

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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Triadimefon

Interim Registration Review Decision Case Number 2700

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for triadimefon (PC Code 109901, case 2700). The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)¹ mandates a periodic review of existing pesticide registrations every 15 years, referred to as registration review.² During registration review, the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard.³ Where appropriate, the Agency may issue an ID before completing a final registration review decision.⁴ However, issuance of an ID is not a decision on whether a pesticide's registrations continue to satisfy the FIFRA standard for registration.⁵ Rather, the ID may include mitigation measures and changes to labeling that EPA has 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.⁶ The Agency is issuing this ID for triadimefon to identify risk mitigations that EPA has determined would address risks of concern for triadimefon, as presented in Section IV and Appendices A and B.

Triadimefon is a broad spectrum, systemic triazole-derivative fungicide. Triadimefon containing products are registered for use in turf and ornamental plant production, Christmas trees, and pine seed (except in CA) and seedlings. There are currently 12 conventional product registrations (10 end use products and 2 technical registrations) for triadimefon from two technical registrants: Environmental Science US, LLC (ESUS) and ChemStarr, LLC. (ChemStarr). There are no longer active antimicrobial registrations for triadimefon. Products containing triadimefon were first registered in the U.S. in 1968, and the Reregistration Eligibility Decision (RED) was published in 2006.

In October 2023, EPA published the amended proposed interim decision (PID) for triadimefon. The amended PID included some of the FIFRA interim ecological mitigation (FIFRA IEM) measures that were described in the ESA Workplan Update Appendix. EPA previously sought public comment on these FIFRA IEM measures⁷, which resulted in updates to the

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

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

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

⁴ 40 C.F.R. §§ 155.56, 155.58. Consistent with 40 C.F.R. § 155.58, EPA must first issue and take comment on a PID before issuing an ID.

⁵ At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration." 40 C.F.R. §§ 155.40(a), 155.57; FIFRA § 3(g), 7 U.S.C. § 136a(g); *see also* FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5) (FIFRA registration standard); FIFRA § 2(bb), 7 U.S.C. § 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] and "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). This document is not a "registration review decision" within the meaning of FIFRA Section 3(g) and 40 C.F.R. § 155.57.

⁶ 40 C.F.R. § 155.56.

⁷ <u>https://www.regulations.gov/document/EPA-HQ-OPP-2022-0908-0002</u>

proposed FIFRA IEM. The FIFRA IEM measures identified for triadimefon in this ID reflect these revisions. For more information, please review Section IV.B of this ID. Supporting documents for this ID (*Triadimefon and Triadimenol. Human Health Draft Risk Assessment in Support of Registration Review* and *Triadimefon: Draft Ecological Risk Assessment for Registration Review*) are available in EPA's public docket (EPA-HQ-OPP-2016-0114).

EPA has not yet fully evaluated triadimefon's effects on federally threatened and endangered (listed) species or designated critical habitats. However, consistent with its obligations under the Endangered Species Act (ESA),⁸ 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 triadimefon 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.⁹ 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.¹⁰ As part of this update, EPA announced that, going forward, EPA may include a variety of FIFRA Interim Ecological Mitigation (IEM) measures in its registration review decisions that seek to reduce exposures for nontarget organisms based on its FIFRA ecological risk assessment(s). EPA expects that this mitigation may also reduce pesticide exposures for listed species.

As part of this ID, EPA has considered a variety of FIFRA IEM measures based on the risks and benefits of triadimefon 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 has identified for triadimefon in this ID (Section IV.B) 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)]."

⁸ Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.

⁹ Balancing Wildlife Protections and Responsible Pesticide Use (Apr. 2022), https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-

https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticideuse_final.pdf.

¹⁰ ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions (Nov. 2022), <u>https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf</u>

This document is organized in five sections:

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

On April 11, 2016, the Agency formally initiated registration review for triadimefon with the opening of the registration review docket (EPA-HQ-OPP-2016-0114) for the case.¹¹ The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of triadimefon:

- April 2016 EPA posted the *Triadimefon and Triadimenol Preliminary Work Plan* (PWP) and supporting documents to the docket for a 60-day public comment period.
- October 2016 EPA posted the *Triadimefon and Triadimenol Final Work Plan* (October 26, 2016; FWP) to the public docket. The Agency received 4 comments on the PWP. These comments did not change the registration review timeline for triadimefon and triadimenol. However, the FWP included corrections to the list of data requirements for triadimefon needed to conduct a risk assessment to support a proposed registration review decision pursuant to 40 CFR § 155.53(b).
- August 2017 EPA issued a generic data call-in (GDCI) for triadimefon and triadimenol to obtain data needed to conduct the registration review risk assessments (GDCI-109901-1722 and GDCI-127201-1633). The Tier II/III honeybee data (*i.e.*, semi-field/field studies) have not been submitted. All other studies were submitted or waived by the Agency. For more information on the study waivers, and the Agency's rationale, see *Response to Waiver Requests for Triadimefon and Triadimenol Studies* (January 12, 2021). For more information on the Tier II/III honeybee data, see Section III.
- August 2021 EPA posted *Triadimefon and Triadimenol. Human Health Draft Risk Assessment* (June 16, 2021; HH DRA) and *Triadimefon: Draft Ecological Risk Assessment for Registration Review* (June 24, 2021; Eco DRA) for a 60-day public comment period,

¹¹ 40 C.F.R. § 155.50

which was extended for 30 days. The Agency received comments from 5 commenters. The comments did change the risk assessments and the registration review timeline for triadimefon and triadimenol. Portions of the U.S. Department of Agriculture's Office of Pest Management Policy's (USDA-OPMP) and Bayer CropScience's (Bayer) comments were technical in nature and included additional use information, which prompted the Agency to reassess portions of dietary, occupational handler, and residential post-application risk. These updates were considered in the PID for registration review.

- June 2022 EPA completed and posted the PID for triadimentiation and triadimenol for a 60-day public comment period. The Agency received 5 comments, which the Agency responded to in the amended PID.
- October 2023 EPA completed and posted the amended PID for triadimefon to propose FIFRA Interim Ecological Mitigation measures (IEM) per the Agency's ESA Workplan Update.¹² The amended PID was open to a 60-day public comment period. The Agency received 3 comments. The Agency has summarized and responded to these comments in Section I.B., below. The comments did not change the risk assessments, risk mitigation, or registration review timeline for triadimefon. Since all registered uses of triadimenol (PC Code 127201, case 7008) were cancelled, EPA issued a case closure for triadimenol in a separate action.¹³
- May 2023 EPA posted this ID for triadimefon. Along with the ID, EPA plans to post the following document into the public docket:
 - Triadimenol Use Characterization on Cotton seeds and a List of Registered Fungicides for Triadimefon to Control Fungal Pests, October 10, 2018.

B. Summary of Public Comments on the Amended Proposed Interim Decision and Agency Responses

During the 60-day public-comment period for the triadimefon amended PID (October 18, 2023 to December 18, 2023), the Agency received 4 public comments. Comments were submitted by the United States Department of Agriculture Office of Pest Management Policy (USDA-OPMP), National Agricultural Aviation Association (NAAA), Washington State's Department of Agriculture (WSDA), and one comment was submitted that did not pertain to this case. The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. The Agency thanks all commenters for participating and has considered all comments in developing this ID.

¹² <u>https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf</u>

¹³ <u>https://www.regulations.gov/document/EPA-HQ-OPP-2016-0114-0086</u>

Comments Submitted by the USDA-OPMP (Docket ID: EPA-HQ-OPP-2016-0114-0089)

Comment: USDA supported EPA's mitigation and label updates including mandatory spray drift measures, droplet size requirements, gloves statement, advisory statements (*e.g.*, groundwater, resistance management, *etc.*), and water-soluble packaging and mixing/loading language. USDA also supported the Agency's IEM measures (Bulletins Live! Two labeling, ecological incident reporting language, wind-directional spray drift buffers, treated seed and pollinator advisories, and surface water protection statement).

EPA Response: EPA thanks the USDA for providing input on the amended PID, as well as its prior comments on the FIFRA IEM, which were considered in the updates to the FIFRA IEM included in this ID.

Comments Submitted by NAAA (Docket ID: EPA-HQ-OPP-2016-0114-0089)

Comment: NAAA supported EPA's proposed spray drift wind-directional buffers to reduce drift into aquatic and conservation areas, as well as the label requirements to measure wind speed and direction. Additionally, NAAA supported the Agency's proposed 10-foot aerial application release height, restriction for applications during temperature inversions, boom length and nozzle selection restrictions, and upwind swath displacement. NAAA also provided comments regarding the spray drift analysis conducted in the draft risk assessment, particularly concerning the spray drift model, AgDRIFT, and the maximum allowable wind speed used in the model (10 mph). NAAA believes that the Tier-1 component of the AgDRIFT model is inadequate because some of the assumptions it uses are unrealistic.

EPA Response: The Agency acknowledges and thanks NAAA for their comments. AgDRIFT is the currently approved model for evaluating potential spray drift from a pesticide application. The Agency appreciates the additional suggestions provided by NAAA for revising the AgDRIFT modeling inputs and continues to work with industry to update and improve modeling methods to better reflect typical application practices. At the December 2020 Center of Excellence in Regulatory Science in Agriculture (CERSA) workshop, EPA, NAAA, and other stakeholders discussed these potential refinements for AgDRIFT modeling. EPA is currently reviewing these suggestions and will consider them for future risk assessment. However, EPA first conducts modeling for a national-level assessment using maximum application rates, limitations, and instructions listed on the pesticide product labels. In the absence of specific use directions and application restrictions implemented across all product labels, EPA uses default assumptions (based on empirical data).

<u>Comments Submitted by Washington State Department of Agriculture (WSDA) (Docket ID:</u> <u>EPA-HQ-OPP-2016-0114-0091)</u>

Comment: WSDA asked if EPA utilized groundwater monitoring data for 1,2,4-triazole in estimating dietary risk from drinking water sources.

EPA Response: The Agency evaluated the common degradate 1,2,4-triazole separately from its parent compounds in *1,2,4-Triazole, Triazole Alanine, & Triazole Acetic Acid: Drinking Water Exposure Assessment for Registration Review*.¹⁴ That drinking water assessment considered exposures of 1,2,4-triazole from all conazole fungicides that degrade to 1,2,4-triazole, including triadimefon, and monitoring data were utilized in the characterization of 1,2,4-triazole exposures in drinking water.

Comment: WSDA noted there are fourteen conazole active ingredients from which 1,2,4triazole is a degradate and asked how EPA accounted for exposures to 1,2,4-triazole from all fourteen active ingredients when estimating dietary risk. WSDA also asked EPA to clarify whether the mitigation proposed in the amended PID adequate to address the risks posed from all sources of 1,2,4-triazole.

EPA Response: In January 2022, the Agency issued a dietary exposure and risk analysis¹⁵ for the common triazole metabolites 1,2,4-triazole, triazolylalanine (TA), and triazolylacetic acid (TAA). The 2022 dietary assessment includes exposure estimates resulting from direct consumption of 1,2,4-triazole as well as indirect exposure resulting from consumption of parent fungicides followed by *in vivo* conversion to 1,2,4-triazole. In addition, in the 2022 dietary assessment acute and chronic assessments were also conducted for combined residues of TA and TAA. At the time of the assessment, acute and chronic dietary exposure estimates were below HED's level of concern for all population subgroups, including those of infants and children, for 1,2,4-triazole as well as the conjugated triazole metabolites.

The Agency's Health Effects Division (HED) is in the process of reviewing data recently submitted by the U.S. Triazole Task Force and updating the dietary risk assessment for 1,2,4-Triazole. As previously stated, the new assessment will include exposure estimates resulting from direct consumption of 1,2,4-triazole as well as indirect exposure resulting from consumption of parent fungicides followed by *in vivo* conversion to 1,2,4-triazole. It is anticipated that acute and chronic dietary exposure estimates are below HED's level of concern for all population subgroups.

Comment: WSDA asked if the Agency has a plan to address antifungal resistance from the use of conazole fungicides and the possible implications that their use could have for future effectiveness of drugs used to treat human and animal diseases.

EPA Response: EPA is aware that evidence suggests that the use of some azole fungicides has led to severe azole-resistant *A. fumigatus* infections in the United States and in Europe, however, this resistance effect is not expected to apply to all of the azole fungicides. EPA is working to clarify how to address this resistance concern in our regulatory processes. Also,

¹⁴ <u>1,2,4-Triazole, Triazole Alanine, & Triazole Acetic Acid: Drinking Water Exposure Assessment for Registration</u> <u>Review</u> (US EPA, 2020).

¹⁵ Morton, T. 2022. Common Triazole Metabolites: Updated Dietary (Food + Water) Exposure and Risk Assessment to Address the Establishment of a Propiconazole Tolerance and Section 3 Registrations on Vegetable, Brassica, head and stem, group 5-16.

through a U.S. government interagency process, EPA, the U.S. Department of Health and Human Services (HHS), and USDA, under the oversight of the White House Executive Office of the President, are developing a framework that will improve assessments of potential risks to human and animal health where the use of pesticides could potentially result in antimicrobial resistance that compromises the effectiveness of medically important antibacterial and antifungal drugs.

As the first step in this process, EPA, HHS, and USDA published a concept note in September 2023.¹⁶ The proposed framework described in the concept note will expand EPA's current process for assessing the risk that antibacterial or antifungal pesticides may pose to the effectiveness of human and animal antibacterial and antifungal drugs when EPA evaluates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA expects to issue a draft framework later this year. Additional information can be found at: https://www.epa.gov/pesticides/feedback-requested-structure-and-scope-proposed-framework-strengthen-assessment.

With specific regard to triadimefon, it is important to note that it is not registered for fungal control in U.S. food production. Therefore, while the extent to which triadimefon's continued use on turf and ornamentals contributes to azole resistance may be further clarified through the continued work related to the draft framework, dietary exposure through residues on food is not anticipated with the exception of imported bananas. Despite this uncertainty, the Agency has identified label changes in this ID as necessary to mitigate the risks of concern identified for exposure to triadimefon through drinking water and aggregate risk (see Section III.A)

II. USE AND USAGE

Triadimefon is a triazole fungicide (FRAC code 3) as per the Fungicide Resistance Action Committee¹⁷ (FRAC); it is a broad-spectrum fungicide that has protectant and curative properties against fungal plant diseases. There are 12 registrations (two technical registrations and ten end-use registrations) for triadimefon. Triadimefon is registered for use on commercial, institutional, and residential turf (including residential lawns and turf sites associated with apartments, daycare centers, playgrounds, recreational parks, schools), sod farms, golf courses, athletic fields, ornamentals (including nurseries, greenhouses, garden centers, and interior plantscapes), Christmas trees, and pine seedlings and pine seed treatment (except in California). Triadimefon products are available as water-dispersible granules, suspension concentrates, and ready-to-use formulations for application via aerial, airblast, and ground boom application equipment, handheld and backpack sprayers, chemigation, seed treatment (pine seed only) and tree injection.

¹⁶ <u>https://www.regulations.gov/document/EPA-HQ-OPP-2023-0445-0002</u>

¹⁷ Fungicide Resistance Action Committee (FRAC). 2024. FRAC Code List 2024: Fungal control agents sorted by cross resistance pattern and mode of action (including coding for FRAC Groups on product Labels). Accessed April 2024. https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2024.pdf?sfvrsn=d49c4e9a_2

The maximum single application rate for golf course turf and sod farms is 2.7 pounds of active ingredient per acre (lbs a.i./A). For residential and recreational turf, the maximum single application rate is 2.0 lbs a.i./A. For ornamentals and Christmas trees, the maximum spray solution concentration for ornamentals is 0.0025 lbs a.i./gallon applied to the point of drip. Currently, triadimefon labels do not specify annual or single maximum application rates by unit area for ornamental use, except for one registered product (Armada 50 WDG; EPA Reg. No. 101563-142), which specifies a maximum annual application rate of 5.39 lbs a.i./A/year. The maximum single application rate for foliar treatment of pine seedlings is 2.0 lbs a.i./A and the maximum for pine seed treatments is 0.0012 lbs a.i./lb seed. One registered product (Tide Triadimefon 500 WDG; EPA Reg. No. 84229-55) specifies a maximum annual application rate of 32.0 lbs a.i./A/year as a foliar application to pine seedlings.

The most recently available survey of pesticide use in turf and ornamentals was conducted in 2021. In 2021, triadimefon was used throughout the U.S. on golf courses, nursery and greenhouse grown plants, institutional turf, sod farms, and by lawn care operators and landscape contractors.¹⁸ In 2021, about 5,800 lbs of triadimefon were applied to golf courses, about 5,200 lbs a.i. were applied to nursery and greenhouse grown plants and about 1,400 lbs a.i. were applied to institutional turf.¹⁸ In 2021, about 2,300 lbs of triadimefon were applied to sod farms.¹⁸ Lawn care operators, who apply pesticides to commercial, institutional, and residential properties, applied about 40,600 lbs of triadimefon nationally.¹⁸ Landscape contractors, who generally design, plant, and care for flower beds and other landscaping, applied about 6,500 lbs of triadimefon in 2021.¹⁸

No triadimefon usage was reported on parks or within cemeteries in 2021.¹⁸ The Agency does not have specific surveys of pesticide usage on pine seedlings or Christmas trees. The absence of such data should not be interpreted as lack of usage.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the Agency's human health risk assessment for triadimefon is presented 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 triadimefon. For additional details on the human health risk assessment for triadimefon, see the 2021 *Triadimefon and Triadimenol. Human Health Draft Risk Assessment in Support of Registration Review* (HH DRA) and the 2022 *Triadimenol. Triadimefon. Addendum to the Human Health Draft Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2016-0114).

While triadimenol's U.S. registrations have been cancelled, triadimenol is also a major mammalian metabolite of triadimefon. The points of departure (PODs) and endpoints are based on studies conducted with triadimefon, but the selected PODs are also protective of effects in

¹⁸ Nonagricultural Market Research Data (NMRD). 2022. Study of turf and ornamental usage in 2021. [Accessed May 2023].

the triadimenol database. This was considered appropriate due to the two chemicals' structural similarity, toxicological similarity and shared pesticidal mode of action.

The anticipated exposure pathways for triadimefon include dietary exposure from food and drinking water, and occupational handler exposure while mixing, loading, and applying triadimefon products. Workers may also be exposed post-application while re-entering treated fields. Exposures for occupational handlers and workers re-entering treated fields are anticipated to be short- (1 - 30 days) and intermediate-term (1 - 6 months). There are no products containing triadimefon that are marketed for consumer use; therefore, a residential handler risk assessment was not conducted for triadimefon. There is the potential for adults and children to be exposed to triadimefon after an application in residential spaces (*e.g.*, apartments, daycare centers, playgrounds, schools, *etc.*), as well as drift from agricultural applications. These exposures are anticipated to be short-term (1-30 days).

1. Risk Summary and Characterization

EPA identified acute and chronic dietary risks of concern that are primarily driven by drinking water residues (greater than 99% of the estimated dietary exposure and risk is from residues found in drinking water) based on applications at the current labeled rates for all use sites. There are no residential risk estimates of concern and short-term aggregate risk estimates are not of concern. The acute and chronic aggregate risk estimates include food (imported bananas) and drinking water and are the same as the acute and chronic dietary risks.

a. Dietary (Food + Water) Risks

Potential acute and chronic dietary risks of concern are identified when the acute or chronic population adjusted dose (aPAD and cPAD, respectively) exceed the level of concern (LOC) of 100% PAD. EPA identified potential acute and chronic risks of concern associated with dietary exposure to triadimefon. Drinking water exposures of triadimefon's residues of concern (ROCs) may occur in surface water and/or groundwater. Following triadimefon applications, residues may be transported to surface water bodies from direct deposition of spray drift and from runoff, where the triadimefon residues undergo transformation to triadimenol, which are more persistent in aerobic aquatic conditions. In soil, triadimefon readily undergoes aerobic degradation to its degradate triadimenol, which is both persistent and moderately mobile, and may be leached to groundwater. The human health endpoint for acute dietary exposure is increased motor activity observed in a rat developmental toxicity study, whereas the chronic dietary endpoint is based on hyperactivity observed in a rat subchronic neurotoxicity study.

Since triadimenol is a structurally similar degradate of triadimefon, and since there is an established tolerance for triadimenol on bananas (imported), bananas were considered in the dietary risk assessment. There are no registered uses for triadimefon on food crops, and, therefore, no other food crops were considered in the dietary assessment. Exposure to food

alone does not result in acute or chronic dietary risks of concern. Exposure to residues in drinking water (groundwater) was the primary contributor to dietary risks, regardless of use site. In the 2021 HH DRA, risk estimates for the most highly exposed population subgroup (all infants) were 164% of the aPAD and 138% of the cPAD. Therefore, there are acute and chronic dietary risks of concern from residues of triadimefon in groundwater drinking water. In accordance with the Guidelines for Classifications of Carcinogens (1986), EPA has classified triadimefon as a "possible human carcinogen." The triadimefon cancer classification is based on an increase in benign hepatocellular adenomas in male and female mice, as well as an increase in benign thyroid adenomas in male rats. The chronic reference dose (cRfD) is considered protective of potential carcinogenicity for the purpose of risk assessment. The chronic dietary risk estimate for cancer was 27% of the cPAD. Based on this chronic dietary risk estimate, cancer risk is not a concern.

b. Residential Post-Application Risks

There is potential for post-application exposure for individuals that are exposed to residues from environments treated with triadimefon. In the 2021 HH DRA, residential post-application exposures to triadime for were based on incidental oral exposures (*i.e.*, hand-to-mouth, objectto-mouth, soil ingestion) to treated residential turf for children aged one to two years old. A previously submitted chemical-specific turf transferrable residue (TTR) study for triadimefon has been determined to be unacceptable for use in risk assessment. Instead, the risk assessment relied on the default assumption that 1% of the application (liquids) is available for transfer on day 0 following the application and a residue dissipation rate of 10% each following day. The margins of exposure (MOEs) were not of concern (MOEs ranged 240 to 110,000, with a LOC of 100). Based on comments on the 2021 HH DRA that noted an incorrect label rate was assessed, EPA corrected the residential turf application rate from 2.7 lbs a.i./A to 2.0 lbs a.i./A to reassess the residential post-application scenarios (see the 2022 Triadimefon/Triadimenol: Addendum to the Occupational and Residential Exposure Assessment in Support of Registration *Review*; available in the docket: EPA-HQ-OPP-2016-0114). The revision did not change any risk conclusions, and there are no risks of concern from residential exposures (revised MOEs ranged from 330 to 150,000).

Since the lowest-observed-adverse-effect level (LOAEL, 2,000 mg/kg) was higher than the dermal limit-dose (1,000 mg/kg/day), a quantitative assessment for dermal post-application exposure and risk was not conducted for adults or children. Furthermore, adults are only exposed to treated turf via the dermal route; therefore, a quantitative post-application risk assessment was not conducted for adults.

c. Bystander Risks

A quantitative spray drift assessment for triadimefon was not conducted since the current labeled maximum single application rate for non-residential turf (*e.g.*, turfgrass, sod farms) multiplied by the drift adjustment factor (0.26) is less than the current labeled maximum single application rate for residential turf (*e.g.*, apartments, daycare centers, schools, *etc.*). Therefore,

residential post-application exposure and risk from application to turf is considered protective of all non-occupational spray drift exposure and is not of concern.

d. 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 triadimefon, acute aggregate risk estimates are equivalent to the acute dietary risk estimates, and, therefore, there are risks of concern for the "all infants" subgroup. Likewise, there are chronic aggregate risks of concern for the "all infants" subgroup.

The short-term aggregate risk assessment (drinking water, food, and residential) is based on children aged one to two years old exposed to treated turf, which resulted in an MOE of 220. As the resulting aggregate MOE is greater than the LOC of 100, short-term aggregate risk is not of concern.

e. Cumulative Risks

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to triadimefon, and any other substances.¹⁹ Although the conazole fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated metabolites, these substances do not contribute to the toxicity of the parent conazole fungicides (triazoles). The Agency assessed the aggregate risks from 1,2,4 triazoles and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately¹⁵ since these metabolites are common to other triazole-derivative fungicides. That assessment did not identify any risks of concern associated with exposure to the triazole metabolites. Triadimefon does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that triadimefon has a common mechanism of toxicity with other substances. In 2016, EPA's Office of Pesticide Programs released a guidance document titled, Pesticide Cumulative Risk Assessment: Framework for Screening Analysis [https://www.epa.gov/pesticide-science-andassessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework]. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a twostep approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs)²⁰ and

¹⁹ EPA's assessments of conazoles prior to the development of the 2016 Framework document noted the lack of conclusive data to make a common mechanism of toxicity finding for the conazoles.

²⁰ <u>Guidance for Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity</u> (US EPA, 1999).

conducting cumulative risk assessments (CRA).²¹ During Registration Review, the Agency will utilize this framework to determine if the available toxicological data for triadimefon suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposures.

f. Occupational Handler Risks

Occupational handler exposure is expected from the registered uses of triadimefon. The occupational handler risk assessments for triadimefon were based on short- and intermediate-term inhalation exposures. Dermal exposures were not assessed due to the lack of dermal hazard identified at doses relevant to human health risk assessment (*i.e.*, LOAEL of 2,000 mg/kg > dermal limit-dose of 1,000 mg/kg/day).

Occupational handler risk estimates for turf and ornamental uses ranged from 94 to 2,100,000 (LOC = 100) with baseline attire (*i.e.*, long-sleeved shirt, pants, shoes, and socks) and no PPE (*i.e.*, no respirator), and were not a concern for all but two exposure scenarios. The two scenarios with risk estimates of concern are for mixers and/or loaders of dry formulations (DF) for aerial and chemigation applications to sod farms (MOEs = 94).

Risks were not identified for occupational handlers exposed during seed treatment operations, where MOEs ranged 82,000 to 7,600,000 (LOC = 100). All seed treatment risk estimates are presented for baseline attire except for the water-soluble packets (WSP) scenarios, which are considered an additional engineering control that reduces exposure potential.

g. Occupational Post-Application Risks

Dermal Exposures

Occupational dermal post-application exposures are expected, however, there was no dermal hazard identified at doses relevant to human health risk assessment. Dermal exposures have not been quantitatively assessed for triadimefon, and risk is not expected.

Inhalation Exposures

There is potential for occupational post-application exposure to triadimefon when workers are performing job functions in previously treated areas. However, since occupational handler exposures are expected to be higher than exposures from post-application, an occupational post-application inhalation exposure assessment was not performed. The Agency has determined that the occupational handler inhalation risk estimates are protective of the occupational post-application exposures in treated turf or ornamentals. For seed treatments,

²¹ <u>Guidance on Cumulative Risk Assessment of Pesticide Chemicals that have a Common Mechanism of Toxicity</u> (US EPA, 2002).

inhalation exposure estimates for handlers are considered protective of any potential postapplication exposure, and, therefore, a post-application assessment was not conducted. The Agency has concluded that there are no post-application inhalation risks of concern.

2. Human Incidents and Epidemiology

EPA reviewed triadimefon 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 May 16, 2022, IDS and SENSOR showed two minor-severity incidents reported from January 1, 2016 to May 16, 2022. One case involved a groundskeeper who touched his face with a glove that had pesticide residue on it. He experienced skin irritation where had had touched his face with the glove. He subsequently went to the emergency room where he was diagnosed and treated for minor chemical exposure (*i.e.*, skin redness, burning sensation and pain on the skin). The second incident involved a bystander who reported that she may have been exposed to spray drift from a neighboring Christmas tree farm. While she did not smell or feel the spray, she reported having a headache, eye pressure, itchy/irritated eyes, runny nose, sneezing, and skin itchiness/irritation. The Agency intends to monitor human incidents for triadimefon and will conduct additional analyses if necessary.

Literature searches were conducted in March and November 2022 for triadimefon. All studies identified in the PubMed search were screened when the citation list was less than a hundred. Screening of larger citations lists (more than a hundred citations) was conducted after prioritization in SWIFT-Review and focused on studies identified with the "Animal" and/or "Human" tag. Following title/abstract and/or full text screening, no studies were identified as containing potentially relevant information (either quantitative or qualitative) for the triadimefon human health registration review risk assessment.

3. <u>Tolerances</u>

Triadimefon is currently registered for use as a fungicide on pine seedlings, Christmas trees, ornamental plantings and landscapes (exterior/interior), and turf in commercial (*i.e.*, golf course and sod) and residential settings. It is also registered for use as a tree injection and seed treatment on pine seeds (both commercial and on-farm). Currently registered uses of triadimefon do not result in residues on food. Triadimefon was previously registered for use on pineapples, but this registration was cancelled in January 2020.²² An existing tolerance for triadimefon residues is still established under 40 CFR § 180.410.²³ Since the registered use for that commodity has been cancelled, EPA has determined that a revision to the CFR is necessary. For more information, see Section IV.D.

²² Cancellation Order for Certain Pesticide Registrations and Amendments to Terminate Uses. 85 Fed. Reg. 310. January 3, 2020.

²³ https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.410

4. Human Health Data Needs

The Agency identified turf transferable residue (TTR) as a data gap. Bayer submitted a TTR study in 1993 that implemented the polyurethane foam roller (PUF) method for residue sample collection; however, in 1999, the Outdoor Residential Exposure Task Force (ORETF) issued a report that the modified California roller method should be used for all future TTR studies. Given the consistency and low-level residue detection capabilities of the modified California roller method, the Agency determined that the submitted PUF TTR study was no longer valid for risk assessment, and that a modified California roller method study is now preferred for assessing risks. A triadimefon study implementing the modified California roller method was not available for the registration review risk assessment, so the Agency relied on conservative default values. EPA has determined that the default values were sufficient to conduct the 2021 HHRA and to support this ID because the conservative assumptions used for the exposure assessment are expected to be protective. Since the Agency did not identify risks of concern, the Agency does not identify a need for additional data, but still considers the TTR a data gap since the default values did not result in risk estimates greater than 10 times the LOC (MOE = 330, LOC = 100).

B. Ecological Risks

The Agency has summarized the 2021 Ecological 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 triadimefon. For additional details on the 2021 Eco DRA, see *Triadimefon: Draft Ecological Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2016-0114).

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 triadimefon's risks to listed species. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the triadimefon 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

Risk quotients (RQs) were compared against the Agency's LOCs to estimate potential risks, where the RQ is the ratio of exposure estimates compared to the toxicity endpoints. RQs greater than the LOC represent potential risks of concern. EPA uses LOC exceedances as one line of evidence to describe the potential risks posed by a pesticide to non-target organisms. Triadimenol is the primary degradate formed by triadimefon in both soil and aquatic systems and has been observed in amounts up to 49% in field dissipation studies. Also, both triadimefon and triadimenol share similar chemical structure and mobility in the environment. Given these similarities, as well as the availability of data for both chemicals, the Agency used the most

sensitive endpoint available from either dataset. For aquatic taxa and bees, triadimefon is considered more toxic. The Agency identified potential chronic risks of concern to freshwater and estuarine/marine fish and freshwater and estuarine/marine invertebrates exposed to triadimefon. Additionally, the Agency identified potential acute and chronic risks of concern to terrestrial invertebrates. For mammals, the Agency identified potential acute risks of concern. For birds and mammals, there are potential chronic risks of concern. There were also potential risks of concern identified to terrestrial plants (dicots only) from aerial and ground applications to turf, and from applications to ornamentals at the maximum single application rates.

a. Terrestrial Risks

EPA estimated potential dietary exposure to triadimefon and its degradate triadimenol for terrestrial wildlife (birds and mammals) based on the consumption of treated turf shortgrass (foliar applications), as well as the consumption of treated pine seeds. Residues of the degradate, 1,2,4-triazole were also considered in the risk assessments for birds as acute avian data indicated it was more toxic than parent triadimefon and the degradate triadimenol.

<u>Mammals</u>

On-field Exposure

Acute RQs range from <0.01 to 0.72, based on the upper bound exposure estimates and using the most sensitive toxicity data (for rats exposed to the degradate triadimenol), exceed the LOC (0.5) for small and medium-sized mammals feeding only on short grass from the turf use. However, there were no LOC exceedances when the mean exposure estimates were considered in the risk assessment.

Rats chronically exposed to triadimefon showed decreased pup weights and viability in the first and second filial generations. The no-observed-adverse-effects concentration (NOAEC) for rat offspring was 50 mg ai/kg-diet, and the lowest-observed-adverse-effects concentration (LOAEC) was 1800 mg ai/kg-diet. Also, rat fertility was affected at the high dose (90 mg/kg-body weight/day) in all generations observed in a three-generation reproduction study. Additionally, rat fertility was decreased in the high-dose first generation parents in the two-generation reproduction study. Rats exposed to the degradate triadimenol showed decreased pup weights in a two-generation chronic toxicity study, where the NOAEC was 100 mg ai/kg-diet and the LOAEC was 500 mg ai/kg-diet. Estimated environmental concentrations (EECs) on terrestrial food items range from 18 to 1139 mg/kg-diet based on upper bound exposure estimates. Dosebased EECs, adjusted for body weight, range from 0.6 to 1086 for mammals.

Potential chronic risks of concern to mammals were identified from all registered uses of triadimefon except for tree injections, which were not quantitatively assessed. Chronic dose-based RQs ranged from 0.3 to 197 and exceeded the Agency's LOC (1.0) for all registered use sites, size classes (0.15 g, 0.35 g, 1,000 g) and dietary items except for large granivore mammals, where the LOC was only exceeded for the highest multiple application turf use. Also,

chronic dietary-based RQs ranged from 0.8 to 22 and exceeded the Agency's LOC (1.0) for all use sites and dietary items except for fruit, pod, or seed consuming mammals (however, there was still an exceedance for the highest multiple application turf use for this genus of mammals). Both the chronic dosed-based and dietary-based RQs were based on the upper bound exposure estimates; however, there were still exceedances to the chronic dietary-based RQs when the mean exposure estimates were considered (RQs ranged 0.4 - 8). Additionally, chronic risks were observed for seed-eating mammals that may potentially consume pine seeds treated with triadimefon (RQs ranged 1.38 to 1.62; LOC = 1.0). Assuming 50,000 pine seeds per acre²⁴, the number of seeds ingested to reach the LOC is 22, 42, and 523 seeds for small, medium and large mammals, respectively. Based on the Agency's standard consumption rates for terrestrial vertebrates²⁵, this translates to 6.7%, 7.6% and 14.0% of the daily diet for small, medium and large mammals, respectively. However, the number of days required to forage these triadimefon-treated seeds to result in a chronic effect is unknown. When the chronic dietary LOAEC for triadimefon (1800 mg a.i./kg-diet) was used to calculate risk, RQs did not exceed the LOC (1.0) for any uses. For dose-based chronic risk using the mammalian LOAEC for triadimefon, there would not be any risk for mammals consuming fruits, pods, seeds or arthropods, but some risks would still remain for mammals eating short grass, tall grass or broadleaf plants.

Off-field Exposure

The Agency used the AgDRIFT model to assess risks associated with off-target spray drift from aerial applications to turf, which use fine to medium droplet sizes and medium or coarser droplet sizes, and ground applications to turf. Risks of concern from aerial applications extend beyond 1000 feet from the edge of the field regardless of droplet size (modeled up to medium and coarser droplets). Dosed-based risks of concern for mammals from ground applications with high boom sprayers (fine to medium/coarse droplets) extend up to 151 feet from the edge of field. Risks of concern from aerial applications extended up to 203 (fine/medium droplets) and 121 (medium and coarser droplets) feet from the edge of field, where ground applications (fine and coarser droplets) extended 13 feet from the edge of field.

Birds, Reptiles, and Terrestrial-Phase Amphibians

The Agency assesses risk to birds directly and uses the assessment as surrogate for reptiles and terrestrial phase amphibians.

²⁴ USDA. 1952. Relationships of Red Pine Seed Source, Seed Weight, Seedling Weight, and Height Growth in Kane Test Plantation. Accessed online at <u>https://www.nrs.fs.fed.us/pubs/sp/sp_ne050.pdf</u> on April 1, 2021. A.J. Hough, Northeastern Forest Experiment Station, Forest Service, USDA.

²⁵ USEPA. 1993. Wildlife Exposure Factors Handbook EPA/600/R-93/187a, Office of Research and Development, Washington, DC.

On-field Exposure

For avian species, an acute endpoint for triadimefon was non-definitive (> 2,000 mg ai/kg-bw) and greater than the maximum EECs (1297 mg/kg-bw). As a result, a quantitative assessment for triadimefon was not conducted, and acute risk to avian birds is not anticipated. However, the acute endpoint for the degradate, 1,2,4-triazole, was more toxic than triadimefon (bobwhite quail $LD_{50} = 770$ mg/kg-bw). Therefore, there is a potential risk for small birds consuming short grass (dose based acute RQ = 0.80; LOC = 0.5) with 1,2,4-triazole residues following multiple application to turf. For passerine birds, there is some uncertainty because there are no valid acute oral data available, and treatment-related regurgitation was observed in a study using triadimenol on passerine birds. There was no mortality observed in the passerine bird study.

The primary chronic effect observed in a bobwhite quail study at the LOAEC (100 mg ai/kg-diet) was a decrease in the number of fertile eggs and viable 14-day old survivors. The NOAEC from the bobwhite quail study was determined to be 20 mg ai/kg-diet. In contrast, a mallard duck study demonstrated a NOAEC at the highest tested concentration of triadimefon at 780 mg ai/kg-diet. Avian reproductive toxicity tests were also performed with the degradate triadimenol. The NOAEC for mallard duck was determined to be 100 mg ai/kg-diet, based on 38% decreases in the number of eggs laid, viability, hatchability, and 14-day survivors at 500 mg ai/kg-diet. Dietary-based chronic RQs ranged 1 - 57 and exceeded the LOC (1.0) for all uses, including treated pine seeds. RQs based on the mean exposure estimates did not reduce potential risks below the LOC (RQs ranged from 0.4 - 20) for all uses except ground applications to turf and ornamentals. Given the magnitude of RQ exceedances and the risk characterization above, the Agency identified chronic risks to birds.

Chronic risks were determined for seed-eating birds that may consume pine seeds treated with triadimefon (RQ = 2.10; LOC = 1.0). Based on USDA's assumption of 50,000 pine seeds per acre¹³, the number of seeds ingested to reach the LOC is 8, 39 and 385 seeds for small, medium and large birds, respectively. Based on EPA's assumptions on terrestrial vertebrate consumption rates¹⁴, these numbers of seeds translate to 1.5%, 2.5% and 5.4% of the daily diet for small, medium and large birds, respectively. The exposure window and/or number of days foraging triadimefon-treated seeds to result in chronic toxicity is not known. The dietary-based risks are expected for all scenarios except for birds consuming fruits, pods, or seeds when considering the LOAEC, where decreased reproduction and avian hatchling survival were observed.

Off-field Exposure

The Agency used the AgDRIFT model to assess risks associated with off-target spray drift from aerial applications to turf, which use fine to medium droplet sizes and medium or coarser droplet sizes, and ground applications to turf. Risks of concern from aerial applications extended 535 and 262 feet from the edge of field (fine/medium and medium to coarser

droplets, respectively), and ground application (medium to coarser droplets) spray drift risk extended 33 feet from the edge of field.

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 triadimefon uses may present risks of concern to honey bees.

As discussed below, in Section III.B.3 "Ecological and Environmental Fate Data Needs," the Agency did not have sufficient information to assess chronic risk to individual bees, and EPA has concluded that additional pollinator data are necessary to fully evaluate risks to bees from use of triadimefon. Once adequate pollinator data are received and reviewed, the Agency will reassess risk to pollinators and consider any additional mitigation changes that will be needed for triadimefon.

On-field Exposure

Triadimefon is registered for use on pollinator attractive flowering plants (ornamentals), and turf. Acute contact and oral risks were identified for some uses (RQs ranged 0.1 - 1.8; LOC = 0.4) with the greatest risks of concern from ground applications to turf and ornamentals and aerial applications to turf, where there is an acute oral risk to adult bees (RQ = 1.8). While turf is a major use (primarily sod farms) for triadimefon, EPA assumes that these areas are likely to be maintained to control for the presence of flowering weeds potentially attractive to pollinators, given the importance of turf aesthetics to triadimefon users. For this reason, the Agency concluded that the likelihood of exposure to adult bees from the turf use is low.

There were chronic risks of concern identified for larval worker honey bees and adult bees, where RQs ranged from 1.2 to 6.3, and 1.3 to 15 (LOC = 1.0), respectively. A 22-day chronic study on larval bees resulted in increased pupal mortality (15%) and decreased adult emergence (17%), where the most sensitive chronic endpoint was adult emergence. The no observed adverse effects level (NOAEL) and lowest observed adverse effect level (LOAEL) were 5.8 and 10 μ g ai/larva/day, respectively. A 10-day chronic study on adult bees resulted in increased mortality (17%). The NOAEL and LOAEL were 5.9 and 11 μ g ai/bee/day, respectively. Using the LOAEL still resulted in potential risks, where the RQs ranged from 0.68 to 3.67 (LOC = 1.0). Based on these results, the Agency has determined that there is potential chronic risk to bees.

The Agency considered risk qualitatively for the tree injection use, consistent with current policy when estimating potential risk to bees without supporting measured residue data.²⁶ While there is uncertainty, the Agency expects that the chronic risks to bees identified from foliar application is protective of tree injection uses.

²⁶ USEPA. 2018. Memo. PRD and EFED Efforts to Meet Registration Review Goals by Ensuring Effective Planning Dialogue and Collaboration. March 9, 2018.

Off-field Exposure

The Agency used the AgDRIFT model to assess risks associated with off-target spray drift from aerial applications to turf, (using either fine to medium or medium to coarser droplet sizes), and ground applications to turf. Acute risks of concern for bees from aerial applications extended at most 16 feet from the edge of field (fine to medium droplets, and for ground applications (medium to coarser) acute risk from spray drift extended at most 3 feet from the edge of field. Chronic risks of concern for bees from aerial applications extended up to 138 (fine to medium droplet sizes) and 69 feet (medium to coarser droplet sizes) from the edge of field and for ground applications (medium to coarser droplet sizes) spray drift extended up to 7 feet from the edge of field.

Terrestrial Plants

EPA identified potential risk to non-target dicot terrestrial plants in semi-aquatic habitats adjacent to a treated field. The endpoints for dicot terrestrial plants were based on reductions in dry weight. The most sensitive dicot and EC_{25} (concentration where 25% of exposed plants are affected) in the seedling emergence study was for tomato (0.060 lbs a.i./A). The most sensitive dicot and EC_{25} in the vegetative vigor study was also for tomato (1.3 lbs a.i./A). However, the tomato endpoint was based on data with the highest variability, and, therefore, the least confidence. For this reason, the sugar beet endpoint (0.38 lbs a.i./A) was used. For dicots, RQs exceeded the LOC (1.0) for aerial and ground use on turf, as well as for ground use on ornamentals at the maximum single application rates in semi-aquatic areas (RQs ranged from 1.11 to 1.78). There were no risks identified for monocots.

b. Aquatic Risks

Freshwater Fish and Aquatic-Phase Amphibians and Estuarine/Marine Fish

Based on the available data, EPA did not identify acute risks of concern to freshwater or estuarine/marine fish from exposure to triadimefon. All RQs were below the LOC of 0.5. The Agency did identify potential chronic risks of concern for freshwater fish and estuarine/marine fish. For freshwater fish, RQs ranged from 0.8 to 5.68 and exceeded the LOC (1.0) for aerial turf and ground ornamental applications. RQs were based on the LOAEC (0.116 mg a.i./L) from a rainbow trout study, where a 20% decrease on larval growth was observed. Off-field risks from spray drift to freshwater fish are not anticipated from applications of triadimefon.

For estuarine/marine fish, potential chronic risks of concern were identified for all registered uses. RQs were based on the LOAEC (0.026 mg a.i./L) from a sheepshead minnow study because a NOAEC was not established. Although a NOAEC was not established, the Agency investigated whether a NOAEC could be derived by applying an acute-to-chronic (ACR) ratio (based on the available freshwater fish acute and chronic data) to the sheepshead minnow acute endpoint (LC₅₀ = 6.3 mg a.i./L). However, applying the generated ACR resulted in a NOAEC

estimate greater than the observed LOAEC. For this reason, the Agency assessed chronic risks to estuarine/marine fish using the LOAEC, where an 11% decrease in hatchling success and overall survival was observed. RQs ranged 1.27 to 8.96. Off-field risks (*i.e.*, runoff, erosion, spray drift) are anticipated 10 feet from the edge of field where fine to medium droplets are applied aerially.

Freshwater Invertebrates and Estuarine/Marine Invertebrates

The Agency did not identify any acute risks of concern to freshwater or estuarine/marine invertebrates from estimated exposures to triadimefon. EPA identified potential chronic risks of concern to freshwater and estuarine/marine invertebrates across several use scenarios (*i.e.*, aerial use on turf, ground use on residential turf, and ground use on ornamentals).

For freshwater invertebrates, the chronic RQ exceedances ranged from 0.65 to 4.5 from exposure to triadimefon residues in the water-column and from 1.77 to 12.77 from exposure to triadimefon residues in sediment (LOC = 1.0). The chronic freshwater invertebrate risk from water-column exposure was based on decreased adult length at the NOAEC (0.052 mg a.i./L). For chronic exposures to triadimefon residues in sediment, the NOAEC and LOAEC were 0.018 and 0.026 mg a.i./L, respectively. RQs still exceeded the LOC for most uses when the study LOAEC (0.119 mg a.i./L) was used to calculate risk.

For estuarine/marine invertebrates, exposure to triadimefon residues in the water-column resulted in chronic RQ exceedances that ranged from 0.23 to 3.06. Also, exposure to triadimefon residues in sediment resulted in chronic RQ exceedances that ranged from 2.0 to 14.3. The chronic estuarine/marine invertebrate risk from water-column exposure and sediment exposure were based on the NOAECs, which were 0.076 and 0.016 mg a.i./L, respectively. Calculations of risk using the LOAECs (0.144 and 0.030 mg a.i./L, respectively) did not reduce the potential risks of concern.

Off-field risks from spray drift to aquatic invertebrates in the water column are not anticipated from applications of triadimefon.

Aquatic Vascular and Non-Vascular Plants

Based on the available data, no risks of concern were identified for aquatic vascular or nonvascular plants exposed to triadimefon. All RQs were below the LOC (1.0). Therefore, the Agency has determined that there are no risks to aquatic vascular and non-vascular plants from exposure to triadimefon.

2. Ecological Incidents

EPA reviewed triadimefon incidents reported to Incident Data System (IDS). As of EPA's latest search on May 16, 2022, IDS showed three incidents reported from January 1, 1990 to May 16,

2022. Two reports were from 2004, and one was reported in 2021. All reports involved damage to plants; however, the severity was not reported. The Agency intends to monitor ecological incidents for triadimefon and will conduct additional analyses if necessary.

3. Ecological and Environmental Fate Data Needs

Due to the potential chronic risk concerns identified for individual bees as a result of utilizing the Tier I data in risk assessment, Tier II data (*i.e.*, nectar and pollen residue data and/or semi-field studies) are needed. Since the Agency has identified potential chronic risks of concern, the registrants will be expected to fulfill the Tier II requirements as specified in GDCI-109901-1722. The Agency will work with registrants regarding the timing of the submission.

C. Benefits Assessment

<u>Turf</u>

Triadimefon is recommended for use on turf to control multiple fungal diseases including anthracnose, brown patch, copper spot, dollar spot, fairy rings, gray leaf spot, leaf smuts (*i.e.*, stripe smut, flag smut), leaf spots, pink snow mold, powdery mildew, red thread, rusts, summer patch, take-all patch.^{27,28} Triadimefon helps in fungicide resistance management when applied as a mixture with other fungicides having different modes of action.²⁹ USDA indicated that triadimefon is one of the primary fungicides providing consistent control of fairy ring and early dollar spot disease in turf.²⁹ Disease-free lawns have high aesthetic value and disease-free turf is very important to golf course aesthetics and playability.³⁰ However, many alternative fungicides are available to triadimefon users that can either be used in place of or alongside triadimefon to achieve desired control. These include propiconazole and tebuconazole, which are FRAC code 3 fungicides that have protectant and curative properties.¹⁴ Moreover, these alternatives are recommended to control the same fungal diseases in turf as triadimefon.^{31,32} While EPA expects that the benefits of triadimefon in turf are likely low, there is some uncertainty about the level of benefits because the Agency does not have information on the cost of these alternatives, which could be more expensive than triadimefon.

²⁷ Clark, BB., Vincelli, P., Koch, P and Munshaw. 2020. Chemical control of turfgrass diseases 2020. Accessed on October 6, 2021. <u>http://www2.ca.uky.edu/agcomm/pubs/PPA/PPA1/PPA1.pdf</u>

²⁸ Williamson, J. 2021. Leaf diseases of lawn. Accessed on October 6, 2021. <u>https://hgic.clemson.edu/factsheet/leaf-diseases-of-lawns/</u>

 ²⁹ United States Department of Agriculture (USDA). 2021. USDA Comments on the Draft Human Health and Ecological Risk Assessments for Triadimefon and Triadimenol for Registration Review; EPA-HQ-OPP-2016-0114.
³⁰ Landschoot, 2015. Developing an integrated turfgrass pest management program. Accessed on February 4th, 2022. <u>https://extension.psu.edu/developing-an-integrated-turfgrass-pest-management-program</u>

³¹ Rutgers. 2012. Disease control recommendations for ornamental crops. Accessed on October 14, 2021. https://njaes.rutgers.edu/pubs/ornamental-crops-sections/e036section2.pdf

³² Gauthier, N. 2020. Fungicides for management of diseases in commercial greenhouses ornamentals. Accessed on October 12, 2021. <u>http://plantpathology.ca.uky.edu/files/ppfs-gh-03.pdf</u>

For more information on available alternatives to triadimefon in turf, see "*Triadimenol Use Characterization on Cotton seeds and a List of Registered Fungicides for Triadimefon to Control Fungal Pests,*" which is available in the docket.

Ornamentals and Christmas Trees

Triadimeton is recommended for controlling/managing multiple fungal diseases (such as fungal leaf spot, powdery mildew, scab, rusts) on different ornamentals. Triadimefon is recommended for controlling rust and scab disease in crabapple; twig rust in Hemlock; fusiform rust in pine trees; rust disease in daylily; leaf blight, leaf spots, flower and petal blight, and gall disease (caused by Alternaria, Cercospora, Cylindrosporium, Phyllosticta, Septoria) in azalea, Rhododendron and Camellia.³³ Triadimefon is used on Christmas trees (pine, douglas-fir and spruce) to control fungal pests such as rust, Diplodia shoot blight and canker, and Sirococcus tip blight.³⁴ Buyers of ornamentals and Christmas trees generally require these plants to be disease-free; accordingly, growers receive a premium price for disease-free ornamentals and Christmas trees. However, like in turf, there are alternative fungicides available to triadimefon users that can be used in place of triadimefon in ornamentals and Christmas tree production to achieve desired disease control. The alternative fungicides (such as propiconazole and tebuconazole) have the same mode of action and are FRAC code 3 and are recommended to control the same fungal diseases in ornamentals and Christmas trees. While EPA expects that the benefits of triadimefon in ornamentals and Christmas trees are likely low³⁵, there is some uncertainty about the level of benefits because the Agency does not have information on the cost of these alternatives, which could be higher than triadimefon.

IV. INTERIM REGISTRATION REVIEW DECISION

The Agency is issuing this ID in accordance with 40 C.F.R. §§ 155.56 and 155.58. Based on the Agency's review of triadimefon at this time in the registration review process, EPA has identified certain changes to the affected registrations and their labeling that will be implemented through label amendments and/or registration changes. EPA has determined 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.

³³ Ivors, KL. 2014. Floral, nursey, landscape and diseases. Fungicides for disease control of greenhouse floriculture crops. 2014 North Carolina Agricultural Chemical Manual. Accessed on September 30, 2021.

https://plantpathology.ces.ncsu.edu/wp-content/uploads/2013/05/2014-ag-chem-tables-10-12-13-14.pdf?fwd=no ³⁴ Michigan State University (MSU). 2021. Michigan Christmas Tree Pest Management Guise 2021. Accessed on November 1, 2021.

https://www.canr.msu.edu/christmas_trees/uploads/files/Michigan%20Christmas%20Tree%20Pest%20Managem ent%20Guide%202021.pdf

³⁵ <u>https://plantsciences.tennessee.edu/wp-content/uploads/sites/25/2021/11/UT-Extension-Disease-control-for-trees-shrubs-and-flowers-2018-W665.pdf</u>

At the end of the registration review process, EPA will decide whether each triadimefon pesticide registration "continues to satisfy the FIFRA standard for registration."³⁶ However, this ID is not a decision on whether triadimefon registrations continue to satisfy the FIFRA standard for registration and implementing the mitigation identified in this ID may not be sufficient for EPA to determine that triadimefon 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.

The Agency has not made ESA effects determinations for triadimeton registrations. However, EPA expects that the mitigation in this ID will reduce environmental exposure to triadimefon and may reduce effects on listed species whose range or critical habitat co-occur with the use of triadimeton. Additionally, EPA has added FIFRA IEM measures in Section IV.B of this ID, which are intended to reduce effects to nontarget organisms, including listed species.³⁷ EPA also believes that the FIFRA IEM measures described in Section IV.B 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 has also requested public input on the FIFRA IEM measures described in this ID. 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 triadimefon. For more information, see Appendix C.

A. Risk Mitigation and Rationale

EPA identified potential dietary and aggregate risks of concern as well as occupational handler risks of concern. The Agency also identified potential risks of concern to both terrestrial and aquatic ecological taxa. Triadimefon is a fungicide used for control of several diseases in turf, ornamentals, and Christmas trees. Disease-free turf (*e.g.*, lawns and golf courses) are highly desirable and consumers of ornamentals and Christmas trees generally require these plants to be disease free. To address the potential risks identified, EPA has identified several mitigation measures and label changes that are necessary for triadimefon to not present unreasonable

³⁶ 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.

³⁷ EPA has published and taken comment on these mitigations. *See* EPA-HQ-OPP-2022-0908.

adverse effects for human health or the environment. In addition, EPA is identifying as necessary label changes to update generic labeling language (*e.g.*, glove statement, environmental hazard statement, *etc.*) for all triadimefon products and uses.

As discussed in Section III.A of this ID, the Agency identified potential aggregate and dietary risks of concern to the "all infants" subgroup based on current registered uses of triadimefon. A significant component of the dietary exposure (via drinking water) driving the aggregate and dietary risk is the use on turf. To address the risk of concern, the Agency has identified as necessary a combination of mitigation measures for triadimefon use on turfgrass and sod farms. These measures include restrictions on application to soils that contribute to higher exposure from groundwater for "vulnerable soils," along with an option for application at a reduced rate. Additionally, EPA has identified applications and use on commercial and residential lawns. These application rate reductions and soil restrictions are expected to reduce dietary exposure of triadimefon through drinking water and are described in greater detail below. These application rate reductions also mitigate potential occupational handler risks of concern that were identified for mixing and loading dry formulations of triadimefon for aerial and chemigation applications to sod and contribute to lower ecological risks.

The Agency has identified updates to the mandatory spray drift management language as necessary to reduce potential ecological risks of concern. These requirements along with the application rate reductions discussed above, are expected to reduce exposure to non-target species, and thereby reduce ecological risk. In addition, EPA has identified a need for FIFRA IEM measures to further reduce exposure to nontarget species, including listed species, at this time based on the use patterns of triadimefon. EPA has identified a need for a surface water protection label statement, mandatory spray drift buffers, seed treatment and pollinator stewardship advisories, Bulletins Live! Two (BLT) reference label language and incident reporting label language. The Agency expects that these measures will reduce risk to non-listed and listed species, while maintaining triadimefon use for resistance management and control of turf and ornamental diseases. For additional details on the identified FIFRA IEM measures, please see Section IV.B for details.

1. Aggregate, Dietary and Occupational Handler Risks

In *Triadimefon and Triadimenol. Human Health Draft Risk Assessment in Support of Registration Review* (available in the docket), the Agency identified potential acute and chronic dietary risks for the "all infants" subgroup. Since the acute and chronic aggregate risk estimates are equivalent to the acute and chronic dietary risk estimates, there are also acute and chronic aggregate risks of concern. To mitigate these risks, the Agency has identified a need for the mitigation described below.

Dietary Risk Mitigation

To address the potential dietary risk of concern, EPA is identifying needed restrictions to applications on vulnerable soils and application rate reductions to reduce leaching of triadimefon and its degradates to groundwater. This section discusses the specific mitigation for each use site along with the expected impacts to users of triadimefon.

Application Rate Reductions for Golf Course Turf and Turfgrass Sod Farms Use

Triadimefon is applied to turf on golf courses and turfgrass sod farms that may be grown in soils susceptible to leaching. EPA is identifying as necessary application restrictions for more permeable soils to mitigate potential aggregate and dietary risks from application of triadimefon for these use sites. However, these soil restrictions may impact the viability of use of triadimefon in certain geographic regions. For that reason, EPA is including an alternative application rate reduction for golf courses and turfgrass sod farms that do not meet the soil requirements (soil texture, organic-matter content, depth to water table) and that attains a similar level of risk reduction. The minimum retreatment interval for either application will remain at 14 days. The Agency is identifying as necessary the following restrictions based on soil conditions and proximity to groundwater for applications of triadimefon to golf courses or turfgrass sod farms:

- "Do not apply more than 3.78 lbs of a.i. per acre per year and no more than 2.5 lbs a.i. per acre per application for applications to sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 3% organic matter content, and where the water table occurs at a depth of 30 feet or less from the surface.
- For all other applications, do not apply more than 5.0 lbs a.i. per acre per year and no more than 2.5 lbs a.i. per acre per application. Minimum retreatment interval for all applications is 14 days."

These restrictions on application based on soil texture, organic matter and depth to groundwater are based on research done in parameterizing the groundwater scenarios used in the Pesticide Root Zone Model for Groundwater (PRZM-GW – OPP's groundwater model) within PWC (Pesticide in Water Calculator). This includes knowledge gained from prospective groundwater monitoring studies submitted to EPA. The scenarios within the PRZM-GW model were developed to provide upper-bound pesticide concentration in the most vulnerable types of aquifers utilized as drinking water sources. As such, the 1) soil texture, (*i.e.*, high sand content of 66 - 96%); 2) organic-matter content, (*i.e.*, < 3%); and 3) shallow depth to groundwater, (*i.e.*, < 30 feet), were all selected for PRZM-GW scenarios because they will result in high-end pesticide concentrations in groundwater. By implementing a reduced maximum annual application rate to those soil conditions most likely to result in high groundwater concentrations from applications to non-restricted soils will be below levels of concern for aggregate and dietary risk.

The Agency expects that the soil restrictions described above will impede the leaching of triadimefon into groundwater sources, and, therefore, reduce the potential for dietary exposure to triadimefon from applications to golf courses or turfgrass sod farms. The Agency has also determined that reducing the maximum annual application rate to 3.78 lbs a.i. per acre will eliminate the potential acute and chronic aggregate and dietary risks from applications to golf courses or turfgrass sod farms (aPAD and cPAD for the most highly exposed "all infants" subgroup are reduced to 78% and 73%, respectively) that do not meet the soil restrictions described above.

The Agency's 2021 human health risk assessment identified two occupational handler scenarios with potential risks of concern. These two scenarios involved mixing and loading of triadimefon dry formulations for aerial and chemigation applications to turfgrass sod farms and golf courses. In a comment received from Bayer (available in the docket: EPA-HQ-OPP-2016-0114), Bayer suggested that a reduction to the maximum single application rate for turfgrass sod farms and golf courses from 2.7 lbs a.i. per acre to 2.5 lbs a.i. per acre would remain effective and also eliminate the risk to occupational handlers. The Agency reassessed these two scenarios at the reduced single application rate in *Triadimefon/Triadimenol: Addendum to the Occupational and Residential Exposure Assessment in Support of Registration Review* and determined that the occupational handler risks of concern would also be eliminated (MOEs = 100; LOC = 100).

In addition to identifying occupational handler risks, EPA also identified potential acute risks to birds, mammals, and terrestrial invertebrates (RQs ranged <0.01 - 1.8), and potential chronic risks to all taxa except monocot plants (RQs ranged 0.07 - 197). These application rate reductions will reduce, though not eliminate, potential ecological risks of concern.

These application rate restrictions based on soil type will not affect most golf courses and sod farms. Golf course and sod farm soils tend to have high organic matter.^{38,39} The lower bound of organic matter is approximately 3% in turf fields.⁴⁰ In rare cases where golf courses and sod farms are on sandy soils or above shallow aquafers, users have the option to apply products containing triadimefon at a lower rate, or switching to alternative fungicides. Applicators who wish to use triadimefon and are concerned with the rate restrictions may switch to an alternative fungicide. There are many alternatives available to triadimefon users that can either be used in place of or used alongside triadimefon to achieve desired control. These include propiconazole and tebuconazole, which are FRAC code 3 fungicides that have protectant and curative properties.¹⁴ Moreover, these alternatives are recommended to control the same

³⁸ Broadbelt, J.2018. Golf course Industry. Organic matter management. Accessed on February 8, 2022. <u>https://www.golfcourseindustry.com/article/organic-matter-management/</u>

³⁹ Miller, D and Candidate, MS. 2007. Evaluating the effects of sod farming on soil quality. Accessed on February 8, 2022. <u>http://nesoil.com/ssssne/2007conference/Millar_SSSSNE2007.pdf</u>

⁴⁰ Santiago, S. 2020. Lower-bound Soil Organic Matter (SOM) Estimates for In-field and Container Ornamental Production, Flower Bed and Turf Use Sites. Accessed on April 20, 2022.

fungal diseases in turf as triadimefon.^{41,42} Because such alternative fungicides are available to control fungal pests controlled by triadimefon, the Agency expects that the mitigation may have low impacts in controlling fungal pests on golf courses and sod farms. However, there is some uncertainty about the level of impacts because the Agency does not have information on the cost of these alternatives. Sod farmers and golf courses may have to pay more to manage and prevent fungal diseases in turf.

Because this mitigation will eliminate occupational handler risks and will reduce ecological risks of concern, and because the mitigation is expected to have limited impacts on users, the Agency is identifying the restrictions described above as necessary. Further application rate reductions would potentially have impacts on the ability of golf course and sod farm users to achieve effective control using triadimefon. Although some ecological risks remain even with these rate reductions, the benefits from the use of triadimefon outweigh these risks.

Application Rate Reductions for Commercial, Institutional and Residential Lawns; and for Ornamentals

The 2021 HHRA identified potential dietary risks of concern from drinking water exposure (primarily driven by exposure from groundwater) from registered uses of triadimefon. The Agency is implementing application rate reductions for commercial, institutional, residential lawns, and for ornamentals to reduce exposure to attain overall dietary exposure that is below the level of concern. These rate reductions mitigate the risks from drinking water for these uses by reducing groundwater drinking water concentrations. The minimum retreatment interval will remain at 14 days. EPA is identifying as necessary the following rate reductions (which are described in greater detail in Appendix B):

For Commercial, Institutional, and Residential Lawns:

• "Do not apply more than 2.0 lbs a.i. per acre per application. Do not apply more than 3.78 lbs a.i. per acre per year. Minimum retreatment interval is 14 days."

[**NOTE TO REGISTRANT:** Labels may contain application rates lower than the maximum rate specified above.]

For All Ornamental Applications:

• "Do not apply more than 3.91 lbs a.i. per acre per year."

⁴¹ Rutgers. 2012. Disease control recommendations for ornamental crops. Accessed on October 14, 2021. <u>https://njaes.rutgers.edu/pubs/ornamental-crops-sections/e036section2.pdf</u>

⁴² Gauthier, N. 2020. Fungicides for management of diseases in commercial greenhouses ornamentals. Accessed on October 12, 2021. <u>http://plantpathology.ca.uky.edu/files/ppfs-gh-03.pdf</u>

Impact of Potential Mitigation on Commercial, Institutional, and Residential Lawns

Applicators who wish to use triadimefon and are concerned with the application rate restrictions may switch to an alternative fungicide. There are many alternatives available to triadimefon users that can either be used in place of or used alongside triadimefon to achieve desired control. Propiconazole and tebuconazole fungicides are FRAC code 3 fungicides having protectant and curative properties¹⁷ and are recommended to control the same fungal diseases in turf as triadimefon.^{27,Error! Bookmark not defined.,Error! Bookmark not defined.} Because alternative fungicides are available, EPA has determined that the mitigation may have low impacts. However, there is some uncertainty about the level of impacts because the Agency does not have information on the cost of these alternatives. Users of triadimefon in residential and commercial lawns may have to pay more to manage and prevent fungal diseases. No impacts are expected from the 14-day minimum retreatment interval since it is already on all turf-use labels and because users rotate fungicides to prevent fungicide resistance from developing.

Impact of Potential Mitigation on Ornamentals

The Agency has determined that the impact on ornamental growers/industry which includes pine seedling growers is likely to be low or negligible as the new annual maximum application rate of 3.91 lbs a.i. per acre per year will allow for up to 7 applications of triadimefon per year at an application rate of 0.5 lbs a.i. per acre (the highest single application rate specified on labels). The Agency has determined that if in the rare case that a applicator needs more than 7 applications of a fungicide then the alternatives (such as propiconazole, tebuconazole) with the same mode of action¹⁴ are registered and recommended for use in ornamentals to control fungal pests controlled by triadimefon.^{33,43} In addition, fungicides with different modes of action, such as captan, chlorothalonil, azoxystrobin, pyraclostrobin, and boscalid, are registered and available to control fungal pests controlled by triadimefon.^{33,34} Given the availability of alternatives and the fact that resistance management plans recommend fungicides be rotated, seventeen applications per year is likely to be sufficient for ornamental growers. Therefore, EPA finds that the mitigation will have low or negligible impacts in controlling fungal pests in ornamentals.

2. Updated Gloves Label Statement

The Agency has identified updates to the gloves statements currently on triadimefon labels as necessary, consistent with Chapter 10 of the Label Review Manual.⁴⁴ In particular, EPA is removing any references to specific categories in EPA's chemical-resistance category selection

⁴³ Windham. A. 2018. Disease control of trees, shrubs and flowers. Accessed on October 15, 2021. <u>https://plantsciences.tennessee.edu/wp-content/uploads/sites/25/2021/11/UT-Extension-Disease-control-for-trees-shrubs-and-flowers-2018-W665.pdf</u>

⁴⁴ Label Review Manual, <u>https://www.epa.gov/pesticide-registration/label-review-manual</u>.

chart and specifying the appropriate types of gloves.⁴⁵ This clarification does not fundamentally change the PPE that workers currently must use.

3. Environmental Hazard Label Statements

The Agency has identified label updates to the terrestrial use, groundwater and surface water advisory statements currently on triadimefon labels, consistent with Chapter 8 of the Label Review Manual.⁴⁶ EPA also determined that the degradate 1,2,4-triazole is relevant for groundwater contamination. 1,2,4-triazole is a degradate of triadimefon and is mobile, persistent, and has been detected in non-targeted groundwater monitoring at up to 5.8 µg/L.⁴⁷ These updates and additions to the terrestrial use, groundwater, and surface water advisory statements do not fundamentally change the advisory statements; are meant to increase awareness among users; and promote improved practices to protect water sources. Additionally, the new groundwater advisory simply indicates that multiple degradates are known to leach through soil into groundwater. No impacts to users are expected to result from these groundwater and surface water advisory language updates. The updates and additive text for the environmental hazard statements can be found in Appendix B.

4. Non-target Organism Spray Drift Advisory

The Agency has identified a nontarget organism spray drift advisory as a necessary addition to triadimefon labels for products that are delivered as liquid spray. EPA prioritizes protecting pollinators, including by reducing spray drift and educating applicators about potential indirect adverse effects of triadimefon on foliage and habitat of nontarget organisms. EPA has determined that triadimefon presents acute and chronic risks of concern to pollinators.⁴⁸ Pollinators may be exposed to triadimefon from residues in pollen or nectar through spray drift. Triadimefon is also toxic to dicot plants and spray drift may negatively impact forage and habitat of pollinators and other non-target organisms. These advisory statements are expected to further reduce potential exposure by increasing awareness and promoting more careful application.

5. Fungicide Resistance Management

The Agency has identified resistance-management language as a necessary addition to triadimefon labels⁴⁹ to address pesticide resistance.⁵⁰ Consistent with EPA's Pesticide

⁴⁵ For specific label language, see Appendix B.

⁴⁶ Label Review Manual, <u>https://www.epa.gov/pesticide-registration/label-review-manual</u>

⁴⁷ 1,2,4-Triazole, Triazole Alanine, & Triazole Acetic Acid Drinking Water Exposure Assessment for Registration Review, <u>https://www.regulations.gov/document/EPA-HQ-OPP-2015-0401-0018</u>

⁴⁸ For a detailed discussion of pollinator risks, see Section III.B, above.

⁴⁹ For specific label language, see Appendix B.

⁵⁰ 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

Registration Notice (PRN) on general pesticide resistance management,⁵¹ EPA intends to implement 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 triadimefon—thereby preserving the benefits of triadimefon and other useful pesticides.⁵² No negative impacts to users are expected to result from the fungicide resistance management language in this decision.

6. Spray Drift Management

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

The Agency is identified the following spray drift mitigation language to be included on all triadimefon product labels for products applied by liquid spray application. The added 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 triadimefon registrants to standardize all advisory language on triadimefon product labels. When submitting labeling consistent with this ID, labeling must not include any advisory language that contradicts the new mandatory spray drift statements noted in this ID.

• 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).

that can drive increased use of pesticides. For more details, see PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration/pesticide-registration-notices-year.

⁵¹ PRN 2017-1, "Guidance for Pesticide Registrants on Pesticide Management Labeling" (Aug. 24, 2017), available at <u>https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year</u>.

⁵² For a detailed discussion of triadimefon's benefits, see Section III.C, above. Resistance-management language is already on most triadimefon labels, but the label mitigation is most effective when all product labels reflect resistance-management best practices.

- For ground applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- 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. 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, applicators must use ½ swath displacement upwind at the downwind edge of the field.
- 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.
- Applicators must not spray during temperature inversions.
- During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 10 miles per hour.
- Wind speed and direction must be measured on location using a windsock, an anemometer, or an aircraft smoke system.
- Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment.

The Agency is identifying a restriction on droplet size as necessary because coarser droplets have been demonstrated to decrease spray drift, and, therefore, reduce potential risks to non-target species. Because 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 (as defined by ASABE S572 and ASABE S641) specifically for triadimefon. Therefore, EPA does not know the effect this requirement will have on the performance of triadimefon across various use patterns. In general, potential negative impacts to applicators from requiring larger droplets could include reductions in efficacy, increased selection pressure for the evolution of fungicide resistance due to a decrease in lethal dose delivered to target fungi, increased application rates used by applicators, increased costs associated with reduced yield, more fungicide applications, purchase of alternative products, or an inability to use tank mix or premix products.

7. Water Soluble Packaging

The Agency also identified the inclusion of instructions for products with water soluble packaging (WSP) as necessary. EPA sent these instructions to registrants of products with WSP in April 2017. However, these instructions have not yet been added to WSP labels for products containing triadimefon. Therefore, the Agency continues to identify instructions to all labels for products with WSP as necessary. EPA believes that these instructions will help ensure that

products with WSP are handled properly to protect handlers from exposure, as was the original intent of the technology.

8. <u>Label update for all liquid products where there are mixers and loaders involved in</u> <u>mixing concentrate</u>

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

The ESA Workplan Update Appendix includes a menu of FIFRA IEM measures, some of which are included in this ID. EPA previously sought public comment on the full suite of FIFRA IEM measures, which is available in the ESA Workplan Docket (<u>EPA-HQ-OPP-2022-0908-0002</u>), at <u>www.regulations.gov</u>. 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 identified for triadimefon in this ID reflects these revisions.

EPA developed the FIFRA IEM measures to reduce exposure to nontarget organisms, including listed species, based on the risks and benefits of triadimefon.⁵³ EPA has identified the following FIFRA Interim Ecological Mitigation measures for triadimefon:

- Surface water protection label statement
- Spray drift reduction measures, including buffers
- Treated seed labeling

⁵³ See the ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions (Nov. 2022), <u>https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf</u>.

- Pollinator stewardship advisory label language
- Ecological incident reporting label language
- Bulletins Live! Two (BLT) labeling

The FIFRA IEM measures in this ID are not designed to fully address EPA's ESA obligations for triadimefon 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 triadimefon during registration review, such as mitigations developed as part of its various ESA initiatives.⁵⁴ Additional measures may also be necessary when EPA conducts effects determinations and, if necessary, consults with the Service(s) on triadimefon.

1. Surface Water Protection Label Statement

In laboratory studies, triadimefon degrades in aerobic soils (half-lives were between 4.1-8.3 days) and aquatic systems (27 days). Also, triadimefon readily degrades to its major degradate, triadimenol, in soil (up to 99%) and water (up to 54%). The total residues of triadimefon and triadimenol are persistent in soil (aerobic half-lives range 236-375 days) and stable to abiotic hydrolysis (half-lives in water/sediment systems range from 217-383 days). According to the Food and Agriculture Organization (FAO) classification scheme, both triadimefon and triadimenol are classified as moderately mobile in soil and may readily move into groundwater and surface water. Runoff was identified in the triadimefon ecological risk assessment as a potential exposure route of concern for non-target terrestrial plants, freshwater fish, estuarine and marine fish, freshwater invertebrates, and estuarine and marine invertebrates.

In order to reduce the potential for surface water runoff and protect non-target organisms, EPA identified the following surface water protection statement as necessary for triadimefon products delivered via liquid spray to turfgrass sod farms and ornamentals:

"Do not apply during rain."

The Agency does not anticipate that a restriction which prohibits triadimefon applications while it is raining will affect applicators. While fungicide applications may be made prior to a rainfall event, applicators are not likely to apply during a rainfall event, as this would not be desirable for the product staying in place and preventing disease.

2. Spray Drift Buffers

For triadimefon, risks of concern from spray drift were identified for non-target birds, mammals, terrestrial invertebrates, freshwater and/or estuarine fish, and terrestrial plants. The

⁵⁴ https://www.epa.gov/endangered-species/implementing-epas-workplan-protect-endangered-and-threatened-species-pesticides
distance from the edge of the field to reach the toxicity threshold ranged from three feet to over 1,000 feet depending on taxa, ground versus aerial application, and droplet size.

As noted previously in section IV.6, EPA has identified spray drift management measures related to maximum wind speed, aerial release height, minimum droplet size, aerial swath displacement, aerial boom length, ground boom height, and other application parameters as necessary to reduce risk to non-target organisms from spray drift. EPA has also identified spray drift buffers for triadimefon as necessary to further reduce off-field spray drift and exposure to non-target organisms.

Buffers from Aquatic Habitats

For triadimefon, off-field risks of concern were identified for freshwater and estuarine/marine fish. To protect fish, the Agency has identified spray drift buffers between the edge of the field and aquatic habitats as necessary. The buffers from aquatic habitats are as follows for aerial, ground, and airblast applications:

 For aerial applications: "Do not apply within 100 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 25 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 25 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

For triadimefon, risks of concern from spray drift were identified for birds, mammals, terrestrial invertebrates, and terrestrial dicot plants. To reduce risks to organisms that reside in conservation areas, the Agency has identified 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) as necessary. The spray drift buffers are as follows for aerial, ground, and airblast applications near conservation areas:

 For aerial applications: "Do not apply within 100 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area and the restrictions on this label. A 50% reduction in the required wind-directional buffer distance can be made if a windbreak or shelterbelt (*e.g.*, trees or riparian hedgerows) between the application site and conservation area is present and meets the criteria listed in the 'Windbreak-Shelterbelt Criteria' section of this label."

- For ground applications: "Do not apply within 25 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area and the restrictions on this label. A 50% reduction in buffer distance can be made if:
 - o 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 25 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area and the restrictions on this label.

A 50% reduction in 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 and/or wildlife conservation area) can substantially reduce

pesticide deposition. Data in the open literature show that hedgerows 22 to 25 feet tall result in a spray drift reduction of 73% to 98% at wind speeds up to 2.5 mph for ground applications.⁵⁵ 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.⁵⁶ A study on pesticide deposition at vegetated sites and non-vegetated sites found deposition was 96.1% lower at vegetated sites.⁵⁷ Due to the limited amount of data available and likelihood that newly established hedgerows will be less than 22 feet tall, EPA assumes only a 50% reduction in spray drift when growers use a hedgerow or windbreak that is taller than the spray nozzle release height.

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

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

"Windbreak-Shelterbelt Criteria

A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (*e.g.*, trees or riparian hedgerows) between the application site and aquatic habitat/conservation area is present and meets the following criteria:

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

⁵⁵ 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.

⁵⁶ 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.

⁵⁷ Hancock, J., Bischof, M., Coffey, T., & Drennan, M. 2019. The effectiveness of riparian hedgerows at intercepting drift from aerial pesticide application. *Journal of Environmental Quality, 48*(5), 1481-1488.

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

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

Accounting for Both Hooded Sprayers and Windbreak

Hooded sprayers are a drift-reducing technology that physically blocks drifting droplets at or near the spray nozzle. For ground application, data from the open literature shows a 50% reduction in spray drift for application of fine to medium droplet sizes up to 30 meters offsite when hooded sprayers are used.⁵⁸ In order to provide more flexibility to users who use hooded sprayers, the Agency is allowing a 50% reduction in the wind directional buffer distance listed above for ground application if a hooded sprayer is used.

In the case where a hooded sprayer is used in combination with a windbreak that meets the windbreak-shelterbelt criteria listed above, the Agency is allowing a 75% reduction in the buffer distance for ground application.

Anticipated Risk Reduction for Conservation Habitat and Aquatic Habitat

The Agency has evaluated the impact of reduced application rates, spray drift buffers, and droplet size restrictions for triadimefon as noted in Section IV.A using the AgDRIFT[®] model (version 2.1.1) for both aquatic and terrestrial taxa. Aerial applications were modeled assuming medium to coarse droplet size distributions, and ground applications assuming fine to medium/coarse droplet size distribution, high boom release height, and 90th percentile data. A summary of the distances at which effects are below LOCs for acute and chronic risk is available in Table 1.

⁵⁸ 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.

Таха	Ac	ute	Chronic		
TdXd	Aerial ¹	Ground ²	Aerial ¹	Ground ²	
Aquatic Taxa (Fish,					
Invertebrates, and	0 ft	0 ft	М	IC	
Plants)					
Birds	N	IC	Up to 250 ft	<25 ft	
Mammals	<100 ft	<25 ft	Up to 945 ft	Up to 75 ft	
Terrestrial	<100 ft	<25 ft	<100 ft	<25 ft	
Invertebrates	<100 It	<25 IL	<100 It	<25 IL	
Monocot Plants	<100 ft	<25 ft	<100 ft	<25 ft	
Dicot Plants	Up to 200 ft	<25 ft	Not Ap	plicable	

Table 1. Distance at which Effects from Spray Drift Exposure of Triadimefon Alone are Below
Species Levels of Concern from Application Area

NC=Not calculated due to non-definitive acute endpoints for birds. Distance to no effects concentrations for chronic risk are not calculated for aquatic taxa.

¹ Aerial applications simulated in AgDRIFT v2.1.1 assuming medium to coarse DSD and applications at 2.5 lb a.i./A. ² Ground applications simulated in AgDRIFT v. 2.1.1 assuming fine to medium/coarse DSD, high boom release height, 90th percentile data, and applications at 2.5 lb a.i./A.

Aquatic Taxa:

 Risk estimates for triadimefon considering exposure to spray drift alone and acute toxicity endpoints for aquatic taxa were below species acute risk LOCs; however, chronic risk LOCs are exceeded considering exposure to runoff alone. Spray drift buffers will reduce but not eliminate the potential for chronic exposure to triadimefon and subsequent risk in aquatic environments. For aerial applications, the 100-foot buffer will reduce drift exposure to EPA's standard farm pond by 60%. For ground applications, the 25-foot buffer will reduce the fraction of applied to EPA's standard farm pond by 57%.

Terrestrial Taxa:

Risk estimates for triadimefon considering exposure to spray drift alone and acute toxicity endpoints for mammals, terrestrial invertebrates, and monocot plants are below LOCs at 100-foot and are below LOCs at 25-foot for mammals, terrestrial invertebrates, and all terrestrial plants for ground applications. Chronic risk estimates from spray drift alone are below LOCs for birds at 25-foot from ground applications, and at 100-foot from aerial applications for terrestrial invertebrates. Therefore, 100-foot aerial and 25-foot ground wind-directional spray drift buffers will reduce spray drift exposure and subsequent risk to mammals, terrestrial invertebrates, and monocot plants within conservation areas to below acute and chronic LOCs. The 25-foot ground buffer will reduce exposure from spray drift of triadimefon and subsequent risk to dicot plants and birds within conservation areas to below the chronic LOC.

Chronic risks of concern from spray drift exposure of triadimefon to mammals are estimated to extend up to 945 feet and 75 feet from the edge of field for aerial and ground applications, respectively. For birds, risks estimates exceeded the chronic LOC from spray drift for aerial applications only and extend up to 250 feet from the edge of field. For terrestrial plants, risks of concern from spray drift off field for aerial applications of triadimefon extend up to 100 feet from the edge of field for dicots. Although off field risks of concern to birds, mammals, and dicot plants within 100-feet of conservation areas from spray drift are estimated for aerial applications of triadimefon, and within 25-feet of conservation areas to mammals for ground applications of triadimefon, the buffers and droplet size restrictions result in a reduction of spray drift exposure to organisms in conservation areas. Spray drift exposure to terrestrial areas is reduced by 89% and 98% for aerial and ground applications, respectively.

Impact of Spray Drift Buffers on Users

To mitigate spray drift risk to non-target species, EPA is requiring spray drift buffers for turfgrass sod farms when applying triadimefon in fields adjacent to aquatic and/or terrestrial habitats.

Applicators who are required to implement a buffer have three options, all of which result in the loss of triadimefon as a control method in the buffer area: 1) replace triadimefon with an alternative control method for treatment of the entire field, 2) replace triadimefon with an alternative control method in just the buffer area while treating the interior field with triadimefon, or 3) leave the buffer areas untreated.

The impacts of the first option are equivalent to the loss of triadimefon; depending on the site, pest, and available alternatives, switching to other controls may increase the cost of control. The second option 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. Also, environmental factors (wind, rain) and equipment availability, may further limit the feasibility of making separate applications to buffers. Beyond the increased application costs, growers would also incur any impacts from using alternatives, as with the first option. Finally, in the third option, yield or quality losses would be highly likely if the buffer area is left completely untreated. In some situations, losses may be large enough that it is no longer worth cultivating the buffer and growers remove the land from production.

Spray drift buffers can affect a substantial portion of a field, especially when fields are small. Larger buffers impact a larger proportion of the field than smaller buffers. To characterize the effect that buffers may have on applicators, the Agency shows how different sizes of no-spray buffers can impact applicators who want to use triadimefon on different sized fields (Table 2). To illustrate the effect of a buffer, consider a rectangular field with length equal to twice its

width, with the buffer on the long side of the field. In this scenario, the field is immediately adjacent to the sensitive area. A 30-foot buffer results in 3% of a 50-acre field impacted, but 6% of a 10-acre field impacted. A 100-foot buffer results in 10% of the 50-acre field impacted, and 21% of the 10-acre field impacted. If the buffer were to fall on the short side, the affected area would be substantially less. Irregularly shaped fields could be affected substantially more. In situations where the field to be treated is not immediately adjacent to the protected area, the part of the field affected by the spray buffers is smaller/narrower than if the field edge is immediately next to the habitat.

Field Size (Acres)	1	10	50	100
Buffer Size		Percent of Field Ir	npacted by Buffer	
30 Feet	20%	6%	3%	2%
100 Feet	68%	21%	10%	7%
150 Feet	100%	32%	14%	10%

Table 2. Percent of fields of various sizes lost to in-field buffers of various sizes.

Calculations based on a rectangular field with length equal to twice its width, with the in-field buffer on the long side of the field.

EPA is only requiring spray drift buffers when winds are blowing in the direction of a non-target site. In this case, applicators have the additional option to apply triadimefon in the buffer area when winds are not blowing towards a non-target site. This increases applicator flexibility, reducing the burden of imposing spray drift buffers that are not wind directional. However, if applicators wait for the wind to blow away from the non-target site to apply triadimefon, they risk missing the opportunity to apply triadimefon.

EPA will allow smaller buffers when using drift reduction tools for applications made by ground boom, such as hooded sprayers or windbreaks/shelterbelts. This reduces the burden of the mitigation by giving applicators additional flexibility in applying triadimefon; however, applicators may incur some up-front costs to use these tools. The burden of purchasing a hooded sprayer or installing windbreaks/shelterbelts may be greater for smaller operations, which may face higher per-acre costs for equipment and potentially higher financing costs.

Applicators who do not currently own a device for measuring wind speed and/or direction will have to purchase and install a windsock, an anemometer, or an aircraft smoke system. There are likely differences in cost in purchasing each of these technologies. The Agency expects that purchasing and installing a windsock is the least expensive option, followed by an anemometer and an aircraft smoke system. There are likely minimal differences in the complexity to interpret the wind speed or direction outputs generated by these technologies. The Agency does not anticipate impacts to users of triadimefon who already own and use a windsock, an anemometer, or an aircraft smoke system to detect the sustained wind speed and/or direction at the application site.

3. Treated Seed Labeling

In *Triadimefon: Draft Ecological Risk Assessment for Registration Review*, the Agency identified chronic risks of concern to birds and mammals consuming treated seeds. To reduce exposure to non-target organisms which may ingest treated seed, the Agency has identified it as necessary to include 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 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,⁵⁹ these 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)⁶⁰ 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

The 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 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)

⁵⁹ Available from www.regulations.gov under Docket ID EPA-HQ-OPP-2018-0805. https://www.regulations.gov/document/EPA-HQ-OPP-2018-0805-0104

⁶⁰ Available from <u>www.regulations.gov</u> under Docket ID EPA-HQ-OPP-2023-0420.

https://www.regulations.gov/document/EPA-HQ-OPP-2023-0420-0001. 88 FR 70625. October 12, 2023.

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).
- Manage excess treated seeds (*e.g.*, spilled, unused, or expired treated seeds) by one or more of the following methods:
 - Collect excess treated seeds for reuse for planting.
 - Bury excess treated seeds (only allowed if totalling 1 pound or less) at least 30 feet away from bodies of water at a depth of 6 inches or double the planing depth, whichever is greater.
 - Dispose of excess treated seed by placing them in a landfill in accordance with applicable laws in your state.
 - Excess treated seeds may be returned to the supplier if permitted by the state.
- Do not contaminate bodies of water when disposing of equipment wash water.

ADVISORY DUST-REDUCING TECHNIQUE

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."

The Agency has also identified it as necessary to include instructions stating 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 in commercial facilities or on-farm and for sale or distribution

The seed bag/container labeling for pesticide products allowed for both commercial and onfarm 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).
- Manage excess treated seeds (*e.g.*, spilled, unused, or expired treated seeds) by one or more of the following methods:
 - Collect excess treated seeds for reuse for planting.
 - Bury excess treated seeds (only allowed if totalling 1 pound or less) at least 30 feet away from bodies of water at a depth of 6 inches or double the planing depth, whichever is greater.
 - Dispose of excess treated seeds by placing them in a landfill in accordance with applicable laws in your state.
 - Excess treated seeds may be returned to the supplier if permitted by the 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

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."

The Agency has also identified it as necessary to include instructions stating 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

Triadimefon is applied to pollinator attractive ornamentals, as well as turf in which pollinator attractive blooming weeds may be present. Acute risks of concern to adult bees were identified for applications to turf and ornamentals. Additionally, chronic risks of concern were identified for honey bees from applications to turf and ornamentals.

EPA has identified advisory language for insect pollinators as necessary. This advisory language distills the most important information applicators 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.⁶¹

The pollinator hazard statement is as follows:

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

EPA has identified that an addition to the pollinator hazard statement above for products with labeled agricultural crop uses is necessary. 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 has identified the following labeling as necessary the following label language to highlight pollinator best management practices:

⁶¹ <u>https://www.epa.gov/pollinator-protection/pollinator-protection-strategic-plan</u>

"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.

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 <u>https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators</u>."

5. 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 label language as part of any necessary ESA consultation. EPA has therefore identified incident reporting label language as necessary to provide consistent information to pesticide users on how to report ecological incidents and in order to expedite any ESA necessary consultation. The incident reporting language is as follows:

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

6. 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.

Triadimefon currently does not have any listed species bulletins. However, the Agency has identified the addition of the following Bulletins language to all triadimefon product labels as necessary. 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 BLT language is as follows:

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

Although the BLT system has been in place for many years, there may be applicators who are unfamiliar with this system. Using the online tool to determine if mitigation is required for a particular treatment area may be a new step that many users will need to take prior to an application. However, the Agency anticipates that over time and with wider implementation, BLT will become a familiar tool that is integrated into a user's planning process for pesticide applications. In February 2022, EPA released an improved version of BLT⁶², which allows users to more easily find the information they need for a particular pesticide product. The Agency has

⁶² <u>https://www.epa.gov/endangered-species/endangered-species-protection-bulletins</u>

also developed a tutorial⁶³ 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.

EPA is currently working on several ESA strategies such as the Vulnerable Species Pilot⁶⁴ and the Herbicide Strategy⁶⁵ to expedite and streamline the ESA consultation process and provide protections for listed species. Pesticide Use Limitation Areas (PULAs) and the associated geographically specific mitigation (*i.e.*, bulletins) are not yet available under these efforts. While the BLT language above is being added on the pesticide label without being linked to PULAs or bulletins for triadimefon at this time, pesticide users should be aware that as 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.

C. 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 across the Nation, including minority, low-income, and indigenous populations who may be disproportionately overburdened by the use of triadimefon.

One community which may experience disproportionate exposure to pesticides is agricultural farmworkers. EPA has conducted assessments of risks to farmworkers who handle triadimefon and has found two inhalation risks of concern for mixers and loaders of dry flowable triadimefon products for use in aerial and chemigation applications to turfgrass sod farms. For these risks, the Agency has identified an application rate reduction as necessary. EPA has also evaluated the risks to people living adjacent to treated fields (*e.g.*, sod farms), which may include many farmworker families, and has not found risks of concern for triadimefon.

The Agency sought information during the public comment periods throughout registration review on any other groups or segments of the population who, as a result of their proximity and exposure to pesticides, unique exposure pathway (*e.g.*, as a result of cultural practices), location relative to physical infrastructure, exposure to multiple stressors and cumulative impacts, lower capacity to participate in decision making, or other factors, may have unusually high exposure to triadimefon compared to the general population or who may otherwise be disproportionately affected by the use of triadimefon as a pesticide. EPA requested but did not receive any comments concerning environmental justice.

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

⁶⁴ <u>https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0327</u>

⁶⁵ <u>https://www.regulations.gov/docket/EPA-HQ-OPP-2023-0365</u>

D. Tolerance Actions

The Agency plans to exercise its FFDCA authority to modify the tolerance for triadimefon as summarized in Table 3.

Table 3: Anticipated Tolerance Revision	n for Triadimefo	n 40 CFR § 180.4	-10
Correct Commodity Definition/ Commodity	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Pineapple	2.0	Remove	Registered Uses Cancelled

E. Data Requirements

A Generic Data Call-In (GDCI) was issued for triadimefon for data needed to conduct the registration review risk assessments. All data requirements have been satisfied with the exception of Tier 2 and 3 honey bee data. The development of Tier 2 honey bee data (*i.e.*, semi-field/field studies) for triadimefon is still required, based on the results of the Tier 1 data (*i.e.*, laboratory studies) and other lines of evidence. See Section III.B.3 Ecological and Environmental Fate Data Needs for additional detail.

An analytical reference standard for triadimefon and triadimenol is available at EPA's National Pesticide Standards Repository (NPSR) (<u>https://www.epa.gov/pesticide-analytical-</u><u>methods/national-pesticide-standard-repository</u>).</u>

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

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

B. Implementation of Mitigation Measures

The mitigations discussed in Part IV are implemented through label amendments and/or registration changes.

Registrants: Submit a cover letter, a completed Application for Registration (EPA form 8570-1), and electronic copies of the amended product labels within 60 days after the announcement of this ID in the Federal Register. Submit two copies for each label—a clean copy and an annotated copy with changes. Include the following statement on the Application for Registration:

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

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

VIA US Mail

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

After all the label amendments or registration changes have been submitted, EPA will review them to ensure that they incorporate the necessary mitigation. If they meet the necessary changes, EPA intends to approve the requested changes and/or amendments. If the registrant does not submit the label amendments or registration changes, EPA reserves the right to take appropriate action under FIFRA. *See* 40 C.F.R. § 155.58(d). This ID does not effect a change in the existing registration, and EPA will not involuntarily cancel any registration without following the procedures and substantive requirements of FIFRA § 6 or is otherwise compelled to cancel.

Appendix A: Summary of Mitigation for Triadimefon

Registration Review Case PC Code: 109901 Chemical Type: Fungicide Chemical Family: Triazole Mode of Action: Demeth	e #: 2700 e e, Conazole ylation (DMI) and s	terol biosynthesis (SBI) i	nhibitor		
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Mitigation
All infants	 Dietary (Groundwater drinking water) 	Ingestion	Acute Chronic	 Developmental Reproductive Neurotoxicity 	 Restrict application on vulnerable soils for golf courses and turfgrass sod farms OR reduce the maximum single and annual application rates Reduce maximum annual application rate for commercial, institutional, and residential lawns and ornamentals
Occupational handlers	 Mixing and Loading DF formulations for aerial and chemigation applications to golf courses and turfgrass sod farms 	• Inhalation	 Short- and intermedia te-term 	 Developmental Reproductive Neurotoxicity 	 Reduce single and annual maximum application rates
• Birds	 Residues on treated field Treated seeds 	Ingestion	Chronic	 Decrease in fertile eggs and 14-day old survivors 	 Reduce single and maximum application rates for turf and ornamental use sites Restrict applications on vulnerable soils Update groundwater advisory statements

					 Mandatory spray drift requirements and updated advisory statements Treated seed advisory statements Spray drift buffers
Mammals	 Residues on treated field Treated seeds 	• Ingestion	• Chronic	 Decreased pup weights and viability Decreased fertility 	 Reduce single and maximum application rates for turf and ornamental use sites Restrict applications on vulnerable soils Update groundwater advisory statements Mandatory spray drift requirements and updated advisory statements Treated seed advisory statements Spray drift buffers
Terrestrial Invertebrates	 Residues from direct applications to ornamentals and from spray drift 	• Ingestion	• Chronic	 Increased pupal mortality Decreased adult emergence Increased mortality 	 Reduce single and maximum application rates for turf and ornamental use sites Restrict applications on vulnerable soils Mandatory spray drift requirements and updated advisory statements Non-target organism advisory statement Pollinator hazard statement Spray drift buffers Advisory Best Management Practices
Terrestrial Plants	Runoff from application sites and spray drift	Foliar absorption	• N/A	Reductions in dry weight	 Reduce single and maximum application rates for turf and ornamental use sites Restrict applications on vulnerable soils Mandatory spray drift requirements and updated advisory statements

 Freshwater fish Aquatic-phase amphibians Estuarine/marine fish 	Runoff from application sites and spray drift	Dermal absorption	• Chronic	 Decreased larval growth Decreased hatchling success and survival 	 Non-target organism advisory statement Spray drift buffers Reduce single and maximum application rates for turf and ornamental use sites Restrict applications on vulnerable soils Update outdoor use advisory statement Update surface water advisory statements Update groundwater advisory statements Add water protection statement Mandatory spray drift requirements and updated advisory statements Treated seed advisory statements Spray drift buffers
 Freshwater invertebrates Estuarine/marine invertebrates 	Runoff from application sites and spray drift	Dermal absorption	• Chronic	Decreased adult length	 Reduce single and maximum application rates for turf and ornamental use sites Restrict applications on vulnerable soils Update outdoor use advisory statement Update surface water advisory statements Update groundwater advisory statements Add water protection statement Mandatory spray drift requirements and updated advisory statements Treated seed advisory statements Spray drift buffers

Appendix B: Labeling Changes for Triadimefon Products

Description			Label Language for Triadimefon Pro	oducts	Placement on Label
			End Use Products		
Mode of Action	Note to registrant: Include the r Include the r Include the I Code, and for ins Include the t	name of the AC word " GROUP" MODE/MECHA secticides this is type of pesticide	TIVE INGREDIENT in the first column in the second column NISM/SITE OF ACTION CODE in the th the Primary Site of Action; for Herbic e (<i>i.e.</i> , FUNGICIDE) in the fourth colum	ird column (for fungicides this is the FRA ides this is MODE OF ACTION) 1n.	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code,
Group Number	Triadimefon	GROUP	MODE OF ACTION CODE 3	Fungicide	which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Updated Gloves Statement	Update the gloves sta reference to specific o chemical-resistant glo	atements to be categories in EF ove types to use	consistent with Chapter 10 of the Lab PA's chemical-resistance category sele e.	el Review Manual. In particular, remove ction chart and list the appropriate	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Non-target Organism Spray Drift Advisory For products delivered as liquid spray	"NON-TARGET ORGA forage and habitat of forage and habitat of	NISM SPRAY DF non-target org non-target org	RIFT ADVISORY: This product is toxic to anisms, including pollinators, in areas anisms by following label directions ir	plants and may adversely impact the adjacent to the treated site. Protect the itended to minimize spray drift."	Environmental Hazards
Outdoor Uses Advisory	"Do not apply directly water mark. Do not c	y to water, or to ontaminate wa	o areas where surface water is present ter when disposing of equipment was	t or to intertidal areas below the mean h hwater or rinsate."	igh Environmental Hazards

Surface Water Label Advisory	"This product may impact surface water quality due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential loading of triadimefon from runoff water and sediment."	Environmental Hazards
Groundwater and Label Advisory	"Groundwater Advisory: Multiple degradates of triadimefon are known to leach through soil into groundwater under certain conditions as a result of label use. This chemical may leach into groundwater if used in areas where soils are permeable, particularly where the water table is shallow."	Environmental Hazards
Pollinator Hazard Statement For all products applied to agricultural crops.	"This product is moderately toxic to bees and other pollinating non-target insects exposed to direct treatment on blooming crops or weeds."	Environmental Hazards under the Heading "POLLINATOR HAZARD STATEMENT"
Best Management Practices for Pollinator Protection For all products delivered via liquid spray applications to agricultural crops.	 "Advisory Best Management Practices for Pollinator Protection The following best management practices (BMPs) can help reduce risk to pollinators: Develop and maintaining clear communication with local beekeepers to help protect bees. To the extent possible, advise beekeepers within a 1-mile radius 48-hrs in advance of the application, and confirm hive locations before spraying. Avoid applications when bees are actively foraging. Avoid applying pesticides to plants in bloom, including flowering weeds. Apply pesticides in the evening or at night when fewer bees are foraging. Use Pollinator Protection Plans when they are available. These plans may be available from state lead agencies and promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees and other pollinators to pesticides. Use integrated pest management to prevent or mitigate potential negative effects to pollinators and consider multiple pest management options before resorting to a pesticide application. 	Directions for Use – Under the Best Management Practices header after Resistance Management section
	 The following BMPs can help promote the health and habitat of ground-nesting bees: For uncultivated land, leaving large undisturbed patches of land un-mowed and untilled can provide nesting and forage sites. 	

Endangered Species Protection Requirements For all products, excluding those • labeled/ registered solely for residential use; or • where exposure is negligible or there are no toxic effects expected across uses included on a product label (<i>e.g.</i> , cattle ear tag, fly baits)	 For uncultivated land, mowing at the highest cutting height possible (minimum of 8-10 inches if possible) can increase and diversify food sources. For additional resources on pollinator BMPs and Pollinator Protection Plans, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators." "ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS: Before using this product, you must obtain any applicable Endangered Species Protection Bulletins ('Bulletins') within six months prior to or on the day of application. To obtain Bulletins, go to Bulletins Live! Two (BLT) at https://www.epa.gov/pesticides/bulletins. When using this product, you must follow all directions and restrictions contained in any applicable Bulletin(s) for the area where you are applying the product, including any restrictions on application timing if applicable. It is a violation of Federal law to use this product in a manner inconsistent with its labeling, including this labeling instruction to follow all directions and restrictions contained in any applicable Bulletin(s). For general questions or technical help, call 1-844-447-3813, or email ESPP@epa.gov." 	Directions for Use, at the beginning under the heading "ENDANGERED AND THREATENED SPECIES PROTECTION REQUIREMENTS"
Ecological Incidents Statement For all products with outdoor uses	" 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: <u>https://www.epa.gov/pesticide-incidents</u> or call [registrant phone number]."	Directions for Use, under the heading "REPORTING ECOLOGICAL INCIDENTS"
Resistance- management for fungicides and bactericides	[NOTE TO THE REGISTRANT: Include resistance management label language for fungicides/bactericides from PRN 2017-1 (<u>https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year</u>). See section 3 (Scope) of the PRN to determine whether the resistance management measures outlined in the PRN apply to your product.]	Directions for Use, prior to directions for specific crops
Water Protection Statements	 *WATER PROTECTION STATEMENT Do not apply during rain." 	Directions for Use – Under the Restriction

For all products		or Use Restriction
delivered via liquid		Section
spray applications		
to crops that do		
not require		
production in		
flooded fields or		
streams.		
For all liquid	"Removable chemical extraction probes (also known as "stingers") used in suction/extraction systems must be rinsed	Directions for Use
products where	within the pesticide container prior to removal."	
there are mixers		
and loaders		
involved in mixing		
concentrate		
Seed Treatment	"REQUIRED DYE STATEMENT	Directions for Use
Dye Statement		section of the FIFRA
	Seed treated with this product must be visually identifiable from untreated seed by the use of an approved colorant	registered pesticide
	or dye to prevent accidental use of treated seed as food for humans or feed for animals. Refer to 21 CFR, Part 2.25.	label (and on the seed
	Any colorant or dye added to treated seed must be cleared for use in accordance with 40 CFR, Part 153.155(c)."	bag tag if the seed has
		not been dyed before
		distribution)
Treated Seed	"Use of On-Farm Treated Seed (when treated seeds are not for sale or distribution)	Directions for Use
Product -		section of the FIFRA
Instructions for	Treated seed sold or distributed for a use not permitted by the following labeling does not qualify as an exempted	registered pesticide
treated seed	treated article under 40 CFR 152.25(a) and is therefore sale or distribution of an unregistered pesticide, pursuant to	label
products produced	FIFRA section 12.	
using on-farm		
seed treatment	 Store treated seed away from food and feedstuffs. 	
(not for	 Do not allow children, pets, or livestock to have access to treated seeds. 	
distribution or sale	• Treated seeds are for planting purposes only. Do not use for food, feed, or oil purposes. Do not use treated	
of the seed) with a	seeds for fuel or ethanol production purposes.	
FIFRA registered	• Do not plant treated seed by broadcasting to the soil surface. Ensure that all planted seeds are thoroughly	
pesticide	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 bazardous to wildlife. Cover or collect treated seeds 	
	spilled during loading and planting (such as in row ends).	

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	• Manage excess treated seeds (e.g., spilled, unused, or expired treated seeds) by one or more of the	
	following methods:	
	 Collect excess treated seeds for reuse for planting. 	
	 Bury excess treated seeds (only allowed if totalling 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.	
	 Dispose of excess treated seed by placing them in a landfill in accordance with applicable laws in 	
	your state.	
	 Excess treated seeds may be returned to the supplier if permitted by the state. 	
	 Do not contaminate bodies of water when disposing of equipment wash water. 	
	ADVISORY DUST-REDUCING TECHNIQUE	
	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."	
	[NOTE TO REGISTRANT: 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 denth plant back intervals personal protective equipment and storage and disposal	
	statements, remain and must be listed.]	
Treated Seed	"Seed Treatment in Commercial Facilities or Seed Treatment On-Farm (when treated seeds are to be sold or	Directions for Use
Treated Seed Product –	"Seed Treatment in Commercial Facilities or Seed Treatment On-Farm (when treated seeds are to be sold or distributed) – Seed Bag Labeling Requirements"	Directions for Use section of the FIFRA
Treated Seed Product – Required Seed	"Seed Treatment in Commercial Facilities or Seed Treatment On-Farm (when treated seeds are to be sold or distributed) – Seed Bag Labeling Requirements"	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container	"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:	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling	"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:	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions -	 "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). 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions -	 "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." 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide	 "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." 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed	 "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 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat	 "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 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in	 "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 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in commercial	 "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 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in commercial facilities or on-	 "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). 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in commercial facilities or on- farm where the	 "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). 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in commercial facilities or on- farm where the treated seed	 "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 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in commercial facilities or on- farm where the treated seed product is	 "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 	Directions for Use section of the FIFRA registered label
Treated Seed Product – Required Seed Bag/Container Labeling Instructions - For pesticide products allowed for use to treat seeds in commercial facilities or on- farm where the treated seed product is intended for sale	 "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 by the following labeling does not generated with [PRODUCT NAME] that is sold or distributed for a use not permitted by the following is 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 	Directions for Use section of the FIFRA registered label

(instructions must		
appear on seed	• The contents of this bag are for planting purposes only. Do not use for food, feed, or oil purposes. Do not	
bag tags when	use for fuel or ethanol production purposes.	
treated seeds are	 Store treated seed away from food and feedstuffs. 	
to be sold or	 Do not allow children, pets, or livestock to have access to treated seeds. 	
distributed)	 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).	
	• Manage excess treated seeds (e.g., spilled, unused, or expired treated seeds) by one or more of the	
	following methods:	
	 Collect excess treated seeds for reuse for planting. 	
	 Bury excess treated seeds (only allowed if totalling 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.	
	 Dispose of excess treated seed by placing them in a landfill in accordance with applicable laws in 	
	your state.	
	 Excess treated seeds may be returned to the supplier if permitted by the state. 	
	Do not contaminate bodies of water when disposing of equipment wash water.	
	 Dispose of seed packaging or containers in accordance with local requirements. 	
	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 "	
	Tollow the recommendations of the planter manufacturer regarding the use of seed now lubicants.	
	NOTE TO REGISTRANT : 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.]	
Directions for	Instructions for Introducing Water Soluble Packages Directly into Spray tanks:	Directions for Use
mixing/loading		
products	"Water Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help	
packaged in water	dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide	
soluble bags	products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural	
	Worker Protection Standard [40 C.F.R. 170.607(d)].	

Handling Instructions	
Follow these steps when handling pesticide products in WSPs.	
1. Mix in spray tank only.	
2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If	
package is broken, put on PPE required for clean-up and then continue with mixing instructions.	
3. Keep the WSP in outer packaging until just before use.	
4. Keep the WSP dry prior to adding to the spray tank.	
5. Handle with dry gloves and according to the label instructions for PPE.	
6. Keep the WSP intact. Do not cut or puncture the WSP.	
7. Reseal the WSP outer packaging to protect any unused WSP(s).	
Mixing Instructions	
Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being	
tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank	
mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all	
the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-	
mixing or have conflicting mixing directions.	
1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank.	
2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray.	
3. Stop adding water and stop any agitation.	
4. Place intact/unopened WSP into the tank.	
5. Do not spray water from a hose or fill pipe to break or dissolve the WSP.	
6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead	
recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation.	
7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness	
and intensity of agitation.	
8. Stop agitation before tank lid is opened.	
9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP	
has fully dissolved and the contents have been thoroughly mixed into the solution.	
10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and	
pesticide is thoroughly mixed.	
11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the	
tank with water to the desired level, close the tank lid, and resume agitation.	
12. Use the spray solution when mixing is complete.	
13. Maintain agitation of the diluted pesticide mix during transport and application.	

	14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label."	
	For Toxicity Category I and II products:	
	"ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down."	
	For Toxicity Category III and IV products:	
	"ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water-soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break- down."	
For all	"Do not apply more than 2.0 lbs a.i. per acre per application. Do not apply more than 3.78 lbs a.i. per acre per year.	Directions for Use
institutional.	Minimum retreatment interval is 14 days.	
residential (e.g.,	[NOTE TO REGISTRANT: Labels may contain application rates lower than the maximum rate specified above.]	
apartment		
buildings, day-		
playgrounds,		
playfields,		
recreational parks		
and elementary, middle and high		
schools) turf		
applications		
except golf		

courses and sod farms		
For all ornamental applications	"Do not apply more than 3.91 lbs a.i. per acre per year."	Directions for Use
For applications to golf courses and sod farms	"Do not apply more than 3.78 lbs of a.i. per acre per year and no more than 2.5 lbs a.i. per acre per application for applications to sandy or coarse-textured soils (sand, sandy loam, and loamy sand), with less than 3% organic matter content, and where the water table occurs at a depth of 30 feet or less from the surface. For all other applications, do not apply more than 5.0 lbs a.i. per acre per year and no more than 2.5 lbs a.i. per acre per application. Minimum retreatment interval for all applications is 14 days."	Directions for Use
Spray Drift Management Application Restrictions for products that are applied as liquid with aerial equipment	 "MANDATORY SPRAY DRIFT MANAGEMENT Aerial Applications: Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 641 (ASABE S641). During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes) must register between 3 and 10 miles per hour. Wind speed and direction must be measured on location using a windsock, an anemometer (including systems to measure wind speed or velocity on an aircraft), or an aircraft smoke system. Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment. Applicators must use a minimum of ½ swath displacement upwind at the downwind edge of the field. The boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. Do not apply during temperature inversions." Spray Drift Buffer to Aquatic Habitats "Do not apply within 100 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). 	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Aerial Applications" Placement for these statements should be in general directions for use, and before use-specific directions.

	A 50% reduction in the required wind-directional buffer distance can be made if a windbreak or shelterbelt (<i>e.g.,</i>	
	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."	
	Spray Drift Buffer to Wildlife Conservation Areas	
	• "Do not apply within 100 feet of any conservation areas when wind is blowing toward the conservation area.	
	Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges,	
	national and state forests, and national and state grasslands. Any land between the conservation areas and	
	the application area can be included in the buffer (including Conservation Reserve Program (CRP) and	
	Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located	
	within a conservation area are acceptable when made in accordance with an approved pesticide	
	management plan for the conservation area and the restrictions on this label.	
	A 50% reduction in the required wind-directional buffer distance can be made if a windbreak or shelterbelt (<i>e.g.,</i>	
	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."	
Spray Drift	"MANDATORY SPRAY DRIFT MANAGEMENT	Directions for Use, in a
Management	Ground Boom Applications:	box titled "Mandatory
Application	• During application, the Sustained Wind Speed, as defined by the National Weather Service (standard	Spray Drift
Restrictions for	averaging period of 2 minutes), must register between 3 and 10 miles per hour.	Management" under
products that are	• Wind speed and direction must be measured on location using a windsock or anemometer (including systems	the heading "Ground
applied as liquid	to measure wind speed or velocity using application equipment).	Boom Applications"
with ground boom	• Wind speed must be measured at the release height or higher, in an area free from obstructions such as	
equipment	trees, buildings, and farm equipment.	
	 Do not release spray at a height greater than 3 feet above the ground or crop canopy. 	
	• Applicators must select nozzle and pressure that deliver medium or coarser droplets in accordance with	
	American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572).	
	 Do not apply during temperature inversions." 	
	Spray Drift Buffer to Aquatic Habitats	
	"Do not apply within 25 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).	

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	 A 50% reduction in buffer distance can be made if: the application is made with a hooded sprayer; or, a windbreak or shelterbelt (<i>e.g.</i>, 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." 	
	Spray Drift Buffer to Wildlife Conservation Areas	
	 "Do not apply within 25 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area and the restrictions on this label. A 50% reduction in buffer distance can be made if: the application is made with a hooded sprayer; or, a windbreak or shelterbelt (<i>e.g.</i>, 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."	
Spray Drift	"MANDATORY SPRAY DRIFT MANAGEMENT	Directions for Use, in a
Management	Airblast Applications:	box titled "Mandatory
Application	Sprays must be directed into the canopy.	Spray Drift
Restrictions for	During application, the Sustained Wind Speed, as defined by the National Weather Service (standard	Management" under
products that are	averaging period of 2 minutes), must register between 3 and 10 miles per hour.	the heading "Airblast
applied as liquid	Winds speed and direction must be measured on location using a windsock or anemometer.	Applications"
equipment	 Wind speed must be measured at the release height or higher, in an area free from obstructions such as troop, buildings, and farm equipment. 	
equipment	 User must turn off outward pointing pozzles at row ends and when spraving outer row. 	
	 Do not apply during temperature inversions 	
	Spray Drift Ruffer to Aquatic Habitate	
	אומי טוווג טעווכו גט איןעמגוג המטונמגא	

	 "Do not apply within 25 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."	
	Spray Drift Buffer to Wildlife Conservation Areas	
	• "Do not apply within 25 feet of any conservation areas when wind is blowing toward the conservation area.	
	Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges,	
	national and state forests, and national and state grasslands. Any land between the conservation areas and	
	the application area can be included in the buffer (including Conservation Reserve Program (CRP) and	
	Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located	
	management plan for the conservation area and the restrictions on this label	
	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-	"Windbreak-Shelterbelt Criteria	Directions for Use –
Shelterbelt		Under the Restriction
Language for	A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt	or Use Restriction
aerial and ground	(<i>e.g.</i> , trees or riparian hedgerows) between the application site and aquatic habitat and conservation area is present	Section
boom Application	and meets the following criteria:	•••••
Wethoas	 The windbreak or shelterbeit must be downwind between the pesticide application and the aquatic nabitat and conservation area. 	Must be placed at the end of the Mandatory
	• The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage is	Spray Drift Section
	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/shelterbeit must run the full length of the treated crop and must have folged that is sufficiently dense such that the aquatic babitat/conservation area is not visible on the 	
	unwind side	
	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 (<i>e.g.</i>, 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." 	
Advisory Spray Drift Management Language for all products applied as liquid spray	"SPRAY DRIFT ADVISORIES THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. Be aware of nearby non-target sites and environmental conditions. IMPORTANCE OF DROPLET SIZE	Directions for Use, just below the Spray Drift box, under the heading, "Spray Drift Advisories"
	 An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. Controlling Droplet Size – Ground boom [NOTE TO REGISTRANT: remove if ground boom is prohibited on product labels] Volume – Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. Pressure – Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. Spray Nozzle – Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. Controlling Droplet Size – Aircraft (note to registrants: remove if aerial application is prohibited on product labels) Adjust Nozzles – Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. 	
	For ground equipment, the boom should remain level with the crop and have minimal bounce.	

RELEASE HEIGHT – Aircraft [NOTE TO REGISTRANT: remove if aerial application is prohibited on product labels]	
Higher release heights increase the potential for spray drift.	
HOODED (OR SHIELDED) SPRAYERS	
Shielding the boom or individual nozzles can reduce spray drift. Consider using hooded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area.	
TEMPERATURE AND HUMIDITY	
When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.	
TEMPERATURE INVERSIONS	
Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions.	
WIND	
Drift potential generally increases with wind speed. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.	
MEASURING WIND SPEED AND WIND DIRECTION	
 Best Management Practices for measuring wind speed and direction of wind: Applicators should check and acquire the predicted wind speed and direction for the application site within 12 hours prior to conducting applications to determine the time periods wind speed is likely to fall outside the applicable thresholds. Applicators should reassess wind speed and direction at the application site every 15 minutes while applications are in progress. 	
 Measuring wind speed and direction can be done by: 	

0	Relying on equipment on the application equipment that measures wind speed (<i>e.g.</i> , aerial equipment).	
0	Using a tower anemometer with telemetry or handheld anemometer. Users should read user manual on	
	how to calibrate, operate and interpret the output from an anemometer. Ground applicators should stop	
	every 15 minutes to take a reading with a tower anemometer with telemetry or handheld anemometer.	
	Some anemometers may have software that would allow users to view wind measurements in real time	
	while making an application, and, those cases, applicators would not have to stop to take measurements.	
0	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]"].	
0	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.	
0	Checking behind the spray rig at least every 15 minutes to see if the spray has changed direction from when	
	the application started."	

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 Approaches⁶⁶ 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 2020.⁶⁷

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.⁶⁸

Consultation on Chemicals in Registration Review

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

⁶⁶<u>https://www.epa.gov/endangered-species/interim-approaches-pesticide-endangered-species-act-assessments-based-nas-report</u>.

⁶⁷<u>https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-</u> <u>conventional</u>.

⁶⁸<u>https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act</u>.
Docket Number EPA-HQ-OPP-2016-0114 www.regulations.gov

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 opinion⁶⁹ from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.⁷⁰ In August 2023, the Agency implemented the FWS malathion biological opinion by issuing Endangered Species Protection Bulletins⁷¹ and approving malathion label amendments⁷² 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.⁷³

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy⁷⁴ 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*.⁷⁵ 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.

⁶⁹<u>https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions</u>.

⁷⁰<u>https://www.epa.gov/endangered-species/biological-opinions-available-public-comment-and-links-final-opinions</u>.

⁷¹ <u>https://www.epa.gov/endangered-species/endangered-species-protection-bulletins</u>.

⁷² https://www.regulations.gov/document/EPA-HQ-OPP-2009-0317-0154.

⁷³<u>https://www.epa.gov/pesticides/epa-announces-implementation-mitigation-measures-insecticides-chlorpyrifos-diazinon-</u>

and#:~:text=For%20chlorpyrifos%2C%20diazinon%2C%20and%20malathion,one%20or%20more%20listed%20spec ies.

 ⁷⁴ <u>https://www.epa.gov/newsreleases/epa-announces-endangered-species-act-protection-policy-new-pesticides</u>.
⁷⁵ <u>https://www.epa.gov/endangered-species</u>.

Docket Number EPA-HQ-OPP-2016-0114 www.regulations.gov

On November 16, 2022, EPA released the *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions.*⁷⁶ 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.⁷⁷ 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.⁷⁸ Visit the public docket for more information about the Vulnerable Species Pilot (docket EPA-HQ-OPP-2023-0327 at <u>www.regulations.gov</u>).

In July 2023, EPA published the framework of the Draft Herbicide Strategy⁷⁹ 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).

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

⁷⁶ <u>https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf</u>.

⁷⁷ https://www.regulations.gov/document/EPA-HQ-OPP-2023-0327-0002.

⁷⁸ View the StoryMaps for the 27 pilot species here: <u>https://storymaps.arcgis.com/collections/896d140363174c9d8ee78e4c471bd7fd</u>.

⁷⁹ <u>https://www.regulations.gov/document/EPA-HQ-OPP-2023-0365-0009</u>.

Appendix D: Endocrine Disruptor Screening Program

To establish or maintain FIFRA registrations and FFDCA tolerances or exemptions from the requirement for a tolerance, EPA currently collects a large amount of data for conventional active ingredients that can be used to determine whether use of an active ingredient has the potential to impact the estrogen, androgen, and thyroid pathways. Collectively, these studies assess acute, sub-chronic, and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints that may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental, and reproductive effects in different taxonomic groups.

FFDCA § 408(p) also requires EPA to develop an EDSP screening program to determine whether certain substances (including pesticide active and other ingredients) may have an effect similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP screening program developed by EPA includes data sets to address human and wildlife testing for estrogen, androgen, and thyroid (E, A, and T) activity and employs a two-tiered approach. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the E, A, or T hormonal systems. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any E, A, or T effect. If EPA finds, based on that data, that the pesticide is found to have an endocrine effect on humans, FFDCA § 408(p)(6) also requires EPA, "as appropriate, [to] take action under such statutory authority as is available to the Administrator ... as is necessary to ensure the protection of public health."

In addition to the data described above that EPA typically collects for conventional active ingredient FIFRA registrations and FFDCA tolerances or exemptions from the requirement for a tolerance, additional data may also be available for some conventional active ingredients. For 50 conventional active ingredients, that includes EDSP Tier 1 data submitted between October 2009 and February 2010 in response to EDSP-related test orders/data call-ins, as well as assessment of that data and other scientifically relevant information (OSRI) released in 2015. For a larger set of conventional active ingredients, that includes data on the estrogen receptor and androgen receptor from the ToxCast Pathway Model that EPA has deemed an alternative to certain EDSP Tier 1 assays. And still other conventional active ingredients may have an updated FIFRA Tier 2 rat reproductive toxicity study, an extended one-generation reproductive toxicity (EOGRT), or OSRI. EPA takes all of this information into consideration to determine whether additional data are needed to assess whether use of the conventional active ingredient has the potential to impact the estrogen, androgen, or thyroid pathways and to determine whether additional measures are needed to protect the public health as contemplated under FFDCA section 408(p)(6). EDSP Tier 1 data were submitted for triadimefon.

Docket Number EPA-HQ-OPP-2016-0114 www.regulations.gov

In 2015, EPA published the EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals which stated that there was a lack of convincing evidence for potential interaction with the estrogen, androgen, or thyroid pathways in mammals and wildlife. For triadimefon, all estrogen, androgen, and thyroid pathway related effects (potential changes to circulating steroid and/or thyroid hormones) were only seen in the presence of overt or systemic toxicity, and the observed effects were due to increased metabolic activity of the liver. Therefore, since there is a lack of convincing evidence of triadimefon interacting with the estrogen, androgen, or thyroid pathways, mammalian or wildlife EDSP Tier 2 testing was not recommended. Consistent with the EDSP Tier 1 recommendations, EPA has determined that no further studies are needed to assess triadimefon for potential interaction with the human E, A, and T pathways, and concludes that, based on all available data, no further action is need under FFDCA section 408(p)(6) to ensure protection of human health for endocrine effects. The review conclusions and DERs for triadimefon are available in the triadimefon public docket (see EPA-HQ-OPP-2016-0114-0005; https://www.regulations.gov/document/EPA-HQ-OPP-2016-0114-0006).

Additional Information may be found in the review conclusions and DERs for triadimefon, and are available in the triadimefon public docket (see EPA-HQ-OPP-2016-0114-0005; EPA-HQ-OPP-2016-0114-0006).