



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

**Mancozeb**

**Proposed Interim Registration Review Decision**  
**Case Number 0643**

**June 2024**

Approved by:           *Jean Overstreet*            
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Date:           July 3, 2024

## Table of Contents

I.	INTRODUCTION .....	4
A.	Summary of Mancozeb Registration Review .....	6
B.	Summary of Public Comments on the Draft Risk Assessments and Agency Responses.....	8
II.	USE AND USAGE .....	13
III.	SCIENTIFIC ASSESSMENTS.....	17
A.	Human Health Risks.....	17
1.	Risk Summary and Characterization.....	17
2.	Human Incidents and Epidemiology.....	22
3.	Tolerances .....	22
4.	Human Health Data Needs.....	23
B.	Ecological Risks.....	23
1.	Risk Summary and Characterization.....	24
2.	Ecological Incidents .....	27
3.	Ecological and Environmental Fate Data Needs.....	28
C.	Benefits Assessment.....	28
IV.	PROPOSED INTERIM REGISTRATION REVIEW DECISION.....	30
A.	Proposed Risk Mitigation and Rationale.....	31
1.	Use Terminations .....	32
a.	Residential post-application .....	32
b.	Occupational handler – seed treatment.....	32
c.	Occupational handler – foliar treatment.....	33
d.	Occupational post-application .....	34
2.	Spray Drift Reduction Measures for Non-Occupational Bystanders .....	34
3.	Personal Protective Equipment and Engineering Controls.....	34
a.	Clothing and Gloves Requirement for Mancozeb Handlers: .....	35

b.	APF10 Respirator Requirement for Certain Handlers.....	35
c.	Closed-Loading System Requirement for Certain Handlers .....	36
d.	Enclosed Cab Requirement for Certain Handlers .....	36
e.	APF10 Respirator and Closed-loading System Requirement for Certain Handlers .....	37
4.	Changes to Restricted-Entry Intervals (REIs) .....	38
5.	Nontarget Organism Advisory Statements.....	39
6.	Resistance Management .....	40
7.	Spray Drift Management .....	40
8.	Label update for all liquid products where there are mixers and loaders involved in mixing a liquid chemical concentrate .....	42
B.	Seed Treatment Questions.....	43
C.	FIFRA Interim Ecological Mitigation (IEM) Measures .....	52
D.	Environmental Justice.....	67
E.	Tolerance Actions .....	67
F.	Data Requirements.....	70
V.	NEXT STEPS AND TIMELINE.....	70
A.	Comment on this Proposed Interim Decision.....	70
B.	Implementation of Mitigation Measures if EPA Issues an ID .....	70
	Appendix A: Summary of Proposed Mitigation for Mancozeb .....	71
	Appendix B: Proposed Labeling Changes for Mancozeb Products.....	73
	Appendix C: Listed Species Assessment.....	104
	Appendix D: Endocrine Disruptor Screening Program (EDSP).....	107
	Appendix E: Surface Water Protection Statement: How to Determine the Amount of Rainfall Predicted Over 48 Hours.....	110

## I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for mancozeb (PC Code 014504, case 0643).

The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)<sup>1</sup> mandates a periodic review of existing pesticide registrations every 15 years, referred to as registration review.<sup>2</sup> During registration review, the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard.<sup>3</sup> Where appropriate, the Agency may issue an Interim Registration Review Decision (ID) before completing a final registration review decision.<sup>4</sup> However, issuance of an ID is not a decision on whether a pesticide's registrations continue to satisfy the FIFRA standard for registration.<sup>5</sup> Rather, the ID may include mitigation measures and changes to labeling that EPA has determined would address risks of concern, identify data or information needed to complete registration review, and include schedules for submitting such data, conducting the new risk assessment, and completing the registration review.<sup>6</sup> The Agency is issuing this PID for mancozeb to identify risk mitigations that EPA has determined would address risks of concern for mancozeb, as presented in Section IV and Appendices A and B.

Mancozeb is the only currently registered member of the ethylene bisdithiocarbamate (EBDC) family of fungicides, which formerly included the related active ingredients maneb, metiram, nabam, and zineb. Maneb, metiram, nabam, and zineb are now cancelled in the United States. There are no existing tolerances for maneb, nabam, or zineb; however, there are remaining metiram tolerances that allow for the importation of commodities that have been treated with metiram outside of the United States.

Mancozeb is a multisite mode of action fungicide used for prevention and control of fungal pathogens. Providing a broad spectrum of disease control, products containing mancozeb are registered for both foliar and seed treatment use on a wide variety of agricultural sites, including fruit trees, potatoes, and vegetable crops, and as an in-furrow use on onions. It is also registered for foliar use on ornamental plants and turfgrass and as a dip treatment for

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<sup>1</sup> Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136w-8.

<sup>2</sup> For more information on the registration review program, see <http://www.epa.gov/pesticide-reevaluation>.

<sup>3</sup> FIFRA § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57; *see also* FIFRA § 3(c)(5).

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 40 C.F.R. § 155.56.

asparagus crowns and caprifigs. This PID also covers the degradate ethylene thiourea (ETU), which is shared with metiram. The first product containing mancozeb was registered in 1948. The Agency completed the reregistration eligibility decision (RED) for mancozeb in 2005.

EPA has not yet fully evaluated mancozeb's effects on federally threatened and endangered (listed) species or designated critical habitats. However, consistent with its obligations under the Endangered Species Act (ESA),<sup>7</sup> 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 mancozeb registration review and issuing a final registration review decision. For more information on EPA's ESA obligations during registration review, see Appendix C.

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.<sup>8</sup> 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.<sup>9</sup> As part of this update, EPA announced that, going forward, EPA may include a variety of FIFRA Interim Ecological Mitigation (IEM) measures in its registration review decisions that seek to reduce exposures for nontarget organisms based on its FIFRA ecological risk assessment(s). EPA expects that this mitigation may also reduce pesticide exposures for listed species.

As part of this PID, EPA has considered a variety of FIFRA IEM measures based on the risks and benefits of mancozeb 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 has determined that early mitigation may shorten the consultation process and improve protections for listed species from currently registered pesticide products. EPA also has determined that the FIFRA IEM measures that the Agency is proposing for mancozeb in this PID (Section IV.B) would 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)]."

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<sup>7</sup> Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.

<sup>8</sup> *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](https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf)

<sup>9</sup> *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>

Before completing registration review, EPA will also address its Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p)(6)-related commitments and obligations to ensure the protection of public health for mancozeb. For more information on EPA's review of mancozeb under this FFDCA provision, see Appendix D.

This document is organized into five sections:

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

#### **A. Summary of Mancozeb Registration Review**

On June 23, 2015, the Agency formally initiated registration review for mancozeb with the opening of the registration review [docket](#) for the case.<sup>10</sup> The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of mancozeb:

- June 2015 – EPA posted the *Mancozeb Preliminary Work Plan (PWP)* (June 16, 2015), *Mancozeb: Tier I (Scoping) Review of Human Incidents* (June 23, 2015), and *Problem Formulation for the Ecological Risk Assessment and Drinking Water Exposure Assessment to be Conducted for Mancozeb* (June 9, 2015) to the public docket for a 60-day public comment period.
- January 2016 – EPA posted the *Mancozeb Final Work Plan (FWP)* (December 22, 2015) to the public docket. The Agency received five comments on the PWP. In the FWP, EPA noted that multiple studies, both guideline and non-guideline, were required to complete registration review of both mancozeb and ETU. No changes were made to the data requirements listed in the PWP.
- September 2016 – EPA issued a generic data call-in (GDCI) for mancozeb to obtain data needed to conduct the registration review risk assessments (DCI GDCI #014504-1566). The registrants submitted all required data. However, three residue chemistry studies were determined to be inadequate for various reasons described below and will need to be resubmitted:

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<sup>10</sup> 40 C.F.R. § 155.50

- 860.1200 Directions for Use – product labeling for SLN treatment of tobacco is inadequate. Evaluation of associated field trial data is not possible without clarification on maximum use rate, which is currently missing from the label.
- 860.1500 Crop Field Trials – residue data for tobacco are not adequate for use in the risk assessment because application rates are not specified. Residue data for safflower seed or propagation stock are inadequate because the study was not conducted at a sufficient application rate.
- 860.1850 Confined Rotational Crop Study – study was not conducted at a sufficient application rate.

Additionally, one residue chemistry study, 860.1300 Nature Residue – plants, was not submitted. Due to studies 860.1500 and 860.1850 (listed above) being deemed inadequate, all data requirements have not been satisfied. For more information, see Sections III.A.4 and III.B.4

- March 2021 – EPA posted *Mancozeb and Ethylene Thiourea (ETU): Draft Human Health Risk Assessment (DRA) for Registration Review (2020 HH DRA)* and *Mancozeb: Draft Ecological Risk Assessment for Registration Review (2020 Eco DRA)* for a 60-day public comment period. The Agency received 51 comments from 51 commenters. The Agency has summarized and responded to these comments in Section I.B., below. The comments did not change the risk assessments or registration review timeline for mancozeb.
- April 2023 – EPA posted:
  - *Mancozeb and Ethylene Thiourea (ETU): Revised Draft Human Health Risk Assessment (DRA) for Registration Review (2023 HH DRA)*
  - *Mancozeb. Acute, Chronic, and Cancer Dietary Exposure and Risk Assessments of Food and Drinking Water for the Ethylene Bisdithiocarbamate (EBDC) Fungicide Mancozeb (2023 Food and Drinking Water Assessment)*
  - *Aggregate Dietary Assessment of the Common Metabolite/Degradate Ethylene Thiourea (ETU) Resulting from the Combined Uses of the EBDC Fungicides Mancozeb and Metiram to Support Registration Review. Update to Dietary Exposure Evaluation Model (DEEM) Version 4.02. (2023 Aggregate Assessment)*
- June 2024 – EPA completed the PID for mancozeb and made it available in the public docket for a 60-day public comment period. Along with the PID, EPA plans to post the following documents to the public docket:
  - *Mancozeb. Second Revision: Occupational and Residential Exposure Assessment in Support of Registration Review. (June 28, 2024)*
  - *Mancozeb and Ethylene Thiourea (ETU): Second Revision: Draft Human Health Risk Assessment (DRA) for Registration Review (2024 HH DRA). (June 28, 2024)*

- *Mancozeb: EPA Response to Comments Related to Mancozeb: Draft Ecological Risk Assessment for Registration Review and Mancozeb: Drinking Water Assessment to Support Registration Review (EPA HQ-2015-0291- 0023) (November 8, 2022)*
- *Mancozeb: Response to Public Comments on the Draft Human Health Risk Assessment in Support of Registration Review (January 25, 2024)*
- *EPA Inquiry – Mancozeb - Usage, Application Methods, and Alternatives (January 25, 2022)*
- *Responses to EPA-OPP Inquiries Regarding Specific Potato Seed Piece Treating with Mancozeb, Loading and Planting Practices (November 22, 2023)*
- *Mancozeb (014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Turf and Ornamental Plants (June 27, 2024)*
- *Mancozeb (PC 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation of Foliar Uses in Cucurbits, Peppers, and Tomatoes (June 26, 2024)*
- *Mancozeb (PC# 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Foliar Uses in Apples, Pears, Almonds, Walnuts, Mango, Papaya, Grapes, and Cranberry (June 28, 2024)*
- *Mancozeb (PC 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation of Foliar Uses in Ginseng and Field Crops Including Potato, Sugar beet, and Sweet Corn) (June 27, 2024)*
- *Mancozeb (014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Seed Treatment Uses (June 12, 2024)*
- *Mancozeb (PC Code # 014504) Registration Review: Assessment of Use, Usage, Benefits, and Impacts of Potential Mitigation in Various Vegetable Crops — Lettuce, Onions, Garlic, Broccoli, Cabbage, and Asparagus (June 28, 2024)*

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

During the initial 60-day public-comment period for the mancozeb Draft Risk Assessments (March 8, 2021 to May 7, 2021), the Agency received a request from the Mancozeb Task Force to extend the comment period 30 days, citing the complexity and volume of information involved. On April 20, 2021 the Agency granted a 15-day extension, bringing the close of the comment period to May 22, 2021. During this comment period the Agency received 51 public comments. Comments were submitted by:

- Agape Tree Care and Orchard Microbiologist
- American Crystal Sugar Company
- American Farm Bureau Federation (AFBF)
- Anonymous public comment
- Arizona Farm Bureau Federation
- Arizona Pest Management Center, University of Arizona
- Audrey Boyd

- Boyer Orchards, LLC
- California Specialty Crops Council (CSCC)
- California Walnut Commission (CWC)
- Center for Biological Diversity (CBD)
- David Drake
- Florida Fruit and Vegetable Association (FFVA)
- Gargiulo Farms
- Ginseng Board of Wisconsin
- Glen Swope
- Golf Course Superintendents Association of America (GCSAA)
- Hollabaugh Bros., Inc.
- IR-4 Project
- James Adaskaveg
- Jay Brenneman
- Jim Cocchiola
- Joseph Brule
- Kari Peter
- Liberty Apple Orchard, Inc.
- Mancozeb Task Force
- Mark Rice
- Minn-Dak Farmers Cooperative
- Neil Hinish
- Northwest Horticultural Council (NHC)
- Paul Bajurny
- Paul DeAngelo
- Red River Valley Sugarbeet Growers Association
- Rex Dimperio
- Rutgers, School of Environmental and Biological Sciences and the IR-4 Project
- Scott Overby
- Southern Minnesota Beet Sugar Cooperative (SMBSC)
- Serman Masser, Inc.
- Steven Johnston
- the American Sugarbeet Growers Association (ASGA)
- the California Fresh Fruit Association (CFFA)
- the Michigan Vegetable Council, Inc. (MVC)
- the National Agricultural Aviation Association (NAAA)
- the Washington State Potato Commission
- Thomas Griffith
- Thomas Kelley
- United States Department of Agriculture (USDA)
- University of Florida (UF)
- University of Maryland Extension
- UPL NA Inc. and UPL Delaware, Inc.

- William Stone

The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. For detailed responses to comments related to risk assessments, please refer to:

- *Mancozeb: EPA Response to Comments Related to Mancozeb: Draft Ecological Risk Assessment for Registration Review and Mancozeb: Drinking Water Assessment to Support Registration Review (EPA HQ-2015-0291- 0023) (November 8, 2022)*
- *Mancozeb: Response to Public Comments on the Draft Human Health Risk Assessment in Support of Registration Review (January 25, 2024)*

These documents have been placed in the docket simultaneously with this PID. The Agency thanks all commenters for participating and has considered all comments in developing this PID.

**Comments Submitted by Center for Biological Diversity (CBD) (Docket ID: EPA-HQ-OPP-2015-0291-0082 and EPA-HQ-OPP-2015-0291-0083)**

**Comment:** CBD's comments focus on EPA's duty under the Endangered Species Act (ESA) to consult with the Services on the registration review of mancozeb. 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 also expressed concern about the effects of mancozeb 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 mancozeb.

**EPA Response:** EPA has reviewed CBD's comments and is addressing many of the concerns about listed species by collaborating with the Services and USDA to improve the consultation process for listed species and pesticides.<sup>11</sup> For more information on this ongoing collaboration, see Appendix C. EPA intends to address listed species concerns specific to mancozeb when developing its final registration review decision. Before completing registration review, EPA will address its Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p)(6)-related commitments and obligations to ensure the protection of public health for mancozeb.<sup>12</sup> For more information on EPA's review of mancozeb under this FFDCA provision, see Appendix D. 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).

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<sup>11</sup> Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.

<sup>12</sup> Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

**Comment:** CBD also submitted comments related to other portions of the 2020 Eco DRA. These comments are detailed in *Mancozeb: EPA Response to Comments Related to Mancozeb: Draft Ecological Risk Assessment for Registration Review and Mancozeb: Drinking Water Assessment to Support Registration Review* (EPA HQ-OPP-2015-0291- 0023)

**EPA Response:** The Agency thanks CBD for their comments. For more detailed information and response, see *Mancozeb: EPA Response to Comments Related to Mancozeb: Draft Ecological Risk Assessment for Registration Review and Mancozeb: Drinking Water Assessment to Support Registration Review* (EPA HQ-OPP-2015-0291- 0023)

**Comments Submitted by:**

- Agape Tree Care and Orchard Microbiologist (Docket ID:EPA-HQ-OPP-2015-0291-0052)
- American Crystal Sugar Company (Docket ID:EPA-HQ-OPP-2015-0291-0029)
- American Farm Bureau Federation (AFBF) (Docket ID:EPA-HQ-OPP-2015-0291-0073)
- Anonymous public comment (Docket ID:EPA-HQ-OPP-2015-0291-0050)
- Arizona Farm Bureau Federation (Docket ID:EPA-HQ-OPP-2015-0291-0077)
- Arizona Pest Management Center, University of Arizona (Docket ID:EPA-HQ-OPP-2015-0291-0071)
- Boyer Orchards, LLC (Docket ID:EPA-HQ-OPP-2015-0291-0035)
- California Specialty Crops Council (CSCC) (Docket ID:EPA-HQ-OPP-2015-0291-0072)
- California Walnut Commission (CWC) (Docket ID:EPA-HQ-OPP-2015-0291-0067)
- David Drake (Docket ID:EPA-HQ-OPP-2015-0291-0058)
- Florida Fruit and Vegetable Association (FFVA) (Docket ID:EPA-HQ-OPP-2015-0291-0081)
- Gargiulo Farms (Docket ID:EPA-HQ-OPP-2015-0291-0044)
- Ginseng Board of Wisconsin (Docket ID:EPA-HQ-OPP-2015-0291-0069)
- Glen Swope (Docket ID:EPA-HQ-OPP-2015-0291-0045)
- Golf Course Superintendents Association of America (GCSAA) (Docket ID:EPA-HQ-OPP-2015-0291-0078 and EPA-HQ-OPP-2015-0291-0084)
- Hollabaugh Bros., Inc. (Docket ID:EPA-HQ-OPP-2015-0291-0038)
- IR-4 Project (Docket ID:EPA-HQ-OPP-2015-0291-0066)
- James Adaskaveg (Docket ID:EPA-HQ-OPP-2015-0291-0061)
- Jay Brenneman (Docket ID:EPA-HQ-OPP-2015-0291-0046)
- Jim Cocchiola (Docket ID:EPA-HQ-OPP-2015-0291-0054)
- Joseph Brule(Docket ID:EPA-HQ-OPP-2015-0291-0030)
- Kari Peter (Docket ID:EPA-HQ-OPP-2015-0291-0060)
- Liberty Apple Orchard, Inc. (Docket ID:EPA-HQ-OPP-2015-0291-0033)
- Mark Rice (Docket ID:EPA-HQ-OPP-2015-0291-0031)
- Minn-Dak Farmers Cooperative (Docket ID:EPA-HQ-OPP-2015-0291-0051)
- Neil Hinish (Docket ID:EPA-HQ-OPP-2015-0291-0043)
- Northwest Horticultural Council (NHC) (Docket ID:EPA-HQ-OPP-2015-0291-0037)

- [Paul Bajurny \(Docket ID:EPA-HQ-OPP-2015-0291-0047\)](#)
- [Paul DeAngelo \(Docket ID:EPA-HQ-OPP-2015-0291-0041\)](#)
- [Red River Valley Sugarbeet Growers Association \(Docket ID:EPA-HQ-OPP-2015-0291-0055\)](#)
- [Rex Dimperio \(Docket ID:EPA-HQ-OPP-2015-0291-0039\)](#)
- [Rutgers, School of Environmental and Biological Sciences and the IR-4 Project \(Docket ID:EPA-HQ-OPP-2015-0291-0075\)](#)
- [Scott Overby \(Docket ID:EPA-HQ-OPP-2015-0291-0048\)](#)
- [Southern Minnesota Beet Sugar Cooperative \(SMBSC\) \(Docket ID:EPA-HQ-OPP-2015-0291-0034\)](#)
- [Sterman Masser, Inc. \(Docket ID:EPA-HQ-OPP-2015-0291-0053\)](#)
- [Steven Johnston \(Docket ID:EPA-HQ-OPP-2015-0291-0056\)](#)
- [the American Sugarbeet Growers Association \(ASGA\) \(Docket ID:EPA-HQ-OPP-2015-0291-0065\)](#)
- [the California Fresh Fruit Association \(CFFA\) \(Docket ID:EPA-HQ-OPP-2015-0291-0063\)](#)
- [the Michigan Vegetable Council, Inc. \(MVC\) \(Docket ID:EPA-HQ-OPP-2015-0291-0062\)](#)
- [the Washington State Potato Commission \(Docket ID:EPA-HQ-OPP-2015-0291-0068\)](#)
- [Thomas Griffith \(Docket ID:EPA-HQ-OPP-2015-0291-0059\)](#)
- [Thomas Kelley \(Docket ID:EPA-HQ-OPP-2015-0291-0057\)](#)
- [University of Florida \(UF\) \(Docket ID:EPA-HQ-OPP-2015-0291-0074\)](#)
- [University of Maryland Extension \(Docket ID:EPA-HQ-OPP-2015-0291-0042\),](#)
- [William Stone \(Docket ID:EPA-HQ-OPP-2015-0291-0049\)](#)

**Comment:** Commentors express support for the continued registration and availability of products containing mancozeb. Many users report that mancozeb plays a critical role in their pest management plans. Users and other stakeholders cite mancozeb's importance in management of fungal pests on a variety of crops and provide usage information on specific crops and geographies. Many users also express concerns of economic impacts that could result from a loss of mancozeb products.

**EPA Response:** EPA thanks those listed above for their comments. All the information provided has been reviewed during the registration review process and will be taken into consideration in any decisions regarding mancozeb. Use, usage, and benefits information received informed both Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation documents which are also included in this docket and ultimately this Proposed Decision.

## II. USE AND USAGE

### *Use*

#### *Agricultural Use Sites*

Mancozeb is a broad-spectrum contact fungicide registered for use on the following agricultural crops: apple, almond, asparagus, barley, broccoli, cabbage, caprifig, corn (field, popcorn, and sweet), cranberry, cucurbit crops (crop group 9), fennel, ginseng, grapes, lettuce, oats, onion (bulb) subgroup 3-07A, parsnip, peanuts, pear, peppers, potatoes, quince, rye, sugarbeets, tomatoes (subgroup 8-10A), triticale, walnut, wheat, and certain tropical and subtropical fruits (banana, plantain, mango, papaya, sugar apple, cherimoya, atemoya, custard apple, sweetsop, star apple [caimito], canistel, mamey sapote, sapodilla, white sapote). Mancozeb is also registered for use on the following field crops grown for seed: sugarbeets, field corn (for hybrid seed), and sweet corn (including for hybrid seed). Mancozeb is also registered for additional uses via Special Local Need (SLN) labels for use in Washington and Oregon state on the following vegetable crops grown for seed: alliums (leek, bunching and dry bulb onion), arugula, beets (garden and sugar), carrots, coriander, crucifers (Brassica spp. and Raphanus spp.), dill, endive, lettuce, parsley, parsnip, Swiss chard, and spinach. Carrots grown for seed is also registered on a SLN label in Idaho.

Mancozeb agricultural/foiar products are formulated as: dry flowables (includes water dispersible granules), flowable concentrates (liquid), water soluble packets and wettable powders.

Depending on the use site, mancozeb products may be applied as a broadcast (ground and aerial equipment), in-furrow, or chemigation (sprinkler/overhead) application. A dip treatment application is registered for asparagus crowns and caprifig (i.e., for mamme figs used in cross pollination).

#### *Seed Treatment Use Sites*

Mancozeb is registered for seed treatment in barley, corn, cotton, flax, oats, peanuts, potatoes, rice, rye, safflower, sorghum, tomato, triticale, and wheat. Mancozeb seed treatments are formulated as dusts and liquids. Seed treatments may be applied on-farm or commercially.

#### *Non-Crop Use Sites*

Mancozeb is registered for non-crop uses including turf and ornamental plants. On turf sites, mancozeb is specifically registered for outdoor use on golf courses, sod farms, and non-residential lawns (this includes industrial and municipal lawns such as at office parks, schools, retail areas, and recreational parks). Mancozeb is not registered for use on residential turf. For use on ornamental plants, mancozeb is broadly registered for use on both ornamentals used in

outdoor landscaping (including residential ornamental landscaping) and ornamentals being produced in nurseries and greenhouses. Mancozeb is also registered for use on Christmas trees and Douglas fir trees.

Mancozeb may be applied to registered turf, ornamental sites, and Christmas and Douglas fir trees aerially, via chemigation (sprinkler/overhead irrigations), or by ground equipment. Mancozeb formulations for use on turf and ornamental use sites include dry flowables, flowable concentrates, and wettable powders.

## **Usage**

### *Agricultural Usage*

According to national surveys, from 2017-2021 about 6.1 million pounds of mancozeb are used to treat about 3.7 million acres of agricultural crops each year.<sup>13</sup> Some smaller acreage crops are not surveyed at a nationally representative level, and are not included in this estimate; therefore, these national usage values may slightly underestimate total national mancozeb usage.

In terms of total pounds of A.I. applied from 2017 to 2021, top sites include potatoes, sugarbeets, apples, and walnuts, where about one million pounds AI were applied on average annually to each use site. Top sites in terms of the percent of crop treated (PCT) were lettuce, walnut, onions, and pears.

Crops that were surveyed but reported low usage nationally between 2017 to 2021 were: almonds, grapes (raisin, table, juice, and wine varieties), wheat, carrots, corn, peanuts, and tobacco. Though national grape PCT was low, it is important to note that there were regional differences in mancozeb usage on grapes due to differences in disease pressure resulting from different moisture conditions.

From 2017-2021, the majority of applications (about 77% of total acres treated) were applied via a dry flowable and water dissolvable granules formulations.<sup>13</sup>

Ground applications of mancozeb include banded, broadcast, chemigation, ground, or spot treatments.<sup>13</sup> Regarding the total acres treated across all crops with mancozeb, about 21% of total acres treated were applied aerially from 2017-2021.<sup>13</sup> Crops with the greatest percentage of total acres treated with mancozeb aerially were sweet corn (about 88%), potatoes (52%), winter wheat (50%), broccoli (32%), onions (23%) and sugarbeet (15%). Other crops which have reported less than 5% of total acres treated with mancozeb aerially include: pumpkin, walnuts, lettuce, watermelons, tomatoes, apples, almonds, garlic, peppers, pears, cucumbers, and

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<sup>13</sup> Kynetec USA, Inc. 2022a. "The AgroTrak® Study from Kynetec USA, Inc." iMap Software. Database Subset: 2017-2021 [Accessed June 2023].

cabbage (2017-2021). Other surveyed crops had no reported aerial applications of mancozeb (2017-2021).

There are no recent, available, and nationally representative usage data for: barley, caprifiig, crabapple, cranberry, fennel, ginseng, oats, parsnip, quince, rye, triticale, registered tropical and subtropical fruits, crops grown for seed, or smaller acreage crops within Crop Group 9, Crop Subgroup 3-07A, or Crop Subgroup 8-10A. The absence of such data should not be interpreted as lack of usage.

### *Seed Treatment Usage*

Seed treatment data available to the Agency can be utilized qualitatively as an indicator of positive usage, though at this time, it is not possible to estimate the geographic extent of the seed treatment usage or provide robust quantitative estimates of usage. Rather, the Agency provides a qualitative description of seed treatment usage based on these available seed treatment data; an understanding of how reported usage or dollar amount of sales of mancozeb rank when compared to other fungicide seed treatments may indicate its relative importance for crops for which data are available.

Mancozeb seed treatment usage was reported on potatoes and cereals (combined estimate of wheat, barley, oats, and rye) over the five most recent years of available data (2017 to 2021). In terms of acres planted with treated seed, dollar amount of sales and volume of AI applied, from 2017 to 2021, mancozeb was a market leading fungicide seed treatment on potatoes. Mancozeb was not a market leading seed treatment fungicide according to usage reported on cereal grains, neither in terms of dollar amount of sales nor pounds of AI applied.

Seed treatment fungicide usage on corn, cotton, peanuts, rice, and sorghum was surveyed from 2017-2021; however, no mancozeb usage was reported, suggesting mancozeb is not widely used as a seed treatment on these crops. The Agency does not have seed treatment data on flax, safflower, tomato, or triticale. The absence of such seed treatment data should not be interpreted as lack of usage.

### *Non-Crop Usage*

#### Golf Courses:

In a 2021 survey, approximately 260,000 lbs of mancozeb was reported to be used on golf courses. In terms of pounds of mancozeb applied, golf courses were the highest usage market sector among surveyed turf and ornamental market sectors. However, in terms of acres treated, mancozeb was not a market leader among fungicides used on golf courses.

#### Sod farms:

Approximately 33,000 lbs of mancozeb was applied to turf sod farms in 2021. In terms of acres treated, mancozeb was not a market leader among fungicides used on sod farms.

#### Lawns and Landscape Ornamentals:

In 2021, mancozeb usage was reported by surveys targeting chemical use in the professional maintenance of lawns and landscaping. Specifically, usage was reported on institutional turf (parks, cemeteries, schools, and colleges), by lawn care operators (defined as pesticide lawn and ornamental applicators for commercial, industrial, residential, and other non-residential properties), and by landscape contractors (management companies that generally design, plant, and care for flower beds and other landscaping). Approximately 175,000 pounds of mancozeb were reported across all these surveyed market sectors.

#### Production Ornamentals:

Nationally, low amounts of mancozeb in terms of pounds applied was reported to be used in the production of ornamentals within nurseries and greenhouses in 2021. This indicates a large decline in usage in the sector when compared to a previous report from 2013. Usage data from California, which represents approximately 12% of national horticultural acreage (second highest among states), corroborate a decline in usage. In California, the annual average area treated between 2017-2021 represents almost a 40% decrease in pounds of mancozeb applied in nurseries and greenhouses compared to the previous five-year period (2012-2016).

#### Christmas Trees:

The Agency does not have usage information on mancozeb use in Christmas tree production. The absence of such data should not be interpreted as lack of usage.

*For more details on the use and usage of mancozeb, see the following documents in the mancozeb registration review docket (EPA-HQ-OPP-2015-0291):*

Mancozeb (014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Turf and Ornamental Plants (June 27, 2024)

Mancozeb (PC 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation of Foliar Uses in Cucurbits, Peppers, and Tomatoes (June 26, 2024)

Mancozeb (PC# 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Foliar Uses in Apples, Pears, Almonds, Walnuts, Mango, Papaya, Grapes, and Cranberry (June 28, 2024 ])

Mancozeb (PC 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation of Foliar Uses in Ginseng and Field Crops Including Potato, Sugar beet, and Sweet Corn) (June 27, 2024)

[Mancozeb (014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Seed Treatment Uses (June 12, 2024)

[Mancozeb (PC Code # 014504) Registration Review: Assessment of Use, Usage, Benefits, and Impacts of Potential Mitigation in Various Vegetable Crops — Lettuce, Onions, Garlic, Broccoli, Cabbage, and Asparagus] (June 28, 2024 ])

### III. SCIENTIFIC ASSESSMENTS

#### A. Human Health Risks

The Agency has summarized the 2024 HH DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of mancozeb. For additional details on the 2024 HH DRA, see *Mancozeb and Ethylene Thiourea (ETU): Revised Draft Human Health Risk Assessment (DRA) for Registration Review* in EPA's public docket (EPA-HQ-OPP-2015-0291-0085).

##### 1. Risk Summary and Characterization

###### *a. Dietary (Food + Water) Risks*

Acute, chronic, and/or cancer dietary exposure and risk assessments were conducted for mancozeb, ETU from mancozeb, and ETU from combined EBDC uses (mancozeb and metiram). There are no risks of concern from these exposure scenarios.

###### *b. Residential Handler Risks*

All registered mancozeb product labels require that handlers wear specific clothing (e.g., long sleeve shirt/long pants) and/or use PPE. Therefore, HED has made the assumption that these products are not for homeowner use and has not conducted a quantitative residential handler assessment.

###### *c. Residential Post-Application Risks*

No dermal point of departure was selected for mancozeb at this time (no dermal hazard); therefore, a quantitative post-application dermal assessment was not conducted for mancozeb. A dermal post-application assessment for ETU was conducted using a point of departure from the extended one-generation reproductive toxicity study (EOGRTS) in rats. There are no assessed non-cancer risks of concern from post-application exposure from use on golf course turf. Residential post-application dermal cancer risk estimates for ETU for adults from exposure to golf courses is  $4 \times 10^{-7}$ . Exposure and potential risk concerns are expected from residential turf and ornamental uses; however, an agreement was reached with the registrant to voluntarily cancel these uses and thus they were not assessed in the 2024 HH DRA.

###### *d. Bystander Risks*

Risks to bystanders were assessed in areas adjacent to mancozeb applications, both for turf and lawns and on agricultural crops. No risks of concern were identified for mancozeb. However, ETU risks of concern were identified for children at the field edge for some agricultural uses.

Scenarios of concern include both orchard crops<sup>14</sup>, vineyards, and typical-acreage field crops<sup>15</sup>, with combined (dermal + incidental oral) margins of exposure (MOEs) for children ranging from 140 to 590 (LOC = 300) for screening level exposure scenarios (e.g., fine to medium droplet size, high boom, etc). For orchard, vineyards, and typical-acreage field crops, a 75 foot distance from the edge of field is required to reach the LOC of 300 for aerial applications when using a fine to medium droplet size. For groundboom and airblast (orchard crops only) applications, this distance is 10 feet. Droplet size also plays a role in the resulting MOEs, with smaller droplets leading to reduced MOEs (or higher risk) for all scenarios. For groundboom and airblast application to orchard crops and typical-acreage field crops, passing MOEs at the field edge are achieved when considering larger droplet sizes (i.e., medium to coarse droplets). However, for aerial application to orchards, vineyards, and typical-acreage field crops, the largest droplet size modeled (coarse to very coarse) will still require a 10-foot buffer to reach the LOC of 300. There are no risks of concern for adult bystanders.

#### *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. For mancozeb, aggregate exposures are equivalent to dietary exposure estimates because there are no residential exposures.

Acute and chronic aggregate risk estimates for mancozeb, ETU from mancozeb, and ETU from EBDCs (mancozeb and metiram) are equivalent to the acute and chronic dietary risk estimates and are not of concern. EPA also aggregated the non-cancer residential exposure for ETU from mancozeb uses and average dietary (food and water) exposure for ETU from mancozeb uses; no short-term aggregate risks of concern were identified. EPA estimated the short-term aggregate risk for ETU from combined EBDCs (mancozeb and metiram) by aggregating the non-cancer residential exposure for ETU from mancozeb uses (there are no registered uses of metiram in the U.S.) and average dietary (food and water) exposure for ETU from mancozeb and metiram; no short-term aggregate risks of concern were identified. The cancer aggregate assessment for ETU from mancozeb combines residential post-application exposure for adults contacting mancozeb-treated turf (based on expected lifetime exposure) with the cancer dietary (food and

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<sup>14</sup> Orchard crops include the following crops currently listed on mancozeb labels: almond, banana, Christmas trees, grapes, papaya, pome fruits (apple, crabapple, quince, pear), subtropical/tropical fruit (sugar apple, cherimoya, atemoya, custard apple, sweetsop, mango, star apple, canistel, mamey sapote, sapodilla, white sapote), walnut. Spray drift assessment conducted using highest application rate of all registered orchard crops (almond @ 4.8 lb ai/A).

<sup>15</sup> Typical-acreage field crops include the following crops currently listed on mancozeb labels: asparagus, broccoli, cabbage, carrots, cucurbits, swiss chard, coriander, sweet corn, cranberry, dill, endive, fennel, garden beet, garlic, ginseng, leafy brassica greens, leek, lettuce, onion, parsley, parsnip, pepper, plantain, shallot, spinach, tobacco, tomato. Spray drift assessment conducted using highest application rate of all registered typical-acreage field crops (cranberry @ 4.8 lb ai/A).

water) exposure for ETU from mancozeb. The cancer aggregate risk estimate is  $2 \times 10^{-6}$  and is not of concern.

#### *f. Cumulative Risks*

EPA has not made a common-mechanism-of-toxicity-to-humans finding for mancozeb and any other substance. Mancozeb does produce a toxic metabolite, ETU, which is produced by other EBDC compounds. Risks from combined exposures to ETU from all EBDC compounds are addressed as a separate ETU aggregate risk assessment. For the purposes of this action, EPA has not assumed that mancozeb has a common mechanism of toxicity with other substances.

#### *g. Occupational Handler Risks*

EPA has identified risks of concern for occupational handlers who mix, load, and apply mancozeb to greenhouse crops, orchard crops, vineyard crops, field crops, and turf. The agency has also identified risks of concern for handlers performing seed treatment activities in the same crops, in both on-farm and commercial settings. Risk estimates are summarized below for both the parent mancozeb and degradate ETU. Additional details and full list of scenarios-specific MOEs are provided in the 2024 HH DRA. Most current mancozeb product labels require handlers to wear single-layer baseline attire (long-sleeved shirt, long pants, shoes, and socks), but do not require additional personal protective equipment (PPE).

#### Endpoint selection and Level of Concern (LOC)

For mancozeb, an occupational inhalation endpoint was determined using a subchronic inhalation study in rats, where toxicity manifested as alterations in thyroid hormones, increased thyroidal weight, and thyroid lesions. A dermal point of departure (POD) for mancozeb was not selected based on a lack of observed dermal toxicity. The LOC = 10 [1X to account for interspecies extrapolation (10X reduced to 1X due to the calculation of HECs accounting for *pharmacokinetic interspecies differences* and the *toxicodynamics interspecies differences* in the human vs. rat thyroid function), 10X to account for intra-species variation, and 1X FQPA SF].

For ETU, both dermal and inhalation occupational endpoints were selected using the extended one-generation reproductive toxicity study (EOGRTS) in rats. Thyroid toxicity also results from ETU exposure, with the addition of pituitary effects. Due to inhalation and dermal routes of exposure having the same effects, combined risk estimates are provided for occupational scenarios. The LOC = 300 (3X to account for interspecies extrapolation, 10X to account for intra-species variation, and 10X FQPA SF).

#### Mancozeb non-cancer risks from foliar uses

There are no non-cancer inhalation risks of concern from these exposure scenarios.

#### ETU non-cancer from foliar uses

Risks of concern are present from ETU in many occupational handler scenarios. Dermal and inhalation MOEs are combined, with dermal exposure being the main driver of risk. Risk values

for occupational handler scenarios in the 2024 HH DRA are provided for each combination of formulation, application and/or loading method, and crop. Each unique scenario was initially assessed with baseline attire (single-layer of clothing plus gloves). For scenarios of concern with baseline attire, PPE was added to the calculations to determine at what point, if any, the level of concern (LOC = 300) could be reached. With baseline attire, several scenarios are of concern with MOEs ranging from 3.7 to 110,000. With the maximum assessed PPE (APF10 respirator, double layer clothing (long sleeve shirt, long pants, shoes, and socks, plus coveralls), and gloves) and/or engineering controls (closed-loading systems and/or enclosed cockpits), there are still some scenarios that remain of concern, with MOEs ranging 28 to 280. The lowest MOEs (28) all come from application of liquid, wettable powder (WP), and dry flowable (DF) formulations with handheld equipment, assuming double layer clothing, gloves and a APF10 respirator. Another particularly low MOE (87) comes from aerial application to sod, assuming engineering controls (i.e., closed cab) with gloves and a respirator. Scenarios of concern occur across all crops with different combinations of formulation, application and/or loading method, and handler activity (mixer/loader, applicator, flagger, and combined mixer/loader/applicator). See the 2024 HH DRA for a full list of occupational handler foliar scenarios and associated MOEs.

#### Mancozeb non-cancer from seed treatment uses

As a dermal POD was not selected, mancozeb risks from seed treatment uses include inhalation risk values only. Risks were calculated separately for on-farm and commercial seed treatment scenarios. For commercial seed treatment scenarios, each unique activity (i.e., treating, packaging, cleaning, loading/planting) is assigned its own risk value for each crop. On-farm seed treatment risks are calculated with two different formulations (liquid and dust/powder) for treating and planting activities combined. Mancozeb seed treatment combined MOEs range from 7.1 to 120,000 (LOC = 10), with one scenario being of concern for on-farm treating and planting of potato seeds (MOE = 7.1). This scenario is no longer of concern after the addition of a APF10 respirator (MOE = 71).

#### ETU non-cancer from seed treatment uses

Seed treatment risks from ETU are expressed as a combined value that includes both dermal and inhalation MOEs. Risks were calculated separately for on-farm and commercial seed treatment. Commercial seed treatment risks are calculated for separate activities conducted by workers (treating, packaging, cleaning, loading/planting). The majority of commercial seed treatment risk estimates from ETU are of concern with baseline attire (i.e., single layer plus gloves and no respirator), with 53 of 60 scenarios falling under the LOC of 300 (combined MOEs range from 1.2 to 9,000). With the addition of PPE (i.e., double layer clothing, gloves, and an APF10 respirator), 49 scenarios remain of concern with combined MOEs ranging from 3 to 31,000. On-farm seed treatment risks are calculated for two different formulations (i.e., liquid and dust/powder) for treating and planting activities combined. For on-farm seed treatment, 16 of 23 scenarios are of concern with baseline attire (i.e., single layer plus gloves and no respirator), with MOEs ranging from 0.85 to 15,000. With the addition of PPE (i.e., double layer clothing plus gloves and a APF10 respirator), nine scenarios remain of concern, with MOEs ranging from 4.9 to 100,000. Scenarios of concern occur across all crops, formulations, and

handler activities. See the 2024 HH DRA for a full list of occupational handler seed treatment scenarios and associated MOEs.

#### Occupational handler cancer

Due to rapid metabolism of mancozeb into ETU, cancer risks from mancozeb are assessed using the ETU cancer classification only, with risk estimates provided for both foliar and seed treatment uses. Risk estimates are provided with baseline attire and with additional PPE for both commercial and on-farm seed treatment risk estimates. There are no cancer risks of concern from seed treatment scenarios even with baseline attire (i.e., single layer clothing plus gloves and no respirator).

For foliar scenarios, cancer risk estimates are provided for each combination of formulation, application and/or loading method, and crop, with cancer risk estimates ranging from  $4 \times 10^{-8}$  to  $2 \times 10^{-3}$  for both private handlers/farmers and commercial/contract handlers with baseline attire (i.e., single layer of clothing) plus gloves and no respirator. The following commercial/contract occupational handler scenarios have cancer risk estimates of concern, with a value of  $2 \times 10^{-3}$  at baseline with gloves and no respirator:

- Mixing/Loading dry flowable formulations for aerial application to sod
- Dry flowable formulations being mixed, loaded, and applied to typical-acreage field crops using mechanically pressurized handgun equipment
- Liquid formulations being mixed, loaded, and applied to typical-acreage field crops and orchard crops using mechanically pressurized handgun equipment
- Wettable powder formulations being applied to typical-acreage field crops and orchard crops using mechanically pressurized handgun equipment

#### *h. Occupational Post-Application Risks*

Occupational post-application risk estimates in the 2024 HH DRA are included for dermal exposure from ETU only, as there is no dermal POD for mancozeb.

#### Mancozeb post-application risks from foliar uses

A dermal POD was not selected for mancozeb and therefore a quantitative dermal assessment was not conducted for post-application risks.

#### Mancozeb post-application risks from seed treatment uses

Post-application exposure from seed treatment applications is not expected and no assessment was conducted for these scenarios.

#### ETU post-application risks from foliar uses

Dermal exposure from ETU is the only category for which post-application risks have been estimated. Both cancer and non-cancer risk estimates are included in the 2024 HH DRA for post-application exposure.

Non-cancer risk estimates are crop and activity-specific and are expressed with a days after treatment (DAT) value to indicate the number of days since treatment for which the associated MOE is calculated. At DAT = 0 (same day as treatment), 48 crop/activity combinations are of concern (MOEs range from 16 to 12,000, LOC = 300), and represent a variety of crops and activities including orchard/vineyards, ornamental, turf, and field crops. For activities that are of concern at DAT = 0, an additional DAT was calculated to represent the point at which a passing MOE would be reached. These values represent the restricted entry interval (REI) that would be needed for occupational post-application risks to become no longer of concern. These REIs range from 1 to 34 days. Some scenarios, particularly post-application activities on grapes, are not able to reach a passing MOE even with REIs >30 days. At a DAT of >30 days, grape activity MOEs still range from 56 to 190. Existing REIs and preharvest intervals (PHI) are not adequate to address most scenarios of concern.

#### ETU post-application risks from seed treatment uses

Post-application exposure from seed treatment applications is not expected and no assessment was conducted for these scenarios.

## **2. Human Incidents and Epidemiology**

EPA reviewed mancozeb incidents reported to both the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR). As of EPA's latest search on November 30, 2020, IDS and SENSOR showed 19 low- to medium-severity incidents reported from January 1, 2015 to July 29, 2020. These searches provided information consistent to the identified risks of concern and the conclusions of the incident reporting are of high certainty. Mancozeb was included in the Agricultural Health Study and EPA continues to monitor the results of that study. More detailed information can be found in *Mancozeb: Tier II Incident and Epidemiology Report* (EPA-HQ-OPP-2015-0291-0026). The Agency intends to monitor human incidents for mancozeb and will conduct additional analyses if necessary.

## **3. Tolerances**

Mancozeb is registered for 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.<sup>16</sup> EPA has determined that the Agency established all of the necessary tolerances for residues resulting from mancozeb's legal use.

However, during the risk assessment process EPA determined that revisions to the tolerances for mancozeb are necessary to become consistent with OECD rounding class practices, to remove tolerances on agricultural products for which new studies indicate no concentration of residues remain after processing, to implement commodity definition revisions, and to alter tolerances where new data indicate changes to existing values are required. For more information, see Section IV.C, below.

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<sup>16</sup> 21 U.S.C. §§ 342, 346(a).

Additionally, during the risk assessment process EPA determined that revisions to the tolerances and tolerance expressions for ETU on ruminant commodities are necessary to establish tolerances on these products. For more information, see Section IV.C, below.

- The Agency has established tolerances for mancozeb under 40 C.F.R. § 180.176(a)(1). Tolerance change recommendations include removal of trailing zeros as necessary to become consistent with OECD rounding class practices, removal of tolerances on agricultural products for which new studies indicate no concentration of residues remain after processing, implementing commodity definition revisions, and altering tolerances where new data indicate changes to existing values are required.
- The Agency has established tolerances for ETU under 40 C.F.R. § 180.176(a)(2).
  - Separate tolerance expression for ETU
  - Recommending establishment of tolerances for ruminant commodities, as mancozeb residues are found in the tissues or milk of cattle
- International harmonization of mancozeb tolerances has been deferred as the EBDCs are currently under re-review by both Canada and Codex. Harmonization will be revisited when these processes are completed.

#### **4. Human Health Data Needs**

Due to studies submitted for 860.1500 Crop Field Trials and 860.1850 Confined Rotational Crop Study being deemed inadequate the human health database for mancozeb is not considered complete.

Although not all human health data requirements have been completely met, EPA has determined that available data were sufficient to conduct the 2023 HH DRA and are sufficient to support this PID because the agency was able to perform risk calculations using conservative risk estimates where data were missing or where submitted data were deemed insufficient. The Agency intends to continue working with the registrants to satisfy these data requirements under existing DCI notice (DCI GDCI # 014504-1566).

#### **B. Ecological Risks**

The Agency has summarized the 2020 Eco DRA below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of mancozeb. For additional details on the 2020 Eco DRA, see *Mancozeb: Draft Ecological Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2015-0291-0021).

EPA is currently working with its federal partners and other stakeholders to improve the consultation process for listed species and their designated critical habitats. The Agency has not yet fully evaluated mancozeb's risks to listed species. However, EPA will complete its listed species assessment and any necessary consultation with the Services before completing the

mancozeb registration review. See Appendix C for more details. As such, only potential risks for non-target species under FIFRA are described below.

## 1. Risk Summary and Characterization

EPA has identified risks of concern, both chronic and acute, for multiple taxa. The risk estimates are based on the current registered uses of mancozeb, the available ecotoxicity data, and environmental fate properties. EPA compares risk estimates (risk quotients, or RQs) with EPA's Level of Concern (LOC) for non-listed species, with risks being of concern when RQs are greater than the LOC. For scenarios in which RQs could not be estimated, EPA compared the estimated environmental concentrations (EECs) of mancozeb with the appropriate toxicological endpoint. No potential risk concerns were identified for terrestrial plants or freshwater invertebrates (both in the water-column and in sediment).

### *a. Terrestrial Risks*

Terrestrial risks were calculated using the dietary exposure pathway, as terrestrial wildlife feeding on treated fields is expected to represent the majority of exposure to these taxa. RQs for both consumption of food items following foliar spray applications and consumption of treated seeds are included for two residues of concern, the parent mancozeb and degradate ETU. While measured half-lives of mancozeb in soil are less than one day, ETU is documented to be equally as toxic as parent mancozeb and has half-lives in soil ranging from 1 to 18.6 days. Because of this, a 35-day half-life for risk calculations is considered protective for ETU.

### Birds, Reptiles, and Terrestrial-Phase Amphibians

As the available studies did not show definitive acute toxicity endpoints for birds and the taxa they represent (dose-based and dietary-based toxicity endpoints for birds surpassed the highest doses and concentrations, respectively tested), acute RQs were not calculated. However, for acute dietary risk, the highest dietary item EECs were compared to the highest treatment concentration in the study, which represent levels that are less than the non-definitive endpoints and therefore offers a conservative risk estimation. For these comparisons, acute EECs were below the maximum dose tested for all uses except turf. Therefore, acute risks cannot be precluded for turf use at the highest application rate of 17.4 lbs a.i./A, as this represents a higher dose than was tested, but for all other uses, the likelihood of adverse effects on birds from the current uses of mancozeb is considered low.

For chronic exposure, dietary dose-based RQs are based on a no observed adverse effect concentration (NOAEC) of 125 mg/kg-diet and a lowest observed adverse effect concentration (LOAEC) of 1,000 mg/kg-diet. At the LOAEC, reductions in egg production, embryo viability, and egg hatchability were observed.

Scenarios are established for birds feeding on short grass, tall grass, broadleaf plants, fruits/pods/seeds, and arthropods where mancozeb is used on corn, fruiting vegetables, pome fruit, and turf. Chronic RQs from foliar application are estimated using the maximum

application rate, maximum number of annual applications, and with typical application intervals and range from 0.62 to 117 (LOC = 1) based on upper-bound EEC values. All scenarios except animals feeding on fruits/seeds/pods for corn are of concern, with turf generally representing the highest RQs (7.3 to 117, LOC = 1). RQs provided in the 2020 Eco DRA were also estimated for single applications to the registered uses of mancozeb crops at the maximum application rate, of which 16 of 20 scenarios (80%) indicate a risk of concern.

Dose-based chronic RQs from seed treatment applications were also provided for small (20g), medium (100g), and large (1,000g) animals consuming various types of mancozeb-treated seed (cotton, safflower, corn, barley, wheat, rice, oats, rye, sorghum, tomato, peanut, and potato). RQs range from 1.8 to 19, exceeding the LOC for all scenarios.

### Mammals

As the available studies did not show definitive acute toxicity endpoints for mammals (dose-based toxicity endpoints for mammals surpassed the highest doses tested), acute RQs were not calculated. For all uses except turf, acute EECs were below the maximum dose tested. However, acute risks cannot be precluded for turf use at the highest application rate of 17.4 lbs a.i./A, as this represents a higher dose than was tested. For all other registered uses besides turf, EECs are below the maximum dose tested and therefore the likelihood of adverse acute effects are expected to be low.

For chronic exposure, dietary dose-based RQs are based on a no observed adverse effect level (NOAEL) of 120 mg/kg-diet and a lowest observed adverse effect level (LOAEL) of 1,200 mg/kg-diet. At the LOAEC, reductions in bodyweight were observed. Additionally, risk calculations are supported by open literature that suggests NOAELs within 5x of the selected endpoints produce reproductive effects.

Scenarios are established for mammals feeding on short grass, tall grass, broadleaf plants, fruits/pods/seeds, arthropods, and seeds (RQs calculated separately from fruits/pods/seeds group to represent granivores compared with herbivores/insectivores), where mancozeb is used on corn, fruiting vegetables, pome fruit, and turf. Additionally, separate RQs are provided for small (15g), medium (35g), and large (1,000g) mammals. Chronic RQs from foliar application are provided using the maximum application rate, maximum number of annual applications, and with typical application intervals and range from 1.1-912 for small mammals, 0.92-779 for medium mammals, and 0.49-418 for large mammals (LOC = 1) based on upper-bound Kenega values. Chronic dietary RQs range from 0.64 to 122 (LOC = 1). All scenarios except medium and large size mammals feeding on corn seeds are of concern. RQs are also provided for single applications to these crops at the maximum application rate of which 16 of 20 (80%) scenarios remain of concern.

Dose-based chronic RQs from seed treatment applications were also provided for small (15g), medium (35g), and large (1,000g) mammals consuming various types of mancozeb-treated seed

(cotton, safflower, corn, barley, wheat, rice, oats, rye, sorghum, tomato, peanut, and potato). RQs range from 1.4 to 32, exceeding the LOC for all scenarios.

### Terrestrial Invertebrates

EPA relies on data about honey bees as a surrogate for terrestrial invertebrate species. Based on the available data, EPA has determined that mancozeb uses may present risks of concern to honey bees.

Mancozeb is registered on a variety of agricultural and non-agricultural crops, including some that are bee attractive and/or require use of managed pollinators. Both on- and off-field assessments were conducted for mancozeb, as drift from foliar spray may affect bees regardless of whether a crop is attractive or not. Tier I toxicity data are available for mancozeb, with contact and dietary exposure being assessed separately. Mancozeb is not a systemic chemical and is not expected to move within or between plant tissues. Therefore, seed treatment uses were not considered in the 2020 Eco DRA.

### On-field risks to terrestrial invertebrates

RQs for contact exposure (adult honey bees only, contact exposure not expected for larvae) are all <0.1 and not of concern. With no mortality reported, acute oral toxicity studies did not yield definitive acute toxicity and thus acute RQs could not be calculated. A conservative risk estimation was conducted instead by comparing peak EECs to the highest test level used in the acute toxicity test. In this screen, adult acute oral RQs range from 0.35 to 1.4 based on the lowest and highest registered application rates, respectively. Because the high end of this RQ range does exceed the LOC of 1, oral risks to adult honey bees cannot be precluded.

RQs for acute and chronic oral exposure range from 1.4 to 5.2 and 5.4 to 22, respectively, exceeding the LOC for all scenarios modeled.

### Off-field risks to terrestrial invertebrates

Bees are expected to forage in fields adjacent to those treated. Off-field drift models produce RQs that exceed the LOC up to 827 feet from the edge of a treated field. This modeling includes both high and low application rates for bee-attractive crops and the highest application rate, which is for turf.

### Terrestrial Plants

There are no risks of concern to terrestrial plants.

#### *b. Aquatic Risks*

EPA estimated the risks associated with mancozeb use for two identified residues of concern, the parent mancozeb and degradate EBIS (ethylene-bis-isothiocyanate sulfide). EBIS is a major transformation product of EBDC units, which are subject to rapid degradation in soils and aquatic systems (<24 hours). RQs were calculated for freshwater and estuarine/marine fish,

invertebrates (water-column and in sediment), and aquatic plants. Mancozeb and its degradates are expected to reach aquatic habitats from all registered application methods. Aquatic concentrations resulting from spray drift are high enough to be above the chronic LOC up to 900 feet from the edge of field. However, it is noted that this distance results from the highest registered single application rate of mancozeb (turf at 17.4 lbs a.i./A), whereas the majority of other single application rates generally range from approximately 1.5 – 5 lbs a.i./A.

#### Freshwater Fish and Aquatic-Phase Amphibians

Available data indicate that mancozeb is moderately to highly toxic to freshwater fish on an acute exposure basis. However, there are no acute risks of concern. Chronic risks range from <0.01 to 4.4 (LOC = 1), with maximum rate applications to bulb vegetables, cucurbits, turf, and rice (seed treatment) being of concern.

#### Estuarine/Marine Fish

Available data indicate that mancozeb is moderately toxic to estuarine/marine fish on an acute exposure basis. However, there are no acute risks of concern. Chronic RQs range from <0.01 to 1.3 (LOC = 1) with a single risk of concern for application to turf at the maximum rate.

#### Freshwater Invertebrates

There are no risks of concern to freshwater invertebrates, both in the water column as well as the sediment.

#### Estuarine/Marine Invertebrates

Mancozeb is very highly toxic to estuarine/marine invertebrates on an acute exposure basis. For risks in the water-column, acute RQs range from <0.01 to 11 (LOC = 0.5), with risks of concern being present for all foliar treatments except Christmas trees and tropical/sub-tropical fruits. One risk of concern from seed treatment on rice is also present (RQ = 11). Chronic RQs range from <0.01 to 7.3 (LOC = 1), with risks of concern being present for rice seed treatment and four of 16 foliar uses. There are no risks of concern for estuarine/marine invertebrates in sediment.

#### Aquatic Vascular and Non-Vascular Plants

Available studies on vascular aquatic plant exposure to mancozeb did not yield a definitive endpoint and RQs were calculated based on reductions in biomass and growth rate. All RQs for vascular plants are below the LOC of 1. RQs for non-vascular plants range from <0.01 to 41 (LOC = 1) with risks of concern being present for all foliar treatments except Christmas trees. One risk of concern from seed treatment on rice is also present (RQ = 41).

## **2. Ecological Incidents**

EPA reviewed mancozeb incidents reported to the Incident Data System (IDS). As of EPA's latest search on May 29, 2020, IDS showed no incidents reported from June 9, 2015 to May 29, 2020. Prior to June 2015 six incidents were reported, with levels of certainty ranging from unlikely to

probable. The Agency intends to monitor ecological incidents for mancozeb and will conduct additional analyses if necessary.

### **3. Ecological and Environmental Fate Data Needs**

The ecological and environmental fate database for mancozeb is considered complete. No additional data are required to support this registration review decision.

EPA did not identify a risk concern for acute exposure of adult honey bees to mancozeb. However, the available study evaluating chronic risks to adult honey bees was not suitable for risk assessment purposes because the treatment concentrations were not analytically verified. Additionally, acute and chronic risk above the LOC to larval bees were determined from all registered uses. For the acute larval study, risk was based on reductions in survival. For the chronic study, risks were based on decreases in pupal survival and adult emergence. Additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators, based on the Guidance for Assessing Pesticide Risks to Bees (June 2014).

#### **C. Benefits Assessment**

##### *Benefits of Seed Treatments of Mancozeb*

The Agency finds that mancozeb has high benefits as a potato seed piece treatment because it has a broad spectrum of control, including diseases not controlled by other available seed treatment fungicides; it is an important component for resistance prevention; and it is cheaper than alternatives. Mancozeb is one of few available seed treatment fungicides for the bacterial disease, common scab, and the oomycete disease, late blight, in potato seed pieces. Mancozeb is also effective on a number of fungal diseases of potato seed pieces, including dry rot, black scurf, and silver scurf. These diseases can rot seed tubers in storage or once planted in the field, resulting in plant losses if not protected by seed fungicides such as mancozeb during the seed cutting process. Dry rot, black scurf, and late blight have developed resistance to several single-site fungicides used as potato seed treatments, so mancozeb, a multisite fungicide, is important for resistance management for these specific seedborne diseases. Without mancozeb, potato growers could manage scab through cultural controls and could use single-site fungicides for the fungal diseases, but this would increase the risk of development or the spread of fungicide resistance. Growers needing to replace mancozeb would incur greatly increased costs for potato seed treatment because they would need to use multiple single-site fungicides to cover the same disease spectrum and prevent resistance.

The Agency finds that mancozeb has low benefits as a seed treatment in cereals, oil seeds, and all other use sites outside of potato, as extension recommendations do not recommend mancozeb seed treatments and/or stakeholders have indicated that mancozeb is not important in these sites. This is supported by available seed treatment usage data, which finds that mancozeb is not a market-leading fungicide seed treatment in surveyed crops (such as cereal

grains, oilseeds, etc). In these sites, as well as in flax, safflower, tomato, or triticale, benefits are expected to be low due to the availability of a broad variety of disease-resistant cultivars, a relatively narrow spectrum of seed pests, and/or the availability of multiple fungicides recommended for seed treatment.

#### *Benefits of Foliar Use of Mancozeb on Crop Sites*

Mancozeb provides moderate to high benefits to users in most sites and high benefits in some, including many vegetable crops (asparagus, cucurbits, lettuce, pepper, tomato); several field, bulb and root vegetable crops (potato, sugar beet, ginseng, sweet corn, onion, garlic); several orchard crops (apples, pears, walnuts, mango, papaya); and grape and cranberry. Mancozeb supports season-long disease control, particularly in regions where weather (high humidity, rain, and/or optimum temperature for disease development) presents greater disease pressure, and frequent (e.g., weekly) fungicide applications may be needed. Mancozeb may be applied several times, depending on use site and location (few as once or twice up to seven times on average) throughout the growing season alone or in combination with one or more other fungicides. Mancozeb is used for preventative control of a broad spectrum of pathogens. For some applications mancozeb is combined with various single-site fungicides for effective disease control and resistance management. Because single site fungicides are prone to resistance development in target pathogens, mancozeb, which acts on multiple fungal pathways and is therefore at low risk of resistance developing, plays an important role in preventing/delaying resistance to these other fungicides.

In some sites (e.g., potato, tomato, pepper, cucurbits grown in the southeast, upper midwest and/or northeast), chlorothalonil, another multisite fungicide, plays a similar role and the two are used in tandem to provide season-long disease control. Recently, the Agency proposed to reduce the maximum annual application rate of chlorothalonil which effectively constrains or reduces the number of applications growers could make. The benefits of using mancozeb are high for use sites where chlorothalonil use is proposed for annual application rate restrictions (e.g., anticipated to impact tomatoes in the southeast and potatoes grown in the upper midwest). Without mancozeb, some growers could use copper but copper is not very effective in controlling plant diseases and it has been reported to be phytotoxic in many cases. Growers that cannot use copper would be solely reliant on single-site fungicides which increases the likelihood that resistance would develop, compromising control and resulting in yield and quality losses. Further, the single-site fungicides are generally substantially more expensive than mancozeb.

In tomato and pepper, use of mancozeb is also highly beneficial because it provides control of bacterial diseases, which can reduce crop yields and the quality of the produce. Bacterial leaf spot in tomato and pepper has shown resistance to copper, the only other fungicide with activity against bacteria. Therefore, mancozeb is the only effective control method.

The Agency found that use of mancozeb has low or low to medium benefits in almonds, broccoli, cabbage, and grapes grown on the West Coast due to low disease pressure and/or the availability of cost-effective alternatives.

#### *Benefits of Foliar Use of Mancozeb in Turf and Ornamental Plants*

Mancozeb is recommended for a variety of turf diseases in golf courses and non-residential lawns. These diseases cause turfgrass to discolor and possibly die, which affects the aesthetic value of managed turf. In addition to its efficacy in managing its target diseases, mancozeb is important for fungicide resistance management in its target diseases, especially gray leaf spot, for which there are few alternative MOAs and documented resistance issues. Alternative fungicides include chlorothalonil and various single-site fungicides, which have a higher risk of fungicide resistance than chlorothalonil or mancozeb. Mancozeb is not currently a market leading fungicide in turf because chlorothalonil, the current market leader fungicide, is more effective on a broader spectrum of diseases than mancozeb. Chlorothalonil is the best potential alternative to mancozeb; however, the Agency has proposed reducing chlorothalonil's annual application rate on turf, so chlorothalonil may not be a viable alternative if turf managers were unable to use mancozeb. If unable to use mancozeb and chlorothalonil was not available as an alternative, turf managers would need to manage diseases using single-site fungicides, which could increase the risk of fungicide resistance development. The Agency finds that mancozeb currently has moderate benefits in turf, but benefits could increase if chlorothalonil, the next best alternative to mancozeb and current market leader fungicide, is restricted.

Mancozeb is also recommended for a spectrum of ornamental diseases across different use sites in commercial ornamental production, including Christmas trees, and landscape maintenance. Ornamental diseases can cause a variety of symptoms on plants, including leaf spots, needle and stem blights, and rusts, that can reduce plant quality and, under severe circumstances, cause plant death if not managed using fungicides such as mancozeb. Alternative effective multisite fungicides include chlorothalonil and captan but these alternatives may not be effective on all of mancozeb's target diseases or may not be registered for every ornamental plant for which mancozeb is registered. While mancozeb's usage in ornamentals is declining, there could be scenarios where mancozeb is still critically important, such as for specific ornamental plants or diseases where alternative control options are limited. Given its broad spectrum, good efficacy, and a lack of recommended alternatives or a lack of effective multisite alternatives for some diseases, mancozeb likely has moderate benefits in ornamental disease management. As in turf, the Agency has proposed annual application rate reductions for chlorothalonil that could make it infeasible as an alternative to mancozeb on ornamentals, and mancozeb's benefits could increase if chlorothalonil is restricted.

#### **IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION**

The Agency is issuing this PID in accordance with 40 C.F.R. §§ 155.56 and 155.58. Based on the Agency's review of mancozeb at this time in the registration review process, EPA is proposing certain changes to the affected registrations and their labeling to be implemented through

label amendments and/or registration changes. EPA proposes that the mitigations identified in Sections IV.A–B and Appendices A–B will address specific risks of concerns identified at this point in the ongoing registration review process.

At the end of the registration review process, EPA will decide whether each mancozeb pesticide registration “continues to satisfy the FIFRA standard for registration.”<sup>17</sup> However, this PID is not a proposed decision on whether mancozeb registrations continue to satisfy the FIFRA standard for registration and implementing the mitigation proposed in this PID may not be sufficient for EPA to determine that mancozeb registrations do so ultimately. EPA may determine that additional mitigations or other measures are necessary in a subsequent interim determination or its final registration review decision. For mancozeb, EPA has identified in this PID additional information that is needed to complete registration review and will issue a data call-in for that information, as discussed in Section IV.E.

The Agency has not made ESA effects determinations for mancozeb registrations. However, EPA proposes that the mitigation in this PID will reduce environmental exposure to mancozeb and may reduce effects on listed species whose range or critical habitat co-occur with the use of mancozeb. Additionally, EPA has added FIFRA IEM measures in Section IV.B of this PID, which are intended to reduce effects to nontarget organisms, including listed species.<sup>18</sup> EPA also believes that the FIFRA IEM measures proposed in Section IV.B would fulfill EPA’s obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Section 711 requires EPA to “include, where applicable, measures to reduce the effect of the applicable pesticide on” listed species and designated critical habitats in any ID noticed in the Federal Register between December 29, 2022 and October 1, 2026 for which EPA has not “made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)].” 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 taken into account input from USDA and other members of the IWG in developing the FIFRA IEM measures. EPA is also requesting public input on the FIFRA IEM measures described in this PID. The Agency 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 mancozeb. For more information, see Appendix C.

### **A. Proposed Risk Mitigation and Rationale**

EPA has identified risks of concern to human health and non-target organisms from the use of mancozeb products. In the 2024 HH DRA, EPA identified risks to bystanders, occupational

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<sup>17</sup> 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.

<sup>18</sup> EPA has published and taken comment on these mitigations. *See* EPA-HQ-OPP-2022-0908.

handlers, and workers conducting re-entry tasks across a variety of registered mancozeb uses, including foliar applications and seed treatment. Risks of concern from residential and golf course uses are also expected, though these uses were not assessed due to prior agreement to voluntary cancellation by the registrant. In the 2020 Eco DRA, EPA identified risks of concern to nontarget mammals, birds, reptiles, terrestrial-phase amphibians, insect pollinators, freshwater fish, estuarine/marine fish, estuarine/marine invertebrates, and non-vascular aquatic plants from registered mancozeb uses. Mancozeb provides benefits to growers because it controls various fungal, oomycetes, and bacterial diseases in multiple agricultural crops to stabilize crop yield and plays a significant role in resistance management in single site mode of action fungicides. Given the extent of the risks identified, and, where appropriate, considering the benefits of use of mancozeb, the Agency is imposing the following package of mitigation measures to ensure mancozeb use does not present unreasonable adverse effects for human health or the environment.

EPA is also proposing label changes to address generic labeling requirements for all mancozeb products and uses.

## **1. Use Terminations<sup>19</sup>**

### **a. Residential post-application**

Residential post-application risks to adults and children from mancozeb application to residential turf (including parks, schools, and other properties with turf landscaping) is expected to be addressed by limiting the use of mancozeb products to golf courses and commercial sod production. As use on golf courses still represents potential exposure and related risk concerns, the Agency proposes the use be limited to tees, greens, and fairways. The Agency also proposes to prohibit the use on residential ornamentals. These use terminations have been discussed with the registrants and both measures have been voluntarily agreed to.

The Agency expects minimal impacts from the cancellation of residential turf and ornamental uses of mancozeb, as labels already prohibit mancozeb use on residential lawns, and mancozeb may only be applied to residential ornamental plants by a professional applicator (not by homeowners). Limiting the golf course use to tees, greens, and fairways will have no impacts on users as fungicides, like mancozeb, are not applied to roughs and most mancozeb labels already limit golf course applications to tees, green, and fairways.

### **b. Occupational handler – seed treatment**

To address risks to workers from on-farm seed treatment uses of mancozeb, the Agency is proposing prohibition of on-farm seed treatment of peanut and potato with all formulations. To address risks to workers from commercial seed treatment uses of mancozeb, prohibition of commercial seed treatment use is proposed. To address risks to workers from both on-farm and

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<sup>19</sup> Registrants may submit a request to cancel their affected registrations in accordance with Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)).

commercial seed treatment uses of mancozeb, as well as on and off-field risks to birds and mammals and aquatic risk to multiple taxa, prohibition of all seed treatment uses on barley, oat, rice, rye, triticale, and wheat is proposed. With the proposed prohibitions listed in this section, all human health risks of concern that remain can be mitigated via other measures, which are described in the sections below.

Without mancozeb, growers treating potato seed pieces would need to use multiple fungicides to replace it, as mancozeb is the only seed fungicide in potato that controls both late blight and fungal diseases. While using multiple alternatives could lead to a large (i.e., double or triple) increase in the cost of controlling these pathogens, these pest control costs are a relatively small percentage of the per acre costs for potato growers. In the near term, economic impacts may be primarily limited to an increase in pest control costs (1 to 3% per acre), but if resistance develops in pests to the alternatives, such that these pests cannot be adequately controlled, then high yield losses (25% to 60%) are possible in the future.

BEAD expects any restrictions on non-potato seed treatment use sites to be less impactful than in potato due to the availability of a broad variety of disease-resistant cultivars, a smaller spectrum of seed pests than potato, and a greater number of registered fungicides than for potato.

For more details on the impacts of this seed treatment proposal, please see *Mancozeb (PC code 014504) Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Seed Treatment Uses* which available in this docket. To refine risk estimates for seed treatment, the Agency welcomes the submission of new data or other lines of evidence that may be used to refine risk estimates for seed treatment on potato and other seed treatment uses where prohibition is currently proposed. The Agency has developed a list of questions for registrants and stakeholders to determine if chemical-specific use information aligns with the data and assumptions in seed treatment risk calculations. Please refer to section IV. B for more information.

### **c. Occupational handler – foliar treatment**

To address occupational handler risks of concern, including cancer risks of concern, prohibition of the following application method and formulation combinations is proposed:

- Mechanically-pressurized handgun applications of wettable powder, liquid, and dry flowable formulations to typical-acreage field crops
- Mechanically-pressurized handgun applications of wettable powder, liquid, and dry flowable formulations to orchard crops
- Aerial applications of all formulations to sod (will also address cancer risks of concern)
- Aerial applications of wettable powder formulations to high-acreage<sup>20</sup> field crops

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<sup>20</sup> High-acreage field crops include the following crops currently listed on mancozeb labels: barley, field/popcorn, peanuts, potato, rye, wheat, triticale, oats, sugar beet.

For these cases, maximum PPE would not fully address the risks of concern. Moreover, prohibiting mechanically-pressurized handguns is anticipated to have minimal impact on users of mancozeb in most sites. However, Hawaii papaya growers may be impacted as these growers may utilize mechanically pressurized handguns to apply mancozeb. The prohibition of aerial applications in sod is not anticipated to impact sod producers as aerial applications of mancozeb are not anticipated to occur or if they do, they are rare; most applications are made via groundboom equipment pulled behind a tractor<sup>21</sup>.

#### **d. Occupational post-application**

To address risks to workers entering treated grape fields, the Agency is proposing to cancel mancozeb use on all types of grapes (including table, wine, juice, and raisin). Multiple grape activities show failing MOEs of 190 (LOC = 300) at 30 days post-treatment. A restricted-entry interval (REI) long enough to bring MOEs above the LOC would render mancozeb use on grapes impractical.

If mancozeb is unavailable in grape, growers would have to rely on single site fungicides (such as myclobutanil) to control black rot that could increase fungicide costs and affect fungicide resistance management in this disease. . For more information on the expected impacts to grapes see the supporting document *Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Foliar Uses in Apples, Pears, Almonds, Walnuts, Mango, Papaya, Grapes, and Cranberry*.

### **2. Spray Drift Reduction Measures for Non-Occupational Bystanders**

To address risks to non-occupational bystanders in residential areas adjacent to treated fields, the Agency is proposing the following requirements:

When using aerial equipment to apply mancozeb products to orchard and typical-acreage field crops adjacent to residential areas a 25-foot buffer from the edge of the treated field is required. Additional spray drift mitigation (e.g., medium to coarser droplet size) will also apply to all use sites but these are discussed in subsection 7 below and in the FIFRA IEM section (Section IV.B.). Impacts of proposed spray drift mitigation are also discussed in the FIFRA IEM section below.

### **3. Personal Protective Equipment and Engineering Controls**

The Agency proposes adding a respirator statement to mitigate potential dermal and inhalation exposure risks to occupational handlers for pesticides covered by the Worker Protection

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<sup>21</sup> Turfgrass Producers International (TPI). 2021. Responses to EPA's inquiry for Turfgrass Producers International Regarding Mancozeb Usage, Application Methods, and Alternatives for Sod. Provided from Casey Reynolds, Executive Director, TPI to Murphey Coy on October 1, 2021.

Standard (WPS),<sup>22</sup> and proposes adding any associated fit test, training, and medical evaluation requirements.<sup>23</sup> Affected scenarios are included in the PPE scenario descriptions below.

**a. Clothing and Gloves Requirement for Mancozeb Handlers:**

To address occupational handler scenarios that require dermal PPE to reach passing MOEs, EPA is proposing requirements for double layer clothing and gloves as universal PPE on all labels for all scenarios.

**b. APF10 Respirator Requirement for Certain Handlers**

To address occupational handler mixer/loader scenarios that require inhalation PPE in addition to dermal PPE of double layer clothing plus gloves to reach passing MOEs, EPA is proposing to require APF10 respirators for the following scenarios (listed by formulation, application method, and crop/crops):

- Dry flowable, aerial, nursery
- Dry flowable, airblast, orchard crops
- Dry flowable, chemigation, greenhouse, nursery, and high-acreage field crops
- Dry flowable, groundboom, nursery, greenhouse, orchard, typical-acreage field crops, and high-acreage field crops
- Liquid, aerial, orchard, typical-acreage field crops, and high-acreage field crops
- Liquid, chemigation, orchard and typical-acreage field crops
- Liquid, ground boom, sod
- Wettable powder, chemigation, high-acreage field crops
- Wettable powder, ground boom, typical-acreage field crops, and high-acreage field crops
- Dust/powder, on-farm seed treatment, safflower

To address occupational handler mixer/loader/applicator scenarios that require inhalation PPE in addition to dermal PPE of double layer clothing plus gloves to reach passing MOEs, EPA is proposing to require APF10 respirators for the following scenarios (listed by formulation, application method, and crop):

- Dry flowable, mechanically-pressurized handgun, greenhouse and nursery crops
- Liquid, mechanically-pressurized handgun, greenhouse and nursery crops
- Wettable powder, mechanically-pressurized handgun, greenhouse and nursery crops
- Water-soluble packet, mechanically-pressurized handgun, greenhouse and nursery crops

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<sup>22</sup> 40 C.F.R. pt. 170

<sup>23</sup> Pursuant to 40 C.F.R. pt. 170, EPA requires fit testing (29 C.F.R. § 1910.134), training (29 C.F.R. § 1910.134(k)(1)(i)-(vi)), and medical evaluations (29 C.F.R. § 1910.134)—conducted in accordance with the cited OSHA regulations—for all handlers that are required to wear respirators and whose work falls within the scope of the WPS. Label Review Manual at Ch. 10, App. A, <https://www.epa.gov/pesticide-registration/label-review-manual>.

To address risks to workers from on-farm seed treatment to safflower using dust/powder formulations, a APF10 respirator requirement is proposed.

Requiring a respirator and any associated fit testing, training, and medical evaluation may impose a cost on handlers or employers. These are further discussed in subsection e.

**c. Closed-Loading System Requirement for Certain Handlers**

To address occupational handler mixers/loader scenarios that require dermal PPE beyond double layer clothing and gloves to reach passing MOEs, EPA is proposing to require closed loading systems plus gloves for mixers/loaders of liquid formulations for chemigation application to sod.

A closed system requirement for chemigation applications of the liquid formulation of mancozeb on sod is not anticipated to impact sod producers because chemigation is not anticipated to be an application method utilized by sod producers. As per input received from the Turfgrass Producers International, the most typical method of applying mancozeb to sod is by ground boom pulled behind a tractor<sup>21</sup>.

**d. Enclosed Cab Requirement for Certain Handlers**

To address occupational handler applicator scenarios that require dermal PPE beyond double layer clothing plus gloves to reach passing MOEs, EPA is proposing requirements for closed-cab equipment plus gloves for the airblast applicator scenario for all formulations to nursery and orchard crops.

The requirement that airblast applicators utilize an enclosed cab is anticipated to have high impacts on growers who do not already own an enclosed cab. Applicators who do not already have the appropriate equipment would either have to purchase the equipment, retrofit their current machinery, or hire a commercial firm with the equipment to make mancozeb applications. All of these options increase the cost of using mancozeb unless applicators already own equipment with an enclosed cab. This will affect smaller farmers more than larger farmers because they have fewer acres over which to spread the fixed cost. In most crops (e.g., apples, pears) for which airblast applications are used, more costly single site alternatives may be used in place of a mancozeb application but additional use of these chemistries could compromise resistance management. The Agency recognizes that the enclosed cab requirement for airblast applications has also been proposed for captan, which is another fungicide that is used and beneficial in some orchard crops<sup>24</sup>; this is relevant because apple growers for example may

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<sup>24</sup> [Captan Amended Proposed Interim Registration Review Decision](#)

already be subject to this requirement if also using captan. For more information on the expected impacts to grapes see the supporting document *Registration Review: Assessment of Use, Usage, Benefits and Impacts of Potential Mitigation for Foliar Uses in Apples, Pears, Almonds, Walnuts, Mango, Papaya, Grapes, and Cranberry*.

**e. APF10 Respirator and Closed-loading System Requirement for Certain Handlers**

To address occupational handler mixer/loader scenarios that require inhalation PPE and dermal PPE beyond double layer clothing plus gloves to reach passing MOEs, as well as to address cancer risks of concern, EPA is proposing requirements for APF10 respirators and closed-loading systems for the following scenarios (listed by formulation, application method, and crop):

- Dry flowable, aerial, orchard, typical-acreage field crops, and high-acreage field crops
- Dry flowable, chemigation, orchard and typical-acreage field crops
- Dry flowable, groundboom, sod and golf course (fairways, tees and greens)
- Wettable powder, aerial, orchard and typical-acreage field crops
- Wettable powder, chemigation, orchard and typical-acreage field crops
- Water-soluble packet<sup>25</sup>, groundboom, golf course (fairways, tees, greens only)

Requiring a respirator and any associated fit testing, training, and medical evaluation may impose a cost on handlers or employers. If a mancozeb handler currently does not have a respirator, additional costs will be incurred by the handler or the handler's employer, including the cost of the respirator and any required respirator fit test, training, and medical exam.<sup>26</sup>

EPA's HHRA assumes National Institute for Occupational Safety and Health (NIOSH) protection factors<sup>27</sup> in estimating the inhalation risks and the risk reduction associated with different respirators.<sup>28</sup> If the respirator does not fit properly, EPA's proposed PPE mitigation for mancozeb may not reduce risks as detailed above and may result in unreasonable adverse effects for the pesticide handler.

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<sup>25</sup> Water soluble packets are already considered a closed system; therefore, this scenario only requires the addition of a PF10 respirator.

<sup>26</sup> Respirator costs are variable, depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates filtered. For example, the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. APF10 or Assigned Protection Factor 10 (APF10) respirators include N95 masks, which are readily available. Under the Worker Protection Standard, users of respirators are required to have a fit test done annually. In 2024, EPA estimated that the annual cost of the WPS requirements (respirator fit test, training, and medical exam) was approximately \$350 per worker. Costs may be different if a mancozeb handler typically uses other chemicals requiring a respirator in the production system or as part of the business (e.g., eliminated cost of additional fit testing, increased cost of purchasing filters for the respirator on a more frequent basis).

<sup>27</sup> NIOSH protection factors assume that respirators are used according to OSHA's standards.

<sup>28</sup> Proper fit and use of respirators is essential to accomplish the protections respirators are intended to provide. Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection. 29 C.F.R. § 1910.134.

A closed system for the dry flowable and wettable powder formulations may entail that the pesticide be enclosed in a water-soluble packet that can then be mixed with water within the pesticide delivery system. Then the container is closed to protect the worker as the packet and pesticide dissolves in water. This requirement means the product cost is likely to increase due to packaging costs and these costs may be passed to growers. Additionally, packages mean that the pesticide would be sold in discrete amounts and therefore could further lead to increased costs and increased complications of disposing of excess pesticide. Moreover, agitation equipment may also be required to ensure the product mixes in water uniformly but does not expose the mixer/loader. Alternatively, growers who currently utilize the dry flowable or wettable powder formulations may opt to switch to the liquid formulation of mancozeb if the closed system (water soluble packet) requirement substantially increases the costs and/or ease of use of the dry flowable and wettable powder formulations. Over the 2017-2021 period, the most commonly used formulation type by mancozeb users was the dry flowable (includes water dispersible granules) formulation<sup>13</sup>. Growers of many crops may have opted to utilize this formulation because the cost is a fraction of (in some cases half) the cost of the liquid formulation on a per acre basis<sup>13</sup>. However, there may be other reasons that growers prefer this formulation method (e.g., length of storage) but there is some uncertainty here because the Agency is not aware of other reasons growers may opt for the dry flowable formulation of mancozeb. In either scenario, growers are anticipated to bear an increased cost of use of mancozeb when the closed system requirement applies.

#### **4. Changes to Restricted-Entry Intervals (REIs)**

Current mancozeb labels require a 12 to 48-hour REI depending on the crop or use site. Risks to workers performing re-entry tasks would be addressed by the addition or lengthening of existing restricted-entry intervals (REIs) for certain crops and activities, and the prohibition of certain re-entry activities. These REIs would be expressed in the number of days workers must wait after the application of mancozeb products until re-entry into the treated field is permitted. A list of the proposed REIs is below:

- Almond – 4 days for all activities
- Pome Fruits (apple, crabapple, pear, quince), sapodilla, and sapote – 4 days for all activities and the prohibition of hand-thinning fruit
- Broccoli – 6 days for all activities
- Cabbage – 6 days for all activities
- Christmas tree – 29 days for hand harvesting and hand-set irrigation<sup>29</sup>
- Corn, sweet, grain – 10 days for all activities
- Cranberry – 4 days for all activities
- Cucurbit Vegetables (cantaloupe, cucumber, gourd, pumpkin, squash, melons, and squash) – 3 days for all activities

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<sup>29</sup> Handset irrigation is the moving of irrigation lines in agricultural crops. Workers typically move sections of irrigation pipes (e.g., 40-foot sections), through large areas of the treated foliage (e.g., approximately 20 rows) and then reassemble the pipes and check fittings.

- Subtropical/Tropical Fruit (mango, papaya, sugar apple, cherimoya, atemoya, custard apple, sweetsop, canistel, mamey sapote, sapodilla, tangerine, white sapote, banana, plantain, sweetsop, star apple [caimito]) – 4 days for all activities and prohibition of hand-thinning fruit
- Onion (green and bulb), garlic, leek, shallot – 3-days for handset irrigation activities; 9-days for hand weeding
- Pepper, bell – 3 days for all activities
- Pepper, chili – 3 days for all activities
- Sod – 7 days for all activities
- Tomato – 3 days for all activities

The Agency assessed the potential impacts that the proposed REIs could have on these crops. In most situations, proposed REIs are expected to be manageable but will require growers to do advanced planning so that any time sensitive production activities can be scheduled prior to an application or can wait until the REI expires. However, growers may experience impacts if unplanned circumstances occur such as a breakdown in an irrigation system just after a mancozeb application is made; if a grower must wait several days to enter the field to resolve the issue, this could be problematic.

For longer REIs, such as those in corn and onion (bulb and green, garlic, leek, shallots) production, the extended reentry period would prevent time sensitive pest scouting and control, which may preclude the use of mancozeb in those crops. Because many of the REIs exceed 48 hours, growers or operators may then be required to post signage to prevent workers from entering a treated field per the Worker Protection Standard. This requires the labor time to post and the costs for the signage if a grower does not already own signage.

In the case of prohibiting hand-thinning in pome fruit crops, this is not anticipated to be impactful because these crops are chemically thinned and do not require hand-thinning. Similarly, disallowing hand-thinning in tropical fruit (e.g., mango) is not anticipated to have an impact on typical production practices.

## **5. Nontarget Organism Advisory Statements**

EPA is proposing nontarget organism advisory statements to reduce nontarget risk concerns for mancozeb. These include risk concerns for terrestrial organisms, including mammals, birds, and pollinating insects. Based on the incomplete data available, EPA is uncertain how much risk mancozeb presents to pollinators, which may be exposed to mancozeb from residues in pollen or nectar through spray drift. EPA prioritizes protecting pollinators, including by reducing spray drift and educating growers about potential indirect adverse effects of pesticides (including mancozeb) on foliage and habitat of nontarget organisms.

## 6. Resistance Management

The Agency proposes adding resistance-management language to mancozeb labels<sup>30</sup> to address pesticide resistance.<sup>31</sup> Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management,<sup>32</sup> EPA proposes pesticide resistance measures for existing chemicals during registration review and for new chemicals and new uses at the time of registration. To combat pesticide resistance, resistance management experts recommend using pesticides with different chemical modes (or mechanisms) of action against the same target pest population as part of integrated pest management (IPM) programs. This approach may prevent or delay target pest populations from developing resistance to a particular mode (or mechanism) of 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 mancozeb—thereby preserving the benefits of mancozeb and other useful pesticides.<sup>33</sup>

## 7. Spray Drift Management

The Agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all mancozeb products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Spray drift mitigation will also address human health risks to bystanders.

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

- Applicators must not spray during temperature inversions.

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<sup>30</sup> For specific label language, see Appendix B.

<sup>31</sup> 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. The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. Currently, there are over 250 weed species worldwide with confirmed herbicide resistance, including over 155 weed species in the United States with confirmed resistance to one or more herbicides. For more details, see PRN 2017-1 and PRN 2017-2, available at <https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year>.

<sup>32</sup> 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>.

<sup>33</sup> For a detailed discussion of mancozeb's benefits, see Section III.C, above. Resistance-management language is already on many mancozeb labels, but the label mitigation is most effective when all product labels reflect resistance-management best practices.

- Do not apply when wind speeds exceed 10 mph at the application site based on human health non-occupational spray risk concerns.
- If maximum wind speed is 10 mph: Aerial applicators must use ½ swath displacement upwind at the downwind edge of the field.
- If maximum wind speed is 10 mph, use: 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.
- For aerial applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- For ground applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- For airblast applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- For ground and aerial applications, applicators must select nozzle and pressure that deliver medium or coarser droplets as indicated in accordance with American Society of Agricultural & Biological Engineers Standard 572 and Standard 641 (ASABE S572 for ground application and ASABE S641 for aerial applications).
- For airblast applications, nozzles directed out of the orchard must be turned off in the outer row.
- For airblast applications, applications must be directed into the canopy foliage.

The Agency is proposing a restriction on droplet size because coarser droplets have been demonstrated to decrease spray drift, and therefore, reduce potential risks to non-target species. However, coverage tends to decline with larger droplets because the droplets hold together rather than spread out over the foliage which could result in a potential reduction in efficacy. As a contact fungicide, mancozeb's efficacy is dependent on coverage. Generally, fungicides are applied using fine to medium droplets<sup>34</sup>. Because of this, the Agency anticipates that growers can use a medium droplet size for mancozeb applications without experiencing reductions in efficacy. However, chemical-specific data for the performance of droplet sizes is limited. EPA was not able to evaluate the effects of medium or coarser droplet sizes specifically for mancozeb. Therefore, EPA does not know the effect this requirement will have on the performance of mancozeb across various use patterns, especially regarding tank mix partners that require a finer droplet size. If a grower were to experience decreased efficacy in the case of mancozeb, growers could compensate by increasing application rates, if allowed by the label, or make additional fungicide applications which could increase the cost of control. EPA

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<sup>34</sup> Grisso, R., Askew, S.D., McCall, D. 2019. Nozzles: Selection and Sizing. Virginia Tech. <https://www.pubs.ext.vt.edu/442/442-032/442-032.html>

encourages comments on any potential impacts to growers from specifying a mandatory minimum droplet size and other spray drift measures on product labels.

Regarding the 10 mph windspeed restriction, wind conditions vary across the U.S. and wind speed restrictions could prevent timely applications of mancozeb. Currently some mancozeb labels require that an applicator not make an application when the windspeed is greater than 15 mph. Mandatory wind speed restrictions complicate pest and crop management by reducing the available time to make applications and make it more likely that a grower may need to alter pest control plans. Changing plans may result in additional costs. If applications are not made in a timely manner, pest control could decline, potentially leading to additional applications, which may result in yield losses, and/or accelerate the development of resistance. In the case of fungicides in particular, disease prevention and early control are critically important because irreversible crop damage can occur very quickly if a disease goes uncontrolled. The Agency welcomes comments from growers and applicators about their fungicide application practices considering wind speeds.

Regarding the proposed spray release height, it is important to obtain proper coverage. If nozzles are placed too low, the spray pattern may be too narrow, and coverage could be uneven. A grower may have to purchase new nozzles to accommodate a spray height. However, a review of manufacturer recommendations found that many nozzles and spray equipment require release heights of 2 ft or greater<sup>35</sup>, so a 3 ft release height for groundboom applications should not be impactful to most growers. For aerial applications, the agency considers this to be standard application practice and does not anticipate any impacts from the requirement for a 10 ft release height.

For airblast applications, the requirement to turn off the nozzles directed out of the orchard and requiring applications to be directed into the canopy foliage is expected to have little impact on growers, as these are already standard practices.

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

#### **8. Label update for all liquid products where there are mixers and loaders involved in mixing a liquid chemical concentrate**

Results from a 2019 study by the Agricultural Handler Exposure Task Force (AHETF), a consortium of pesticide manufacturing companies, indicate that incorrect probe extraction for suction/extraction systems, resulted in direct exposure to liquid chemical concentrate for

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<sup>35</sup> Tindall, K. and Hanson, C. 2018. Qualitative Benefits and Usage Assessment of Diflufenzopyr (PC Code 005108) and Diflufenzopyr-Sodium (PC Code 005107). Available at: <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0911-0022>

mixers and loaders. This monitoring data measured high exposure to the liquid concentrate, when mixers/loaders removed chemical extraction probes in suction/extraction systems, without rinsing them prior to removal from the pesticide container. The AHETF submitted the dataset to the Agency that excludes monitoring of those workers who handled unrinsed chemical extraction probes and recommended that the Agency take additional regulatory actions to ensure workers do not remove and handle chemical extraction probes still coated with the concentrated liquid formulation. Reflecting the results of the 2019 task force data and also to ensure that all mixers and loaders of liquid formulations are protected from direct exposure to liquid concentrate, EPA is proposing the following label language to be included on all liquid formulation product labels for mixers and loaders:

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

### **B. Seed Treatment Questions**

In 2022, EPA updated the Seed Treatment Policy 14.1<sup>36</sup> to incorporate more contemporary and reliable data than previous seed treatment worker exposure assessments. The update resulted in higher worker exposure estimates than in previous risk assessments. When all else is equal from previous assessments (e.g., toxicity reference values are the same), there has been a large increase in the estimated dermal and/or inhalation risks of concern for workers conducting seed treatment activities. The Agency has developed a list of questions for registrants and stakeholders to determine if chemical-specific use information aligns with the data and assumptions supporting the Policy 14 Update. The questions are divided by seed treatment risk scenario and include cleaning, treating, loading/planting, and packaging in commercial seed treatment facilities. Each scenario includes the description of the data used to assess the risk and is followed by a list of chemical-specific use questions.

#### **Soliciting seed treatment information - for the *cleaning scenario***

For mancozeb, potential risks of concern have been identified for those who clean seed treatment equipment. This worker subset has not been systematically evaluated for pesticide exposure and risk by EPA in the past because sufficient data were not available on which to base such evaluations. Recently, data on the pesticide exposures of cleaners of seed treatment equipment became available and have been reviewed by the Agency. Based on data from these studies, the potential exposures of these workers, who we will refer to as “cleaners” are far greater than any other *commercial* seed treatment activity (mixer/loaders, treaters, and packagers).

The studies of exposure to cleaners of seed treatment equipment were based on:

- Closed system for treating seed:

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<sup>36</sup> [https://www.epa.gov/system/files/documents/2022-01/exposac-policy-14\\_seed-treatment-exposure-data.pdf](https://www.epa.gov/system/files/documents/2022-01/exposac-policy-14_seed-treatment-exposure-data.pdf)

- Single batch treaters
- Continuous-batch treaters
- Equipment had treated the following seed types before it was cleaned:
  - Cotton
  - Canola
  - Corn
  - Barley
  - Maize
  - Oats
  - Wheat

Risks of concern were identified for cleaners who clean equipment after the commercial treatment of the following seed types:

- Barley
- Cotton
- Field corn
- Flax
- Oat
- Peanut
- Rice
- Rye
- Safflower
- Sorghum
- Tomato
- Triticale
- Wheat

Questions for stakeholders:

- Does your seed treatment equipment require cleaning? If so, describe in detail the process by which your machine to treat seeds is cleaned.
- How representative are the types of equipment used in the exposure studies<sup>36</sup> to treat seeds in your area?
  - What other types of equipment are in use?
  - How do other types of equipment differ in how they are cleaned from single and continuous batch treaters?
  - Schematics, photos, and videos of the equipment are appreciated.
- Describe how seed treatment equipment differs, particularly with respect to how they are cleaned, that treat small seeds (e.g., many vegetables) and large seeds (e.g., cotton or corn).
- Describe the clothing and/or PPE that the cleaner wears when cleaning equipment and name/describe the type of seed treater.
- How many hours in one workday does a person spend cleaning equipment?
- How many days per year does a person spend cleaning equipment?

- Do you use the maximum label application rate on the [type/use] seeds?
- If you do not use the maximum label application rate, what is the maximum rate used to treat [type/use] seeds?
- What is the average (“typical”) rate used to treat [type/use] seeds?
- What is the median rate (some XX<sup>th</sup> percentile) used to treat [type/use] seeds?

### **Soliciting seed treatment information - for the *treating scenario***

For mancozeb, potential risks of concern have been identified for those individuals who treat seeds. Individuals who treat seeds with pesticides will be referred to as “treaters.” The treating scenario represents any possible commercial seed treatment (CST) workday during which CST worker exposure is the result of performing any combination of packaging, treating, or cleanout tasks, but not exclusively packaging or exclusively cleanout. This “treater” scenario includes several tasks that are very critical to the CST process and generally involve just a few specially trained workers at each facility, including mixing and loading chemical, calibrating the treater, treating/coating the seed and sampling “wet” treated seed. This worker subset has not been specifically evaluated for pesticide exposure and risk by EPA in the past because sufficient data were not available on which to base such evaluations. Recently, data on the pesticide exposures of treaters became available and have been reviewed by the Agency and are now implemented in the updated Policy 14.

The studies of exposure to treaters were based on:

- Closed system for treating seed:
  - Continuous flow treaters
  - Single batch treaters
  - Continuous-batch treaters
- Treaters working with the following seed types (range of pounds of seed treated):
  - Barley (163,803 – 289,908)
  - Canola (29,829 – 142,378)
  - Corn (33,656 – 349,383)
  - Cotton (12,250 – 121,455)
  - Maize (58,422 – 96,562)
  - Oats (72,312)
  - Oilseed rape (19,511 – 62,082)
  - Wheat (61,895 – 189,597)
- Exposure to liquid formulations of fungicides and insecticides

Risks of concern were identified for commercial treaters who had treated the following seed types:

- Barley
- Cotton
- Field corn

- Flax
- Oat
- Peanut
- Potato
- Rice
- Rye
- Safflower
- Sorghum
- Triticale
- Wheat

Questions for stakeholders:

- How prevalent is the use of liquid versus solid (dust) formulations on each type of seed that you treat?
- Is one formulation preferred over the other? If so, why? Please list the type of seed when providing a preference for a formulation.
- Given that “treaters” who were monitored in exposure studies performed multiple activities that included some equipment cleaning and seed packaging as well as mixing and loading chemicals, calibrating the treater, treating/coating the seed, and sampling “wet” treated seed, please describe in detail all the activities performed by a worker who is a designated seed treater in your treatment facility. (Please do not include details for workers who exclusively clean equipment or package seeds.)
- Please describe the PPE worn by the worker who is the designated treater in your operation when they treat seed.
- Do you use the maximum label application rate for [type/use] seeds?
- What is the maximum rate used to treat [type/use] seeds?
- What is the average (“typical”) rate used to treat [type/use] seeds?
- What is the median rate (some XX<sup>th</sup> percentile) used to treat [type/use] seeds?
- For **small-seeded vegetables**, the Agency assumes that 3,000 pounds (lbs) of seed are treated per day by one worker. For the types of small-seeded vegetables that are treated in your facility, how many lbs of small-seeded vegetable seeds are treated by each worker in an eight-hour day? Please state the type of small-vegetable seed when providing an estimate of weight.
- For **large-seeded vegetables** (e.g., beans, squash, watermelon, pea, cowpea, and pumpkins), the Agency assumes that 339,500 lbs of seed are treated by each worker in one eight-hour day. For large-seeded vegetables treated in your facility, how many lbs of large-seeded vegetable seeds are treated by each worker in an eight-hour day? Please state the type of large-vegetable seed when providing an estimate of weight.
- For other non-vegetable seeds treated in your facility, please provide an estimate of weight treated by a worker in an eight-hour day. Please state the type of seed treated when providing your estimate.

### **Soliciting seed treatment information - for the *loading/planting scenario***

For mancozeb, potential risks of concern have been identified for those individuals who load and plant treated seeds. Individuals who load and plant seeds with pesticides will be referred to as “loader/planters.” Workers in the exposure studies were monitored while both loading treated seed and planting the treated seed. Separate samples were not taken during each activity. Therefore, it is not possible to differentiate exposure from the loading versus the planting activity. Workers typically performed other tasks in addition to driving the tractor through the field while planting, such as making sure that the seed is properly planted (e.g., by checking seed depth and making adjustments or repairs as needed) or leveling the seed in the hopper as needed. It would also include any ‘background’ exposure such as contact with contaminated surfaces or equipment in the workday environment. This worker subset has not been specifically evaluated for pesticide exposure and risk by EPA in the past because sufficient data were not available on which to base such evaluations. Recently, data on the pesticide exposures of loader/planters became available and have been reviewed by the Agency and are now implemented in the updated Policy 14.

The studies of exposure to loader/planters were based on:

- Treated seed loading techniques:
  - forklift
  - manual pour
  - container lift
- Planting equipment:
  - pneumatic
  - conventional
- Workers loaded and planted the following seed types (acres planted by seed type).
  - Corn 13.6 – 101.6 acres
  - Wheat 12.4 – 46.9 acres

Risks of concern were identified for commercial loader/planters who had loaded/planted the following seed types:

- Barley
- Cotton
- Field corn
- Flax
- Oat
- Peanut
- Potato
- Rice
- Rye
- Safflower

- Sorghum
- Triticale
- Wheat

Questions for stakeholders:

- Given that “loaders/planters” who were monitored in exposure studies performed multiple activities that included some short periods of equipment cleaning and repairing, checking seed planting depth, and leveling seed in the hopper, please list and describe in detail all the activities performed by a worker who is designated to load/plant in your operation.
- Describe how treated seeds are loaded into the planter in your operation. Please state the type of seed that is loaded with this method.
- Describe the planting equipment used to sow seeds. Please state the type of seed that is sown with this method.
- To the best of your knowledge, please describe how loading/planting treated corn and wheat seeds is **different** than loading/planting treated seeds in use in your operation. Please state the type of seed in your response.
- Do you use the maximum label application rate to treat [type/use] seeds?
- What is the maximum rate used to treat [type/use] seeds?
- What is the average (“typical”) rate used to treat [type/use] seeds?
- What is the median rate (some XX<sup>th</sup> percentile) used to treat [type/use] seeds?
- The Agency assumes that 61, 80, and 200 acres are planted by a loader/planter in one eight-hour day for potatoes, vegetables and other specialty annual crops, and large acreage field crops (i.e., alfalfa, some beans, sugar beets, canola, field and pop corn, cereal grains, cotton, mint, rice, and soybean), respectively. How many acres are planted by a loader/planter in your operation? Please state the type of seed planted.
- The Agency assumes a high-end seeding density (or number of seeds/acre) for each type of seed in its models of dermal and inhalation exposure to loader/planters. The current assumptions for seeding density are found in Table 3.1 (pages 16-18) in Policy 15: [https://www.epa.gov/system/files/documents/2022-01/exposac-policy-15\\_amount-seed-treated-planted.pdf](https://www.epa.gov/system/files/documents/2022-01/exposac-policy-15_amount-seed-treated-planted.pdf)
  - There are more types of seeds with their associated seeding density listed in the worksheet named “Amount Seed Planted\_variables” in the seed treatment calculator (Microsoft Excel file). Look at values in Column ‘D’.  
[https://www.epa.gov/system/files/documents/2022-02/seed-treatment-and-planting-exposure\\_mar2022.xlsx](https://www.epa.gov/system/files/documents/2022-02/seed-treatment-and-planting-exposure_mar2022.xlsx)
  - What is the highest seeding density used in your operation? Please state the type of seed planted at this density.

**Soliciting seed treatment information – for the *packaging scenario***

For mancozeb, potential risks of concern have been identified for those individuals who package treated seeds. Individuals who packaged treated seeds with pesticides will be referred to as “packagers.” The packaging scenario represents any possible commercial seed treatment

(CST) workday during which CST worker exposure is the result of performing one or more packaging tasks, but none of the treating or cleanout tasks. The packaging-related tasks identified include bagging, closing/sewing, tagging, stacking, and moving packaged seed via forklift. Worker-day exposure associated with these scenario-specific tasks is expressed relative to the amount of active ingredient handled. Recently, data on the pesticide exposures of packers became available and have been reviewed by the Agency and are now implemented in the updated Policy 14.

The studies of exposure to packagers were based on:

- Types of packaging that contained treated seeds handled by workers:
  - small bags
  - mini-bulk containers
  - loose bulk containers
- Types of bagging/stacking systems
  - automated
  - semi-automated
  - manual
- Packagers working with the following seed types (range of pounds of seed treated):
  - Barley (163,803 – 289,908)
  - Canola (29,829 – 142,378)
  - Corn (33,656 – 349,383)
  - Cotton (12,250 – 121,455)
  - Maize (58,422 – 96,562)
  - Oats (72,312)
  - Oilseed rape (19,511 – 62,082)
  - Wheat (61,895 – 189,597)

Risks of concern were identified for treaters who had treated the following seed types:

- Barley
- Cotton
- Field corn
- Flax
- Oat
- Peanut
- Potato
- Rice
- Rye
- Safflower
- Sorghum
- Triticale
- Wheat

Questions for stakeholders:

- How prevalent is the use of liquid versus solid (dust) formulations on each type of seed that you treat?
- Is one formulation preferred over the other? If so, why? Please list the type of seed when providing a preference for a formulation.
- Given that “packagers” who were monitored in exposure studies performed multiple activities that included bagging, closing/sewing, tagging, stacking, and moving packaged seed via forklift, please describe in detail all the activities performed by a worker who is a designated packager in your treatment facility. (Please do not include details for workers who exclusively clean equipment or treat seeds.)
- Please describe the PPE worn by the worker who is the designated packager in your operation when they package seed.
- Please describe the type of packaging that contain treated seeds handled by the designated packager and state the type of seed in that packaging.
- Please describe the bagging/stacking (e.g., automated, semi-automated, manual) system in your operation and state the type of seed that uses this system.
- Do you use the maximum label application rate for [type/use] seeds?
- What is the maximum rate used to treat [type/use] seeds?
- What is the average (“typical”) rate used to treat [type/use] seeds?
- What is the median rate (some XX<sup>th</sup> percentile) used to treat [type/use] seeds?
- For **small-seeded vegetables**, the Agency assumes that 3,000 pounds (lbs) of seed are packaged per day by one worker. For the types of small-seeded vegetables that are packaged in your facility, how many lbs of small-seeded vegetable seeds are packaged by each worker in an eight-hour day? Please state the type of small-vegetable seed when providing an estimate of weight.
- For **large-seeded vegetables** (e.g., beans, squash, watermelon, pea, cowpea, and pumpkins), the Agency assumes that 339,500 lbs of seed are packaged by each worker in one eight-hour day. For large-seeded vegetables packaged in your facility, how many lbs of large-seeded vegetable seeds are packaged by each worker in an eight-hour day? Please state the type of large-vegetable seed when providing an estimate of weight.
- For other non-vegetable seeds treated in your facility, please provide an estimate of weight packaged by a worker in an eight-hour day. Please state the type of seed when providing your estimate.

**Soliciting seed treatment info, for use in affected PIDs—for the *on farm treating/planting (OFST-P) scenario***

For mancozeb, potential risks of concern have been identified for those individuals who are on farm to treat, load, and plant seeds. Seeds in this scenario are treated with a liquid or solid formulation of mancozeb and are labeled as OFST-P/L or OFST-P/S, on-farm seed treatment and planting for products formulated as liquids (OFST/P-L) or for products formulated as solids (OFST/P-S). In the exposure studies, workers were monitored for pesticide exposure while

treating, loading, and planting seeds. However, separate samples were not taken during each activity. Therefore, it is not possible to differentiate exposure from the treating, loading, and the planting activities. Workers often performed other tasks that may have included maintenance, cleaning of nozzles, checking seed depth at planting, among others. Recently, data on the pesticide exposures of OFST-P/L and OFST-P/S became available, have been reviewed by the Agency and are now implemented in the updated Policy 14.

Because the workers in the exposure study used open loading systems to treat seeds, the OFST/P-L and OFST/P-S dataset are used to represent **open loading systems** only.

The following seed types and amounts were used in the studies to measure on-farm worker exposure:

- Treating and planting **cotton** seeds (with solid formulation pesticide): 640 – 1,480 lb seed treated and 64 – 213 acres planted
- Treating and planting **wheat** seeds (with liquid formulation pesticide): 3,901 – 59,380 lb seed treated and 16 – 186 acres planted
- Treating activity only for **potato** seed pieces (with liquid formulation pesticide) (Amount of potato seed pieces treated was not documented in the study - no planting monitored in this study)

Risks of concern were identified for the OFST/P-S (solid formulations) for the following seed types:

- Barley
- Oat
- Potato
- Rice
- Rye
- Safflower
- Triticale
- Wheat

Risks of concern were identified for the OFST/P-L (liquid formulations) for the following seed types:

- Barley
- Oat
- Peanut
- Potato
- Rice
- Rye
- Triticale

- Wheat

Questions for stakeholders:

- Please list and describe in detail all the activities performed by a worker who is designated to treat on farm and then plant seeds in your operation. Please state the seed type in your response. Is a liquid or solid formulation of mancozeb in use for that seed type?
- Describe the pesticide loading system in your operation on farm to treat seed. Is this an open or closed loading system? Please state the type of seed in your response. Is a liquid or solid formulation of mancozeb in use for that seed type?
- Describe the treating equipment used to treat seeds on farm. Please state the type of seed treated with this equipment. Is a liquid or solid formulation of active ingredient in use for that seed type?
- Describe the planting equipment used to sow seeds after they have been treated on farm. Please state the type of seed that is sown with this equipment.
- To the best of your knowledge, please describe how treating potato seeds and treating and planting cotton and wheat seeds on farm is **different** than treating and plantings seeds in your operation. Please state the type of seed in your response.
- Do you use the maximum label application rate to treat [type/use] seeds?
- What is the maximum rate used to treat [type/use] seeds?
- What is the average (“typical”) rate used to treat [type/use] seeds?
- What is the median rate (some XX<sup>th</sup> percentile) used to treat [type/use] seeds?
- The Agency assumes that 61, 80, and 200 acres are planted by a loader/planter in one eight-hour day for potatoes, vegetables and other specialty annual crops, and large acreage field crops (i.e., alfalfa, some beans, sugar beets, canola, field and pop corn, cereal grains, cotton, mint, rice, and soybean), respectively. How many acres are planted in one eight-hour day in your operation after you treat seeds on farm? Please state the type of seed planted.
- The Agency assumes a high-end seeding density (or number of seeds/acre) for each type of seed in its models of dermal and inhalation exposure to those workers who treat seeds on farm and then plant. The current assumptions for seeding density are found in Table 3.1 (pages 16-18) in Policy 15: [https://www.epa.gov/system/files/documents/2022-01/exposac-policy-15\\_amount-seed-treated-planted.pdf](https://www.epa.gov/system/files/documents/2022-01/exposac-policy-15_amount-seed-treated-planted.pdf)
  - There are more types of seeds with their associated seeding density listed in the worksheet named “Amount Seed Planted variables” in the seed treatment calculator (Microsoft Excel file). Look at values in Column ‘D’.  
[https://www.epa.gov/system/files/documents/2022-02/seed-treatment-and-planting-exposure\\_mar2022.xlsx](https://www.epa.gov/system/files/documents/2022-02/seed-treatment-and-planting-exposure_mar2022.xlsx)
  - What is the highest seeding density used in your operation? Please state the type of seed planted at this density.

### C. FIFRA Interim Ecological Mitigation (IEM) Measures

The ESA Workplan Update Appendix includes a menu of FIFRA IEM measures, some of which are included in this PID. EPA previously sought public comment on the full suite of FIFRA IEM

measures, which is available in the ESA Workplan Docket ([EPA-HQ-OPP-2022-0908-0002](https://www.regulations.gov)), at [www.regulations.gov](https://www.regulations.gov). 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 proposed for mancozeb in this PID 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 mancozeb.<sup>37</sup> EPA is proposing the following FIFRA Interim Ecological Mitigation measures for mancozeb:

- Surface water protection statement (rain statement only)
- Spray drift reduction measures, including buffers
- Treated seed labeling
- Pollinator stewardship advisory language
- Ecological incident reporting label language
- Bulletins Live! Two (BLT) labeling

The proposed FIFRA Interim Ecological Mitigation measures in this PID are not designed to fully address EPA's ESA obligations for mancozeb 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 mancozeb during registration review, such as mitigations developed as part of its various ESA initiatives.<sup>38</sup> Additional measures may also be necessary when EPA conducts effects determinations and, if necessary, consults with the Service(s) on mancozeb.

## **1. Surface Water Protection Statement to Reduce Ecological Risks from Soil Erosion**

### *Surface Water Protection Statement*

Mancozeb is persistent in soil in the form of ETU, with average half-lives of about 8.9 days in laboratory soil metabolism studies. According to the Food and Agriculture Organization (FAO) classification scheme, mancozeb is classified as slightly mobile. ETU has Freundlich organic carbon adsorption coefficients ( $K_{oc}$ s) that range from 34 to 150 L/g<sub>oc</sub>, depending on soil type. Transport off the field via soil erosion was identified in the mancozeb ecological risk assessment as a potential exposure route of concern.

In order to reduce the potential for transport off the field of mancozeb via soil erosion and reduce risk to non-target organisms, EPA is proposing the following surface water protection

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<sup>37</sup> 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>.

<sup>38</sup> <https://www.epa.gov/endangered-species/implementing-epas-workplan-protect-endangered-and-threatened-species-pesticides>

statement for mancozeb for products delivered via liquid spray to crops that do not require production in flooded fields or streams:

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

The surface water protection statement is intended to reduce the amount of pesticide that moves off a treated field via erosion during a rain event. The Agency does not anticipate that a restriction which prohibits mancozeb applications while it is raining will affect applicators. While fungicide applications may be made prior to a rainfall event, applicators would not apply during a rainfall event, as this would not be desirable for the product staying in place and preventing disease.

EPA also expects few impacts from a restriction on applying mancozeb to saturated soil for most users. Users are more likely to apply mancozeb prior to a known rain event and not after (when soils are more likely to be saturated). For some users with certain soil types, this prohibition would limit the available window users have to make time sensitive applications as some soil types retain water for longer periods of time. For example, users operating on soil with a greater clay content are expected to experience more noticeable impacts from this restriction than those operating on sandier soils, as clay soils retain water longer. In such cases, the application window for mancozeb would be narrower.

## **2. Spray Drift Buffers**

For mancozeb, spray drift risks of concern were identified for multiple taxa. RQ exceedances for birds and mammals are related to drift of mancozeb products to all crops. RQ exceedances are estimated for terrestrial invertebrates up to 827 feet from the edge of the field, for aquatic vertebrates up to 900 ft from the edge of the field, and for aquatic invertebrates up to 750 feet from the edge of the field.

As noted previously in section IV.A, EPA is proposing spray drift management measures related to maximum wind speed, aerial and ground release height, minimum droplet size, aerial swath displacement, aerial boom length, ground boom height, and other application parameters to reduce risk to non-target organisms from spray drift. In addition to these measures, EPA is proposing spray drift buffers for mancozeb to further reduce off-field spray drift and exposure to non-target organisms.

### *Buffers from Aquatic Habitats*

In order to protect aquatic plants, vertebrates, and invertebrates, and thereby, aquatic communities, the Agency is proposing spray drift buffers between the edge of the field and aquatic habitats. The proposed buffers from aquatic habitats are as follows for aerial, ground, and airblast applications:

- For aerial applications: “Do not apply within 50 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams or ephemeral streams when water is present, wetlands or natural ponds, estuaries, and commercial fish farm ponds) when wind is blowing toward the aquatic habitat. On-farm irrigation ditches, irrigation canals, other on-farm water conveyances, and irrigation management structures such as tailwater collection ponds are not considered aquatic habitat. Any land between the aquatic habitat and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas).

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 aquatic habitat is present and meets the criteria listed in the ‘Windbreak-Shelterbelt Criteria’ section of this label.”

- For ground boom applications: “Do not apply within 15 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams or ephemeral streams when water is present, wetlands or natural ponds, estuaries, and commercial fish farm ponds) when wind is blowing toward the aquatic habitat. On-farm irrigation ditches, irrigation canals, other on-farm water conveyances, and irrigation management structures such as tailwater collection ponds are not considered aquatic habitat. Any land between the aquatic habitat and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas).

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 aquatic habitat 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 15 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams or ephemeral streams when water is present, wetlands or natural ponds, estuaries, and commercial fish farm ponds) when wind is blowing toward the aquatic habitat. On-farm irrigation ditches, irrigation canals, other on-farm water conveyances, and irrigation management structures such as tailwater collection ponds are not considered aquatic habitat. Any land between the aquatic habitat and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas).

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 aquatic habitat is present and meets the criteria listed in the 'Windbreak-Shelterbelt Criteria' section of this label."

### *Buffers from Conservation Areas*

In order to reduce risks to organisms that reside in conservation areas, the Agency is proposing spray drift buffers between the edge of the field and conservation areas (e.g., public lands and parks, wilderness areas, National Wildlife Refuges, reserves, and conservation easements). The proposed spray drift buffers are as follows for aerial, ground, and airblast applications near conservation areas:

- For aerial applications: "Do not apply within 50 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 15 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 15 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 Aquatic Habitats and Conservation Areas*

A windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the treated area and the protected area (aquatic habitat 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.<sup>39</sup> 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.<sup>40</sup> A study on pesticide deposition at vegetated sites and non-vegetated sites found deposition was 96.1% lower at vegetated sites.<sup>41</sup> 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.

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<sup>39</sup> 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.

<sup>40</sup> 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.

<sup>41</sup> 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.

EPA is proposing 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 meet the following criteria in order to qualify for a buffer reduction:

- The windbreak or shelterbelt must be downwind between the pesticide application and the protected area.
- 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 protected 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 protected 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.

Manmade structures (e.g., a building or curtain that is raised prior to application) can be substitutes for a windbreak or shelterbelt. The Agency is proposing that manmade structures can be used in lieu of a windbreak or shelterbelt if the following criteria are met:

- the structure is downwind between the application area and the protected area,
- the structure covers the entire distance of field adjacent to the protected area, and
- the structure is higher than the release height of the application.

The proposed labeling for the windbreak-shelterbelt criteria 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.
- 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 (99 feet) offsite when hooded sprayers are used.<sup>42</sup> In order to provide more flexibility to users who use hooded sprayers, the Agency is proposing 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 proposing a 75% reduction in the buffer distance for ground application.

#### **Anticipated Risk Reduction for Conservation Habitat and Aquatic Habitat**

Spray drift reduction measures are expected to result in a reduction of risk to both terrestrial and aquatic taxa. While exact RQ reductions are not available, many risks of concern are near the LOC and it is reasonable to expect scenarios of concern being addressed with this mitigation.

#### **Impact of Spray Drift Buffers on Users**

Spray drift buffers can affect a substantial portion of a field, especially when fields are small as may be the case for many of the crops for which mancozeb is utilized. Larger buffers impact a larger proportion of the field than smaller buffers. For some growers, meaning those with

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<sup>42</sup> 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.

particularly small fields (e.g., <2 acres), even a 15-foot buffer may have substantive impacts. Growers who would be required to implement a buffer have three main options, all of which result in the loss of mancozeb as a control method in the buffer area: 1) replace mancozeb with an alternative control method for treatment of the entire field if a suitable multisite fungicide alternative is available (see BEAD crop specific memos also included in this docket), 2) replace mancozeb with an alternative control method in just the buffer area while treating the interior field with mancozeb, or 3) use mancozeb to treat only the interior of the field and leave the buffer areas untreated but this would be expected to result in yield and/or quality losses; in some situations, losses may be large enough that it is no longer worth cultivating the buffer and growers remove the land from production. The second option listed would likely necessitate extra trips through the field. Extra trips through a field imposes a burden beyond just the time it takes a grower to make the extra trip – growers must clean equipment before switching to another chemical.

### **3. Treated Seed Labeling [Required for all products with seed treatment use]**

The 2020 Eco DRA for mancozeb identified chronic risks of concern to birds and mammals consuming treated seeds from all assessed mancozeb seed treatment uses, and to aquatic plants, aquatic vertebrates, and aquatic invertebrates in aquatic ecosystems adjacent to treated rice fields. In order to reduce exposure to non-target organisms which may ingest treated seed, the Agency is proposing labeling for seeds treated on-farm and not sold and distributed, and seeds treated on-farm or in commercial facilities for sale and distribution. In general, the proposed seed labeling instructions address the proper storage, planting, and disposal of treated seeds and provide other common sense best management practices to instruct the user on ways to prevent exposure to non-target wildlife.

EPA solicited comment on the language in the ESA Workplan Update. The Agency received comments specific to treated seed on the ESA Workplan Update, concerning the planting depth, the burial depth and disposal of excess treated seeds, and reducing pesticide dust-off. EPA considered the comments and amended the language regarding treated seed.

Consistent with EPA's September 28, 2022, response to the treated seed petition filed by Center for Food Safety,<sup>43</sup> these proposed treated seed labeling instructions will continue to be updated as EPA reviews currently registered pesticides. EPA also issued an advanced notice of proposed rulemaking (ANPRM)<sup>44</sup> [88 FR 70625, October 12, 2023] to solicit comment on the use and usage of treated seed, including storage, planting, and disposal of treated seed, which will further inform the labeling instructions.

#### *a. Dye statement*

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<sup>43</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2018-0805-0104>

<sup>44</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2023-0420-0001>

The proposed dye statement is as follows: “Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant or dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR, Part 2.25. Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR, Part 153.155(c).”

*b. Labeling instructions for seeds treated on-farm and not for distribution or sale of the seed)*

The proposed seed treatment labeling for products allowed for on-farm seed treatment (not for distribution or sale of the seed) is as follows:

**“Use of On-Farm Treated Seed (when treated seeds are not for sale or distribution)**

Treated seed sold or distributed for a use not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12.

- Store treated seed away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seeds.
- Treated seeds are for planting purposes only. Do not use for food, feed, or oil purposes. Do not use treated seeds for fuel or ethanol production purposes.
- Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting. Additional incorporation may be required to thoroughly cover exposed seeds.
- Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).
- Treated seed may be collected for reuse for planting. If not collected for reuse, bury or dispose of all spilled seed in accordance with the following language:
  - Bury spilled seed at a depth of 6 inches or double the planting depth, whichever is greater. Bury all spilled seed at least 30 feet away from bodies of water.
  - If seed spilled during loading or planting exceeds 1 pound, or if disposing of excess treated seed (such as expired, unused seed), dispose of seeds in accordance with applicable laws in your state.
- Do not contaminate bodies of water when disposing of equipment wash water.

**ADVISORY DUST-REDUCING TECHNIQUE**

Fluency agents are recommended to be applied to treated seed prior to the planting.”

The Agency is also proposing that all other requirements regarding the use of the treated seed, which include, but are not limited to, instructions relating to endangered species protection, environmental hazard statements, maximum use rates, soil incorporation depth, plant back

intervals, personal protective equipment, and storage and disposal statements, remain and must be listed.

*c. Seed bag/container labeling instructions for seeds treated on-farm and for sale or distribution*

The proposed seed bag/container labeling for pesticide products allowed for both commercial and on-farm seed treatment use, where the treated seed product is for sale or distribution, is as follows:

**“Seed Treatment in Commercial Facilities or Seed Treatment On-Farm (when treated seeds are to be sold or distributed) – Seed Bag Labeling Requirements**

The Federal Seed Act requires that bags containing treated seeds shall be labeled with the following statements:

- This seed has been treated with (insert name of active ingredient of pesticide).
- Do not use for food, feed, or oil purposes.”

“The U.S. Environmental Protection Agency requires that bags containing treated seeds shall be labeled with the following statements. Any seed treated with [PRODUCT NAME] that is sold or distributed without these statements or that is sold or distributed for a use not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12(a)(1)(A).

This seed has been treated with [INSERT PRODUCT NAME(S) (EPA REG. NO(S))] containing [INSERT NAME(S) OF ACTIVE INGREDIENT(S)]. **Any seed treated with [PRODUCT NAME] that is sold or distributed for a use not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12(a)(1)(A).**

- The contents of this bag are for planting purposes only. Do not use for food, feed, or oil purposes. Do not use for fuel or ethanol production purposes.
- Store treated seed away from food and feedstuffs.
- Do not allow children, pets, or livestock to have access to treated seeds.
- Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.
- Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).
- Treated seed may be collected for reuse for planting. If not collected for reuse, bury or dispose of all spilled seed in accordance with the following language:

- Bury spilled seed at a depth of 6 inches or double the planting depth, whichever is greater. Bury all spilled seed at least 30 feet away from bodies of water.
- If spilled seed during loading or planting exceeds 1 pound, or if disposing of excess treated seed (such as expired, unused seed), dispose of seeds in accordance with applicable laws in your state.
- Do not contaminate bodies of water when disposing of equipment wash water.
- Dispose of seed packaging or containers in accordance with local requirements.

#### **ADVISORY DUST-REDUCING TECHNIQUE**

Fluency agents are recommended to be applied to seed after pesticide treatment prior to the planting.”

The Agency is also proposing that all other requirements regarding the use of the treated seed, which include, but are not limited to, instructions relating to endangered species protection, environmental hazard statements, maximum use rates, soil incorporation depth, plant back intervals, personal protective equipment, and storage and disposal statements, remain and must be listed on the seed bag tag.

#### **4. Advisory Pollinator Stewardship Language**

Mancozeb is applied to pollinator attractive crops such as potato, ornamentals, pears, apples, and tomato. Acute risks of concern to larval bees were identified for all registered uses and multiple feeding strategies. Chronic risks of concern to larval bees were identified for all registered uses and multiple feeding strategies. No RQ exceedances were estimated for adult bees, however, risk cannot be precluded for adult bees based on a conservative risk screen.

EPA is proposing to include advisory language for insect pollinators. This advisory language distills the most important information growers need to know to voluntarily reduce risk to insect pollinators. The language is intended to raise awareness of potential hazard to bees and other insect pollinators. Although this language is advisory, the goal is to promote 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.<sup>45</sup>

EPA is proposing 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 in order to protect non-target organisms and mitigate environmental impacts. The Agency is proposing the following labeling to highlight pollinator best management practices:

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<sup>45</sup> <https://www.epa.gov/pollinator-protection/pollinator-protection-strategic-plan>

### **“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> .”

### **Ecological Incident Reporting Label Language**

EPA has proposed and subsequently required ecological incident reporting language on some labels in the past, and ecological incident reporting has been included as a reasonable and prudent measure in Biological Opinions issued by the Services. The Agency anticipates the need to add incident reporting labeling as part of any necessary ESA consultation. EPA is proposing incident reporting labeling to provide consistent information to pesticide users on how to report ecological incidents and in order to expedite any ESA necessary consultation. The proposed incident reporting language is as follows:

**“REPORTING ECOLOGICAL INCIDENTS:** For guidance on reporting ecological incidents, including death, injury, or harm to plants and animals, including bees and other non-target insects, see

EPA's Pesticide Incident Reporting website: <https://www.epa.gov/pesticide-incidents> or call (registrant phone number)."

## 5. 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 extensions of the general labeling accessed through a website. EPA is using a web-based system, Bulletins Live! Two (BLT), to provide timely protections for listed species and to minimize pesticide product labeling changes.

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

Mancozeb does not currently have any listed species bulletins. However, the Agency is proposing the following Bulletins language be added to all mancozeb product labels. This language instructs users to check the Bulletins Live! Two website in order to understand listed species use restrictions that may apply to them, if available. 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 proposed BLT language is as follows:

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

The BLT system has been in place for many years but the requirement to access BLT before using a pesticide is relatively new for many pesticide products. As discussed in the ESA Workplan Update issued by the Agency in November 2022, the requirement to access BLT will

eventually apply to most pesticides<sup>46</sup>. Therefore, over time and with wider implementation, BLT will become a tool that growers are familiar with, and consulting BLT ahead of a pesticide application will become routinely integrated into a user's application process. In February 2022, EPA released an improved version of BLT<sup>47</sup>, which allows users to more easily find the information they need for a particular pesticide product. The Agency has also developed a tutorial<sup>48</sup> 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. Growers must obtain the relevant bulletin and check for additional mitigation no earlier than six months prior to the intended application. Some requirements may be more stringent versions of measures described and could even prohibit use for the designated area. If land use practices (additional mitigation measures) are required, growers may need substantial time (potentially more than six months) and careful planning to implement them. The requirement to obtain and follow Bulletins on at least an annual basis (depending on how often a chemistry is used) in addition to the additional restrictions that could change over time, adds additional complexity and uncertainty for operating a farm business.

A recent USDA (2023) report on farm computer usage and ownership reported that 85 percent of farms have internet access, a number that is up from 73 percent in 2017, and a similar proportion of farms own smart phones and/or computers<sup>49,50</sup>. However, fewer farms reported using the internet to conduct business. Therefore, while BLT will be easily accessible for most growers, it will be more burdensome for growers who must rather seek other means to access Bulletins relevant to their farm or field (e.g., call a telephone number and request information). 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 such as the Vulnerable Species Pilot<sup>51</sup> and the Herbicide Strategy<sup>52</sup> 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 proposed to be added on the pesticide label without being linked to PULAs or bulletins for mancozeb at this time, pesticide users should be aware that as

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<sup>46</sup> EPA (Environmental Protection Agency). 2022. ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions, November 2022. Available online: <https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf>

<sup>47</sup> <https://www.epa.gov/endangered-species/endangered-species-protection-bulletins>

<sup>48</sup> <https://www.epa.gov/endangered-species/bulletins-live-two-blt-tutorial>

<sup>49</sup> 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>

<sup>50</sup> USDA, 2019. Farm Computer Usage and Ownership. Published August 2019. Available at: [https://www.nass.usda.gov/Publications/Todays\\_Reports/reports/fmpc0819.pdf](https://www.nass.usda.gov/Publications/Todays_Reports/reports/fmpc0819.pdf)

<sup>51</sup> <https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0327>

<sup>52</sup> <https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0365>

various ESA pilot efforts 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 C: Listed Species Assessments for more information.

#### **D. Environmental Justice**

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

One community which may experience disproportionate exposure to pesticides is agricultural farmworkers. EPA has conducted assessments of risks to farmworkers who handle mancozeb or may be exposed to mancozeb when mixing, loading, and/or applying and has found risks of concern for mancozeb. Risks of concern have been found for many occupational handler scenarios. EPA has also evaluated the risks to people living adjacent to treated fields, which may include many farmworker families, and has found risks of concern for mancozeb. Risks of concern are found for children near the treated field. EPA has also evaluated risk to residential handlers (such as homeowners) and adults/children that may be exposed to residues after pesticide application and has not found risks of concern.

The Agency requests information on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (e.g., as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to mancozeb compared to the general population or who may otherwise be disproportionately affected by the use of mancozeb as a pesticide.

#### **E. Tolerance Actions**

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

*“Tolerances are established for residues of ethylenethiourea (ETU), including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only ethylenethiourea, 2-Imidazolidinethione, in or on the commodity.”*

The Agency plans to exercise its FFDCA authority to establish the tolerances for ETU as summarized in Table 1.

<b>Table 1 – ETU 40 C.F.R. § 180.176(a)(2): Summary of Anticipated Tolerance Actions</b>			
Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Cattle, fat	-	0.04	
Cattle, meat	-	0.04	
Cattle meat byproducts	-	0.02	
Goat, fat	-	0.04	
Goat, meat	-	0.04	
Goat, meat byproducts	-	0.02	
Horse, fat	-	0.04	
Horse, meat	-	0.04	
Horse, meat byproducts	-	0.02	
Milk	-	0.02	
Sheep, fat	-	0.04	
Sheep, meat	-	0.04	
Sheep, meat byproducts	-	0.02	

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

<b>Table 2 – Mancozeb 40 C.F.R. § 180.176(a)(1): Summary of Anticipated Tolerance Actions</b>			
Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Atemoya	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Barley, bran	2	remove	New study shows no concentration of residues upon processing.
Barley, flour	2	remove	
Barley, pearled barley	20	remove	
Beet, sugar, dried pulp	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Beet, sugar, leaves <sup>1</sup>	-	60	Commodity definition revision.
Beet, sugar, tops	60	remove	
Canistel	15.0	15	Corrected value to be consistent with OECD Rounding Class Practice.
Cattle, meat byproducts	-	remove <sup>2</sup>	Commodity definition revision. Tolerance residue definition revision recommended; move to (40 CFR §180.176(a)(2) <i>General</i> ).
Cattle, kidney	0.5	remove	
Cattle, liver	0.5	remove	
Corn, field forage	40	50	Data cited for tolerance reassessment report residues greater than the established limit (D305815, C. Olinger, 06/14/2005).
Corn, pop, stover	40	50	Data cited for tolerance reassessment report residues greater

<b>Table 2 – Mancozeb 40 C.F.R. § 180.176(a)(1): Summary of Anticipated Tolerance Actions</b>			
<b>Commodity/ Correct Commodity Definition</b>	<b>Established Tolerance (ppm)</b>	<b>Recommended Tolerance (ppm)</b>	<b>Comments</b>
			than the established limit (D305815, C. Olinger, 06/14/2005).
<b>Corn, sweet, stover</b>	40	50	Data cited for tolerance reassessment report residues greater than the established limit (D305815, C. Olinger, 06/14/2005)
<b>Cotton, undelinted seed</b>	0.5	remove	Concluded to be a non-food use (D344719, C. Olinger, 04/30/2008).
<b>Cherimoya</b>	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Custard apple</b>	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Fennel, Florence, fresh leaves and stalk</b>	-	2.5	Commodity definition revision.
Fennel	2.5	remove	
<b>Goat, meat byproducts</b>	-	remove <sup>2</sup>	Commodity definition revision. Tolerance residue definition revision recommended; move to (40 CFR §180.176(a)(2) <i>General</i> ).
Goat, kidney	0.5	remove	
Goat, liver	0.5	remove	
<b>Hog, meat byproducts</b>	-	remove	No expectation of finite residues in livestock, 40 CFR 180.6(a)(3).
Hog, kidney	0.5	remove	
Hog, liver	0.5	remove	
<b>Horse, meat byproducts</b>	-	remove <sup>2</sup>	Commodity definition revision. Tolerance residue definition revision recommended; move to (40 CFR §180.176(a)(2) <i>General</i> ).
Horse, kidney	0.5	remove	
Horse, liver	0.5	remove	
<b>Mango</b>	15.0	15	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Oat, flour</b>	1.2	remove	New study shows no concentration of residues upon processing.
<b>Oat, goats/rolled oats</b>	20	remove	
<b>Peanut, hay</b>	65	remove	Labels are amended to include a livestock feeding restriction (D305815, C. Olinger, 06/14/2005).
<b>Pepper, bell</b>	-	12	Commodity definition revision.
<b>Pepper, nonbell</b>	-	12	
Pepper	12	remove	
<b>Poultry, meat byproducts</b>	-	remove	No expectation of finite residues in livestock, 40 CFR 180.6(a)(3).
Poultry, kidney	0.5	remove	
Poultry, liver	0.5	remove	
<b>Rye, flour</b>	1.2	1.5	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Sapodilla</b>	15.0	15	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Sapote, mamey</b>	15.0	15	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Sapote, white</b>	15.0	15	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Sheep, meat byproducts</b>	-	remove <sup>2</sup>	Commodity definition revision.

Commodity/ Correct Commodity Definition	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Sheep, kidney	0.5	remove	Tolerance residue definition revision recommended; move to (40 CFR §180.176(a)(2) <i>General</i> ).
Sheep, liver	0.5	remove	
<b>Star apple</b>	15.0	15	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Sugar apple</b>	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
<b>Walnut, black</b>	-	0.7	Commodity definition revision. Corrected value to be consistent with OECD Rounding Class Practice.
<b>Walnut, English</b>	-	0.7	
Walnut	0.70	remove	New study shows no concentration of residues upon processing.
<b>Wheat, bran</b>	2	remove	
<b>Wheat, flour</b>	1.2	remove	
<b>Wheat, germ</b>	20	remove	
<b>Wheat, middlings</b>	20	remove	
<b>Wheat, shorts</b>	2	remove	

## F. Data Requirements

EPA does not anticipate calling-in additional data for mancozeb's registration review at this time.

## V. NEXT STEPS AND TIMELINE

### A. Comment on this Proposed Interim Decision

A Federal Register Notice will announce the availability of the mancozeb PID and open a 60-day comment period. The Agency may issue an ID after the close of this comment period if appropriate or may proceed to a final registration review decision for mancozeb without previously issuing an ID. However, a final registration review decision for mancozeb will only be made after EPA (1) completes effects determinations, and (2) meets EPA's ESA section 7 obligations (*e.g.*, initiates any necessary consultation with the Services, consistent with ESA section 7(a)(2)). The Agency also intended to make a determination on its EDSP obligations under FFDCA section 408(p).

### B. Implementation of Mitigation Measures if EPA Issues an ID

If EPA ultimately posts an ID for mancozeb to the public docket, then the mancozeb registrants will be expected to submit amended labels, include the label changes described in the Appendices to the ID, and requests for amendment of registrations within 60 days.

### Appendix A: Summary of Proposed Mitigation for Mancozeb

Registration Review Case #: PC Code: Chemical Type: fungicide Chemical Family: ethylene bisdithiocarbamate (EBDC) Mode of Action: multisite						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Mitigation	Comment
By-standers (infants and children)	Aerial application	<ul style="list-style-type: none"> <li>Dermal and incidental oral</li> </ul>	Short- term	<ul style="list-style-type: none"> <li>Developmental</li> <li>Neuro-developmental</li> </ul>	Require enforceable spray drift reduction measures	
Occupational handler mixing/loading/applying	Aerial and ground application	<ul style="list-style-type: none"> <li>Inhalation</li> <li>Dermal</li> </ul>	Short and intermediate term	Thyroid effects	<ul style="list-style-type: none"> <li>Use prohibitions</li> <li>Double layer clothing requirement</li> <li>Glove requirement</li> <li>APF10 respirator requirement</li> <li>Engineering controls requirement (closed-loading systems and closed cabs)</li> </ul>	
Workers/handlers entering a treated site after application	Residues on treated site	<ul style="list-style-type: none"> <li>Dermal</li> </ul>	Short and intermediate term	Thyroid effects	Lengthen REI	
Pollinators (terrestrial invertebrates)	Residues on treated site and adjacent fields	Contact with residues	Acute and chronic larval	Decreased survival and adult emergence	Require enforceable spray drift reduction measures	
Avian and reptiles and terrestrial-phase amphibians	Residues on treated site and adjacent fields	Ingestion	Chronic	Decreased hatchling weight, egg production, hatchability, and embryo viability	Require enforceable spray drift reduction measures	

Mammals	Residues on treated site and adjacent fields	Ingestion	Chronic	Decreased growth rate and reproduction	Require enforceable spray drift reduction measures	
Fish and aquatic-phase amphibians	Runoff from soil at treated sites	Contact with residues in runoff	Chronic	Reductions in length	Measures to reduce runoff	
Aquatic Invertebrates (estuarine/marine)	Runoff from soil at treated sites	Contact with residues in runoff	Acute and chronic	Reductions in survival	Measures to reduce runoff	
Aquatic Plants	Runoff from soil at treated sites	Contact with residues in runoff	N/A	Decrease of biomass	Measures to reduce runoff	

### Appendix B: Proposed Labeling Changes for Mancozeb Products

Description	Proposed Label Language for Mancozeb Products	Placement on Label
	<b>Technical and Manufacturing Use Products</b>	
<p>Use Deletion</p> <p>[Note to CRMs: there may be other changes needed for your tech products, this is just one example]</p>	<p>Remove the following use sites.</p> <p>Remove the following use sites (please note some are specific to certain combinations of crop, application method, and starting formulation):</p> <p>Foliar uses:</p> <ul style="list-style-type: none"> <li>• Residential turf</li> <li>• Residential ornamentals</li> <li>• Grapes, table</li> <li>• Grapes, raisin</li> <li>• Grapes, wine</li> <li>• Grapes, juice</li> <li>• Handgun applications to typical-acreage field crops using               <ul style="list-style-type: none"> <li>○ wettable powder (WP)</li> <li>○ liquid</li> <li>○ dry flowable</li> </ul> </li> <li>• Handgun applications to orchard crops using:               <ul style="list-style-type: none"> <li>○ wettable powder (WP)</li> <li>○ liquid</li> <li>○ dry flowable</li> </ul> </li> <li>• Aerial applications of all formulations to sod</li> <li>• Aerial applications of WP to high-acreage field crops</li> </ul> <p>Seed treatment uses:</p> <ul style="list-style-type: none"> <li>• All seed treatment use on:               <ul style="list-style-type: none"> <li>○ barley</li> <li>○ oat</li> <li>○ rice</li> <li>○ rye</li> <li>○ triticale</li> </ul> </li> </ul>	

	<ul style="list-style-type: none"> <li>○ wheat</li> <li>● On-farm treatment on:           <ul style="list-style-type: none"> <li>○ Potato</li> <li>○ Peanut</li> </ul> </li> <li>● All currently registered commercial seed treatment crops</li> </ul> <p>Post-treatment field activities</p> <ul style="list-style-type: none"> <li>● Hand-thinning of Pome Fruits (Apple, Crabapple, Quince, Pear)</li> <li>● Hand-thinning of Subtropical/Tropical Fruit (Sugar Apple, Cherimoya, Atemoya, Custard Apple, Sweetsop, Mango, Star Apple, Canistel, Mamey sapote, sapodilla, white sapote))</li> </ul>	
	<b>End Use Products</b>	
<b>Use Deletion</b>	<p>Remove the following use sites. (Please note some are specific to certain combinations of crop, application method, and starting formulation):</p> <p>Foliar uses:</p> <ul style="list-style-type: none"> <li>● Residential turf</li> <li>● Residential ornamentals</li> <li>● Grapes, table</li> <li>● Grapes, raisin</li> <li>● Grapes, wine</li> <li>● Grapes, juice</li> <li>● Handgun applications to typical-acreage field crops using           <ul style="list-style-type: none"> <li>○ wettable powder (WP)</li> <li>○ liquid</li> <li>○ dry flowable</li> </ul> </li> <li>● Handgun applications to orchard crops using:           <ul style="list-style-type: none"> <li>○ wettable powder (WP)</li> <li>○ liquid</li> <li>○ dry flowable</li> </ul> </li> <li>● Aerial applications of all formulations to sod</li> <li>● Aerial applications of WP to high-acreage field crops</li> </ul>	

	<p>Seed treatment uses:</p> <ul style="list-style-type: none"> <li>• All seed treatment use on:           <ul style="list-style-type: none"> <li>○ barley</li> <li>○ oat</li> <li>○ rice</li> <li>○ rye</li> <li>○ triticale</li> <li>○ wheat</li> </ul> </li> <li>• On-farm treatment on:           <ul style="list-style-type: none"> <li>○ Potato</li> <li>○ Peanut</li> </ul> </li> <li>• All currently registered commercial seed treatment crops</li> </ul> <p>Post-treatment field activities:</p> <ul style="list-style-type: none"> <li>• Hand-thinning of Pome Fruits (Apple, Crabapple, Quince, Pear)</li> <li>• Hand-thinning of Subtropical/Tropical Fruit (Sugar Apple, Cherimoya, Atemoya, Custard Apple, Sweetsop, Mango, Star Apple, Canistel, Mamey sapote, sapodilla, white sapote))</li> </ul>					
<p>Mode/Mechanism          [Pick one of Action Group Number</p> <p>See page 7 of PR Notice 2017-1:  <a href="https://www.epa.gov/sites/products/files/2017-09/documents/prn-2017-1-pesticide-resistance-management-labeling.pdf">https://www.epa.gov/sites/products/files/2017-09/documents/prn-2017-1-pesticide-resistance-management-labeling.pdf</a></p>	<p><b>Note to registrant:</b></p> <ul style="list-style-type: none"> <li>• Include the name of the <b>ACTIVE INGREDIENT</b> in the first column</li> <li>• Include the word “<b>GROUP</b>” in the second column</li> <li>• Include the <b>MODE/MECHANISM/SITE OF ACTION CODE</b> 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 <b>MODE OF ACTION</b>)</li> <li>• Include the type of pesticide (i.e., <b>FUNGICIDE</b>) in the fourth column.</li> </ul> <table border="1" data-bbox="390 1195 1614 1409"> <tr> <td style="text-align: center;">Mancozeb</td> <td style="text-align: center;">GROUP</td> <td style="background-color: black; color: white; text-align: center;">M3</td> <td style="text-align: center;">FUNGICIDE</td> </tr> </table>	Mancozeb	GROUP	M3	FUNGICIDE	<p>Front Panel, upper right quadrant.</p> <p>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.</p>
Mancozeb	GROUP	M3	FUNGICIDE			

<p><b>Application Method Prohibitions</b> <i>For all products that do not prohibit these application methods</i></p>	<p>Note to registrant - If your label has any of the application methods specified below, include the following statement(s) as applicable to your label.</p> <p>“Do not apply as broadcast application using a mechanically pressurized handgun in the following use scenarios:</p> <ul style="list-style-type: none"> <li>• Applications to typical-acreage field crops using formulations of             <ul style="list-style-type: none"> <li>○ wettable powder</li> <li>○ liquid</li> <li>○ dry flowable</li> </ul> </li> <li>• Applications to orchard crops using formulations of:             <ul style="list-style-type: none"> <li>○ wettable powder (WP)</li> <li>○ liquid</li> <li>○ dry flowable</li> </ul> </li> </ul>	<p>Restrictions Section Under Directions for Use</p>
<p><b>Updated Gloves Statement</b></p>	<p>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.</p>	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</p>
<p><b>Double layer clothing requirement</b></p>	<p>A double layer clothing requirement should be included for occupational handlers for all formulations, application methods, and crops. The requirement should specify that double layer clothing should consist of both long sleeve shirt, long pants, shoes, and socks, plus coveralls.</p>	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</p>
<p>Updated Respirator Language for APF10</p>	<p>An APF10 respirator requirement should be included in the use scenarios below and should be included on any product labels that have registrations for those use scenarios:</p> <p>Mixer/loaders:</p>	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements</p>

	<ul style="list-style-type: none"><li>• dry flowable formulation, aerial application:<ul style="list-style-type: none"><li>○ nursery</li><li>○ orchard</li><li>○ typical-acreage field crops</li><li>○ high-acreage field crops</li></ul></li><li>• dry flowable formulation, airblast application:<ul style="list-style-type: none"><li>○ orchard</li></ul></li><li>• dry flowable formulation, chemigation application:<ul style="list-style-type: none"><li>○ greenhouse</li><li>○ nursery</li><li>○ high-acreage field crops</li><li>○ orchard</li><li>○ typical-acreage field crops</li></ul></li><li>• dry flowable formulation, ground boom application:<ul style="list-style-type: none"><li>○ nursery</li><li>○ greenhouse</li><li>○ orchard</li><li>○ typical-acreage field crop</li><li>○ high-acreage field crops</li><li>○ sod</li><li>○ golf courses (fairways, tees, greens)</li></ul></li><li>• liquid formulation, aerial application:<ul style="list-style-type: none"><li>○ orchard</li><li>○ typical-acreage field crops</li><li>○ high-acreage field crops</li></ul></li><li>• liquid formulation, chemigation application:<ul style="list-style-type: none"><li>○ orchard</li><li>○ typical-acreage field</li></ul></li><li>• liquid formulation, ground boom application:<ul style="list-style-type: none"><li>○ sod</li></ul></li><li>• wettable powder formulation, aerial application:<ul style="list-style-type: none"><li>○ orchard</li><li>○ typical-acreage field crops</li></ul></li><li>• wettable powder formulation, chemigation application:<ul style="list-style-type: none"><li>○ orchard</li><li>○ typical-acreage field crops</li></ul></li><li>• wettable powder formulation, ground boom application:</li></ul>	
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	<ul style="list-style-type: none"><li>○ typical-acreage field crops</li><li>○ high-acreage field crops</li><li>● water-soluble packet formulation, ground boom application:<ul style="list-style-type: none"><li>○ golf course</li></ul></li><li>● dust/powder formulation, seed treatment application:<ul style="list-style-type: none"><li>○ safflower</li></ul></li></ul> <p>mixer/loader/applicators:</p> <ul style="list-style-type: none"><li>● dry flowable formulation, mechanically-pressurized handgun application:<ul style="list-style-type: none"><li>○ greenhouse</li><li>○ nursery</li></ul></li><li>● liquid formulation, mechanically-pressurized handgun application:<ul style="list-style-type: none"><li>○ greenhouse</li><li>○ nursery</li></ul></li><li>● wettable powder formulation, mechanically-pressurized handgun application:<ul style="list-style-type: none"><li>○ greenhouse</li><li>○ nursery</li></ul></li><li>● water-soluble packet formulation, mechanically-pressurized handgun application:<ul style="list-style-type: none"><li>○ greenhouse</li><li>○ nursery</li></ul></li></ul> <p>[Note to registrant: If your end-use product only requires protection from particulates (low volatility), use the following language:]</p> <p>“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.”</p> <p>*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.</p> <p>[Note to registrant: For respiratory protection from organic vapor and particulates (or aerosols), use the following language:]</p>	
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	<p>“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.”</p> <p>[Note to registrant: For products requiring protection for organic vapor only, use the following language:]</p> <p>“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.”</p> <p>*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.</p>	
<p><b>Respirator Fit Testing Requirements for Non-WPS Uses</b></p>	<p><b>“Respirator fit testing, medical qualification, and training</b></p> <p>Using a program that conforms to OSHA’s requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is:</p> <ul style="list-style-type: none"> <li>• Fit-tested and fit-checked,</li> <li>• Trained, and</li> <li>• Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use conditions change.</li> </ul> <p>Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements.”</p>	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements</p>
<p><b>Closed-loading system requirement for certain scenarios</b></p>	<p>A closed-loading system requirement should be included for the below use scenarios:</p> <ul style="list-style-type: none"> <li>• dry flowable formulation, aerial application:             <ul style="list-style-type: none"> <li>○ orchard</li> <li>○ typical-acreage field crops</li> <li>○ high-acreage field crops</li> </ul> </li> <li>• dry flowable formulation, chemigation application:             <ul style="list-style-type: none"> <li>○ orchard</li> <li>○ typical-acreage field crops</li> </ul> </li> <li>• dry flowable formulation, ground boom application:</li> </ul>	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements</p>

	<ul style="list-style-type: none"> <li>○ sod</li> <li>○ golf courses (fairways, tees, greens)</li> <li>● liquid formulation, chemigation application: <ul style="list-style-type: none"> <li>○ sod</li> </ul> </li> <li>● liquid formulation, aerial application: <ul style="list-style-type: none"> <li>○ sod</li> </ul> </li> <li>● wettable powder formulation, aerial application: <ul style="list-style-type: none"> <li>○ orchard</li> <li>○ typical-acreage field crops</li> </ul> </li> <li>● wettable powder formulation, chemigation application: <ul style="list-style-type: none"> <li>○ orchard</li> <li>○ typical-acreage field crops</li> </ul> </li> </ul>	
<b>Engineering Controls Enclosed Cabs (Airblast application to orchard crops)</b>	Orchard Crops: <ul style="list-style-type: none"> <li>● Airblast Applicators must use an enclosed cab.</li> </ul>	DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS Engineering Controls (List under specific crops)
<b>Engineering Controls Enclosed Cabs (Airblast application to orchard crops)</b>	Nursery Crops:  Airblast Applicators must use an enclosed cab.	DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS Engineering Controls (List under specific crops)
<b>Increased or new restricted entry intervals (REI)</b>	“Do not enter or allow workers to enter during the restricted-entry interval (REI). The REI and exceptions are listed in the Directions for Use associated with the crop.”  “Notify workers of the exception (including when entry is permitted for each of the tasks named in the exception).”	<b>AGRICULTURAL USE REQUIREMENTS Box</b>
<b>Prohibition of specific reentry activity for Pome fruits (Apple, Crabapple,</b>	“Workers may not enter the field for the purposes of hand-thinning fruit”	<b>AGRICULTURAL USE REQUIREMENTS Box</b>

<p><b>Quince, Pear), sapodilla, and sapote</b></p>		
<p><b>Increased or new restricted entry intervals (REI) Almond</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI) Pome fruits (Apple, Crabapple, Quince, Pear)</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI) Sapodilla</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI) Sapote</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI) Broccoli</b></p>	<p>Broccoli – 6 days “Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 6 days”</p>	<p><b>DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI) Cabbage</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 3 days”</p>	<p><b>DIRECTIONS FOR USE Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>

<p><b>Increased or new restricted entry intervals (REIs)</b> <b>Christmas tree</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 3 days when hand harvesting or repairing hand set irrigation for christmas trees”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI)</b> <b>Sweet corn</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 10 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI)</b> <b>cranberry</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI)</b> <b>Cucurbit vegetables (Cantaloupe, Cucumber, Gourd, Pumpkin, Squash, Melons, and Squash)</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 3 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REIs)</b> <b>Garlic, shallot, and leek</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 3 days when repairing hand set irrigation or during the restricted entry interval (REI) of 9 days when hand harvesting”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p><b>Increased or new restricted entry intervals (REI)</b> <b>Certain tropical and subtropical</b></p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>

<p>fruit (Sugar Apple, Cherimoya, Atemoya, Custard Apple, Sweetsop, Mango, Star Apple, Canistel, Mamey sapote, sapodilla, white sapote)</p>		
<p>Increased or new restricted entry intervals (REIs) Bulb onion</p>	<p>“Do not enter or allow workers to enter treated areas during a restricted entry interval (REI) of 3 days when repairing hand set irrigation or during a restricted entry interval (REI) of 9 days when hand harvesting”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p>Increased or new restricted entry intervals (REIs) Green onion</p>	<p>“Do not enter or allow workers to enter treated areas during a restricted entry interval (REI) of 3 days when repairing hand set irrigation or during a restricted entry interval (REI) of 9 days when hand harvesting”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p>Increased or new restricted entry intervals (REI) Papaya</p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 4 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p>Increased or new restricted entry intervals (REI) Bell pepper</p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 3 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>
<p>Increased or new restricted entry intervals (REI) Tomato</p>	<p>“Do not enter or allow workers to enter treated areas during the restricted entry interval (REI) of 3 days”</p>	<p><b>DIRECTIONS FOR USE</b> <b>Below GENERAL USE PRECAUTIONS</b> (List under specific crops)</p>

<p><b>Non-target Organism Spray Drift Advisory</b></p> <p>For products delivered as liquid spray</p>	<p>“NON-TARGET ORGANISM SPRAY DRIFT ADVISORY: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift.”</p>	<p>Environmental Hazards</p>
<p><b>Best Management Practices for Pollinator Protection</b></p> <p>For all products delivered via liquid spray applications to agricultural crops.</p>	<p><b>“Advisory Best Management Practices for Pollinator Protection</b></p> <p>The following best management practices (BMPs) can help reduce risk to pollinators:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Avoid applications when bees are actively foraging.</li> <li>• Avoid applying pesticides to plants in bloom, including flowering weeds.</li> <li>• Apply pesticides in the evening or at night when fewer bees are foraging.</li> <li>• 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.</li> <li>• 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.</li> <li>• [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.]</li> </ul> <p>The following BMPs can help promote the health and habitat of ground-nesting bees:</p> <ul style="list-style-type: none"> <li>• For uncultivated land, leaving large undisturbed patches of land un-mowed and untilled can provide nesting and forage sites.</li> <li>• For uncultivated land, mowing at the highest cutting height possible (minimum of 8-10 inches if possible) can increase and diversify food sources.</li> </ul> <p>For additional resources on pollinator BMPs and Pollinator Protection Plans, visit <a href="https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators">https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators</a>.”</p>	<p>Directions for Use – Under the Best Management Practices header after Resistance Management section</p>

<p><b>Endangered Species Protection Requirements</b></p> <p>For all products, excluding those</p> <ul style="list-style-type: none"> <li>• labeled/ registered solely for residential use; or</li> <li>• where exposure is negligible or there are no toxic effects expected across uses included on a product label (e.g., cattle ear tag, fly baits)</li> </ul>	<p><b>“ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS:</b> 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 <a href="https://www.epa.gov/pesticides/bulletins">https://www.epa.gov/pesticides/bulletins</a>. 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 <a href="mailto:ESPP@epa.gov">ESPP@epa.gov</a>.”</p>	<p>Directions for Use, at the beginning under the heading “ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS”</p>
<p><b>Ecological Incidents Statement</b></p> <p>For all products with outdoor uses</p>	<p><b>“REPORTING ECOLOGICAL INCIDENTS:</b> 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: <a href="https://www.epa.gov/pesticide-incidents">https://www.epa.gov/pesticide-incidents</a> or call (registrant phone number).”</p>	<p>Directions for Use, under the heading “REPORTING ECOLOGICAL INCIDENTS”</p>
<p><b>Resistance-management for fungicides and bactericides</b></p>	<p>[NOTE TO THE REGISTRANT: Include resistance management label language for fungicides/bactericides from PRN 2017-1 (<a href="https://www.epa.gov/pesticide-registration/pesticide-registration-notice-year">https://www.epa.gov/pesticide-registration/pesticide-registration-notice-year</a>). See section 3 (Scope) of the PRN to determine whether the resistance management measures outlined in the PRN apply to your product.]</p>	<p>Directions for Use, prior to directions for specific crops</p>
<p><b>Spray Drift Buffer for Bystanders</b></p> <p><b>For products that are applied as</b></p>	<p>Aerial Applications:</p> <ul style="list-style-type: none"> <li>• “Do not apply within 25 feet of areas frequented by non-occupational bystanders (especially children). These areas include residential lawns, pedestrian sidewalks, outdoor recreational areas such as school grounds, athletic fields, parks and all property associated with buildings occupied by humans for residential or</li> </ul>	

<p><b>liquid with aerial and ground boom equipment</b></p>	<p>commercial purposes. This includes homes, farmworker housing, or other residential buildings, schools, daycare centers, nursing homes, and hospitals. Buffer distances are measured from the edge of the application site to the edge of the area frequented by bystanders.”</p>	
<p><b>Water Protection Statements</b> For all products delivered via liquid spray applications to crops that do not require production in flooded fields or streams.</p>	<p><b>“WATER PROTECTION STATEMENT</b></p> <ul style="list-style-type: none"> <li>• Do not apply during rain.</li> <li>• 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).”</li> </ul>	<p>Directions for Use – Under the Restriction or Use Restriction Section</p>
<p><b>Additional Required Labelling Action</b> <b>Applies to all products delivered via liquid spray applications [for cases with ultra low volume applications</b></p>	<p>Remove information about volumetric mean diameter from all labels where such information currently appears.</p>	<p>Directions for Use</p>
<p><b>For all liquid products where there are mixers and loaders involved in mixing concentrate</b></p>	<p>“Removable chemical extraction probes (also known as “stingers”) used in suction/extraction systems must be rinsed within the pesticide container prior to removal.”</p>	<p>Directions for Use</p>
<p><b>Directions for mixing/loading</b></p>	<p>Instructions for Introducing Water Soluble Packages Directly into Spray tanks:</p>	<p>Directions for Use</p>

<p><b>products packaged in water soluble bags</b></p>	<p>"Water Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 C.F.R. 170.607(d)].</p> <p>Handling Instructions Follow these steps when handling pesticide products in WSPs.</p> <ol style="list-style-type: none"> <li>1. Mix in spray tank only.</li> <li>2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions.</li> <li>3. Keep the WSP in outer packaging until just before use.</li> <li>4. Keep the WSP dry prior to adding to the spray tank.</li> <li>5. Handle with dry gloves and according to the label instructions for PPE.</li> <li>6. Keep the WSP intact. Do not cut or puncture the WSP.</li> <li>7. Reseal the WSP outer packaging to protect any unused WSP(s).</li> </ol> <p>Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions.</p> <ol style="list-style-type: none"> <li>1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank.</li> <li>2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray.</li> <li>3. Stop adding water and stop any agitation.</li> <li>4. Place intact/unopened WSP into the tank.</li> <li>5. Do not spray water from a hose or fill pipe to break or dissolve the WSP.</li> <li>6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation.</li> <li>7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.</li> <li>8. Stop agitation before tank lid is opened.</li> <li>9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution.</li> </ol>	
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	<p>10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.</p> <p>11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation.</p> <p>12. Use the spray solution when mixing is complete.</p> <p>13. Maintain agitation of the diluted pesticide mix during transport and application.</p> <p>14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label.”</p> <p>For Toxicity Category I and II products:</p> <p>“ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p> <p>For Toxicity Category III and IV products:</p> <p>“ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p>	
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		End Use Products	
	<b>Spray Drift Management Application Restrictions for products that are applied as liquid with aerial equipment (except</b>	<p>“MANDATORY SPRAY DRIFT MANAGEMENT Aerial Applications:</p> <ul style="list-style-type: none"> <li>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.</li> </ul>	Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Aerial Applications”

	<p><b>Ultra Low Volume/ULV applications for mosquitocides)</b></p>	<ul style="list-style-type: none"> <li>• Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural &amp; Biological Engineers Standard 641 (ASABE S641).</li> </ul> <p><b>[wind speed options]</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Wind speed and direction must be measured on location using a windsock, an anemometer (including systems to measure wind speed or velocity on an aircraft), or an aircraft smoke system.</li> <li>• Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.</li> <li>• Applicators must use a minimum of ½ swath displacement upwind at the downwind edge of the field.</li> <li>• 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.</li> <li>• Do not apply during temperature inversions.”</li> </ul> <p><b>Spray Drift Buffer to Aquatic Habitats</b></p> <ul style="list-style-type: none"> <li>• “Do not apply within 50 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams or ephemeral streams when water is present, wetlands or natural ponds, estuaries, and commercial fish farm ponds) when wind is blowing toward the aquatic habitat. On-farm irrigation ditches, irrigation canals, other on-farm water conveyances, and irrigation management structures such as tailwater collection ponds are not</li> </ul>	<p>Placement for these statements should be in general directions for use, and before use-specific directions.</p>
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		<p>considered aquatic habitat. Any land between the aquatic habitat and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas).</p> <p>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 aquatic habitat is present and meets the criteria listed in the ‘Windbreak-Shelterbelt Criteria’ section of this label.”</p> <p><b>Spray Drift Buffer to Wildlife Conservation Areas</b></p> <ul style="list-style-type: none"> <li>• “Do not apply within 50 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.</li> </ul> <p>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.”</p>	
<p><b>Only include this language if there are</b></p>	<p><b>Spray Drift Management Application Restrictions for products that are</b></p>	<p><b>“MANDATORY SPRAY DRIFT MANAGEMENT Ground Boom Applications:</b></p>	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under</p>

<p><b>ground boom application methods on the label</b></p>	<p><b>applied as liquid with ground boom equipment</b></p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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).</li> <li>• Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.</li> <li>• Do not release spray at a height greater than 3 feet above the ground or crop canopy.</li> <li>• Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural &amp; Biological Engineers Standard 572 (ASABE S572).</li> <li>• Do not apply during temperature inversions.”</li> </ul> <p><b>Spray Drift Buffer to Aquatic Habitats</b></p> <ul style="list-style-type: none"> <li>• “Do not apply within 15 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams or ephemeral streams when water is present, wetlands or natural ponds, estuaries, and commercial fish farm ponds) when wind is blowing toward the aquatic habitat. On-farm irrigation ditches, irrigation canals, other on-farm water conveyances, and irrigation management structures such as tailwater collection ponds are not considered aquatic habitat. Any land between the aquatic habitat and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas).</li> </ul> <p>A 50% reduction in buffer distance can be made if:</p> <ul style="list-style-type: none"> <li>○ the application is made with a hooded sprayer; or,</li> <li>○ a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and aquatic habitat is present and meets the criteria</li> </ul>	<p>the heading “Ground Boom Applications”</p>
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		<p>listed in the ‘Windbreak-Shelterbelt Criteria’ section of this label.</p> <p>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.”</p> <p><b>Spray Drift Buffer to Wildlife Conservation Areas</b></p> <ul style="list-style-type: none"> <li>• “Do not apply within 15 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: <ul style="list-style-type: none"> <li>○ the application is made with a hooded sprayer; or,</li> <li>○ 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.</li> </ul> </li> </ul> <p>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.”</p>	
<p><b>Only include this language if there are airblast application methods on the label</b></p>	<p><b>Spray Drift Management Application Restrictions for products that are</b></p>	<p><b>“MANDATORY SPRAY DRIFT MANAGEMENT Airblast Applications:</b></p> <ul style="list-style-type: none"> <li>• Sprays must be directed into the canopy.</li> </ul>	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under</p>

	<p><b>applied as liquid with airblast equipment</b></p>	<ul style="list-style-type: none"> <li>• During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 15 miles per hour.</li> <li>• Winds speed and direction must be measured on location using a windsock or anemometer.</li> <li>• Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.</li> <li>• User must turn off outward pointing nozzles at row ends and when spraying outer row.</li> <li>• Do not apply during temperature inversions.</li> </ul> <p><b>CRM: delete following bullets if not applicable for your chemical case</b></p> <p><b>Spray Drift Buffer to Aquatic Habitats</b></p> <ul style="list-style-type: none"> <li>• “Do not apply within 15 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, permanent streams or ephemeral streams when water is present, wetlands or natural ponds, estuaries, and commercial fish farm ponds) when wind is blowing toward the aquatic habitat. On-farm irrigation ditches, irrigation canals, other on-farm water conveyances, and irrigation management structures such as tailwater collection ponds are not considered aquatic habitat. Any land between the aquatic habitat and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas).</li> </ul> <p>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 aquatic habitat is present and meets the criteria listed in the ‘Windbreak-Shelterbelt Criteria’ section of this label.”</p> <p><b>Spray Drift Buffer to Wildlife Conservation Areas</b></p>	<p>the heading “Airblast Applications”</p>
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		<ul style="list-style-type: none"> <li>“Do not apply within 15 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.</li> </ul> <p>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.”</p>	
<p><b>Windbreaks are not considered a risk reduction measure for human health bystander risks.</b></p> <p><b>See Mandatory Spray Drift rows for aerial, ground boom, and airblast applications.</b></p>	<p><b>Windbreak-Shelterbelt Language for aerial and ground boom Application Methods</b></p>	<p><b>“Windbreak-Shelterbelt Criteria</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>The windbreak or shelterbelt must be downwind between the pesticide application and the aquatic habitat/conservation area.</li> <li>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.</li> <li>The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have</li> </ul>	<p>Directions for Use – Under the Restriction or Use Restriction Section</p> <p>Must be placed at the end of the Mandatory Spray Drift Section</p>

		<p>foliage that is sufficiently dense such that the aquatic habitat/conservation area is not visible on the upwind side.</p> <ul style="list-style-type: none"> <li>• The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application.</li> <li>• 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.</li> <li>• The windbreak or shelterbelt must be maintained such that their functionality is not compromised.</li> </ul> <p>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.”</p>	
<p><b>Only include this language if there are boomless ground application methods on the label</b></p>	<p><b>Spray Drift Management Application Restrictions for products that are applied as liquid with boomless ground sprayer equipment</b></p>	<p><b>“MANDATORY SPRAY DRIFT MANAGEMENT Boomless Ground Applications:</b></p> <ul style="list-style-type: none"> <li>• Do not apply when wind speeds exceed 10 miles per hour at the application site.</li> <li>• Do not apply during temperature inversions.”</li> </ul>	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Boomless Applications”</p>
<p><b>Advisory drift language for products delivered as liquid spray via aerial and ground boom equipment</b></p>	<p><b>Advisory Spray Drift Management Language for all products applied as liquid spray</b></p>	<p><b>“SPRAY DRIFT ADVISORIES</b></p> <p>THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. Be aware of nearby non-target sites and environmental conditions.</p> <p><b>IMPORTANCE OF DROPLET SIZE</b></p> <p>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.</p>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

		<p>Controlling Droplet Size – Ground Boom (note to registrants: remove if ground boom is prohibited on product labels)</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Pressure – Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size.</li> <li>• Spray Nozzle – Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.</li> </ul> <p>Controlling Droplet Size – Aircraft (note to registrants: remove if aerial application is prohibited on product labels)</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>BOOM HEIGHT – Ground Boom (note to registrants: remove if ground boom is prohibited on product labels)</b></p> <p>For ground equipment, the boom should remain level with the crop and have minimal bounce.</p> <p><b>RELEASE HEIGHT – Aircraft (note to registrants: remove if aerial application is prohibited on product labels)</b></p> <p>Higher release heights increase the potential for spray drift.</p> <p><b>HOODED (OR SHIELDED) SPRAYERS</b></p> <p>Shielding the boom or individual nozzles can reduce spray drift. Consider using hooded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area.</p> <p><b>TEMPERATURE AND HUMIDITY</b></p> <p>When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.</p>	
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		<p><b>TEMPERATURE INVERSIONS</b></p> <p>Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions.</p> <p><b>WIND</b></p> <p>Drift potential generally increases with wind speed. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.</p> <p><b>MEASURING WIND SPEED AND WIND DIRECTION</b></p> <p><b>Best Management Practices for measuring wind speed and direction of wind:</b></p> <ul style="list-style-type: none"><li>• 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.</li><li>• Applicators should reassess wind speed and direction at the application site every 15 minutes while applications are in progress.</li><li>• Measuring wind speed and direction can be done by:<ul style="list-style-type: none"><li>○ Relying on equipment on the application equipment that measures wind speed (e.g., aerial equipment).</li><li>○ 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</li></ul></li></ul>	
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		<p>anemometer. Ground applicators should stop every 15 minutes to take a reading with a tower anemometer with telemetry or handheld anemometer. Some anemometers may have software that would allow users to view wind measurements in real time while making an application, and, those cases, applicators would not have to stop to take measurements.</p> <ul style="list-style-type: none"> <li>○ Using a windsock. Wind can be estimated with a windsock using the strips on a windsock. The applicator should consult the user manual for the windsock on wind speed estimation and direction of wind. Applicators should look at the sock at least every 15 minutes to estimate wind speed and direction. [If there is a conservation area or aquatic habitat, buffer, include “The windsock should be pointed in the opposite direction of the windbreak and [CONSERVATION AREA/AQUATIC HABITAT]”].</li> <li>○ 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.</li> <li>○ Checking behind the spray rig at least every 15 minutes to see if the spray has changed direction from when the application started.”</li> </ul>	
<p><b>Advisory boomless ground sprayer drift language</b></p>	<p><b>Advisory Spray Drift Management Language for products that are applied as liquid with boomless ground sprayer equipment</b></p>	<p><b>“SPRAY DRIFT ADVISORIES Boomless Ground Applications:</b></p> <ul style="list-style-type: none"> <li>• Setting nozzles at the lowest effective height will help to reduce the potential for spray drift.”</li> </ul>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>
<p><b>Advisory handheld technology drift language</b></p>	<p><b>Advisory Spray Drift Management Language for products that are applied as liquid with handheld equipment</b></p>	<p><b>“SPRAY DRIFT ADVISORIES Handheld Technology Applications:</b></p> <ul style="list-style-type: none"> <li>• Take precautions to minimize spray drift.”</li> </ul>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

Description	Label Language	Placement on Label
<p><b>Seed Treatment Dye Statement</b></p>	<p><b>“REQUIRED DYE STATEMENT</b></p> <p>Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant or dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR, Part 2.25. Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR, Part 153.155(c).”</p>	<p>Directions for Use section of the FIFRA registered pesticide label (and on the seed bag tag if the seed has not been dyed before distribution)</p>
<p><b>Treated Seed Product</b> - Instructions for treated seed products produced using on-farm seed treatment (not for distribution or sale of the seed) with a FIFRA registered pesticide</p>	<p><b>“Use of On-Farm Treated Seed (when treated seeds are not for sale or distribution)</b></p> <p><b>Treated seed sold or distributed for a use not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12.</b></p> <ul style="list-style-type: none"> <li>• Store treated seed away from food and feedstuffs.</li> <li>• Do not allow children, pets, or livestock to have access to treated seeds.</li> <li>• Treated seeds are for planting purposes only. Do not use for food, feed, or oil purposes. Do not use treated seeds for fuel or ethanol production purposes.</li> <li>• Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting. Additional incorporation may</li> </ul>	<p>Directions for Use section of the FIFRA registered pesticide label</p>

	<p>be required to thoroughly cover exposed seeds.</p> <ul style="list-style-type: none"><li>• Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).</li><li>• Manage excess treated seeds (e.g., spilled, unused, or expired treated seeds) by one or more of the following methods:<ul style="list-style-type: none"><li>○ Collect excess treated seeds for reuse for planting.</li><li>○ Bury excess treated seeds (only allowed if totaling 1 pound or less) at least 30 feet away from bodies of water at a depth of 6 inches or double the planting depth, whichever is greater.</li><li>○ Dispose of excess treated seed by placing them in a landfill in accordance with applicable laws in your state.</li><li>○ Excess treated seeds may be returned to the supplier if permitted by the state.</li></ul></li><li>• Do not contaminate bodies of water when disposing of equipment wash water.</li></ul> <p><b>ADVISORY DUST-REDUCING TECHNIQUE</b> The use of seed flow lubricants or polymer coatings may help decrease the amount of dust released during planting. Follow the recommendations of the planter manufacturer regarding the use of seed flow lubricants.”</p> <p><b>[NOTE TO REGISTRANT:</b> All other requirements regarding the use of the treated seed, which include, but are not limited to, instructions</p>	
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	<p>relating to endangered species protection, environmental hazard statements, maximum use rates, soil incorporation depth, plant back intervals, personal protective equipment, and storage and disposal statements, remain and must be listed.]</p>	
<p><b>Treated Seed Product – Required Seed Bag/Container Labeling Instructions -</b></p> <p>For pesticide products allowed for use to treat seeds in commercial facilities or on-farm where the treated seed product is intended for sale or distribution (instructions must appear on seed bag tags when treated seeds are to be sold or distributed)</p>	<p><b>“Seed Treatment On-Farm (when treated seeds are to be sold or distributed) – Seed Bag Labeling Requirements”</b></p> <p><b>“The Federal Seed Act requires that bags containing treated seeds shall be labeled with the following statements:</b></p> <ul style="list-style-type: none"> <li>• <b>This seed has been treated with (insert name of active ingredient of pesticide).</b></li> <li>• <b>Do not use for food, feed, or oil purposes.”</b></li> </ul> <p><b>“The U.S. Environmental Protection Agency requires that bags containing treated seeds shall be labeled with the following statements. Any seed treated with [PRODUCT NAME] that is sold or distributed without these statements or that is sold or distributed for a use not permitted by the following labeling does not qualify as an exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12(a)(1)(A).</b></p> <p>This seed has been treated with [INSERT PRODUCT NAME(s) (EPA REG. NO(s))] containing [INSERT NAME(S) OF ACTIVE INGREDIENT(S)]. <b>Any seed treated with [PRODUCT NAME] that is sold or distributed for a use not permitted by the following labeling does not qualify as an</b></p>	<p>Directions for Use section of the FIFRA registered label</p>

	<p><b>exempted treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to FIFRA section 12(a)(1)(A).</b></p> <ul style="list-style-type: none"><li>• The contents of this bag are for planting purposes only. Do not use for food, feed, or oil purposes. Do not use for fuel or ethanol production purposes.</li><li>• Store treated seed away from food and feedstuffs.</li><li>• Do not allow children, pets, or livestock to have access to treated seeds.</li><li>• Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.</li><li>• Treated seeds exposed on the soil surface may be hazardous to wildlife. Cover or collect treated seeds spilled during loading and planting (such as in row ends).</li><li>• Treated seed may be collected for reuse for planting. If not collected for reuse, bury or dispose of all spilled seed in accordance with the following language:<ul style="list-style-type: none"><li>• Bury spilled seed at a depth of 6 inches or double the planting depth, whichever is greater. Bury all spilled seed at least 30 feet away from bodies of water.</li><li>• If seed spilled during loading or planting exceeds 1 pound, or if disposing of excess treated seed (such as expired, unused seed), dispose of seeds in accordance with applicable laws in your state.</li></ul></li></ul>	
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	<ul style="list-style-type: none"><li>• Do not contaminate bodies of water when disposing of equipment wash water.</li><li>• Dispose of seed packaging or containers in accordance with local requirements.</li></ul> <p><b>ADVISORY DUST-REDUCING TECHNIQUE</b> Fluency agents are recommended to be applied to seed after pesticide treatment prior to the planting.”</p> <p><b>[NOTE TO REGISTRANT:</b> All other requirements regarding the use of the treated seed, which include, but are not limited to, instructions relating to endangered species protection, environmental hazard statements, maximum use rates, soil incorporation depth, plant back intervals, personal protective equipment, and storage and disposal statements, remain and must be listed on the seed bag tag. All seed bag tags must be legible and set in at least 8-point font size.]</p>	
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## Appendix C: Listed Species Assessment

This Appendix provides general background about the Agency's assessment of the effects of pesticides on listed species and designated critical habitats under the Endangered Species Act (ESA).

### *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<sup>53</sup> 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.<sup>54</sup>

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.<sup>55</sup>

### *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 reinstate formal consultation with NMFS on malathion, chlorpyrifos and diazinon to consider new information that was not available when NMFS issued its 2017 biological opinion.

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<sup>53</sup> <https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report>.

<sup>54</sup> <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional>.

<sup>55</sup> <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.

In February 2022, EPA received a final malathion biological opinion<sup>56</sup> from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.<sup>57</sup> In August 2023, the Agency implemented the FWS malathion biological opinion by issuing Endangered Species Protection Bulletins<sup>58</sup> and approving malathion label amendments<sup>59</sup> 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.<sup>60</sup>

### *EPA's New Actives Policy and the 2022 Workplan*

In January 2022, EPA announced a policy<sup>61</sup> 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*.<sup>62</sup> This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

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<sup>56</sup> <https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions>.

<sup>57</sup> <https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions>.

<sup>58</sup> <https://www.epa.gov/endangered-species/endangered-species-protection-bulletins>

<sup>59</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0154>

<sup>60</sup> <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>.

<sup>61</sup> <https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides>.

<sup>62</sup> <https://www.epa.gov/endangered-species>.

On November 16, 2022, EPA released the *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions*.<sup>63</sup> 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 June 2023, EPA announced proposed mitigation for the Vulnerable Species Pilot, an implementation plan, and information on potential expansion of the pilot.<sup>64</sup> EPA also published interactive maps (StoryMaps) for the 27 pilot species to convey geospatial information about the location of the affected species and the location of draft pesticide application minimization and avoidance zones to protect these species.<sup>65</sup> Visit the public docket for more information about the Vulnerable Species Pilot (docket EPA-HQ-OPP-2023-0327 at [www.regulations.gov](http://www.regulations.gov)).

In July 2023, EPA published the framework of the Draft Herbicide Strategy<sup>66</sup> for public comment along with various supporting documents. For more information about the Herbicide Strategy, visit the public docket (docket EPA-HQ-OPP-2023-0365 at [www.regulations.gov](http://www.regulations.gov)).

EPA continues to work on these pilot efforts and once finalized, expects to implement these through registration review and new active ingredient registration.

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<sup>63</sup> <https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf>.

<sup>64</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2023-0327-0002>

<sup>65</sup> View the StoryMaps for the 27 pilot species here:

<https://storymaps.arcgis.com/collections/896d140363174c9d8ee78e4c471bd7fd>

<sup>66</sup> <https://www.regulations.gov/document/EPA-HQ-OPP-2023-0365-0009>

## Appendix D: Endocrine Disruptor Screening Program (EDSP)

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)).<sup>67</sup>

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.<sup>68</sup>

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

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<sup>67</sup> For additional details of the EDSP, please visit <https://www.epa.gov/endocrine-disruption>.

<sup>68</sup> 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 FFDC section 408(p) requirements and near-term strategies for EPA to further its compliance with FFDC 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 FFDC Section 408(p);*
- *List of Conventional Registration Review Chemicals for Which an FFDC 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](http://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<sup>69</sup> and November 2022 ESA Workplan Update<sup>70</sup>). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE memoranda<sup>71</sup> indicate that available data were sufficient for FFDC 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 FFDC 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

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<sup>69</sup> [https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use\\_final.pdf](https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf)

<sup>70</sup> <https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf>

<sup>71</sup> <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 FFDC 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 FFDC 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. Mancozeb was placed in Group 3 due to the lack of bioactivity in the ToxCast™ data for the Pathway Models.<sup>72</sup>

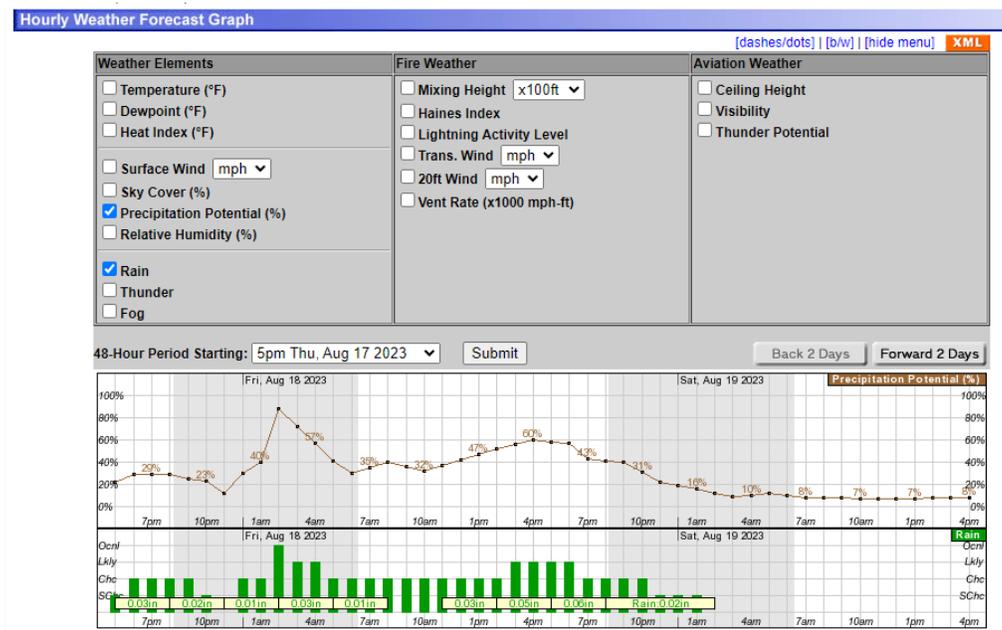
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<sup>72</sup> *List of Conventional Registration Review Chemicals for Which an FFDC 408(p)(6) Determination is Needed*; EPA-HQ-OPP-2023-0474-0002; <https://www.regulations.gov/document/EPA-HQ-OPP-2023-0474-0002>

## Appendix E: Surface Water Protection Statement: How to Determine the Amount of Rainfall Predicted Over 48 Hours

Current steps to determine the amount of rainfall predicted over 48 hours:

1. Navigate to: <https://www.weather.gov/>
2. Click the region where the pesticide application area is located.
3. Click the more specific region where the pesticide application area is located (this option may not be available for all locations)
4. Click on the 'Hourly Weather Forecast' link. The location of this link on the screen is different depending on your local forecasting office. *Tip: Can't find the link? On your keyboard press 'Ctrl' + 'F' at the same time to open up a search bar. In the search bar type: hourly weather. This will find the hourly weather forecast link on the page.*
5. Deselect all graph variables except "Precipitation Potential (%)" and "Rain", as shown in the screen shot below. Click the 'Submit' button to update the forecast.



6. Update the '48-Hour Period Starting' to the anticipated date/time of application.

*Note: the weather forecast should be accessed no more than 24 hours in advance of the anticipated pesticide application.*

7. Check the precipitation potential (brown line).

- a. If the precipitation potential meets or exceeds 50% for any hour during the 48-hour period, proceed to Step 8.
  - b. If the precipitation potential is less than 50% for all hours during the 48-hr period, then the pesticide application starting at the '48-Hour Period Starting' date selected for the pesticide application area would be compliant with the pesticide rain restriction.
8. Add the anticipated rainfall amount over the course of the 48-hour period. Below is an example based on the calculation of anticipated rainfall amount using the "Hourly Weather Forecast Graph" screen shot in Step 5 above:

Rain amount forecasted (in)
0.03
+ 0.02
+ 0.01
+ 0.03
+ 0.01
+ 0.03
+ 0.05
+ 0.06
+ 0.02
Total amount forecasted: <b>0.26</b> <b>inches</b>

- a. If the cumulative forecasted rain amount is less than 1 inch (as it is in the example above), then the pesticide application starting at the '48-Hour Period Starting' date selected for the pesticide application area would be compliant with the pesticide rain restriction.
- b. If the cumulative forecasted rain amount is 1 or more inches, then the pesticide application starting at the '48-Hour Period Starting' date selected for the pesticide application area would **NOT** be compliant with the pesticide rain restriction.