues (including chlorothalonil) in wax, pollen, bee and associated hive samples.[63] Based on the non-guideline data with honey bee larvae[60,61] and the non-guideline bumble bee study conducted at the colony level,[62] the Agency identified that chlorothalonil uses may present risks of concern to honey bees and that calling in additional pollinator data is necessary (see Section III.B.3 for more details). The available evidence does not indicate that bees are being exposed at toxic levels from the single contact exposure pathway, but the non-guideline studies do suggest

[60] Dai, P., Jack, CJ., Mortensen, AN, Bloomquist, JR., J. Ellis, JD., (2018). The impacts of chlorothalonil and diflubenzuron on Apis mellifera L. larvae reared in vitro. Ecotoxicology and Environmental Safety 164 (2018) 283–288.

[61] Zhu W, Schmehl DR, Mullin CA, Frazier JL (2014) Four Common Pesticides, Their Mixtures and a Formulation Solvent in the Hive Environment Have High Oral Toxicity to Honey Bee Larvae. PLoS ONE 9(1): e77547.

[62] McArt SH, Urbanowicz C, McCoshum S, Irwin RE, Adler LS. 2017 Landscape predictors of Pathogen prevalence and range contractions in US bumblebees. Proc. R. Soc. B 284: 20172181. http://dx.doi.org/10.1098/rspb.2017.218

[63] Mullin CA, Frazier M, Frazier JL, Ashcraft S, Simonds R, vanEngelsdorp D, et al. (2010) High Levels of Miticides and Agrochemicals in North American Apiaries: Implications for Honey Bee Health. PLoS ONE 5(3). E9754.

there could be toxic effects through oral exposure pathways. Open literature studies/data assessing chronic exposure to adult bees were not available at the time of review.

One of the two open literature studies EPA reviewed with larval honey bees generally followed the guideline protocols for larval oral acute and chronic toxicity tests. While this study does not satisfy EPA guideline study requirements, the methodology was similar to guideline protocols. This study 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 but was not conducted in a methodology similar to guideline protocols.

The guideline honey bee study conducted with a formulated pesticide product (that includes chlorothalonil and other active ingredients) established an oral LC_{50} and contact LD_{50} for honeybees. Because this study was conducted with a formulated pesticide product containing multiple active ingredients, it is unclear if the effects observed are a result of chlorothalonil toxicity or from one of the other active ingredients. For this reason, the Agency does not typically use studies with multiple active ingredients for risk assessment. However, because toxicity data for chlorothalonil is sparse and the adult acute contact study with chlorothalonil TGAI had no effects, EPA calculated the LC_{50} and LD_{50} for chlorothalonil based on the results of this study as an additional line of evidence. For chlorothalonil, this study demonstrated a 48-hr acute oral LC_{50} greater than 28.08 µg chlorothalonil/bee and a 48-hr acute contact LD_{50} greater than 22.8 µg chlorothalonil/bee (LC_{50} and LD_{50} are the concentration or dose, respectively, that are lethal to 50% of the test subjects).

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. An open literature study describing pesticide residues in bees and hive matrices was used for overall risk characterization and demonstrated that chlorothalonil is found frequently in pollen and wax samples taken from hives in the field.[63] The data collected in this study are the result of several surveys where residues of 200 pesticide ingredients were quantified in hive matrixes. The study was not specifically designed for measuring single pesticide applications and the resulting pollen and nectar residues, but does demonstrate that chlorothalonil residues are detected in hive matrices.

Finally, EPA reviewed several submitted non-guideline non-target studies with other terrestrial invertebrates, including earthworms, wasps, and beneficial insects. These data suggest that other terrestrial invertebrates are sensitive to chlorothalonil toxicity, but effects were observed at concentrations higher than the EECs expected from maximum label application rates.

Because the only guideline honey bee study available (acute contact) resulted in a non-definitive endpoint (*i.e.,* a greater than LC_{50} of >181 µg a.i./bee), EPA could not calculate RQs to quantify honey bee and terrestrial invertebrate risks. RQs are not calculated for non-definitive endpoints, however, when comparing the exposure from a sampling of the crops that are attractive to honeybees, the estimated EECs are well below the highest test concentration with no mortality or sublethal effects, thus, risk is low on an adult contact exposure basis. However, guideline data are not available for the remaining Tier 1 studies (*i.e.,* adult acute oral, adult chronic, acute and chronic toxicity to larval honey bees).

EPA's review of the available open literature data, however, provides additional evidence to inform on the potential for chlorothalonil to effect larval stage honey bees. While used qualitatively, the EECs are more than 200 times the NOAEL, suggesting that risks of concern may result. Therefore, these comparisons strongly support the need for the remaining guideline honeybee toxicity data for chlorothalonil in order to fully quantify the risk to bees.

As stated previously because of the potential risks identified in the open literature studies with larval honey bees, the Agency identified that chlorothalonil uses may present risks of concern to honey bees and that calling in additional pollinator data is necessary (see Section III.B.3 for more details).

In conclusion, the available data do not preclude the possibility of risk to honey bees and terrestrial invertebrates. Therefore, registered conventional uses of chlorothalonil may present risks of concern to honey bees. Chlorothalonil is registered for foliar use on numerous bee attractive crops and applications may occur during bloom. More data are necessary to fully quantify the potential risks of concern for these taxa from registered conventional uses of chlorothalonil. EPA has initiated the process to call in data necessary to fully assess risks to these taxa. Pollinator studies that the Agency intends to call in are described in Section III.B.3.

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 low.

c) 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 aquatic-phase 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 surface water monitoring data and values up to 56 µg a.i./L from a golf course. Overall, the surface water 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

Currently registered chlorothalonil products' labeling 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.

EPA 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 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.

EPA 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).

EPA has concluded that 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 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 low, while potential risks of concern are likely to occur for non- vascular plants.

d) 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. Most bee incidents included one or more insecticides in addition to chlorothalonil, so it is difficult to determine causation with the information available. 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), a herbicide, and chlorothalonil (Bravo Ultrex) that accidentally drifted to the residential area where the chickens were exposed..

There is a 2021 reported incident that is currently in review. The incident reports fish mortality in Chartiers Creek near a golf course in Pennsylvania. While causation is still being investigated, the incident is consistent with the risk assessment findings for chlorothalonil. 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 database for chlorothalonil is not complete. The environmental fate database is considered complete.

Given the uncertainties surrounding potential risks to terrestrial invertebrates for conventional uses of chlorothalonil, EPA identified that additional data are necessary to fully evaluate risks to

non-target terrestrial invertebrates, especially invertebrate 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*[64]. This 2014 guidance lists pollinator studies that were not included in the chlorothalonil registration review DCI. EPA identified that additional pollinator exposure and effects data are necessary for chlorothalonil, and has initiated the DCI process to obtain these data. The pollinator studies that EPA intends to require are listed in Table 2 below.

Table 2: Pollinator Data EPA Intends to Call In

OCSPP Guideline #	Study
Tier 1	
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.

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.

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

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.

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.[65] 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.

[65] Thiram and ziram would also be considered potential multisite fungicide alternatives. As of the publication of this ID, products containing these active ingredients are still registered. However, in April 2024, the Agency released an amended PIDs for both fungicides proposing cancellation of all conventional use sites, including turf and ornamentals.

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.[66] Though information from the U.S. Department of Agriculture (USDA) suggests that chlorothalonil is not a key active ingredient in the anti-sapstain 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.[67,68]

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.[69] Anti-sapstain treatments such as chlorothalonil are applied to debarked logs or rough sawn lumber at the wood mill.[70] 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.[71] 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

[66] EPA. 2017. *Overview of wood preservative chemicals*. Available online: https://www.epa.gov/ingredients-used-pesticide-products/overview-wood-preservative-chemicals
[67] "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)
[68] Ibid
[69] Wolman Wood and Fire Protection. *Sapstain/Blue Stain Fungi*. https://www.wolman.de/en/infocenter-wood/about-wood-pests/sapstain
[70] Sidhu, Avtar. *Antisapstain Industry in North America*. 2011. Wood Preservation Canada (CWPA) Annual Meeting. Available online: https://woodpreservation.ca/wp-content/uploads/2021/09/sidhu32.pdf
[71] Kline and Company. 2017b. Specialty Biocides 2016: United States Market Analysis. Accessed September 2021

control. Data specific to chlorothalonil was unavailable, suggesting that chlorothalonil products make up a small portion of the mold control market.[72]

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.[73]

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.[74]

Chlorothalonil is an efficacious and widely used fungicide in paints 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 degrees Celsius and stability in neutral, as well as acidic conditions, however chlorothalonil may be prone to hydrolysis in the pH range above 9.[75]

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.[76]

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

[72] Ibid
[73] "Extending the Life of Dry-Film Coatings by Selecting the Right Preservative Systems." McGough, 2019. (https://www.coatingsworld.com)
[74] Ibid
[75] Ibid
[76] Kline and Company. 2017b. Specialty Biocides 2016: United States Market Analysis. Accessed September 2021

and is subsequently dried and rolled before shipment.[77] 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.[78]

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.[79]

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, [72] suggesting that it is used minimally in that use site.

IV. INTERIM REGISTRATION REVIEW DECISION

EPA is issuing this ID in accordance with 40 C.F.R. §§ 155.56 and 155.58. Based on the Agency's review of chlorothalonil in the registration review process, EPA has identified certain changes to the affected registrations and their labeling that are needed and will be implemented through label amendments and/or registration changes. EPA identified that the mitigations identified in Sections IV.A–B and Appendices A and B are necessary to address specific risks of concern identified at this point in the ongoing registration review process.

[77] "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)
[78] Ibid
[79] Adhesives and Sealants Industry (ASI): Biocides. 2004. The necessary evil of protecting and preserving adhesives and sealants. https://www.adhesivesmag.com/articles/85555-biocides

During the registration review process, EPA will decide whether each chlorothalonil pesticide registration "continues to satisfy the FIFRA standard for registration."[80] However, the mitigation specified in this ID may not be sufficient for EPA to determine that chlorothalonil registrations continue to satisfy the FIFRA standard for registration. EPA may determine that additional mitigations or other measures are necessary in subsequent interim determinations or its final registration review decision.

Even though EPA has not made section 7(a)(2) ESA effects determinations for chlorothalonil registrations, the Agency has identified mitigation in this ID that are necessary to reduce environmental exposure to chlorothalonil. These mitigations are expected to also reduce exposure to nontarget organisms including listed species whose range or critical habitat could co-occur with the use of chlorothalonil. EPA has identified FIFRA IEM measures in Section IV.B of this ID that are necessary to reduce adverse effects to nontarget organisms, including listed species. EPA believes that the FIFRA IEM measures discussed in Section IV.B fulfill EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022) for the conventional uses of chlorothalonil. EPA also believes that the ecological risk mitigation measures described in Section IV.E fulfill EPA's obligations under Section 711 for the antimicrobial uses of chlorothalonil.

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)]." Section 711 also requires EPA to "take into account the input" of the Secretary of Agriculture and other members of the Interagency Working Group (IWG), established under FIFRA Section 3(c)(11), in developing such measures. EPA has considered input from USDA and other members of the IWG in developing various mitigation measures consistent with Section 711, including FIFRA IEM measures and the ecological risk mitigation measures described in this ID. EPA has previously requested public input on the FIFRA IEM measures and ecological risk mitigation measures described in this ID. EPA will complete 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 Appendix D.

A. Risk Mitigation and Rationale

[80] 40 C.F.R. §§ 155.40(a), 155.57; 7 U.S.C. § 136a(g); *see also* 7 U.S.C. §§ 136a(c)(5) (FIFRA registration standard), 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). This document is not a "registration review decision" within the meaning of FIFRA Section 3(g) and 40 C.F.R. § 155.57.

For conventional uses of chlorothalonil, EPA identified human health risks of concern from dietary (food + drinking water) exposure. Drinking water exposure via groundwater was the major contributor to dietary exposure. Considering the available information on toxicity and exposure, EPA found human health dietary risks exceeding the Agency's levels of concern. Based on currently available information, EPA cannot conclude that dietary residues of chlorothalonil are safe without changes to the registrations to include the vulnerable soil maximum annual application rates 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. EPA found it necessary to mitigate the ecological risks with the mitigation measures described below.

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 found it necessary to mitigate these risks as described below.

EPA also evaluated the benefits of chlorothalonil's conventional and antimicrobial uses. The Agency found that chlorothalonil provides high benefits to users and has a unique mode of action (the only M05 fungicide) with efficacy against a broad range of economically important diseases. In addition, utilizing chlorothalonil in a season long disease control program helps growers prevent or delay resistance to highly effective single site fungicides. By delaying resistance and maintaining effectiveness of these highly effective/ specialized single site fungicides, growers ensure that these the single site fungicides maintain effectiveness when pest pressures are high and/or few single site alternatives are available to include in a season-long disease control program. More information on the benefits of chlorothalonil is available in Section III.C. of this document.

Considering the risks and the benefits of the use of chlorothalonil, EPA identified that annual application rate reductions, buffers to all aquatic areas (with the option for use of a vegetative filter strip for ground applications to turf), soil saturation statements, updated environmental hazard and advisory statements, updates to PPE language, and FIFRA IEM, are necessary to reduce exposure to humans and nontarget species based on the use patterns of chlorothalonil. The Agency expects that these measures will also reduce exposure and risk to listed species. See Section IV.B for details. EPA is also implementing the 2011 NMFS Salmonid BiOP with this ID.

In the PID, the Agency proposed the following mitigation measures:

- reductions to maximum annual application rates with further reductions in areas with soils vulnerable to groundwater leaching
- buffers to all aquatic areas
- FIFRA IEM measures to reduce exposure to nontarget species, including listed species, based on the use patterns of chlorothalonil including:
    - spray drift mitigation,
    - wind-directional drift buffers to conservation areas,
    - incident reporting label language,
    - Bulletins Live Two (BLT) reference label language,
    - and pollinator advisory label language,
- implementation of the 2011 NMFS Salmonid BiOp for chlorothalonil with the general pesticide product labeling that is applicable nationwide and other restrictions on a geographically specific basis in Endangered Species Protection Bulletins (Bulletins) that are accessed and made enforceable through the BLT website,[81]
- general labeling requirements for all chlorothalonil products and uses,
- the requirement of PF10 respirators for occupational handlers for the antimicrobial uses of chlorothalonil,
- limitation of the use of chlorothalonil to the dry-end of the papermaking process.

Since the PID, based on consideration of the public comments received and consultation with stakeholder groups, EPA identified minor changes to mitigation measures including: (1) increased maximum annual application rates for some crops, (2) instructions for identifying the types of cranberry bogs and putting greens where the maximum annual application rate for vulnerable soils does not apply and the maximum annual application rate for non-vulnerable soil may be used because groundwater leaching is not expected, (3) supplemental instructions for determining soil texture and organic matter content to help growers and applicators identify vulnerable soils, and (4) the option for turf users to implement a vegetative filter strip instead of the ground buffer to aquatic areas. Additionally, after coordination with the Occupational Safety and Health Administration (OSHA), EPA made a change to the identified respirator language for antimicrobial chlorothalonil products. EPA is now directing registrants to cite the OSHA Standard regarding respirator fit testing on product labels rather than to quote the Standard directly on the labels.

1. Conventional Mitigations and Label Updates

a) Mitigation: Reductions to Maximum Annual Application Rates

EPA identified dietary risks of concern and ecological risks of concern for chlorothalonil and identified necessary rate reductions to reduce the amount of chlorothalonil entering drinking water, thus reducing dietary exposure and risk in vulnerable soils. “Vulnerable soils” are sand, loamy sand, or sandy loam soil (as defined by USDA’s soil classification system without a restrictive layer that impedes the movement of water through soil) with less than 2% organic

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

matter content and occur where the water table is 30 feet or less from the surface. Soils that do not meet all three of these criteria are considered "non-vulnerable." The annual application rate reductions partially mitigate the ecological risks identified. For some uses, a maximum annual application rate for vulnerable soils was not identified because the maximum annual application rate necessary to address dietary exposure and risk in vulnerable soils is equivalent to the maximum annual application rate necessary to address ecological risks. When this is the case, only one maximum annual application rate is identified for a use and that rate applicable to all soil types. See Appendix B for use-specific label language.

Maximum Annual Application Rate Reductions for use on Non-Vulnerable Soils

To address ecological risks of concern, EPA has identified reductions to maximum annual application rates (in lbs a.i./acre/year) that are necessary. 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 annual rates were derived from crop usage data, which suggests that, while the necessary annual application rates are lower than the current labeled rates, the reduced maximum annual application rates are not likely to unduly impact users. Tables 3 and 4 list the annual rates by use site.

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

Use Sites- Ag	**Maximum annual application rate (lbs a.i./acre/year)**
Almond, Filbert (Hazelnut), Pistachio; Beans, Dried; Lentils; Lupine; Parsnip; Sugar beet (grown for seed)	6.0
Asparagus	7.5
Beans (Snap)	7.2
Blueberry	6.5
Brassica/Cole vegetables (e.g., Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	3.75
Cabbage	7.5
Carrot	7.5
Celery	7.5
Corn, Field (grown for seed); Mint	3.0
Corn, Sweet	7.5
Cranberry	10.0
Cucurbits	9.0
Fruiting Vegetables[1] (except Tomato)	6.75
Fruiting Vegetables[1] (except Tomato) in Florida, Georgia, North Carolina, and South Carolina	7.9
Ginseng	12.0

Use Sites- Ag	Maximum annual application rate (lbs a.i./acre/year)
Grass Grown for Seed*	4.5
Grass (Forage, Hay, Seed); Soybean; Strawberry (nursery seedlings for pre-transplant; non-food)	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;* Peanut	6.75
Passion Fruit*	7.5
Peach; Nectarine	12.4
Persimmon	4.7
Potato; Yam	8.0
Rhubarb*	13.5
Apricot; Plum; Prune; Mango; Cherry west of the Rocky Mountains; Tomato in all states except Florida, Georgia, North Carolina, South Carolina	6.5
Cherries* east of the Rocky Mountains	15.4
Tomato in Florida, Georgia, North Carolina, and South Carolina	10.5
Turf – Sod Farms	12.6
Mushrooms (Indoor)*	8.25**

[1]The fruiting vegetables use site does not include cucurbits. Fruiting vegetables include: eggplant, groundcherry, okra, pepino pepper, bell pepper, chili pepper, cooking pepper, pimento, sweet pepper, and tomatillo
*no application rate change
**application rate in fl oz/1000 sq ft of bed; rate based on cropping cycles not annual applications

Any agricultural food use site not listed in Table 3 does not have a maximum annual application rate change.

Exposure to non-target organisms is unlikely to occur from applications of chlorothalonil to mushrooms grown indoors; therefore, EPA has not identified any changes to the indoor mushroom maximum application rates.

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

Use Sites Non-Ag	**Maximum annual application rate (lbs a.i. /acre/year)**
Conifers* (i.e., nursery beds, seed orchards, and landscape ornamentals; Christmas tree plantations)	16.5
Ornamentals – Field Grown	18.75
Ornamentals – Root/Bulb Dip (spent dip fluid applied to field)	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 application rate change

For ornamentals grown in containers or indoors (greenhouse), the potential for chlorothalonil to enter groundwater sources is greatly reduced and the potential exposure to nontarget organisms is unlikely; therefore, for ornamentals grown in containers or indoors, EPA has not identified any changes to current maximum annual application rates.

For each outdoor use site, EPA has identified the following necessary label language:

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

Maximum Annual Application Rate Reductions for use on Vulnerable Soils

To address potential groundwater contamination and drinking water risks, EPA has identified that the maximum annual application rate restrictions listed in Table 5 are necessary for all outdoor uses of chlorothalonil in areas where soil is vulnerable. EPA has also identified necessary labeling language changes to describe the maximum annual application rate restrictions, as discussed below. Vulnerable soil is described as having all three of the following characteristics:

- The soil texture of the application area is comprised of over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil. If you need to determine soil texture, see USDA's Web Soil Survey, which may be found here: https://websoilsurvey.nrcs.usda.gov/app/; **and**

- less than 2% organic matter content; **and**

- the water table occurs at a depth of 30 feet or less from the surface.

If the soil does not meet any one of these three criteria, then the soil does not qualify as vulnerable soil and the vulnerable soil maximum annual application rate is not applicable. Vulnerable soil restrictions are based on groundwater modeling, and the scenarios used to simulate transport to the water table. To help prevent chlorothalonil and its degradates of concern from leaching into groundwater, EPA has identified the annual maximum application rates, listed by use site in Table 5, for soils that meet all three vulnerable soil criteria listed above.

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. If the soil is not classified as sandy or coarse-textured per USDA's soil classification system (https://websoilsurvey.nrcs.usda.gov/app/HomePage.htm), then the soil does not qualify as a vulnerable soil.

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 the soil has greater than 2% organic matter, then the soil does not qualify as a vulnerable soil for the purpose of the mitigation requirement.

If the water table occurs at a depth of 30 feet or more from the surface, then the soil does not qualify as a vulnerable soil for the purpose of the mitigation requirement. The range of depths to the water table in the 6 modeling scenarios used in the drinking water assessment is 10 to 30 feet below ground surface.

Peat-bottom cranberry beds and upland marsh cranberry beds have a confining layer that enables flooding and completely isolates the cranberry bed from groundwater. Therefore, the soil of these cranberry beds does not qualify as a vulnerable soil and the annual application rate listed in Table 3 may be used. However, some cranberry beds are not built on peat or upland marshes and can't hold a flood, and the vulnerable soil annual application rate is necessary for these cranberry beds. See Appendix B for specific label language.

Putting greens constructed to USGA or California green specifications or constructed as push up greens[82] do not have the same vulnerability to groundwater leaching as soils considered in the

[82] Term originating from the technique of using bulldozers or similar equipment to "push up" the native soil (rather than imported soil or other material) to form the contours of the putting green. Push up greens, unlike USGA and California greens, rely on surface drainage as the primary method for draining excess water from the green. Push up greens may be topped with 4 or more inches of sand to improve smoothness and water drainage.

Agency's model for vulnerable soils,[83] and therefore the non-vulnerable soil maximum annual application rate is more appropriate for these style greens. While less common, some putting greens are not constructed in any of the aforementioned formats. The maximum annual application rate for vulnerable soils is necessary for any putting green that is not a California Green, USGA Green, or push up green.

For some uses, the maximum annual application rate or the rate described in Tables 3 or 4 is less than 6.5 lbs a.i./acre/year. If a use site's maximum annual application rate is less than or equal to 6.5 lbs a.i./acre/year for non-vulnerable soils, then the vulnerable and non-vulnerable soil rates for that use are equivalent and the user does not need to determine the vulnerability of their soil. See Appendix B for use-specific label language. Table 5 lists the annual rates by use site for vulnerable soils.

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

Use Sites	**Annual application rate (lbs a.i. /acre/year)**
Corn, Field (grown for seed); Mint*	3.0
Brassica/Cole (Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	3.75
Grass (Forage, Hay, Seed); Grass Grown for Seed*; Soybean*; Strawberry (nursery seedlings for pre-transplant; non-food)	4.5
Persimmon	4.7
Almond, Filbert (Hazelnut), Pistachio; Beans, Dried*; Lentils; Lupine; Parsnip*; Sugar beet (grown for seed)	6.0
Turf (Sod, Industrial, Athletic Fields; Golf Courses)	6.2
All other use sites	6.5

*no application rate change

For products with each outdoor use site in Table 5 other than cranberries and turf use sites that aren't sod farms (*i.e.* industrial, athletic fields; golf courses), the following label language for vulnerable soils is needed:

> "Do not apply more than [XX] lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are soils that meet **all three** of the following criteria: **(1)** The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, **(2)** having less than 2% organic matter content, and **(3)** the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are **not** met, the soil is not considered vulnerable."

[83] Meeting Notes: Turf Grass Discussion with University of Wisconsin Extension Specialists (August 27, 2024) available on the public docket EPA-HQ-OPP-2011-0840 on www.regulations.gov

For products with use on cranberries, the following label for vulnerable soils is needed:

> "Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Peat bottom cranberry beds or upland marsh cranberry beds with a confining layer for flooding that completely isolates the cranberry bed from groundwater are not considered vulnerable soils and 10 lbs chlorothalonil active ingredient per acre per year may be applied. For other cranberry beds, vulnerable soils are soils that meet **all three** of the following criteria: **(1)** The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, **(2)** having less than 2% organic matter content, and **(3)** the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are **not** met, the soil is not considered vulnerable."

For products with turf use sites other than sod farms (*i.e.* industrial, athletic fields; golf courses), the following label language for vulnerable soils is needed:

> "Do not apply more than 6.2 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Turf putting greens constructed to USGA or California green specifications or constructed as push up greens are not considered vulnerable soils and 45.2 lbs chlorothalonil active ingredient per acre per year may be applied. For other turf, vulnerable soils are soils that meet **all three** of the following criteria: **(1)** The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, **(2)** having less than 2% organic matter content (thatch/mat included), and **(3)** the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are **not** met, the soil is not considered vulnerable."

To provide instructions for a user to determine whether they have vulnerable soil, additional labeling language about determining organic matter content and soil texture is needed:

> "Supplemental Recommendations for Determining Soil's Organic Matter Content:
> If you need to determine the organic matter content of your soil to confirm soil vulnerability, do so before applying chlorothalonil. To obtain a representative soil sample for soil testing, take a composite of several soil samples collected throughout the intended application area. Ideal soil sampling depth varies depending on use site. Consult local extension publications for additional information on recommended soil sampling procedures and soil testing methods. Annual, or more frequent, soil testing for organic matter provides more accurate soil characteristic identification.
>
> Supplemental Instructions for Determining Soil Texture:
> If you need to determine soil texture to confirm soil vulnerability, see USDA's Web Soil Survey tool which may be found here: https://websoilsurvey.nrcs.usda.gov/app/."

These annual application rate reductions fully mitigate the human health risks identified and partially mitigate the ecological risks identified. To further mitigate the ecological risks, EPA has identified additional necessary mitigation measures listed in the subsequent mitigation measure sections.

Restrictions and Advisory Statements for Residential Users with On-Site Drinking Wells
EPA has identified vulnerable soil application rate limits (Table 5) that are necessary for residential users who obtain their drinking water from an on-site well. Additionally, EPA has identified necessary advisory language warning applicators to not apply within 30 feet of wells. EPA has identified the following necessary 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."

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

An annual application rate reduction of chlorothalonil may affect growers who currently utilize multiple applications of chlorothalonil to control/prevent disease on their crop/site. A reduced maximum annual application rate means that growers may 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). 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.

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. EPA 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, EPA found that limiting the maximum allowed annual application rate on vulnerable soils to 6.5 lbs a.i./acre/year is most likely to affect cherry, potatoes, carrot, and ginseng growers in the upper Midwest, and tomatoes in the Southeast. This mitigation is also likely to affect growers producing multiple crop cycles per year. For example, for Florida tomatoes, the allowed annual application rate is being reduced from 15.0 lbs a.i./acre/season to 6.5 lbs a.i./acre/year for growers operating on vulnerable soils. With two crops of tomatoes grown in a year in Florida the 6.5 lbs a.i./acre/year translates to 3.25 lbs a.i./acre/crop cycle or 6.5 lbs a.i./acre for one crop cycle and no applications of chlorothalonil for the second crop cycle of the year.

For those growers operating on non-vulnerable soils and/or where the disease pressure is not high, the Agency expects that the reductions of annual application rates listed in Table 3 to have little to no impacts to growers of many crops. For more details, see *Chlorothalonil [PC Code 081901] Use, Usage, Pest Management Benefits, and Impacts of Potential Mitigation for Agricultural Use Sites* as well as the *BEAD Response to Public Comments on the Chlorothalonil Proposed Interim Decision (PID)* (September 19, 2024).

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 lbs a.i./acre up to eight times per year. Reducing annual maximum application rates to a rate below the current single application rate 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. 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 of 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. This may result in higher operational costs, decreased product quality, and/or the discontinuation of certain commodity 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, EPA-HQ-OPP-2011-0840.

Based on the mitigation, the dietary risks of concern would be resolved and would no longer be of concern. Without the mitigation for the vulnerable soils, EPA cannot conclude that residues of chlorothalonil in or on food are safe without changes to the registrations to include the vulnerable soil maximum annual application rates identified below. 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.

b) Mitigation: Buffers to All Aquatic Areas with Vegetative Filter Strip Option for Turf

EPA has identified a need to apply buffers to all aquatic areas. Buffers were previously only required for estuarine/marine habitats. Buffers are now needed for freshwater habitats. These

restrictions are expected to partially mitigate aquatic risks from spray drift and runoff. The following label language is necessary under Use Restrictions:

> "For aerial and airblast applications, this product must not be applied within 150 feet of water bodies (estuarine/marine and freshwater).
>
> For ground applications, this product must not be applied within 25 feet of water bodies (estuarine/marine and freshwater). If applying to turf, you may choose to construct and maintain a 10-foot vegetative filter strip of grass or other permanent vegetation between the field or application area edge and nearby aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds) in lieu of the 25-foot buffer.
>
> If using a vegetative filter strip, only apply this product onto fields or application areas where a maintained vegetative filter strip of at least 10 feet exists between the field or application area edge and down-gradient aquatic habitat."

EPA expects some chlorothalonil users to be impacted by this requirement. If the treated area is adjacent to freshwater habitats, affected users would have to use an alternate fungicide(s) or forego treatment within the established buffer area. Disease and resistance management costs may increase and or be compromised, leading to yield or quality losses. Smaller acreage fields are expected to be more impacted than large areas, as a larger share of the total productive area may be affected by a buffer.

EPA also expects impacts from the option of a vegetative filter strip for turf. Vegetative filter strips are strips of land in permanent vegetation designed to protect sensitive downslope areas from runoff from application areas. Vegetative filter strips slow water movement and increase water infiltration, reduce runoff, and remove sediment and pesticides from runoff. However, establishing and maintaining vegetative filter strips may be costly. USDA OPMP previously provided cost estimates for vegetated filter strips. Based on the USDA Natural Resource Conservation Service (NRCS) payment schedule for California, the cost of establishing a vegetated filter strip was estimated to be $165 to $927 per acre of strip and yearly maintenance costs were estimated to be $40 to $240 per acre of strip (for mowing or weed control applications).[84] Costs, including labor costs, would differ across states and regions and vary according to the size and shape of the application area.

c) Label Mitigation: Soil Saturation Statement

Runoff was identified as a potential exposure route of concern for aquatic risks of chlorothalonil. To reduce the potential for surface water runoff and protect non-target

[84] U.S. Department of Agriculture, Office of Pest Management Policy (USDA OPMP). 2018. Comments on the National Marine Fisheries Service Biological Opinion Issued under Endangered Species Act: Chlorpyrifos, Diazinon, and Malathion" (EPA-HQ-OPP-2018-0141). Docket ID EPA-HQ-OPP-2018-0141-0106 on www.regulations.gov

organisms, EPA has identified a need for 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)."

EPA 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. However, potato growers, who often have standing water on portions of their fields, may have more significant impacts if timely applications cannot be made to a crop infected with the pathogen that causes late blight. Users may have to resort to an alternative fungicide without such saturated soil restrictions.

d) 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 is updating these statements to provide clearer guidance to users on protecting surface water and aquatic organisms. Updated language is derived from EPA's Label Review Manual. Chlorothalonil has been detected in groundwater and may pose a dietary risk via drinking water from groundwater exposure from the labeled conventional uses without changes to the registrations to include the vulnerable soil maximum annual application rates identified in this ID. The following updates to the groundwater and surface water advisory language are needed to increase awareness among users and promote improved practices to protect water sources:

- *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 feet of drinking water wells will further reduce the risk of drinking water contamination."

e) Label Update: Chemical Extraction Probe Rinsing Statement

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 EPA 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 needed 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) Label Update: Glove Statement

EPA is updating the gloves statements on chlorothalonil labels, consistent with Chapter 10 of the Label Review Manual[85]. In particular, EPA is 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 clarification does not fundamentally change the PPE that workers must use.

g) Label Update: Respirator Statement

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

h) Label Update: PPE for Residential Uses

Any PPE statements on chlorothalonil labels registered for residential uses should be removed. EPA did not identify risks of concern for residential handlers in the human health DRA. Further, PPE is not considered a mitigation option for residential handlers.

[85] https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm_2-22-21.pdf

i) Label Update: Resistance Management

EPA is adding resistance-management language to chlorothalonil labels[86] to address pesticide resistance.[87] Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management,[88] EPA has identified pesticide resistance measures that are applicable for chlorothalonil. 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 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.[89] EPA does not expect this language to affect the risks or benefits of chlorothalonil.

2. FIFRA Interim Ecological Mitigation Measures for Conventional Uses

The ESA Workplan Update Appendix includes a menu of FIFRA IEM measures, some of which are included in this ID. EPA previously sought public comment on the full suite of FIFRA IEM measures, which is available in the ESA Workplan Docket.[90] EPA updated some of the FIFRA IEM measures after considering public comments on the ESA Workplan Update and additional EPA and interagency review of the mitigations. The FIFRA IEM measures described for chlorothalonil in this ID reflect these revisions.

EPA developed the FIFRA IEM measures to reduce exposure to nontarget organisms, including listed species, based on the risks and benefits of chlorothalonil.[91] EPA has identified the following FIFRA Interim Ecological Mitigation measures as necessary to mitigate risks of concern for chlorothalonil:

- Pollinator stewardship advisory label language

[86] For specific label language, see Appendix B.
[87] 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.
[88] 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.
[89] 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.
[90] https://www.regulations.gov/document/EPA-HQ-OPP-2022-0908-0002
[91] See the *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.

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

The FIFRA IEM measures in this ID are not designed to fully address EPA's 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 during registration review before issuing a final registration review decision. EPA may subsequently propose additional mitigation measures for chlorothalonil during registration review, such as mitigations developed as part of its various ESA initiatives.[92] Additional measures may also be necessary when EPA conducts effects determinations and, if necessary, consults with the Service(s) on chlorothalonil.

EPA has included updated spray drift language and wind-directional conservation area buffers in the FIFRA IEM section of this ID (buffers to aquatic areas are in the previous mitigation section). 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, including listed species. These updates include a labeling statement to measure wind speed and direction prior to application, as well as best management practices for measuring windspeed and direction.

1. Advisory Pollinator Stewardship Label Language

Chlorothalonil is registered for foliar use during bloom on numerous bee attractive crops. Risks to pollinators were not assessed. 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 including advisory language for insect pollinators. This advisory language distills the most important information growers need to know to voluntarily reduce exposure 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 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.[93]

The pollinator hazard statement is as follows:

> "This product may be toxic to bees and other pollinating non-target insects exposed to direct treatment on blooming crops or weeds."

[92] https://www.epa.gov/endangered-species/implementing-epas-workplan-protect-endangered-and-threatened-species-pesticides
[93] https://www.epa.gov/pollinator-protection/pollinator-protection-strategic-plan

EPA is adding the pollinator hazard statement above for products with labeled agricultural crop uses. The language is derived from language in EPA's Label Review Manual and appears on many labels already and should not have adverse impacts to the user.

Best management practices describe ways to manage pesticide applications to protect non-target organisms and mitigate environmental impacts. The Agency is adding the following labeling to highlight pollinator best management practices:

"Advisory Best Management Practices for Pollinator Protection

The following best management practices (BMPs) can help reduce risk to pollinators:

- Develop and maintain 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.
- 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."

2. 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. Consistent with the 2011 BiOp, EPA has identified incident reporting labeling as necessary to provide consistent information to pesticide users on how to report ecological incidents and to expedite any necessary ESA consultation. The 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)."

Including incident reporting language on the labeling is not expected to have large impacts on applicators of chlorothalonil.

3. 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 accessed through a website. EPA is using a web-based system, Bulletins Live! Two (BLT), to provide timely protections for listed species.

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 has identified the addition of the following Bulletins language to all chlorothalonil product labels as necessary. This language will be used to implement the 2011 NMFS BiOp and any Bulletins developed through future registration, registration review, or ESA actions. 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.

The 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. 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[94], which allows users to more easily find the information they need for a particular pesticide product. EPA has also developed a tutorial[95] 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. A recent USDA (2023) report on farm computer usage and ownership reported that 85% of farms have internet access and a similar proportion of farms own smart phones and/or computers.[96] However, fewer farms reported using the internet to conduct business. As mentioned earlier, growers not accustomed to accessing BLT as a part of their regular farm business, especially those not used to using online tools to conduct business could face a learning curve but with time and as users become acquainted with this system, this burden will diminish.

EPA is currently working on several ESA strategies to expedite and streamline the ESA consultation process and provide protections for listed species. Pesticide Use Limitation Areas (PULAs) and the associated geographically specific mitigation (i.e., bulletins) are not yet available under these efforts. While the BLT language above is being added on the pesticide label without being linked to PULAs or bulletins for TM at this time, pesticide users should be aware that as various strategies are finalized, EPA expects to add new PULAs and new bulletins to BLT. Before new PULAs and bulletins are added in BLT, EPA will notify stakeholders and provide an opportunity for public comment. See Appendix D: Listed Species Assessments for more information.

4. Spray Drift Mitigation

EPA has identified necessary label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across chlorothalonil products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. These label changes are also expected to reduce the extent of exposure for

[94] https://www.epa.gov/endangered-species/endangered-species-protection-bulletins
[95] https://www.epa.gov/endangered-species/bulletins-live-two-blt-tutorial
[96] USDA, 2023. Technology Use (Farm Computer Usage and Ownership). Published August 17, 2023. Available at: https://downloads.usda.library.cornell.edu/usda-esmis/files/h128nd689/4j03fg187/fj237k64f/fmpc0823.pdf

and may reduce impacts to listed species whose range or critical habitat co-occur with the use of chlorothalonil.

The following spray drift mitigation language is needed on all agricultural use chlorothalonil labels for products applied by liquid spray application. The 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 registrants to standardize advisory language on chlorothalonil product labels. When submitting labeling consistent with this ID, advisory language may not contradict the new mandatory spray drift statements noted in this ID.

- 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 or are below 3 miles per hour. 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. 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 or are below 3 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 the most current version of the American Society of Agricultural & Biological Engineers Standard 572 and Standard 641 (ASAE 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.

Updates to label language are needed that address wind speed and direction measurements for aerial, ground, and airblast 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, 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.

Advisory best management practices are needed 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 windsock 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 removed from all chlorothalonil labels where such information currently appears. The new language above, which cites the most recent versions of the ASAE S572 (for ground application) and ASABE S641 (for aerial application) standards, eliminates the need for VMD information.

The Agency has identified droplet size restriction as necessary 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,[97,98] EPA does not have the information necessary to determine the impact of this requirement on the performance of chlorothalonil across various use patterns. In general,

[97] Crop Protection Network. 2021. Fungicide Use in Field Crops Web Book: Section 3.1: Foliar Fungicide. https://cropprotectionnetwork.org/web-books/fungicide-use-in-field-crops?section=31-foliar-fungicide [Accessed August 2024]

[98] Virginia Cooperative Extension. 2009. Droplet Chart/Selection Guide. Hipkins, P., Grisso, R., Wolf, B., Reed, T. https://bae.k-state.edu/faculty/wolf/PDF/442-031_DropletChart-SelectionGuide.pdf

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.

Prohibiting applications during inversions and having windspeed restrictions 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. Growers who do not currently own a device for measuring wind speed and/or direction will have to purchase and install a windsock, an anemometer, or an aircraft smoke system. There are likely differences in cost in purchasing each of these technologies however, once a purchase is made, it can be utilized for other pesticides that also require growers to measure windspeed ahead of an application. EPA expects that purchasing and installing a windsock is the least expensive option, followed by an anemometer and an aircraft smoke system. There are likely minimal differences in the complexity to interpret the wind speed or direction outputs generated by these technologies.

There are no specific requirements for airblast applications on current labels. EPA does not anticipate impacts to the users of chlorothalonil from requirements to direct spray into the canopy and to turn off nozzles that would treat the outer orchard rows, as this corresponds to best application practices.

5. 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, EPA has identified needed spray drift buffers (100-foot for aerial and airblast applications and 25-foot for ground applications) 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, national and state grasslands, and conservation easements). A 50% reduction in the aerial and airblast wind-directional buffer distance described 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 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 and the restrictions on this label.

A 50% reduction in the required wind-directional buffer distance 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 criteria listed in the 'Windbreak-Shelterbelt Criteria' section of this label."

- 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 and the restrictions on this label. A 50% reduction in buffer distance can be made if:
    - the application is made with a hooded sprayer; or,
    - a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets the criteria listed in the 'Windbreak-Shelterbelt Criteria' section of this label.

  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."

- 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 and the restrictions on this label.

  A 50% reduction in the required wind-directional buffer distance 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 criteria listed in the 'Windbreak-Shelterbelt Criteria' section of this label."

Windbreak-Shelterbelt Criteria for Buffers from Conservation Areas

A windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the treated area and the protected area (aquatic habitat and/or wildlife conservation area) can substantially reduce pesticide deposition. Data in the open literature show that hedgerows 22 to 25 feet tall result in a spray drift reduction of 73% to 98% at wind speeds up to 2.5 mph for ground applications.[99] A study using artificial screens and artificial christmas trees found a reduction in deposition, especially when the height of the spray nozzles was lower in relation to the height of the drift reducing structures. Deposition was reduced by 65% to 80% when nozzles were 1.6 feet lower than the height of the windbreaks.[100] A study on pesticide deposition at vegetated sites and non-vegetated sites found deposition was 96.1% lower at vegetated sites.[101] Due to the limited amount of data available and likelihood that newly established hedgerows will be less than 22 feet tall, EPA assumes a 50% reduction in spray drift when growers use a hedgerow or windbreak that is taller than the spray nozzle release height.

EPA is allowing labeling to include a 50% reduction in the wind-directional buffer distance noted above if a windbreak or shelterbelt (e.g., trees or riparian hedgerows) is present between the application site and the protected area. The windbreak or shelterbelt must be downwind of the application, must have a minimum of one row of trees/shrubs with foliage of sufficient density, must run the full length of the treated crop, must be at a height higher than the application release height, must be planted according to local/regional/federal conservation program standards, and must be maintained for continued functionality.

Additionally, manmade structures (*e.g.*, a building or curtain that is raised prior to application) can be used in lieu of a windbreak or shelterbelt if the structure is downwind between the application area and the protected area, covers the entire distance of the field adjacent to the protected area, and is higher than the release height of the application.

The labeling for the windbreak-shelterbelt criteria, including requirements for manmade structures, is as follows:

Windbreak-Shelterbelt Criteria

"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 aquatic habitat/conservation area is present and meets the following criteria:

- The windbreak or shelterbelt must be downwind between the pesticide application and the aquatic habitat/conservation area.

[99] Lazzaro, L., Otto, S., & Zanin, G. 2008. Role of hedgerows in intercepting spray drift: Evaluation and modelling of the effects. *Agriculture, Ecosystems & Environment, 123*(4), 317-327.
[100] De Schampheleire, M., Nuyttens, D., Dekeyser, D., Verboven, P., Spanoghe, P., Cornelis, W., et al. 2009. Deposition of spray drift behind border structures. *Crop Protection, 28*(12), 1061-1075.
[101] Hancock, J., Bischof, M., Coffey, T., & Drennan, M. 2019. The effectiveness of riparian hedgerows at intercepting drift from aerial pesticide application. *Journal of Environmental Quality, 48*(5), 1481-1488.

- The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage is sufficiently dense such that the aquatic habitat/conservation area is not visible on the upwind side 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 aquatic habitat/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 aquatic habitat/conservation area, cover the entire distance of field adjacent to the aquatic habitat/conservation area, and higher than the release height of the application."

Accounting for Both Hooded Sprayers and Windbreak

Hooded sprayers are a drift-reducing technology that physically blocks drifting droplets at or near the spray nozzle. For ground application, data from the open literature shows a 50% reduction in spray drift for application of fine to medium droplet sizes up to 30 meters offsite when hooded sprayers are used.[102] In order to provide more flexibility to users who use hooded sprayers, the Agency is allowing a 50% reduction in the wind-directional buffer distance listed above for ground application if a hooded sprayer is used. In the case where a hooded sprayer is used in combination with a windbreak that meets the windbreak-shelterbelt criteria listed above, the Agency is allowing a 75% reduction in the buffer distance for ground application.

Impact of Spray Drift Buffers on Users

The aerial buffer requirements of 100 and 150 feet next to conservation lands and freshwater areas respectively may impact growers who are reliant on aerial applications, including potato growers in several regions, and cucurbits, tomatoes, other vegetable crops growers in California and Washington. The 25-foot ground buffer to freshwater areas may impact some growers that are directly adjacent to bodies of water, or non-agricultural users, such as turf and golf courses, where water bodies are commonly directly within the treatment area. 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

[102] Foster, H. C., Sperry, B. P., Reynolds, D. B., Kruger, G. R., & Claussen, S. 2018. Reducing herbicide particle drift: effect of hooded sprayer and spray quality. *Weed Technology, 32*(6), 714-721, 718.

chlorothalonil. Some users may not be able to achieve the same level of disease and resistance control with alternative fungicides. Additionally, some users could be forced to put productive land out of production. Aerial buffers distances may influence growers to use ground equipment to reduce buffer sizes. However, for potato growers, ground application equipment can disrupt the soil and potato tubers development, resulting in increased risk of greening and the disease development. 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 crop yield. 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.

3. Endangered Species: 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).[103] In 2011, NMFS released a partial Biological Opinion (BiOp) specific to listed Pacific salmon and steelhead species for various pesticides, including chlorothalonil. EPA is implementing 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.[104] See Appendix E for additional information.

The 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 has identified additional necessary mitigation within the salmonid habitat to implement NMFS' salmonid BiOp. EPA concludes that, with the mitigation for chlorothalonil outlined in this ID, the Agency is able to predict that there is not a likelihood of adverse modification of listed Pacific salmon and steelhead designated critical habitat.

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. Additionally, EPA is implementing a 10-mph maximum wind speed requirement and a 3-mph minimum wind speed requirement. The 48-hour rain restriction and 10-mph wind speed

[103] *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.
[104] https://www.fisheries.noaa.gov/resource/document/biological-opinion-chlorpyrifos-diazinon-and-malathion

restriction for chlorothalonil will be implemented on a geographic-specific basis in Bulletins. See Appendix C for the Bulletins mitigation for chlorothalonil.

EPA is implementing general label language limiting chlorothalonil applications to conifers to the only 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) and prohibiting application to forest stands of conifers. 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. This change clarifies 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 label language for this chlorothalonil mitigation measure.

The Bulletins Live! Two label 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.

4. 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 has identified a need for occupational handlers to use PF10 respirators in this scenario. Since the PID, the Agency has made a slight change to the respirator fit-testing language for antimicrobial chlorothalonil products. This change follows suggestions made by OSHA.

Ecological risks of concern were also identified resulting from the discharge of chlorothalonil-treated water from pulp/paper mills. EPA has identified as necessary limitations on 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. In particular, the model assumes that 100% of

chlorothalonil applied to a structure via treated paint will leach directly into the nearest body of water during a single rainfall event. Because the chlorothalonil in treated paints is meant to provide long-lasting fungicidal protection to the paint itself when applied to buildings, it is not realistic to assume that 100% of all chlorothalonil would leach out of the paint during one rainfall event. However, leaching data would help to refine those exposure assumptions.

Due to chlorothalonil's important paint preservative benefits in a niche sector of the paint market (i.e., dry film mildewcides) and the conservatism of this aspect of the ecological risk assessment, EPA believes that ecological exposure and potential risk is likely minimal and so the Agency is not currently calling for additional mitigation for the paint and coatings uses of chlorothalonil. However, EPA has identified as necessary inclusion of ecological incident reporting instructions on chlorothalonil product labels. EPA 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, EPA may initiate further risk assessment or risk mitigation, as appropriate to determine whether this use poses unreasonable risks.

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

To mitigate the inhalation risks of concern for occupational handlers, EPA has identified needed label language instructing occupational handlers to use respirators when open-pouring powdered chlorothalonil products. Product labels will instruct occupational handlers to wear a NIOSH approved air-purifying half-face mask elastomeric respirator (PF10) with any R or P filter during use. By directing users to wear 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.

If a chlorothalonil handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler's employer for the respirator and fit testing. Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. 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) Mitigation for Chlorothalonil Products Used in Pulp and Paper Mills

To mitigate the ecological risks of concern for aquatic organisms, EPA has identified necessary limitations to the use of chlorothalonil to the dry-end of the paper making process only. By limiting the use of chlorothalonil to the dry-end of the process, EPA anticipates that chlorothalonil will 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 current use practices and not have any impact on users. For more information, see Appendices A and B.

c) Ecological Incident Reporting Language

EPA has identified the need to add incident reporting language to antimicrobial product labels 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 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)."

B. Environmental Justice

EPA seeks to achieve environmental justice—the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability, in Agency decision-making and other Federal activities that affect human health and the environment so that people are fully protected from disproportionate and adverse human health and environmental effects (including risks). Throughout the registration review process, EPA has sought to include all communities and persons who may be impacted by the use of 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 residential handlers (such as homeowners) and 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.[105] 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.[106,107] The Agency evaluated risk to those who may use treated materials after manufacturing and did not find risks of concern.

EPA sought information during the public comment periods throughout registration review 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. EPA requested comment on the PID concerning environmental justice and received one comment (EPA-HQ-OPP-2011-0840-0267) regarding the disproportionate impacts of mitigation measures on African-American (black) growers in coastal plain areas of Georgia, South Carolina, and North Carolina. EPA recognizes that the vulnerable soil mitigation measures may have disproportionate economic impacts on African-American (black) agricultural growers in southern coastal areas. However, EPA also notes that the use of chlorothalonil based on current labeled use (without the mitigation measures described in this ID) results in human health dietary risks of concern. Specifically, groundwater contamination (which is typically localized to application area) leading to drinking water exposure was the main contributor to the dietary risks identified. While the Agency acknowledges the economic burden, EPA notes that dietary exposure via ground water contamination from chlorothalonil is likely also greater in agricultural communities where chlorothalonil is applied, and that the mitigation measures identified in this ID are necessary in these areas.

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

> 40 CFR §180.275(a)(1): "Tolerances are established for residues of the fungicide 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

[105] 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.
[106] Ibid.
[107] United States Census Bureau, 2022. Vintage 2022 Population Estimates. Accessible at: https://www.census.gov/quickfacts/fact/table/US/PST045222.

> 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 the fungicide 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 expects to implement certain tolerance revisions 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. Data Requirements

Other than pollinator studies described in Section III.B., EPA does not anticipate calling in additional data for chlorothalonil's registration review. EPA has initiated the process to call in the pollinator studies described in Section III.B after releasing this ID.

V. NEXT STEPS AND TIMELINE

A Federal Register Notice will announce the availability of the chlorothalonil ID. A final registration review decision for chlorothalonil will only be made after EPA (1) completes effects determinations and (2) meets EPA's ESA section 7 obligations (*e.g.*, initiate any necessary consultation with the Services, consistent with ESA § 7(a)(2)).

Implementation of Mitigation Measures

The mitigations discussed in Part IV are implemented through label amendments and/or registration changes. Registrants: Submit a cover letter, a completed Application for Registration (EPA form 8570-1), and electronic copies of the amended product labels within 60 days after the announcement of this ID in the Federal Register. Submit two copies for each label, a clean copy and an annotated copy with changes. Include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment is consistent with the chlorothalonil Interim Registration Review Decision and satisfies the requirements of EPA regulations at 40 CFR Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the statute or regulations, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Submit the required documents to the Registration Review section of the EPA's Pesticide Submission Portal (PSP), which can be accessed through the EPA's Central Data Exchange (CDX) at https://cdx.epa.gov/. Registrants may instead send a cover letter, a completed Application for Registration (EPA form 8570-1) for an Agency-initiated non-PRIA label amendment, and paper copies of their amended product labels to Rachel Blatnick at the following address, so long as the labels and application are submitted within the timeframe specified above:

VIA US Mail
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

After all the label amendments or registration changes have been submitted, EPA will review them to ensure that they incorporate the necessary mitigation. If they include the necessary changes, EPA intends to approve the requested changes and/or amendments. If the registrant does not submit the label amendments or registration changes, EPA reserves the right to take appropriate action under FIFRA. 40 C.F.R. § 155.58. This ID does not effect a change in the existing registration, and no registration will be canceled involuntarily unless EPA follows the procedures and substantive requirements of 7 U.S.C. section 136d or is under court order to cancel. *See* 7 U.S.C. section 136a(g)(1)(A)(v).

Appendix A: Summary of Mitigation 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	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	• Immersion in contaminated water	• Acute • Chronic	• Mortality • Reductions in growth,	

	runoff, spray drift, and atmospheric transport			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: Labeling Changes for Chlorothalonil Products

<table>
<tr><th>Description</th><th>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.

<table><tr><td>CHLOROTHALONIL</td><td>GROUP</td><td>M05</td><td>FUNGICIDE</td></tr></table></td><td>Front Panel, upper right quadrant.
All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.</td></tr>
<tr><td>Updated Gloves Statement</td><td>Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.</td><td>In the Personal Protective Equipment (PPE) within</td></tr>
</table>

		the Precautionary Statements and Agricultural Use Requirements, if applicable
Updated Respirator Language for PF10	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products. [**Note to registrant:** For respiratory protection from organic vapor a**nd** particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
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."	Environmental Hazards

	[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."	
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 (Required for products intended for homeowner use formulated as liquid concentrates)	"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
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	"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

(Required for products intended for homeowner use formulated as ready to use (RTU) products)		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 spray applications to agricultural crops	"**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. • 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.	Directions for Use – Under the Advisory Best Management Practices header after Resistance Management section

	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"
Advisory Instructions: Soil Organic Matter Content For all products	"Advisory Recommendations for Determining Soil's Organic Matter Content: If you need to determine the organic matter content of your soil to confirm soil vulnerability, do so before applying chlorothalonil. To obtain a representative soil sample for soil testing, take a composite of several soil samples collected throughout the intended application area. Ideal soil sampling depth varies depending on use site. Consult local extension publications for additional information on recommended soil sampling procedures and soil testing methods. Annual, or more frequent, soil testing for organic matter provides more accurate soil characteristic identification."	Directions for Use, prior to directions for specific crops

Advisory Instructions: Web Soil Texture Link For all products	"Advisory Instructions for Determining Soil Texture: If you need to determine soil texture to confirm soil vulnerability, see USDA's Web Soil Survey tool which may be found here: https://websoilsurvey.nrcs.usda.gov/app/."	Directions for Use, prior to directions for specific crops
Maximum Annual Application Rate Reductions for Almond, Filbert (Hazelnut), Pistachio; Beans, Dried; Lentils; Lupine; Parsnip; Sugar beet (grown for seed)	"Do not apply more than 6.0 pounds of chlorothalonil active ingredient per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Brassica/Cole vegetables (e.g., Broccoli, Brussels Sprouts, Cauliflower) except Cabbage	"Do not apply more than 3.75 pounds of chlorothalonil active ingredient per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for 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 active ingredient per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for	"Do not apply more than 6.5 pounds of chlorothalonil active ingredient per acre per year."	Directions for Use

Blueberry; Apricot; Plum; Prune; Mango		
Maximum Annual Application Rate Reductions for Tomato in all states except Florida, Georgia, North Carolina, South Carolina; Cherry west of the Rocky Mountains	"Do not apply more than 6.5 pounds of chlorothalonil active ingredient per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Persimmon	"Do not apply more than 4.7 pounds of chlorothalonil active ingredient per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions for Corn, Field (grown for seed); Mint	"Do not apply more than 3.0 pounds of chlorothalonil active ingredient per acre per year."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Asparagus; Celery; Cabbage; Carrot; Corn, Sweet; Passion Fruit	"Do not apply more than 7.5 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil	"Do not apply more than 7.2 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three	Directions for Use

Restriction for Beans (Snap)	criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Cranberry	"Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Peat bottom cranberry beds or upland marsh cranberry beds with a confining layer for flooding that completely isolates the cranberry bed from groundwater are not considered vulnerable soils and 10 lbs chlorothalonil active ingredient per acre per year may be applied. For other cranberry beds, vulnerable soils are soils that meet **all three** of the following criteria: **(1)** The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, **(2)** having less than 2% organic matter content, and **(3)** the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are **not** met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Cucurbits; Onion (Dry Bulb); Garlic	"Do not apply more than 9.0 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Tomato in Florida, Georgia, North	"Do not apply more than 10.5 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use

Carolina, South Carolina		
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Fruiting Vegetables except Tomato; Papaya; Peanut	"Do not apply more than 6.75 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Fruiting Vegetables except Tomato in Florida, Georgia, North Carolina, South Carolina	"Do not apply more than 7.9 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Ginseng	"Do not apply more than 12.0 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate	"Do not apply more than 18.0 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the	Directions for Use

Reductions and Vulnerable Soil Restriction for Horseradish	following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	
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 active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Peach and Nectarine	"Do not apply more than 12.4 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Potato; Yam	"Do not apply more than 8.0 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic**	Directions for Use

	Matter Content and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Rhubarb	"Do not apply more than 13.5 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Cherries east of the Rocky Mountains	"Do not apply more than 15.4 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Conifers	"Do not apply more than 16.5 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	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 active ingredient per acre per year to field grown ornamental plants. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Ornamentals – Root/Bulb Spent Dip Fluid	"For spent dip tank treatment water applied to field grown ornamentals, do not apply more than 18.75 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability." *Note to registrant: provide the pounds of chlorothalonil per 100-gallon (or equivalent) dip tank treatment to simplify the spent dip tank application rate calculation.*	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 active ingredient per acre per year as a spot treatment to ornamental plants. Do not apply more than 6.5 lbs chlorothalonil active ingredient per acre per year as a spot treatment to ornamental plants in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	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 active ingredient per acre per year. Do not apply more than 6.2 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content, and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Turf – Industrial, Athletic Fields; Turf – Golf Course Fairways	"Do not apply more than 22.6 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.2 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content (thatch/mat included), and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Turf – Golf Course Tees	"Do not apply more than 33.9 pounds of chlorothalonil active ingredient per acre per year. Do not apply more than 6.2 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Vulnerable soils are defined as meeting all three of the following criteria: (1) The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, (2) having less than 2% organic matter content (thatch/mat included), and (3) the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are not met, the soil is not considered vulnerable. See **Supplemental Recommendations for Determining Soil's Organic Matter Content** and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	Directions for Use
Maximum Annual Application Rate Reductions and Vulnerable Soil Restriction for Turf – Golf Course Greens	"Do not apply more than 6.2 lbs chlorothalonil active ingredient per acre per year in vulnerable soils. Turf putting greens constructed to USGA or California green specifications or constructed as push up greens are not considered vulnerable soils and 45.2 lbs chlorothalonil active ingredient per acre per year may be applied. For other turf greens, vulnerable soils are soils that meet **all three** of the following criteria: **(1)** The soil texture of the application area is over 50% sand, loamy sand, or sandy loam soil as defined by USDA's soil classification system without a restrictive layer that impedes the movement of water through soil, **(2)** having less than 2% organic matter content (thatch/mat included), and **(3)** the water table occurs at a depth of 30 feet or less from the surface. If any one of these three criteria are **not** met, the soil is not considered vulnerable. See **Supplemental Recommendations**	Directions for Use

	for Determining Soil's Organic Matter Content and **Supplemental Instructions for Determining Soil Texture** if additional guidance is needed for confirming soil vulnerability."	
Maximum Annual Application Rate Reductions for Residential Uses for Almond, Filbert (Hazelnut), Pistachio; Beans, Dried; Lentils; Lupine; 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 active ingredient 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 active ingredient 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 Grass (Forage, Hay, Seed); Grass Grown for Seed; Soybean; Strawberry (nursery seedlings for pre-transplant; non-food)	"For residential users who obtain their drinking water from an on-site well, do not apply more than 4.5 pounds of chlorothalonil active ingredient 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 active ingredient 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 active ingredient 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
Chemical Extraction Probe Rinsing Statement	"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 Restrictions for products that are applied as liquid with aerial equipment	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**: • 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 the most current version of the 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, 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. • Applicators must use a minimum of ½ swath displacement upwind at the downwind edge of the field.	Directions for Use, in a box titled "Mandatory Spray Drift Management " under the heading "Aerial Applications" Placement for these

	• 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."	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. • 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** **<u>Ground Boom Applications:</u>** • 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 (including systems to measure wind speed or velocity using 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 applications, do not release spray at a height greater than 2 feet above the ground. • Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASAE S572). • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift Management " under the heading "Ground Boom Applications"
Spray Drift Management Application Restrictions for products that are	**"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 (ASAE S572). • Do not apply when wind speeds exceed 10 miles per hour at the application site.	Directions for Use, in a box titled "Mandatory Spray Drift

applied as liquid with boomless ground sprayer equipment	• Do not apply during temperature inversions."	Management " under the heading "Boomless Applications"
Spray Drift Buffer to Aquatic Habitats	"For aerial and airblast applications, this product must not be applied within 150 feet of water bodies (estuarine/marine and freshwater). For ground applications, this product must not be applied within 25 feet of water bodies (estuarine/marine and freshwater). If applying to turf, you may choose to construct and maintain a 10-foot vegetative filter strip of grass or other permanent vegetation between the field or application area edge and nearby aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds) in lieu of the 25-foot buffer. If using a vegetative filter strip, only apply products containing chlorothalonil onto fields or application areas where a maintained vegetative filter strip of at least 10 feet exists between the field or application area edge and down-gradient aquatic habitat."	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: "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 and the restrictions on this label. 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.	Directions for use – Under the Restriction or Use Restriction Section

	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: o the application is made with a hooded sprayer; or, o 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. 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. **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.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

	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).	

	○ 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. ○ 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."	
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 applied as liquid with handheld equipment	**"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"
Use Restriction for Conifers	"Use on conifers is restricted to the following use sites: nursery beds, Christmas tree and bough production plantations, tree seed orchards, and landscaping. Do not apply on forest stands of conifers."	Directions for Use
	<u>Antimicrobial End Use Products</u>	
Requirement of PF10 Respirator for Occupational Handlers During the	"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"	Personal Protective Equipment (PPE) section

Manufacture of Preserved Materials - Products Used in Materials Preservation		within the Precautionary Statements
Respirator Fit Testing, Medical Qualification, and Training - Products Used in Materials Preservation	"See OSHA's Respiratory Protection Standard for federal requirements on how to safely fit-test, train, and medically examine workers who will be using respirators."	Personal Protective Equipment (PPE) section within the Precautionary Statements
Restricting Chlorothalonil's Use to the Dry End of the Papermaking Process - Products used in 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: "Bulletins Live! Two" Mitigation for Chlorothalonil Products to Implement NMFS Salmonid Biological Opinion

Species	Description	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 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 at the conclusion of this Appendix and 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[108] 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.[109]

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.[110]

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.

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

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 received a final malathion biological opinion[111] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos, and diazinon in June 2022.[112] In August 2023, the Agency implemented the FWS malathion biological opinion by issuing Endangered Species Protection Bulletins[113] and approving malathion label amendments[114] to incorporate measures to protect listed species. In March 2024, EPA implemented the NMFS biological opinion for malathion, chlorpyrifos (for non-food uses), and diazinon.[115] EPA was granted an extension by NMFS to implement the NMFS biological opinion for the food uses of chlorpyrifos by September 2024.

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy[116] 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*.[117] 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

[111] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.
[112] https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions.
[113] https://www.epa.gov/endangered-species/endangered-species-protection-bulletins.
[114] https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0154.
[115] https://www.epa.gov/pesticides/epa-announces-implementation-mitigation-measures-insecticides-chlorpyrifos-diazinon-and#:~:text=For%20chlorpyrifos%2C%20diazinon%2C%20and%20malathion,one%20or%20more%20listed%20species.
[116] https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides.
[117] https://www.epa.gov/endangered-species.

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*.[118] 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.

The *ESA Workplan Update* also discussed additional efforts to expedite and streamline ESA consultation, including the Vulnerable Species Pilot, regional strategies (i.e., a Hawaii strategy), approaches for specific niche pesticide uses (e.g., mosquito adulticide applications), and programmatic approaches to consultation (e.g., the Herbicide Strategy).

In September 2024, EPA published the final Vulnerable Species Action Plan with various supporting documents. For more information about the Vulnerable Species Action Plan, visit the public docket (docket EPA-HQ-OPP-2023-0327 at www.regulations.gov).

In November 2024, EPA published the final Biological Evaluation, Effects Determinations, and Mitigation Strategy for Federally Listed and Proposed Endangered and Threatened Species and Designated and Proposed Critical Habitats. For more information, visit the public docket (EPA-HQ-OPP-2023-0567 at www.regulations.gov).

EPA continues to work on these and other efforts to further listed species protection. When finalized, EPA expects to implement these through registration review and new active ingredient registration.

ESA Assessments or Biological Opinions Impacting Chlorothalonil

In 2011, NMFS released a Biological Opinion specific to listed Pacific salmon and steelhead species for various pesticides, including chlorothalonil. EPA is in the process of implementing this biological opinion as part of its registration review process. The Agency will complete a nationwide listed-species assessment and any necessary consultation with the Services before completing the chlorothalonil registration review.

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

Background

[118] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.

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 implementing 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.[119] As noted in the Services' Consultation Handbook,[120] 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 freshwater buffers) were greater than the selected acute aquatic toxicity endpoints[121] 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

[119] See p. 131 at https://www.fisheries.noaa.gov/resource/document/biological-opinion-chlorpyrifos-diazinon-and-malathion

[120] See pp. 47-48, https://www.fws.gov/sites/default/files/documents/endangered-species-consultation-handbook.pdf

[121] Aquatic algae is most sensitive: *Navicula pelliculosa* EC_{50} = 12 ppb.

salmonid designated critical habitat. However, EPA is implementing 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 in this ID for chlorothalonil were not accounted for in the 2011 NMFS BiOp. The Agency is implementing a variety of FIFRA mitigation measures (see Section IV), including application 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). When the FIFRA mitigations from this ID are considered, EPA concludes that the mitigation measures included in this ID provide exposure reduction that is equivalent or greater to the 2011 NMFS salmonid BiOp RPAs and no additional mitigation is needed to address the adverse modification finding for chlorothalonil in the 2011 NMFS salmonid BiOp.

EPA concludes that with the 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

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

The EDSP initiatives developed by EPA in 1998 includes human and wildlife testing for estrogen, androgen, and thyroid pathway activity and employs a two-tiered approach. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid pathways. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any adverse estrogen, androgen, or thyroid effect. If EPA finds, based on that data, that the pesticide has an adverse endocrine-related effect on humans, FFDCA § 408(p)(6) also requires EPA, "… as appropriate, [to] take action under such statutory authority as is available to the Administrator … as is necessary to ensure the protection of public health." (21 U.S.C. 346a(p)(6)).[122]

Between October 2009 and February 2010, EPA issued Tier 1 test orders/data call-ins (DCIs) for its first list of chemicals ("List 1 chemicals") for EDSP screening and subsequently required submission of EDSP Tier 1 data for a refined list of these chemicals. EPA received data for 52 List 1 chemicals (50 pesticide active ingredients and 2 inert ingredients). EPA scientists performed weight-of-evidence (WoE) analyses of the submitted EDSP Tier 1 data and other scientifically relevant information (OSRI) for potential interaction with the estrogen, androgen, and/or thyroid signaling pathways for humans and wildlife.[123]

In addition, for FIFRA registration, registration review, and tolerance-related purposes, EPA collects and reviews numerous studies to assess potential adverse outcomes, including potential outcomes to endocrine systems, from exposure to pesticide active ingredients. Although EPA has been collecting and reviewing such data, EPA has not been explicit about how its review of required and submitted data for these purposes also informs EPA's obligations and commitments under FFDCA section 408(p). Consequently, on October 27, 2023, EPA issued a

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

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

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

The EDSP Strategies Notice and the support documents are available on www.regulations.gov in docket number EPA-HQ-OPP-2023-0474. As explained in these documents, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans, focusing first on conventional active ingredients. Although EPA voluntarily expanded the scope of the EDSP to screening for potential impacts to the estrogen, androgen, and thyroid systems in wildlife, EPA announced that it is not addressing this discretionary component of the EDSP at this time, considering its current focus on developing a comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan[124] and November 2022 ESA Workplan Update[125]). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE memoranda[126] indicate that available data were sufficient for FFDCA section 408(p) assessment and review for potential adverse effects to the estrogen, androgen, or thyroid pathways for wildlife. For the remaining 17 List 1 chemicals, Tier 1 WoE memoranda made recommendations for additional testing. EPA expects to further address these issues taking into account additional work being done in concert with researchers within the EPA's Office of Research and Development (ORD).

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

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

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

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

Chlorothalonil is on List 1. In 2015, EPA published the Tier 1 WoE analyses for chlorothalonil, and that evaluation determined that no further data to assess the potential for impacts on the estrogen, androgen, or thyroid pathways are needed for humans[127]. Based on that evaluation, EPA has concluded that the points of departure for human health risk assessment to evaluate the EPA-registered uses and established tolerances of chlorothalonil are protective of potential adverse estrogen, androgen, and thyroid effects in humans.

There was no convincing evidence of an interaction with the estrogen, androgen, or thyroid hormone pathways for chlorothalonil. Therefore, EPA has completed its FFDCA section

[127] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0840-0028

408(p)(6)-related commitments and obligations “to ensure the protection of public health.” For additional information, please see the List 1 Screening Conclusions.

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	
Coffee, green bean	-	0.2	Commodity term revision.
Coffee, bean, green	0.20	remove	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, sweet, forage	-	65	Recommended for previously[4].
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.
Mushroom	1.0	remove	Corrected values to be consistent with OECD Rounding Class Practice.
Ginseng	4.0	4	Corrected values to be consistent with OECD Rounding Class Practice.
Horseradish	4.0	4	
Kohlrabi	-	5	Crop group

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Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
			conversion/revision.[2,3]
Lentil, dry seed	-	0.1	Commodity term revision. Corrected value to be consistent with OECD Rounding Class Practice.
Lentil	0.10	remove	
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[4].
Plum, prune, fresh	-	0.2	Commodity term revision.
Plum, prune	0.2	remove	
Rhubarb	4.0	7	Harmonization with Codex.
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.

Table G. Summary of Tolerance Revisions for Chlorothalonil (40 CFR §180.275)[1].			
Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
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	
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 *Chlorothalonil: Revised Human Health Draft Risk Assessment for Registration Review* (DP# 457661) (April 9, 2021).

[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] The Revised HED Chapter of the Reregistration Eligibility Decision (RED) Document for Chlorothalonil (January 7, 1998).

OECD = Organization for Economic Cooperation and Development.