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Oxyfluorfen

Amended Proposed Interim Registration Review Decision
Case Number 2490

February 2023

Approved by: _____

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Date: 2/16/2024

Contents

I. INTRODUCTION 3
A. Updates to the 2021 Proposed Interim Decision 5
B. Summary of Oxyfluorfen Registration Review 6
C. Summary of Public Comments on the June 2021 Preliminary Interim Decision and Agency Responses 8
II. USE AND USAGE 18
III. SCIENTIFIC ASSESSMENTS 19
A. Human Health Risks 19
B. Ecological Risks 28
C. Benefits Assessment 35
IV. AMENDED PROPOSED INTERIM REGISTRATION REVIEW DECISION 38
A. Risk Mitigation and Regulatory Rationale 39
B. FIFRA Interim Ecological Mitigation Measures 42
C. Required Label Mitigation 43
D. Environmental Justice 60
E. Tolerance Actions 61
F. Data Requirements 63
V. NEXT STEPS AND TIMELINE 63
Appendix A: Summary of Proposed Actions for Oxyfluorfen 65
Appendix B: Proposed Labeling Changes for Oxyfluorfen Products 71
Appendix C. Listed Species Assessment 84
Appendix D: Endocrine Disruptor Screening Program 86

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Amended Proposed Interim Registration Review Decision (Amended PID) for oxyfluorfen (PC Code 111601, case 2490). Oxyfluorfen is a light-dependent peroxidizing herbicide (LDPH) (Weed Science Society of America Class 14) in the diphenyl-ether chemical family and is used for broad spectrum pre- and post-emergent control of annual broadleaf and grassy weeds. Oxyfluorfen provides contact (foliar) and residual (soil) control of weeds. Oxyfluorfen is readily absorbed by leaves of most target species. However, little absorption occurs by the roots and there is limited translocation throughout the target plant. Products containing oxyfluorfen are currently registered for use on a variety of sites including orchard, vine, vegetable, and field crops; Non-agricultural use sites of oxyfluorfen include turf grasses (including residential and recreational areas); forestry; ornamental plants; and non-crop areas. The first product containing oxyfluorfen was registered in 1979. The Agency completed the reregistration eligibility decision (RED)[1] for oxyfluorfen in 2002.

The Federal Insecticide, Fungicide, Rodenticide Act (FIFRA)[2] mandates a periodic review of existing pesticide registrations every 15 years, referred to as registration review.[3] All pesticides distributed or sold in the United States must be registered by EPA. During registration review, the Agency ultimately determines whether a currently registered pesticide continues to meet FIFRA's registration standard, showing based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling.[4] Where appropriate, the Agency may issue an interim registration review decision (ID) before completing a final registration review decision.[5] However, issuance of an ID is not a decision on whether a pesticide's registrations continue to satisfy the FIFRA standard for registration.[6] 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.[7] The Agency is issuing this Amended PID

[1] EPA738-R-02-014. 2002. Reregistration Eligibility Decision (RED) : Oxylfuorfen. Issued October 2002.
[2] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136w-8.
[3] For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.
[4] FIFRA § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57; *see also* FIFRA § 3(c)(5).
[5] 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.
[6] 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.
[7] 40 C.F.R. § 155.56.

for oxyfluorfen to identify additional risk mitigations that EPA has determined would address risks of concern for oxyfluorfen, as presented in Section IV and Appendices A and B.

EPA issued a PID for oxyfluorfen in 2021. In that document, EPA proposed numerous mitigations intended to reduce the identified risks dietary and occupational human health as well as some proposed mitigation for the reduction of risks to wildlife. In this Amended PID, EPA is proposing FIFRA Interim Ecological Mitigation (IEM) measures, and in addition, is modifying the mitigation that was proposed in the original PID for oxyfluorfen based on the input from the public on the risk, benefits, and use of oxyfluorfen. For more details on how public comments influenced these changes, see Section I.C, which summarizes EPA's responses to public comments on the PID, and EPA's separate response to comments documents.[8,9,10] These documents, as well as documents related to preceding steps in registration review are available in EPA's public docket for oxyfluorfen (EPA-HQ-OPP-2014-0778) at www.regulations.gov.

EPA has not yet fully evaluated oxyfluorfen's effects on federally threatened and endangered (listed) species or designated critical habitats. However, consistent with its obligations under the Endangered Species Act (ESA),[11] 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 oxyfluorfen 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.[12] 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.[13] As part of this update, EPA announced that, going forward, EPA may include a variety of FIFRA 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.

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[8] McFarley, Heather. *BEAD Response to Oxyfluorfen Usage, Benefit, and Impact of Mitigation Related Comments Received on the Preliminary Interim Decision of Oxyfluorfen (PC# 111601).* EPA memorandum dated December 16, 2021.
[9] Koper, Christopher M. *Oxyfluorfen: EFED's Response to Comments on the Proposed Interim Decision for Registration Review.* EPA memorandum dated January 1, 2022.
[10] Britt, Adrian, Sheila Piper, and Wade Britton. *Oxyfluorfen: Response to Public Comments on the Draft Human Health Risk Assessment for Registration Review.* EPA memorandum dated December 15, 2021.
[11] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[12] *Balancing Wildlife Protections and Responsible Pesticide Use* (Apr. 2022), https://www.epa.gov/system/files/documents/2022-04/balancing-wildlife-protection-and-responsible-pesticide-use_final.pdf.
[13] *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions* (Nov. 2022), https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf

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

Before completing registration review, EPA will also include address its obligations for oxyfluorfen under the endocrine screening program at section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA).[14] For more information on the endocrine screening for the oyxfluorfen registration review, see Appendix D.

This document is organized in five sections:

- *Introduction* (summarizing the registration review milestones and responding to public comments),
- *Use and Usage* (discussing how and where oxyfluorfen is 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 decision, regulatory rationale, and any mitigation measures to address risks of concern), and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete of this registration review).

A. Updates to the 2021 Proposed Interim Decision

EPA issued a PID for oxyfluorfen in 2021. In this Amended PID, EPA is modifying the mitigation that was proposed in the 2021 PID for oxyfluorfen based on the input from the public on the risk, benefits, and use of oxyfluorfen. In addition, EPA is proposing FIFRA Interim Ecological Mitigation (IEM) measures, which are detailed in Section IV.B.

[14] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

A number of changes have made to the proposed risk management decision as a result of public comments (see Section I.C) and additional information received since the 2021 PID for oxyfluorfen. These changes include:

- No longer proposing to terminate the use on bananas, as there are no longer any registered banana uses on any oxyfluorfen product label. The Agency proposes to convert the banana tolerance to an import-only tolerance.
- Simplifying risk mitigation for the use in orchards to an application at 30% of the row width only.
- Continuing to allow a single non-dormant application to almonds, pistachios, and walnuts at 0.25 to 0.5 lb-ai/acre as an alternative to the proposed mitigation for banding applications for orchard crops.
- Expanding the proposed exemption for vegetated filter strips from Pacific Coast states to also include the following states with irrigated agriculture: Idaho, Nevada, Utah, Arizona, Wyoming, Colorado, New Mexico, and Texas west of Interstate 35.
- Propose to add a single maximum application rate of 1.5 lb ai/acre and an annual maximum application rate of 2 lb ai/acre to technical labels to assure future new uses do not result in dietary risks of concern.
- Clarification that the Agency proposes that *all* chemigation uses are being prohibited, not only those for orchards and vineyards.
- The Agency intends to require the subchronic inhalation study using its Data Call In authority.
- Several corrections were made to address typographical errors or incorrect numerical values throughout the original PID.

B. Summary of Oxyfluorfen Registration Review

On December 19, 2014, the Agency formally initiated registration review for oxyfluorfen with the opening of the registration review docket for the case.[15] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of oxyfluorfen:

- December 2014 – EPA posted the *Oxyfluorfen Preliminary Work Plan Registration Review: Initial Docket Case Number 2490*[16], *Oxyfluorfen: Human Health Assessment Scoping Document in Support of Registration Review*,[17] and *Registration Review Problem Formulation for Oxyfluorfen*[18] to the oxyfluorfen public docket for a 60-day public comment period.

[15] 40 C.F.R. § 155.50
[16] Keigwin, Richard P. *Oxyfluorfen Preliminary Work Plan Registration Review: Initial Docket Case Number 2490*. EPA document dated December 5, 2014.
[17] Nieves, Ivan, Ayaad Assaad, Marquea King, Bonnie Cropp-Kohlligian, and Sue Hummel. *Oxyfluorfen: Human Health Assessment Scoping Document in Support of Registration Review.*EPA memorandum dated October 9 2014.
[18] Sternberg, Robin, and He Zhong. *Registration Review Problem Formulation for Oxyfluorfen.* EPA memorandum dated November 3, 2014.

- September 2015 – EPA posted *Oxyfluorfen Final Work Plan*[19] (FWP) for oxyfluorfen to the oxyfluorfen public docket. The Agency received five public comments on the PWP. These comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP. In the FWP, EPA added the semi-field testing for pollinators to the planned data needs. The FWP required 16 studies for registration review.[20]

- May 2017 – EPA issued a generic data call-in (GDCI) for oxyfluorfen to obtain data needed to conduct the registration review risk assessments (GDCI-111601-1515). The GDCI required 16 studies. Of these, the registrants submitted 13 studies, two studies were waived, and one study has not been submitted as of the date of this decision. Of the submitted studies, EPA determined that two chronic oral honey bee toxicity studies, one for adults (SS-1313) and one for larvae (SS-1314) provide some useful information but were insufficient to meet guideline data requirements. The primary registrant, Adaura, submitted these studies in May of 2023 and they are in review. In addition, EPA denied a waiver request for a requirement for foliar dislodgeable residues (875.2100). The primary registrant, Adaura, has agreed to conduct this study and expects to complete and submit the study in 2024.

- September 2019 – EPA posted *Oxyfluorfen: Draft Ecological Risk Assessment for Registration Review*[21] and *Oxyfluorfen Draft Human Health Risk Assessment for Registration Review*[22] for a 60-day public comment period. The Agency received comments from seven commenters. The comments did not change the risk assessments or registration review timeline for oxyfluorfen.

- June 2021 – The Agency posted the Proposed Interim Decision (PID) for oxyfluorfen in the oxyfluorfen public docket for a 60-day public comment period on August 3, 2021. Along with the PID, the following documents were also posted to the oxyfluorfen public docket:

    - Oxyfluorfen: Addendum to Drinking Water Exposure Assessment for Registration Review.[23]
    - Oxyfluorfen: Updated Chronic and Cancer Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments to Support Registration Review[24].

[19] Keigwin, Richard P. *Oxyfluorfen Final Work Plan: Registration Review, Case Number 2490.*EPA document datedJune 10, 2015.
[20] 40 C.F.R. § 155.53(b)
[21] Connoly, Jennifer, and Christopher M. Koper. *Oxyfluorfen: Draft Ecological Risk Assessment for Registration Review.* EPA Memorandum dated June 27 2019.
[22] Craig, Evisabel, Ivan Nieves, Amelework Habtemichael, and Sheila Piper. *Oxyfluorfen Draft Human Health Risk Assessment for Registration Review.* EPA memorandum dated June 19 2019.
[23] Koper, Christopher. Oxyfluorfen: *Addendum to Drinking Water Exposure Assessment for Registration Review*. EPA Memorandum dated March 1, 2021
[24] Piper, Sheila. *Oxyfluorfen: Updated Chronic and Cancer Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments to Support Registration Review.* EPA memorandum dated March 17, 2021.

- Oxyfluorfen: Addendum to the 2019 Draft Human Health Risk Assessment for Registration Review.[25]
- Oxyfluorfen: Response to Comments on the Draft Ecological Risk Assessment and Drinking Water Exposure Assessment for Registration Review.[26]
- Oxyfluorfen: Response to Public Comments on the Draft Human Health Risk Assessment for Registration Review.[27]
- Oxyfluorfen: Use, Usage, Benefits, and Impact Assessment[28].

- February 2024 – The Agency is posting this Amended PID to the oxyfluorfen public docket. The Agency received comments from 15 commenters on the 2021 PID. The Agency has summarized and responded to these comments in Section I.C, below. Along with the Amended PID, the following documents are also being posted to the oxyfluorfen public docket:

  - BEAD Response to Oxyfluorfen Usage, Benefit, and Impact of Mitigation Related Comments Received on the Preliminary Interim Decision of Oxyfluorfen (PC# 111601).[8]
  - Oxyfluorfen: EFED's Response to Comments on the Proposed Interim Decision for Registration Review.[9]
  - Oxyfluorfen: Response to Public Comments on the Draft Human Health Risk Assessment for Registration Review.[10]

C. Summary of Public Comments on the June 2021 Preliminary Interim Decision and Agency Responses

The 60-day public comment period for the oxyfluorfen PID (beginning August 3, 2021) ended on October 4, 2021. During this time, the Agency received comments from 15 commenters (Docket IDs in parentheses):

- Adaura LLC, the primary technical registrant (EPA-HQ-OPP-2014-0778-0071 and EPA-HQ-OPP-2014-0778-0086)
- American Soybean Growers (EPA-HQ-OPP-2014-0778-0082 and EPA-HQ-OPP-2014-0778-0083)
- Arizona Farm Bureau Federation (EPA-HQ-OPP-2014-0778-0078-0061)
- Arizona Pest Management Center (EPA-HQ-OPP-2014-0778-0074)
- California Stormwater Quality Association (EPA-HQ-OPP-2014-0778-0085)
- Center for Biological Diversity (EPA-HQ-OPP-2014-0778-0072)

[25] Craig, Evisabel, Sheila Piper, and Wade Britton. *Oxyfluorfen: Addendum to the 2019 Draft Human Health Risk Assessment for Registration Review*. EPA memorandum dated March 17, 2021.
[26] Koper, Christopher M. *Oxyfluorfen: Response to Comments on the Draft Ecological Risk Assessment and Drinking Water Exposure Assessment for Registration Review*. EPA memorandum dated June 11, 2020.
[27] Craig, Evisabel, Amelework Habtemichael, and Shelu Shelat. *Oxyfluorfen: Response to Public Comments on the Draft Human Health Risk Assessment for Registration Review*. Memorandum dated March 19, 2020.
[28] McFarley, Heather, and Dexter Sells. *Oxyfluorfen: Use, Usage, Benefits, and Impact Assessment*. EP memorandum dated March 30, 2021.

- Control Solutions Incorporated, a division of Adama Group (EPA-HQ-OPP-2014-0778-0077)
- Malheur County Onion Growers (EPA-HQ-OPP-2014-0778-0079)
- Michigan Farm Bureau (EPA-HQ-OPP-2014-0778-0073)
- National Agricultural Aviation Association (NAAA) (EPA-HQ-OPP-2014-0778-0084)
- National Association of Landscape Professionals (EPA-HQ-OPP-2014-0778-0080)
- Sacramento River Storm Water Protection Program (EPA-HQ-OPP-2014-0778-0075)
- Spectrum Group, a Division of United Industries Corp. (not in oxyfluorfen public docket because it contains Confidential Business Information)
- Stuart Reitz (EPA-HQ-OPP-2014-0778-0081)
- United States Department of Agriculture (USDA) (EPA-HQ-OPP-2014-0778-0076)

The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below. Comments of a specific or technical nature are addressed in the accompanying response documents cited herein. The public comment and response process for registration review is an important part of producing quality risk management decisions and the Agency thanks all commenters for participating and has considered all comments in developing this Amended PID.

Comments Submitted by Adaura, LLC (EPA-HQ-OPP-2014-0778-0071**) and Adaura and NuFarm Americas, inc. (**EPA-HQ-OPP-2014-0778-0086**)**

Comment: Adaura, LLC, one of the technical registrants for oxyfluorfen, provided several comments on the oxyfluorfen PID. Adaura submitted a second set of comments in coordination with another registrant, NuFarm Americas, that provided additional information regarding application of oxyfluorfen through drip irrigation systems and discussed the continuing need for a broadcast application to nut crops.

Adaura pointed out that the proposed changes in the maximum concentration of prepared spray solution being allowed for orchards, vineyards, and Christmas tree farms was not consistent throughout the document. They also had concerns because the Agency assessed use patterns without personal protective equipment (PPE) that is required on Adaura's labels. In the second set of comments from Adaura, they requested that the Agency reconsider the requirement for banded-only applications for certain nut crops and that a post-emergent broadcast application be allowed at rate of 0.25-0.5 lb-ai/acre on pistachios, almonds, and walnuts, less than the 6 lb/acre rate currently on the label for dormant applications. Adaura commented that the broadcast or "trunk to trunk" application of oxyfluorfen is part of the preharvest program in tree nut farms and is typically conducted at this lower rate. The USDA (EPA-HQ-OPP-2014-0778-0076) and Michigan Farm Bureau (EPA-HQ-OPP-2014-0778-0073) submitted similar comments regarding row spacing in orchards and application rate.

In Adaura's first public comment, they requested to retain application by chemigation by drip irrigation to orchard crops. However, in their subsequent submission, they withdrew this request citing it is not a significant application method for these crops.

EPA Response: Consistency issues with the units on the application concentration for orchard/vineyard, forestry, and Christmas trees have been corrected. The Agency agrees that Adaura's labels already requires more than baseline PPE. However, labels for other registrants do not have equivalent requirements for PPE, and the Agency assesses risk based on the labels with the least protective requirements. The Agency assesses occupational risks on base level PPE and assesses increasing levels of PPE or engineering controls (ECs) as necessary to identify risks that are not of concern.

The importance of broadcast or "trunk-to-trunk" oxyfluorfen treatments prior to harvest in walnuts was not assessed in BEAD's Use, Benefits and Impact Assessment supporting the PID.[29] Comments that state that "trunk-to-trunk" or broadcast treatments are needed before harvest are consistent with the Agency's knowledge of nut harvesting. However, the Agency has since assessed these benefits and notes that there are pre-emergence and post-emergence alternatives to oxyfluorfen available for this application timing (*i.e.*, that can be used prior to harvest).[30] Therefore, the Agency does not expect a significant impact to growers from prohibiting broadcast applications.[31]

The post-emergent application rate is currently on the label for pre-harvest cleanup of the orchard floor at 0.5–1.5 lb-ai/acre. The mitigation proposed in the PID was for a single application at 1.5 lb-ai/acre only to be applied as a banded application on no more than 30% of the row spacing. The Agency has evaluated the registrant's proposed use pattern and found that the dietary risks would be nearly identical to the use pattern of 6 lb/acre as a banded application to a band no more than 30% of the total row width as proposed in the PID. The Agency is also removing the proposed requirement that the bands be no more than 6 feet as this simplifies the language and gives the growers more flexibility. Therefore, the proposed mitigation for the use pattern for almonds, pistachios, and walnuts is being modified accordingly (see Section IV and Appendix B below).

Comments Submitted by the Arizona Farm Bureau (EPA-HQ-OPP-2014-0778-0078-0061**) and Arizona Pest Management Center (**EPA-HQ-OPP-2014-0778-0074**)**

Comment: These two commenters both requested that the Agency consider expanding the exemption for Vegetated Filter Strips (VFS) from California, Washington, and Oregon to include Arizona. These comments were echoed in the comments provided by the USDA (EPA-HQ-OPP-

[29] McFarley, Heather, and Dexter Sells. 2021. *Oxyfluorfen Use, Usage, Benefits, and Impact Assessment.*
[30] Roncoroni, J. A., K. J. Hembree, & C. A. Ingels. 2016. *Susceptibility of Weeds to Herbicide Control. Grape Agricultural Pest Management*. University of California Agriculture & Natural Resources. Available at: http://ipm.ucanr.edu/PMG/r302700411.html#SPRING [Accessed March 2020]
[31] BEAD Response to Oxyfluorfen Usage, Benefit, and Impact of Mitigation Related Comments Received on the Preliminary Interim Decision of Oxyfluorfen (PC# 111601) (EPA-HQ-OPP-2014-0778)

2014-0778-0076) which asked the Agency to reconsider the exemption for all western states where irrigated agriculture is prevalent. These commenters assert that Arizona agriculture has much in common with the Pacific Coast states in that very little of Arizona's agricultural land is found near water bodies as described in EPA's proposed language ("such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds"), stating "100% of our agriculture in Arizona is irrigated and nearly all agricultural fields are laser-leveled to conserve water on the field and to reduce runoff, Arizona receives less rainfall than states with exceptions, and, similar to the excepted states, many of the crops grown in Arizona are under contracts which require "clean" field borders to minimize product contamination." Conversely the Sacramento River Source Water Protection Program (Docket ID: EPA-HQ-OPP-2014-0778-0075), noted that the labels for the two most commonly used products for oxyfluorfen already have the buffer in place in the western states where it is now to be exempted.

Response: As discussed in the 2021 PID**,** the Agency proposed making an exception to the requirement for VFS because the rainfall that causes runoff mostly occurs during the winter and out of the growing season in certain states (CA, WA and OR). Consequently, VFS would have little effect on the runoff of pesticides. In addition, most agriculture in these states is irrigated and vegetated filter strips are not easily compatible with irrigated agriculture, especially flood and furrow irrigated systems. The Agency agrees that the conditions that reduce the usefulness of VFS in California, Oregon, and Washington also apply to other states with irrigated agriculture. Therefore, the exemption from VFS is being extended to irrigated agriculture in Idaho, Nevada, Utah, Arizona, Wyoming, Colorado, New Mexico, and Texas west of Interstate 35. See Section IV.B.12 of this document for details on mitigation of vegetated filter strips.

Comments Submitted by the Center for Biological Diversity (CBD) (EPA-HQ-OPP-2014-0778-0072)

Comment: CBD's comments focus on EPA's obligation to consult with the Services on the registration review of oxyfluorfen in accordance with the Endangered Species Act (ESA). The CBD comments mention various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the agency's preliminary determinations regarding the effects of oxyfluorfen on listed species and their designated critical habitat for the oxyfluorfen registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects, effects on human health or environmental safety concerning endocrine disruption, and any additive, cumulative or synergistic effects of the use of the pesticide.

EPA Response: EPA has reviewed CBD's comments and is addressing many of the concerns regarding listed species as part of its ongoing collaborative work with the Services and USDA to improve the consultation process for listed species for pesticides in accordance with the Endangered Species Act (ESA) § 7. See Endangered Species Assessment in Appendix C of this

document for more information. EPA has not completed an assessment of potential effects to listed species or their designated critical habitat from current uses of oxyfluorfen. However, consistent with the ESA Workplan Update, EPA is proposing several FIFRA IEM measures for oxyfluorfen, as detailed in Section IV.B. While these mitigation measures do not satisfy EPA's ESA obligations, EPA believes that early mitigation (and including Bulletins Live Two (BLT) reference language) may improve protections for nontarget organisms, including listed species, from currently registered pesticide products. EPA will address concerns specific to ESA and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See Endocrine Disruptor Screening Program in Appendix D of this document for more information regarding endocrine disruption. EPA is currently developing an agency policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, EPA released an interim process for public comment, available at regulations.gov in docket EPA-HQ-OPP-2017-0433. After the Agency has received and considered public comment on the proposed policy, and once that policy has been finalized, EPA will consider its implications on EPA's final decision for oxyfluorfen.

Comments Submitted by the Control Solutions Corporation (CSI), (EPA-HQ-OPP-2014-0778-0077), **National Association of Landscape Professionals (NALP)** (EPA-HQ-OPP-2014-0778-0080)**, and the California Stormwater Quality Association (CASQA)** (EPA-HQ-OPP-2014-0778-0085)**, Spectrum Group, a division of United Industries Corporation (not in docket), and USDA** (EPA-HQ-OPP-2014-0778-0076)

Comment: Comments from these five groups all related to the proposed prohibition of the use in residential areas. CSI noted that the PID states that the "Agency has identified potential for residential handler's cancer risk concerns for all formulations and use patterns **except** hose-end sprayers using the ready-to-use formulation (cancer risks = $9.2x10^{-7}$) and applying liquid formulation outdoors around buildings ($1.2x10^{-6}$). Yet, the Agency is proposing to eliminate all residential uses of oxyfluorfen." They propose to retain the use with the following alternative mitigations:

- Products for residential use should only be formulated as ready-to-use products for spot, crack and crevice, and/or building perimeter use and contain no more than 0.1% oxyfluorfen. They should not be formulated into products for hose-end application or into concentrates.
- For end-use products with residential use, applications should be restricted to spot, crack and crevice, and/or building perimeter use.

NALP pointed out that, based on the BEAD assessment, it was not clear whether the residential uses by commercial applicators would be retained or not. CASQA supports the cancellation of application at residential use sites as it will contribute to the reduction of pesticides in runoff in urban watersheds thereby reducing risks to aquatic invertebrates. USDA questioned whether the impacts of cancelling use on residential use sites has been adequately assessed and noted that the flumioxazin is only available to professional applicators. CSI noted that oxadiazon is also only available to professional applicators.

The Spectrum Group disagreed with Agency's statement that it does use PPE to mitigate residential uses because it is difficult to implement and enforce. Noting that this is a departure from other EPA reregistration and registration review decisions where labels for residential use products were amended to include PPE to mitigate risk to residential handlers/applicators.

Response: While the residential risks for some uses did not exceed the level of concern (LOC) by themselves, the aggregate risk (food, water, and residential risk combined) does exceed the LOC. In order to mitigate aggregate risks, the Agency is proposing that all residential use be prohibited. Risks to residential users are considered as part of aggregate risk along with dietary routes of exposure as defined by the Food Quality Protection Act of 1996. As such, the Agency cannot consider benefits in making its decision about whether and how much risk needs to be reduced. However, the Agency does consider benefits when comparing different mitigation options to reduce the overall impact of the mitigation on users and the general population.

The Agency is aware that there are other pesticide products on the market which specify PPE for residential use products when the product can be used by both commercial and residential applicators. However, during the registration review process, the Agency is proposing mitigation alternatives to PPE for residential products, since PPE is "difficult to implement and enforce on residential products" as noted in the PID.

The Agency has considered retaining residential application of oxyfluorfen by commercial applicators. However, it is not possible to preclude residential users from using products intended for professional applicators; therefore, residential uses will be removed from all products. The Agency acknowledges that there may be impacts to residential users from this proposal[8]. The Agency may consider retaining commercial use products on residential use sites if the products are marketed to preclude purchase by residential applicators.

Comments Submitted by the Michigan Farm Bureau (EPA-HQ-OPP-2014-0778-0073)

Comment: The Michigan Farm Bureau requested that the Agency reconsider the prohibition of broadcast sprays in orchards and the lowering of the height of the spray boom from 4 feet to 2 feet as it would cause gaps in herbicide spray coverage when there is uneven terrain.

EPA Response: These proposed mitigation measures are part of a suite of measures which reduce the dietary risk, and consequently, the aggregate risk to acceptable levels so the tolerances for oxyfluorfen can be retained. This suite of measures was optimized to reduce the overall impact on growers while maintaining the important uses of the product.

In general, spray release height is important to minimize overlap of spray from nozzles while maintaining proper coverage. If nozzles are placed too low, they will not provide adequate coverage and could lead to weed control failure. The Agency agrees that in orchards with uneven terrain, the 2-foot boom height may impact grower's ability to use oxyfluorfen, but due to the aggregate risk concerns previously discussed, the Agency is proposing to retain this restriction.

For a more detailed response to the comment see BEAD's Response to Comments Received on the PID. [8]

Comments Submitted by the Sacramento River Source Water Protection Program (SRSWPP) (EPA-HQ-OPP-2014-0778-0075)

Comment: The SRSWPP commented on their desire to retain VFS in California. They also reiterated their support for comparing Estimated Drinking Water Concentrations (EDWC) to Human Health Benchmarks for Pesticides (HHBP) maintained on the Agency's website. The SRSWPP noted several discrepancies and typographical errors in the document. The SRSWPP also noted that the proposed maximum number of applications for corn, dry beans, and soybeans are greater than the current average number of applications per year in Table 5, so none of the proposed maximums are reductions compared to current practice. Additionally, the SRSPP noted that the crops with the highest use, almonds, walnuts, and wine grapes, collectively account for 59% of all acres treated but were not included in the discussion of changes in use rate or number.

Response: The comment regarding VFS is addressed with the comments from the Arizona Farm Bureau and Arizona Pest Management Center above. HHBP are based on human health risk assessments from the Office of Pesticide Programs and are updated when Registration Review is complete. The current HHBP is based on the Agency's Registration Review Risk Assessment from 2002.[32] The Agency does not compare current EDWCs to HHBP, because new human health endpoints have been generated for this assessment that supersede those from the RED on which the HHBP is based. After the ID is published, the Agency will update the oxyfluorfen HHBP based on the new values in this assessment.

Regarding the proposed maximum application rates and the current average number of applications per year in Table 5 of the PID, it is important to note the proposed reduction is relative to the maximum number of applications currently allowed on the label, not the average number typically in use. For its drinking water assessments, the Agency uses the maximum label rate as a model input when calculating EDWCs as users can legally apply up this amount, although they may choose to use a lesser amount if they can still achieve efficacy. Comparing the proposed label rates with average rates gives the Agency some idea of how much impact these changes will have on growers. In this case, these changes are not expected to significantly impact growers as most of them are already using a lower number of applications than is allowed on the label. The use of oxyfluorfen on walnuts, almonds, and wine grapes were not discussed for a proposed application rate change because the risks associated with these crops are mitigated by restricting use to banded applications. The Agency determined that banding would effectively mitigate the risk with less impact on the growers compared to reducing the overall application rate and number of applications.

The Agency has corrected the other discrepancies and typographical errors noted by SRSWPP.

[32] 2002. Oxyfluorfen. Revised Human Health Risk Assessment.

Comments Submitted by the Spectrum Group, a division of United Industries Corporation (not in docket to protect Confidential Business Information)

Comment: The Spectrum Group markets oxyfluorfen products for residential markets and the Agency has proposed to cancel all residential uses for the aggregate risk to be at an acceptable level. Spectrum group submitted an alternative occupational cancer assessment refined to address label-specific use directions and application rates. The refinement retained the dermal absorption factor of 18%, the cancer potency factor of 0.0732 mg/kg/day, an 80-kg body weight, and the dermal and inhalation unit exposure values for an estimated cancer risk of 1.1×10^{-6}. Spectrum Group also believes that a weight-of-evidence evaluation of oxyfluorfen demonstrates that it is not a potential carcinogen in humans and therefore the cancer risk calculation discussed in this document are theoretical and not relevant to homeowner use. Note that this comment has been withheld from the oxyfluorfen public docket as it contains confidential business information.

EPA Response: The aggregate cancer risk from dietary (food + water) and residential exposure by EPA's estimate is at 3×10^{-5}. For the product, Spectracide® Weed and Grass Killer with Extended Control Concentrate (Reg. No. 9688-259-8845), it is correct to assume a reduced maximum amount handled; 3.4 gallons of product could be mixed and applied daily. The Agency has presented a cancer risk estimate with use of the correction of daily amount handled from 5 to 3.4 gallons specific to this product and assuming the use frequency for gardens and trees of 2 applications per year found in the Residential Exposure Joint Venture dataset. The resulting cancer risk estimate for this product is 5.1×10^{-6} which the Agency is identifying as a risk of concern for cancer.

EPA has also presented a cancer risk estimate specific to the ready-to-use (RTU) product, Spectracide Weed and Grass Killer with Extended Control (Reg. No. 9888-264-8845) containing 0.10% oxyfluorfen equivalent to 0.0086 lb oxyfluorfen per gallon (in a 1.33 gallon ready to use battery powered trigger sprayer). Each container of the RTU product contains 0.011 lb ai, with 2 containers applied daily, and per the REJV use frequency for gardens and trees of 2 applications are made per year. The resulting cancer risk estimate for this product is 3.2×10^{-6} which the Agency is identifying as a risk of concern. Since risks from residential exposure must be aggregated with the dietary risk, there is room in the risk cup only for this residential use, or all the food uses. The food uses are being retained, and residential uses are being prohibited. The resulting aggregate cancer risk is not of concern.

The cancer classification of oxyfluorfen was determined using a weight-of-evidence approach in accordance with the EPA Final Guidelines for Carcinogen Risk Assessment. The Office of Pesticide Programs (OPP) Cancer Assessment Review Committee (CARC) classified oxyfluorfen as "Likely to be Carcinogenic to Humans" (J. Kidwell, 04/20/2010, TXR No. 0055343) and recommended that a linear low-dose quantitative approach (Q_1*) be retained for human risk characterization. The CARC suggests that the registrant consider submitting a combined chronic/carcinogenicity study in the rat as an alternative to additional mechanistic studies. This study can be submitted as a PRIA action for cancer reclassification. Until additional data related to oxyfluorfen are submitted to the Agency for review, the cancer classification and

the quantification of cancer risk will not change. A more detailed response to this comment can be found in HED's response to comments.[33]

Comments Submitted by United States Department of Agriculture (USDA) (EPA-HQ-OPP-2014-0778-0076)

Comment: USDA requested the reconsideration of the proposed cancellation of the banana use and proposed revocation of the associated tolerances. USDA noted that while bananas were a minor use in the United States, the use of oxyfluorfen is very important to this small market because the only alternatives are contact herbicides like glyphosate, diuron, and paraquat. Furthermore, the marginal risk reduction from removing bananas from the dietary assessment is negligible—dietary exposure is reduced by ~0.000003 mg/kg/day and the cancer risk estimate remains at $2x10^{-6}$ (*sic*)[34] with or without banana—and therefore does not appear to translate into any meaningful public health benefit.

USDA had concerns regarding the extent of the VFS exemption in Pacific Coast states similar to comments submitted by the Arizona Pest Management Center and the Arizona Farm Bureau. In addition, USDA had concerns regarding the water body examples used in the VFS language to be used on the labels related to ongoing concerns with 'Waters of the United States' language currently under review by the Agency.

USDA also had concerns about how the reduced rates of oxyfluorfen that were proposed for cacao and coffee would affect growers of these crops in Puerto Rico and Hawaii. USDA urged the Agency to reconsider the rate reductions for cacao and coffee. A reduction in maximum application rates could lead to poor weed control and may cause growers to increase use of the two available post-emergence herbicides, *i.e.*, glyphosate or paraquat.

USDA agreed with the following mitigations proposed in the PID: reduction in the maximum application rate and number of applications for several crops (not including cacao and coffee), restrictions on the use of backpack sprayers, restriction on application by mechanically pressurized handguns, restriction on hand application of granules, removal of application through chemigation systems, and inclusion of resistance management language on labels.

EPA Response: While the initial assessments of dietary risk showed that bananas were a significant contributor to dietary exposure, the Agency agrees that the current assessment shows that contribution of bananas to the overall risk is small, does not contribute meaningfully to cancer risk concerns, and therefore the use can be retained. However, according to the state of Hawaii, the Special Local Needs label for use of oxyfluorfen on bananas, (reg. no. HI020010) is no longer active. The Agency therefore intends to convert the current tolerance to an import-only tolerance.

[33] Oxyfluorfen: Response to Public Comments on the Draft Human Health Risk Assessment for Registration Review., dated December 15, 2021.

[34] The Agency evaluated cancer risks against a $3x10^{-6}$ life risk standard for this assessment.

While the Agency understands there is uncertainty regarding impacts of the proposed rate changes on cacao and coffee production, the mitigation is intended to reduce the dietary and aggregate cancer risks to meet the 'reasonable certainty of no harm' standard which does not allow adjustments for consideration of benefits. In order to maintain the current application rate for cacao and coffee, the registrants would need to propose voluntary cancellations for other use(s) to make room within the dietary risk threshold for the increased application. The Agency recognizes that reducing the maximum single use rate could reduce the period of effective residual control, increasing dependence on the only other herbicides recommended (glyphosate and paraquat), or necessitating the application of oxyfluorfen at a shorter retreatment interval. As these are very minor crops in the United States, the Agency has determined that this mitigation has a lower overall impact than cancelling a different crop.

USDA's comment regarding the exemption for VFS in western states is addressed with the response to Arizona commenters above. Regarding clarity of the language and whether consideration of the Waters of the United States issues needed to be addressed, the water body language proposed in this amended PID has gone through extensive review within the Agency, with federal agency stakeholders, and through public comment processes over many years. Major reviews of the water body description were conducted as part of the process to develop label language for the pyrethroid class of pesticides[35], and conducted again in 2023 as part of the effort to describe water bodies as part of FIFRA IEM label language. With regard to the Waters of the United States definition, EPA can require mitigation to protect any water body within the United States - regardless of whether it falls under the Waters of the United States definition – if it is necessary for the pesticide's registration to meet the FIFRA standard. Therefore, the Agency will leave this language as it was proposed in the PID.

Comment Submitted by NAAA (EPA-HQ-OPP-2014-0778-0084)

Comment: The NAAA provided comments regarding the spray drift analysis conducted in the draft risk assessment, particularly concerning the spray drift model, AgDRIFT, and the inputs used in the model (*e.g.*, aircraft type, swath width and displacement, number of passes, wind speed, height for wind speed measurement, boom length and boom drop, droplet size, atmospheric stability, and surface roughness). NAAA believes that the tier-1 component of the AgDRIFT model is inadequate because some of the assumptions it uses are unrealistic. NAAA recommended the use of the Multiple Application Assessment Method (MAAM) to model drift potential for products that can be applied multiple times annually on a crop. NAAA also recommended a refined assessment with a higher tiered model.

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

[35] USEPA. 2021. *Updated Label Language for the Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals, September 30, 2020.* Docket Number EPA-HQ-OPP-2012-0167-0169.

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, modeling for a national-level assessment is first conducted using maximum application rates, limitations, and instructions listed on the pesticide (oxyfluorfen) labels. In the absence of specific use directions and application restrictions implemented across all product labels, default assumptions (based on empirical data) are used.

II. USE AND USAGE

Oxyfluorfen is a light-dependent peroxidizing herbicide (LDPH) (Class 14) in the diphenyl-ether chemical family and is used for broad spectrum control of annual broadleaf and grassy weeds. Oxyfluorfen provides contact (foliar) and residual (soil) control of weeds and is readily absorbed by leaves of target species. Oxyfluorfen is currently registered on a variety of sites including orchard, vine, vegetable, and field crops. Non-agricultural use sites of oxyfluorfen include turf grasses (including residential and recreational areas), forestry, ornamental plants, and non-crop areas. Oxyfluorfen is used on about 40 different crops across the United States to control broadleaf weeds, including common mallow, filaree and redstem filaree, wild mustard, and morning glory. Oxyfluorfen is formulated as an emulsifiable concentrate, a granular, a ready-to-use solution, a soluble concentrate, and a flowable concentrate. It is applied as a banded and broadcast sprays, through irrigation systems (chemigation), and by mechanical and hand-application of granules. Application equipment includes aircraft, handheld sprayers, and tractor-mounted conventional ground sprayers.

On average, between 2014-2018, U.S. agricultural crop growers annually applied one million pounds of oxyfluorfen to about 2.6 million acres, with almonds, walnuts, and wine grapes collectively accounting for 59% of all acres treated and 66% of all pounds applied.[36] Between 2014-2018, the majority of usage with oxyfluorfen was in California, where growers applied 92% of all pounds applied and treated 87% of all acres treated nationally.[36]

On non-agricultural use sites, in 2013, approximately 29,000 lbs of active ingredient (AI) of oxyfluorfen were applied in horticultural nurseries and greenhouses.[37] In 2016 and 2019, oxyfluorfen was applied via garden herbicides, or to outdoor residential settings, although usage, in terms of pounds applied, was minimal and a specific usage amount for oxyfluorfen was not reported.[38,39] The Agency cannot determine the relative importance of oxyfluorfen in non-agricultural settings.

[36] Kynetec, *The AgroTrak® Study from Kynetec USA, Inc.* (2019) (Database Subset: 1998-2018).
[37] Kline and Company. 2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities. [Accessed June 2020.]
[38] Kline and Company. 2017. Consumer Markets for Pesticides and Fertilizers 2016: U.S. Market Analysis and Opportunities - Volume 1. [Accessed June 2020].
[39] Nonagricultural Market Research Data (NMRD). 2020. Study on consumer markets. [Accessed November 2020].

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of oxyfluorfen. For additional details on the 2019 HHRA, see "*Oxyfluorfen: Draft Human Health Risk Assessment for Registration Review*" in EPA's oxyfluorfen public docket (EPA-HQ-OPP-2014-0778-0025). In addition, EPA has developed updated dietary, aggregate, and occupational[40,41] risk assessments since publishing the 2019 HHRA. The Agency published those documents along with the 2021 PID. For dietary risk, the updated assessment shows final risk estimates that include both some refinements and proposed mitigation. Since the updated risk assessments already reflect proposed mitigation, they cannot be used to show the level of risk in the absence of mitigation. Consequently, the 2019 risk estimates for dietary risk are provided below to demonstrate the need for mitigation. The dietary risk estimates with mitigation are discussed in section IV below. Because the updated occupational and residential risk assessments allowed identification of risks before mitigation, they have been used to describe these risks in this section. For clarity, the document used for support for each subsection is identified below.

Risk Summary and Characterization

A summary of the results of the 2019 human health risk assessment are in Table 1 and are discussed below.

[40] Environmental Protection Agency, *Updated Chronic and Cancer Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments to Support Registration Review* (March 17, 2021).
[41] Environmental Protection Agency, *Addendum to the 2019 Draft Human Health Risk Assessment for Registration Review* (March 17, 2021).

Table 1. Summary of risks of concern for oxyfluorfen

Risk Category	Risks of Concern (Y/N)	Affected Uses
dietary (food + water), cancer	Y	all food uses
dietary, non-cancer, chronic	N	N/A
dietary, acute	N	N/A
residential	Y	all residential homeowner uses
aggregate	Y	dietary + residential
occupational, short and intermediate term non-cancer	Y	backpack sprayer application to: Christmas tree farms forestry, landscape trees/shrub/bushes mechanically pressurized handgun application to: soil-directed spray to 'orchards/vineyards foliar to many use sites,
occupational handler, cancer	Y	aerial application to: high acreage field crops hand application of granules to: Christmas tree farms forestry landscape trees/shrubs/bushes backpack sprayers application to: orchards and vineyards Christmas tree farms forestry landscape trees/shrubs/bushes mechanically pressurized handgun application to: most uses sites
post-application non-cancer chronic	Y	handset irrigation in field ornamentals
post-application cancer	Y	handset irrigation in field ornamentals

Dietary (Food + Water) Risks

No acute dietary risk was identified in either the 2019 or 2021 assessments as there was no toxicological effect observed from acute (single) dose exposure from a study suitable for assessing acute dietary risk and risk assessment was not performed.

Chronic dietary risks were assessed based on liver toxicity in both males and females with the appearance of microscopic liver lesions, increases in absolute and relative liver weights and

elevated liver enzymes. The chronic population adjusted dose based on this endpoint was 0.04 mg/kg/day. For the 2019 HHRA, all chronic dietary results were less than 1% of the chronic population adjusted dose (cPAD), so chronic dietary risk is not expected from use of oxyfluorfen.

Oxyfluorfen is classified as a Group C 'possible' human carcinogen based on combined hepatocellular adenomas/carcinomas in the mouse carcinogenicity study. The oxyfluorfen Q1* (cancer slope factor) is 7.32×10^{-2} ($mg/kg/day^{-1}$). According to the 2019 HHRA, the estimated dietary cancer risk for adults, 50-99 years old, based on the highly refined assessment is 4.5×10^{-6}. This represents the dietary risk based on a lifetime exposure at the average food consumption rate for adults, 50-99 years, and the 30-year average concentration of oxyfluorfen in drinking water at a site more vulnerable than most sites to runoff of oxyfluorfen into the source water of the drinking water facility. Surface-water source drinking water is the driver of exposure, representing 82% of the contribution to cancer risk. Based on the dietary assessment from current labeled uses, there may be a dietary cancer risk of concern from use of oxyfluorfen, and this is discussed further in Section IV of this document.

The Agency refined the drinking water assessment to provide additional characterization of the risks from this source of exposure.[42] Typical application rates and number of applications were used to estimate 30-year mean concentrations in water rather than using the maximum label rates for the standard assessments. Of the 8 crops which typical application rates were available, 3 still had mean concentrations in water greater than 1.97 ppb, the concentration at which concerns for cancer risk would expect to be exceeded when food and water are considered together. As discussed in the responses to public comments, revised dietary assessment shows that bananas are no longer a driver of dietary risk and keeping the tolerance on bananas does not result in cancer risks above levels of concern.

Residential Handler Risks

There are residential use sites for oxyfluorfen, so the Agency evaluated risks to those individuals who are involved in the pesticide application process who are termed "residential handlers." Since the residential applications of oxyfluorfen are limited to spot treatments, residential post-application exposures to treated turf or ornamental foliage are not expected. The Agency evaluated the following residential handler exposure scenarios:

- liquid formulation application on gardens/trees and lawns/turf with manually pressurized hand wand, hose-end sprayer, backpack, and sprinkler can equipment,
- ready to use formulation application on gardens/trees and lawns/turf with hose-end sprayer equipment, and
- ready to use formulation application on lawns/turf with trigger-spray bottle equipment.

[42] Koper, Christopher M. 2021. Oxyfluorfen: Update to the Drinking Water Exposure Assessment for Registration Review. DP 458588. date March 1, 2021

Estimated short- and intermediate-term combined (dermal and inhalation) risks were assessed using an Aggregate Risk Index (ARI) approach. An ARI was used since the LOCs for dermal exposure (100) and inhalation exposure (1000) are different. When using the ARI approach, the LOC is an ARI of 1; therefore, risk estimates less than one are of concern. The most recent residential handler assessment, from the 2019 HHRA, is described below.

The toxicity endpoints for both the dermal and inhalation route were based on two co-critical studies: reduced litter size in rabbits in a developmental toxicity study and decreased pup body weight and smaller litter size in rat reproduction study. The point of departure selected based on the endpoints in these studies was 33 mg/kg/day.

Risks from both dermal and inhalation exposure were considered in a combined assessment using an ARI[43] approach where risk estimates ranged from 5 (for application outdoors around buildings with a hose end sprayer) to 140 for Ready-To-Use (RTU) hose end sprayer applied to gardens and trees. In all cases the ARI was greater than the LOC of 1 so there are no non-cancer risks of concern to residential handlers.

A Q_1* of 7.32 x 10^{-2} $(mg/kg/day)^{-1}$ was used to quantify residential handler cancer risks. Residential handler cancer risks are of concern for all formulations and use patterns except hose-end sprayers using the ready-to-use formulation (cancer risks = $9.2x10^{-7}$) and applying liquid formulation outdoors around buildings ($1.2x10^{-6}$). Residential handler cancer risks ranged as high as 2.6 x 10^{-5} using a hose-end sprayer for applications with a liquid formulation outdoors around buildings.

Residential Post-Application Risks

A residential post-application risk assessment was not conducted because exposures to treated turf or ornamental foliage are expected to be negligible as labels with these uses specify that oxyfluorfen should only be applied as a spot treatment to areas where vegetation is not desired, such as on driveways and mulched areas; along fences, sidewalks, walkways, patios, curbs; around established shrubs and trees; and in landscaping and around ornamentals. For this reason, EPA concludes that no residential post-application risks are expected to result from these uses of oxyfluorfen.

Bystander Risks

For the 2019 HHRA, a non-occupational bystander's assessment was conducted for potential spray drift following aerial and ground agricultural applications. Dermal and incidental oral (*e.g.*, hand to mouth) exposures and risks were assessed for children 1 to <2 years old, and dermal exposures and risks were assessed for adults using an MOE approach. Bystander risks for both children and adults following agricultural aerial and ground spray applications are not of concern

[43] For more details on how the ARI was calculated, *see* 2019 HHRA.

(*i.e.*, the LOCs are < MOE = 100) for the use sites with the highest application rates, 4.5 lb/acre for ground boom and 0.5 lb/acre for aerial sprays.

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources together: food, drinking water, and residential exposures. An acute dietary endpoint was not selected for oxyfluorfen, as there were no effects in the database attributable to a single exposure relevant for the purpose of risk assessment. Therefore, an acute aggregate assessment was not conducted. Short-term, chronic and cancer aggregate exposures and risks were assessed using an ARI approach, with values below an LOC of 1 being risks of concern. The aggregate risks described here are discussed fully in the 2019 HHRA. The aggregate risk assessment was updated in the 2021 DRA addendum.

Short-Term Aggregate Risk

As described previously, residential post-application exposure for children is expected to be negligible. Therefore, the short-term aggregate risk for children is the same as the dietary (food and drinking water) exposure and this risk is not of concern, as described above. For adults, short-term aggregate risk calculations include dietary exposures and exposure estimates from the application of liquid formulations outdoors around buildings using a hose-end sprayer. The short-term aggregate for adults is not of concern; the resulting ARI of 5.1 is greater than the LOC of 1.

Chronic Aggregate Risk

The chronic aggregate risk assessment combines exposures to oxyfluorfen in food and drinking water only. The chronic (food and drinking water) exposure and risk estimates (as described above) were <1% of the cPAD for all population subgroups. Therefore, there are no chronic aggregate risk estimates of concern.

Cancer Aggregate Risk

The cancer aggregate exposure assessment combines dietary risk from both food and water with an estimate based on the residential use pattern with the highest exposure— the application of liquid formulations outdoors around buildings using a hose-end sprayer. The aggregate cancer risk is $3x10^{-5}$ which is a risk estimate of concern.

Cumulative Risks

EPA has not made a common mechanism of toxicity to humans finding for oxyfluorfen and any other substance. Oxyfluorfen does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has premised this ID and the underlying risk assessments on oxyfluorfen not having a common mechanism of toxicity with other substances.

Occupational Handler Risks

Occupational handler risks were updated in the March 2021 addendum to the 2019 HHRA for both non-cancer (short-term and intermediate-term) and cancer risks. This assessment used updated unit exposure for handlers as well as addressing some additional PPE considerations not included in the 2019 HHRA. The short- and intermediate-term toxicity endpoints for exposure by both the dermal and inhalation routes were based on two co-critical studies: increased late resorption of kits in rabbits in a developmental toxicity study and decreased pup body weight and smaller litter size in rat reproduction study. Risks were assessed using an ARI approach, with values below an LOC of 1 being risks of concern.

Short- and intermediate-term risks

Short-term and intermediate non-cancer risks of concern were identified for the following exposure scenarios with baseline attire of a single layer of clothing with no gloves:

- Liquid formulations for mixer/loaders for aerial application: field crops (ARI:0.91)
- Liquid formulations from backpack sprayers: forestry (ARI range: 0.51-0.99)
- Liquid formulations from backpack sprayers, foliar spray: Christmas trees, landscaping trees, bushes, and shrubs (ARI range: 0.23-0.51)
- Liquid formulations from mechanically pressurized handguns foliar applications: orchards/vineyards; Christmas tree farm; nursery; landscaping, trees/shrubs/bushes (ARI range: 0.14-0.79)
- Liquid formulations from mechanically pressurized handguns, ground-directed applications: orchards/vineyards and nurseries (ARI range: 0.14-0.79).

The exposure in all these cases was dominated by the dermal route. All other use scenarios assessed presented risks estimates below the LOC.

Cancer risks

Occupational exposure scenarios risks of concern were identified for baseline attire of a single layer of clothing and no gloves (Table 2). In the 2021 DRA Addendum,[44] risks were calculated for both private and commercial applicators. Occupational cancer risk estimates that are not of concern are also included in the Addendum. The following summary focuses on identified occupational cancer risks of concern, specifically for commercial applicators, as risks were higher for this group on a scenario-by-scenario basis.

Aerial application scenarios yielded risk estimates of $1x10^{-3}$ for commercial mixer/loaders when applications were applied at 0.6 lb/acre with baseline attire. High-acreage field crops with labeled use for oxyfluorfen are agricultural fallow/idle land/conservation reserve program

[44] Craig, Evisabel, Sheila Piper, and Wade Britton. 2021. ***Oxyfluorfen:*** *Addendum to the 2019 Draft Human Health Risk Assessment for Registration Review (D445742)*.

lands/uncultivated areas; clover; corn, field; cotton; chickpeas; grasses grown for seed; mint; nonagricultural uncultivated areas/soils; shelterbelt; and soybeans. These risks are not of concern with the addition of gloves.

For mixer/loaders in baseline attire for liquid sprays applied by ground boom to field-grown ornamentals and high-acreage field crops. Risk estimates were $1x10^{-4}$ and $2x10^{-4}$ respectively, indicating that there are risks of concern. In both cases, risks are not of concern with the addition of gloves to baseline attire.

Oxyfluorfen can be applied by chemigation to orchards, vineyards, conifer seedbeds, onions, and garlic. Chemigation risk estimates with baseline attire were $7x10^{-4}$. Risks are not of concern when a second layer of clothing and a PF 10 respirator are added to baseline attire.

Hand dispersal of granular formulations were assessed to Christmas tree farms, nurseries, and landscape trees, shrubs, and bushes. In baseline attire, the cancer risk was $6x10^{-4}$ and was reduced to $3x10^{-4}$ in two layers of clothing, gloves, and a PF10 respirator, the risk was reduced to $2x10^{-4}$ and remains a risk of concern.

Risk estimates for spray of a liquid formulation with a ground boom to high acreage field crops ($5x10^{-4}$), but they are not of concern with the addition of gloves at $9x10^{-5}$.

Backpack sprayers were evaluated for mixer/loader/applicators combined. For backpack-sprays for orchards, vineyards and artichokes, only ground-directed applications of liquid formulations were evaluated. Risk estimates for these scenarios in baseline attire ranged from $3x10^{-5}$ to $4x10^{-4}$. Adding a second layer of clothing and gloves reduced the risk to $1x10^{-4}$. Backpack sprayer applications for forestry and Christmas tree farms were evaluated for both foliar and ground directed sprays. Risks from foliar broadcast applications at a concentration of 0.2 lb-ai/gal with baseline attire were $7x10^{-4}$ and $6x10^{-3}$ respectively. These were reduced to $2x10^{-4}$ and $8x10^{-4}$, by adding a second layer of clothing and gloves and therefore remain risks of concern. However, for ground/soil directed sprays using a concentration 0.1 lb-ai/gal and PPE of two layer of clothing and gloves, risks are reduced to $1x10^{-4}$ and are not of concern for both of these uses. Only foliar sprays were evaluated for landscaping trees, shrub, and bushes, and estimates indicated these scenarios don’t present risks of concern.

Mechanically pressurized handguns were evaluated for mixer/loader/applicators combined. For mechanically pressurized handguns risk estimates for all scenarios except treatment of landscape trees, shrubs and bushes with baseline attire were $9x10^{-7}$, indicating risk was not of concern. Risk estimates for some uses of mechanically pressurized handguns applied as a foliar spray were not of concern with the addition of gloves, but oxyfluorfen is unlikely to be used this way as it is a general herbicide and thus likely to damage the crop. Even with the addition of a second layer of clothing or a PF10 respirator, the remaining mechanically pressurized handgun risk estimates indicated risks of concern. The addition of PF10 respirators did not change the risk estimate.

Table 2. Cancer risks of concern for commercial occupational handlers with different PPE. Ranges represent variation across scenarios.				
Scenario	**SL/No G***	**SL/Gloves****	**DL/Gloves†**	**DL/Gloves/PF 10‡**
Applicator Scenarios				
applicator - ground boom	$1x10^{-5}$ - $2x10^{-4}$	$2x10^{-6}$ – $4x10^{-5}$	$2x10^{-6}$ – $4x10^{-5}$	$2x10^{-6}$ – $3x10^{-5}$
hand dispersal of granules	$6x10^{-4}$	$4x10^{-4}$	$3x10^{-4}$	$2x10^{-4}$
Mixer/Loader Scenarios				
mixer/loader - liquid aerial‡‡	$1x10^{-4}$-$1x10^{-3}$	$2x10^{-5}$-$2x10^{-4}$	$2x10^{-5}$ – $1x10^{-4}$	$2x10^{-5}$ – $1x10^{-4}$
mixer/loader - chemigation	$1x10^{-4}$ -$7x10^{-4}$	$1x10^{-4}$	$1x10^{-4}$	$9x10^{-5}$
mixer/loader - ground boom	$1x10^{-5}$ – $2x10^{-4}$	$2x10^{-5}$ – $3x10^{-5}$	$1x10^{-5}$ – $3x10^{-5}$	$1x10^{-5}$ – $2x10^{-5}$
Mixer/Loader/Applicator Scenarios				
liquid backpack sprayer - foliar	$7x10^{-4}$ – $3x10^{-3}$	$3x10^{-4}$ – $3x10^{-3}$	$2x10^{-4}$ – $2x10^{-3}$	$2x10^{-4}$ – $2x10^{-3}$
liquid backpack sprayer – soil directed	$3x10^{-5}$ - $4x10^{-4}$	$2x10^{-4}$	$1x10^{-4}$	$1x10^{-4}$
mechanically pressurized handguns	$3x10^{-4}$ - $2x10^{-2}$	$2x10^{-5}$ - $6x10^{-3}$	$4x10^{-4}$- $5x10^{-3}$	$1x10^{-4}$ – $4x10^{-3}$

* SL/No G: single layer clothing with no gloves, no respirator
** SL/Gloves: single layer clothing with gloves, no respirator
† DL/Gloves: double layer clothing with gloves, no respirator
‡ DL/Gloves: double layer clothing with gloves, PF10 respirator
‡‡ Calculated using a 0.6 lb/acre rate.

Occupational Post-Application Risks

Occupational post-application risks were evaluated for short and intermediate term non-cancer risks and cancer risks using the same dermal toxicity endpoint selected for occupational handlers. For occupational post-application, only the dermal route of exposure is assessed. Placing handset irrigation for ornamental nursery crops was the only exposure scenario and use site that resulted in a non-cancer risk of concern on the day of application (LOC = MOE < 100) with an MOE of 66; MOEs are 81 two days after application and reach the LOC of 100 at 4 days following application. This exposure scenario was also determined to be a cancer risk of concern (using a thirty-day average residue) with a risk estimate of $4x10^{-4}$ at the maximum application rate of 4.5 lb/acre. However, decreasing the application rate to 2 lbs ai/acre increases the non-cancer MOE to 150 on the day of application which is then not of concern and improves the cancer risk estimate to $2x10^{-5}$.

Human Incidents and Epidemiology

EPA reviewed oxyfluorfen 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 January 28, 2019, Main IDS showed one incident involving a single active ingredient and 13 incidents involving multiple active ingredients. Aggregate IDS showed 35 incidents. SENSOR showed 37 incidents from 2011 to 2015, including six incidents involved a single active ingredient and 31 incidents involving multiple active ingredients. Of the 37 incidents, 10 were moderate severity and 27 were low severity. The Agency intends to conduct ongoing human incident monitoring for oxyfluorfen and additional analyses if that monitoring indicates risks of concerns.

Tolerances

Oxyfluorfen is registered for uses that result in residues in or on food. Generally, a tolerance or tolerance exemption exists for all uses. For some uses, FDA regulations or food contact notifications must cover the residues, or the affected food is considered adulterated.[45] EPA believes that all of the necessary tolerances, exemptions, and FDA clearances are in place for residues resulting from oxyfluorfen's legal use.

The Agency has established tolerances for oxyfluorfen under 40 C.F.R. § 180.381. The tolerance expressions for oxyfluorfen in 40 CFR § 180.381 have not been updated to reflect current policies.[46] The revised tolerance expression should be revised as follows:

> (a) General. Tolerances are established for residues of oxyfluorfen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene].
>
> (c) Tolerances with regional registrations. Tolerances with regional registrations, are established for residues of oxyfluorfen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene].

Additionally, EPA has identified the need for updated crop group definitions and updated tolerance levels (based on residue data submitted in response to the RED document). Those revisions are detailed in Table 7 in Section IV below. The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

Human Health Data Needs

The human health database for oxyfluorfen is not complete. The Agency required a foliar dislodgeable residue study to support registration review (GDCI 111601-1515). The registrant has agreed to conduct the study but has yet to submit the required protocol. The Agency intends

[45] 21 U.S.C. §§ 342, 346(a).
[46] S. Knizner, *HED Interim Guidance on Tolerance Expressions* (2009)

to continue working with the registrant to satisfy these data requirements under the existing data call-in notice (GDCI 111601-1515).

The Agency also indicated in the 2019 HHRA that a subchronic inhalation study was required to completely characterize inhalation risk. The addition of a 10X FQPA database uncertainty factor is being applied in its absence. These data remain required, but their absence does not prevent EPA from conducting the risk assessment with addition of the safety factor. Although registrants have not fully satisfied all human health data requirements, EPA believes the available data were sufficient to conduct the 2019 HHRA and 2021 addendum and are sufficient to support this amended PID. The Agency intends to require the subchronic inhalation study using its Data Call In authority.

B. Ecological Risks

The Agency has summarized the 2019 ecological risk assessment (ERA) 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 oxyfluorfen.[47] For additional details on the 2019 ERA, see *Draft Ecological Risk Assessment for Registration Review* in EPA's oxyfluorfen public docket (EPA-HQ-OPP-2014-0778).

The 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 oxyfluorfen's risks to listed species. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the oxyfluorfen registration review. See Appendix C for more details. As such, only potential risks for non-target species generally are described below.

Risk Summary and Characterization

Terrestrial Risks

Mammals

Acute risks to mammals are not expected because no effects were seen at the highest dose. Chronic risks were assessed based on a 2-generation laboratory rat study that had a no observed adverse effects concentration (NOAEC) and lowest observable adverse effect level (LOAEC) of 400 and 1600 mg-a.i./kg-diet respectively. The effects observed at the LOAEC include decreased body weight for parental males and females (8% -12% decline) and offspring (11% decline). The LOC for chronic mammalian risk is an RQ of 1. RQs are calculated for exposure through

[47] The 2019 ERA only addresses potential risks to species not listed under the Endangered Species Act. EPA is working with its federal partners and other stakeholders to implement a Revised Method (EPA-HQ-OPP-2019-0185-0054) for assessing potential risk to listed species and their designated critical habitats. The Agency will complete oxyfluorfen's listed-species assessment once EPA has fully implemented the scientific methods necessary to complete listed species' risk assessments. For more details, see Appendix C.

consumption of five different food types: short grass; tall grass; broadleaf plants; fruits, pods, and seeds; and arthropods. Based on a dose-based assessment, risks exceeded the LOC for all crops with an application rate greater than a single application of 0.25 lb/acre for at least some food classes using upper-bound estimated environmental concentrations (EECs). RQ values ranged from 0.02 to16 for the crops with the highest application rate—coffee and cacao. When using mean exposure estimates, the LOC is exceeded for uses with application rates greater than 1.5 lb/acre and only for short grass foragers. One way to characterize the risk is to look at how long after application concentrations above the LOC persist. When considering the mean Kenaga values, the days exceeding the LOC for use on cacao and coffee are 118 and 52 days for the NOAEC and LOAEC, respectively. Based on this assessment, the Agency concludes that there is chronic risk of concern on-field to mammals for the higher application rate use patterns and that risks may persist several months after an application.

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. The highest acute test dose (2150 mg a.i./kg-bw) for birds resulted in less than 50% mortality. As a result, risk can only be evaluated qualitatively. However, this nondefinitive endpoint is 475% greater than the maximum modeled EEC (452 mg a.i./kg-bw). Based on these data, the Agency has determined that the risk of mortality from acute exposures to birds, terrestrial-phase amphibians, and reptiles is low.

The chronic avian assessment risk concerns were identified for birds on a chronic exposure basis, based on a 20-week reproductive study with northern bobwhite, which resulted in a NOAEC and LOAEC of 124 and 256 mg a.i./kg-diet, respectively. The LOAEC was based on a 7% decline in survivor weight. RQs ranged from 0.06 to 9 based on this NOAEC and upper-bound estimated environmental concentrations (EECs). RQs for uses with application rates greater than 0.75 lb a.i./A (corn, berries, forestry, artichoke, citrus, pome fruit, stone fruit, tree nut, coffee, and grapes) exceed the chronic LOC for all dietary items except fruits/pods/seeds, while crops with multiple applications at lower use rates (*e.g.*, corn use with 3 applications of 0.5 lb a.i./A) exceed the chronic LOC for some food classes. Single applications at 0.5 lb a.i./acre and lower do not exceed the LOC for any food class. The LOAEC exceeds the EEC for uses with multiple applications at the two highest rates, 2 lb a.i./A for coffee and cacao and 1.5 lb a.i./A for forestry, indicating that risk concerns were identified for these application scenarios. For the use patterns with highest exposure, coffee and cacao, the LOC is exceeded for 210 days. For the most common use pattern with 1 application at 1.5 lb a.i./A, the LOC is exceeded for 124 days, indicating the chronic risk to birds can extend for a significant part of a year after application. Based on this assessment, the Agency concludes that chronic risks on-field to birds, reptiles, and terrestrial phase amphibians can persist for long periods after application for crops with higher use rates.

Terrestrial Invertebrates

EPA uses data for honey bees as a surrogate for other terrestrial invertebrate species. Based on the available toxicity data, the Agency concluded that oxyfluorfen uses may present risks to honey bees and, by extension, other terrestrial invertebrate species. Oxyfluorfen is currently registered for use on a variety of bee-attractive uses, including several that require the use of managed pollinators.

EPA considers risk to be low for acute exposures to adult bees. However, there is some additional uncertainty in this conclusion due to data gaps that were identified in the Tier I toxicity data set. The Tier I toxicity data set is considered incomplete because there is no acute larval bee toxicity study, and the chronic adult and larval bee toxicity studies are classified as supplemental because the highest dose in the tests did not consider the highest application rates. Although mortality data collected in a chronic larval bee toxicity study can be used as a surrogate for the acute toxicity study, the test doses were not high enough to represent all potential exposures; therefore, there is Agency is less certain about risks at the highest application rates. The NOAEL from the larval chronic toxicity study was nondefinitive and, as a result, only suitable for risk characterization.

Chronic RQs for honey bees exceed the risk LOC for applications to artichokes, berries, cacao, citrus, coffee, corn, cotton, forestry, garlic, grapes, onion, soybeans, pome fruits, stone fruits, and tree nuts for adults (RQs: 0.95 - 7.5), and applications to cacao, coffee, and grapes for larvae (RQs: 0.2 - 1.2). Some factors increase the uncertainty above that in a more typical assessment are that a lowest observed adverse effect level (LOAEL) was not established in the adult study (so, the RQs could potentially be lower) and a no observed adverse effect level (NOAEL) was not established in the larval study (NOAEL < 23 µg a.i./bee/day) because it only included one treatment level so, the RQs could potentially be higher. In the chronic larval bee study, 19% mortality to larvae was observed at the highest test dose, so in addition to the usual concerns for growth, there are also concerns for mortality.

No bee incidents have been reported for oxyfluorfen. The submission of new adult and larval bee chronic toxicity studies, in addition to higher-tiered bee studies, are needed to fully evaluate exposure risk for this taxon.

In addition to the toxicity tests on bees, six acute contact studies were available on predacious mites, parasitic wasps, ground beetles, and spiders, and a subchronic toxicity study was available for earthworms. Mortality is observed at the single test dose in the majority of studies. All test application rates are below the most common application rate of 1.5 lbs a.i./A, indicating a risk concern for the majority of oxyfluorfen uses. These limit tests indicate that other terrestrial invertebrates are more sensitive than honey bees. However, there is uncertainty related to these results due to the studies only having one treatment concentration.

In summary, while no definitive chronic effects on bees were observed in laboratory studies for oral toxicity, terrestrial invertebrate risk cannot be precluded because the highest application

rates would result in doses that exceed the highest doses tested. There are additional studies available, which suggest that the observed effects on these organisms are likely from oxyfluorfen.

Terrestrial Plants

Risk concerns were identified for terrestrial plants. Lettuce was the most sensitive dicot tested with concentration where 25% of the plants were affected (EC_{25}) of 0.0072 lbs a.i./A, which was based on a 47-83% reduction in plant dry weight. For monocots, oats were the most sensitive species with exposure to seeds in treated soils resulting in 42-85% reduction in plant dry weight at an EC_{25} of 0.0063 lbs a.i./A. Since oats are somewhat more sensitive than lettuce, the risks below are described relative to the oat toxicity.

Spray drift modeling was conducted to determine the distance to LOC exceedance from the edge of a treated field, which would result in exposure to oxyfluorfen at and above the EC_{25}. For crops at the lowest application rate of 0.25 lb a.i./acre, a fine spray applied from high (4 ft) ground boom would exceed the LOC up to 102 ft from the edge of the field. For crops at the highest application of 2.0 lb a.i./acre, the same spray pattern would exceed the LOC up to 584 ft from the edge of the field. Conversely, using a coarse spray and a low (20 inch) ground boom at the highest application rate would reduce this distance to 160 ft.

Aerial sprays travel much farther from the edge of the field because they are applied from higher in the air and the vortices on the wing tips can throw them to even higher elevations before they begin to settle. For aerial sprays at 0.5 lb a.i./acre, the highest rate currently allowed on the label, a fine spray would exceed the LOC up to 873 ft, while a coarse aerial spray would exceed up to 226 ft. These results indicate that oxyfluorfen spray drift can travel significant distances from the edge of the field at levels that can impact non-target plants when conditions are favorable for drift.

Aquatic Risks

Freshwater Fish and Aquatic-Phase Amphibians

Freshwater fish serve as surrogates for aquatic-phase amphibians. The acute toxicity value selected to represent freshwater fish is 200 µg a.i./L based on the LC_{50} for bluegill sunfish. The chronic toxicity effects value is a 30 µg a.i./L NOAEC based on a 30-day test with fathead minnows. An additional test evaluating chronic risk for fathead minnows with enhanced UV lighting resulted in a NOAEC of 1.3 µg a.i./L. For acute effects, no risks of concern were identified with an LOC of 0.5 for freshwater fish and aquatic phase amphibians. No risk was identified for chronic effects based on the LOC of 1 but using the more sensitive NOAEC from the UV-enhanced study, the chronic LOC was exceeded for use on artichokes, beans, berries, broccoli, cabbage, citrus, coffee, corn, cotton, forestry, grapes, onions, pome fruits, stone fruits, and tree nuts with RQs ranging up to 19. The UV-enhanced study takes into account clear shallow water where UV light can penetrate, which is consistent with conditions in a natural

environment in some locations. However, there are some limitations, and the simulated scenario represents small water bodies at the top of watersheds where a single agricultural field dominates the watershed. Larger water bodies, with more diverse land use in their basin, would have proportionally less oxyfluorfen exposure.

It is possible that this assessment underestimates the actual risk in the environment due to the presence of unextracted unidentified residues in the soil and sediment metabolism studies used to generate degradation input parameters in the simulation modeling. These unextracted residues may be bound and unavailable to organisms or they may, in fact, be parent compound or toxic degradates which were not adequately extracted by methods used to measure these residues in the studies. If these unextracted residues are toxic and available like the parent compound, all uses with multiple applications of 0.5 lbs a.i./A or greater exceed the acute LOC of 0.5 and the chronic LOC of 1 including beans, berry, citrus, cotton, pome fruit, soybean, stone fruit, and tree nuts. Although this is an uncertainty in the aquatic risk assessment and carry through into the other aquatic risk assessments described below, some scientific literature suggests that aniline-containing compounds similar to oxyfluorfen have a tendency to form covalent bonds with soil organic matter and, thus, tend to be bound residues. In order to adequately capture aquatic exposure risks, this assessment includes a bounding exercise: a lower bound exposure estimate is calculated including parent oxyfluorfen only, and an upper bound is calculated including the residues of concern (i.e., parent plus 3 major degradates) exposure estimate and ROC plus unextracted residues.

Estuarine/Marine Fish

The acute toxicity endpoint for both estuarine and marine fish is nondefinitive (> 11 ppb) from a study using sheepshead minnow. No acute risks of concern were identified using this endpoint. The chronic endpoint for sheepshead minnow of > 4.1 µg a.i./L is also non-definitive as no significant effects were observed in the study at this treatment level. Exposure modeling conducted with the NOAEC from this study (4.1 µg a.i./L) resulted in chronic LOC exceedances for all crops except garlic, onion, and fruiting vegetables. However, because the endpoint is non-definitive, it is possible that the LOAEL is much higher, in which case there may be no risk. The nondefinitive endpoint used represents a major uncertainty in risk conclusions for this taxon. However, considering that aquatic organisms are expected to be more sensitive to the parent compound in the presence of UV light based on the freshwater tests above, chronic risk concerns may extend to all crops. The conditions that would result in aquatic risk (shallow, clear pools) exist in upper tidal portions of estuarine creeks where turnover is slow. In conclusion, the risk assessment identified possible chronic risks to estuarine/marine fish. However, the actual risk posed by oxyfluorfen exposure in the environment is uncertain.

Freshwater Invertebrates

The acute toxicity endpoint for freshwater invertebrates is an LC_{50} for the water flea (*Daphnia magna*) with a value of 1500 µg a.i./L. Based on this endpoint, no LOC exceedances (RQ > 0.5) were identified. For chronic effects, the assessment endpoint is from 21-day study on *D. magna* based on the NOAEC of 13 µg a.i./L. Effects seen at the LOAEC of 28 ppb were a 17% reduction in adult survival, a 21% reduction in growth, and a 75% reduction in reproduction

output. Based on the acute endpoint, no acute risks above the LOC were identified. Chronic RQs ranged from 0.1 to 2.7. Uses with three applications of 0.5 lbs a.i./A or greater, or a single application at the label rate of 1.5 lbs a.i./A—including artichoke, coffee, corn, forestry, and grape—exceed the chronic risk LOC of 1. The LOC is also exceeded for the maximum use pattern for coffee, so there is more confidence that there will be effects in the environment for this use. An alternative way of looking at these risks is to estimate the number of days the LOC is exceeded in each year. For corn, coffee and grape, the LOC is exceeded for more than 30 days per year, increasing the likelihood and frequency of effects.

Estuarine/Marine Invertebrates

The acute toxicity endpoint for estuarine/marine invertebrates is a nondefinitive LC_{50} for grass shrimp with a value of >31.7 µg a.i./L. No acute risk RQs were calculated due to the nondefinitive endpoint. However, some labeled uses, specifically coffee, corn, forestry, and grape, had application rates that resulted in EECs that would exceed the LOC based on the non-definitive endpoint, so acute risk cannot be precluded for these uses. For chronic exposure, the most sensitive toxicity endpoint was from a 30-day study with mysid shrimp with a NOAEC of 8.1 µg a.i./L. Effects seen at the LOAEC of 16 µg a.i./L include a 47% reduction in reproduction and a 9% reduction in growth (length and dry weight). RQs calculated using this NOAEC exceeded the LOC of 1 for artichokes, beans, coffee, cacao, corn, cotton, forestry, and grapes. When calculating RQs using the LOAEC, RQs exceed the LOC for only coffee, corn, and forestry.

As previously discussed, there is some additional uncertainty in the EECs used in this assessment due to the presence of unextracted unidentified residues in the metabolism studies used in the simulation modeling. These residues may be bound and therefore unavailable to organisms or they may be the parent compound or toxic degradates which were not adequately extracted by methods used to measure these residues in the studies. If these unextracted residues are toxic and available like the parent compound, all uses with multiple applications of 0.5 lbs a.i./A or greater exceed the acute LOC of 0.5 and the chronic LOC of 1 including beans, berry, citrus, cotton, pome fruit, soybean, stone fruit, and tree nuts. This is a significant uncertainty in the aquatic risk assessment.

Benthic Invertebrates

Soil eroding from application areas is likely to carry bound oxyfluorfen, which can be persistent in the sediment to the lowest layers of aquatic areas because of oxyfluorfen's tendency to bind to soil. These residues could potentially impact benthic invertebrates. Acute risks to benthic invertebrates are based on the same toxicity endpoints as water column invertebrates. Chronic risks to benthic freshwater invertebrates were evaluated using an endpoint from a 10-day spiked sediment test with the midge (*Chironomus dilutus*), which resulted in a NOAEC and LOAEC of 55.7 and 97.6 µg a.i./kg-sediment and 484.5 and 498.5 µg a.i./L-pore water, respectively. The LOAEC for these endpoints was based on a 24% reduction in survival. Marine and estuarine benthic invertebrates were evaluated using a marine amphipod (*Leptocheirus plumulosus*) in a

ten-day spiked sediment test resulting in a for a NOAEC and LOAEC of 16 and 41 µg a.i./kg-sediment, respectively, and 27.9 and 144 µg a.i./L-pore water. The LOAEC was based on a 55% reduction in survival in a bulk sediment. The NOAECs from these studies, which were conducted under standard lighting, exceed the maximum 21-day mean pore water EECs. Therefore, enhanced toxicity would be expected for sediment dwelling invertebrates under natural UV light conditions.

All acute RQs are below the acute LOC of 0.5 for freshwater and estuarine/marine benthic invertebrates and there are no exceedances of the chronic LOC of 1 for freshwater or saltwater benthic invertebrates for assessment considering exposure through pore water. When considering RQs calculated using organic-carbon-normalized sediment EECs and toxicity endpoints, RQs for all uses exceed the chronic LOC of 1. For freshwater chronic exposure, the RQs range from 3.2 to 88, and for marine/estuarine, RQs range from 22 to 603. EECs for all uses exceed both the NOAEC and LOAEC. The difference observed between the pore water and sediment RQs is not surprising given the high K_{oc} (12,223 L/kg-oc) of oxyfluorfen. Typically, sediment toxicity data are also recommended for a freshwater amphipod (*Hyalella azteca*). The lack of the freshwater amphipod data is an uncertainty in the sediment toxicity dataset.

Aquatic Vascular and Non-Vascular Plants

Risks to aquatic plants were assessed for both vascular and non-vascular plants. The effects endpoint for vascular plants is based on 22% reduction in duckweed (*Lemma gibba*) frond number with an EC_{50} of 0.33 µg a.i./L. The toxicity endpoint for non-vascular plants is based on a 28% reduction in marine diatom biomass at an EC_{50} of 1.10 µg a.i./L. Maximum EECs for all uses exceed the EC_{50} for both vascular and non-vascular plants indicating risks of concern for aquatic vascular and non-vascular plants (RQs 5.7-178 and 1.7-53, respectively). Risks may be higher than assessed here because the toxicity testing was done under standard light and may be enhanced in the presence of UV light in the environment, as previously discussed.

Ecological Incidents

EPA reviewed oxyfluorfen incidents reported to the Incident Data System (IDS). As of EPA's latest search on August 1, 2018, IDS showed 15 incidents reported from 2006 to 2016. This only includes incidents whose certainty is classified as either 'possible', 'probable', or 'highly probable' and excludes incidents classified as 'unlikely' or "unrelated' or stemming from misuse. All incidents involved plants. Ten of the incidents involved legal use of oxyfluorfen products and the legality of use in the other five was undetermined. Four of the incidents involved other pesticides in addition to oxyfluorfen. Several of the incidents involved multiple affected species. Based on the frequency and severity of the oxyfluorfen incidents, they do not indicate that oxyfluorfen presents a significant risk to non-target plants or wildlife at this time. The Agency intends to conduct ongoing ecological incident monitoring for oxyfluorfen and additional analyses if that monitoring indicates risks of concern to non-target organisms.

Ecological and Environmental Fate Data Needs

The environmental fate database is considered complete. However, the ecological effects data requirements have not been completely satisfied. The maximum doses tested in the chronic adult bee chronic oral toxicity study and the chronic larval bee oral toxicity studies were not high enough to cover the application rates for the crops with the highest application rates. To complete an assessment with these kinds of data, risk was evaluated using limiting conservative assumptions (*e.g.*, using the highest dose tested as the NOAEC). This allows an assessment to be performed, but the additional uncertainty may result in more risks being identified that would be the case with a better dataset. In addition, lethality estimates from the chronic larval bee oral study were used in place of the larval bee acute oral study (SS-1312) because this data requirement was not satisfied. These studies were submitted to the Agency in May of 2023 but the reviews have not been completed in time to be considered in this amended PID. While the available data were sufficient to conduct the DRA, Tier 2 and 3 honey bee data requirements are now triggered based on the LOC exceedances in the assessment for chronic adult and larval honey bee exposure. The additional Tier 2 and 3 honey bee studies will provide additional clarity regarding the risk to bees and other terrestrial invertebrates.

C. Benefits Assessment

Below is a discussion of the benefits of oxyfluorfen use in orchard crops, vineyards, ornamentals, Christmas tree farms, forestry, banana, coffee, and cacao, which are sites in which EPA expects the impacts of the mitigation on users to be the greatest based on usage data and known production practices. A complete discussion of the benefits of can be found in the memo *"Oxyfluorfen Use, Usage, Benefits, and Impact Assessment",* dated March 30, 2021.

Orchard Crops

Oxyfluorfen is important in orchard sites as there are limited alternatives for the control of broadleaf weeds and grasses. Thirty-seven percent of plums and prunes (dried plums) acreage is treated with oxyfluorfen which is mostly used for the control of common mallow, redstem, filaree, wild mustard, and morning glory in plum and prune production.[48,49] The most likely alternatives to oxyfluorfen use in orchard production are rimsulfuron as well as indaziflam if partnered with a contact control option (*e.g.*, glyphosate or glufosinate). The spectrum of weed species controlled differs among these herbicides and, therefore, control of key weed species targeted with oxyfluorfen, such as filaree, may become more difficult or require multiple herbicides, such as rimsulfuron or indaziflam plus glyphosate or glufosinate to achieve the same spectrum of control as oxyfluorfen.

Vineyards

[48] Kynetec USA, Inc. 2019. "The AgroTrak® Study from Kynetec USA, Inc." Database Subset: 1998-2018.
[49] Note that Kynetec does not distinguish between plums and prunes in its survey.

Oxyfluorfen is used in the establishment of new vineyards as well as in established vineyards and is normally applied as a band down the vine row or in an area three to six feet around each vine.[50] Oxyfluorfen offers control of a range of annual broadleaf weeds and grasses, such as barnyardgrass, hairy fleabane, as well as perennial seedlings such as field bindweed.[51] Oxyfluorfen's residual control can last from four to ten months.[52]

Oxyfluorfen is important in vineyard sites because there are limited alternatives for controlling broadleaf weeds and grasses. Similar to orchard crops, for vineyard growers to achieve the same spectrum of weed control achieved with oxyfluorfen they would likely have to use a contact herbicide such as glyphosate or glufosinate in combination with a residual herbicide such as indaziflam, flumioxazin, or rimsulfuron.

Ornamental Use (established landscapes, containerized and field grown tree and shrubs)

Oxyfluorfen is a preferred chemical for use in field and container-grown woody and landscape ornamentals, conifer seedbeds, grounds maintenance, conifer seedbeds, nursery stock, and selected field-grown deciduous trees.[53] Growers prefer oxyfluorfen because generally it causes less phytotoxicity in the ornamental crops while achieving effective weed control, especially for conifer seedlings.[54] Based the species being produced and the grower's knowledge of potential phytotoxicity, possible alternatives to oxyfluorfen in ornamental production include dimethenamid-P, dithiopyr, flumioxazin, indaziflam, isoxaben, oxadiazon, pendimethalin, prodiamine, simazine, and trifluralin.[54]

Christmas Tree Production and Forestry

Effective weed control is essential in seedling beds and in the first three years after transplanting in the field to obtain a good stand and vigorous growth.[55,56] Oxyfluorfen provides control of annual broadleaf weeds and grasses, such as common lambsquarters, pigweeds (*Amaranthus*

[50] Roncoroni, J. A., Hembree, K. J., & Ingels, C. A. (2016b). Integrated Weed Management. Grape Agricultural Pest Management. University of California Agriculture & Natural Resources. Available at: http://ipm.ucanr.edu/PMG/r302700111.html [Accessed March 2020]
[51] Roncoroni, J. A., Hembree, K. J., & Ingels, C. A. (2016). Susceptibility of Weeds to Herbicide Control. Grape Agricultural Pest Management. University of California Agriculture & Natural Resources. Available at: http://ipm.ucanr.edu/PMG/r302700411.html#SPRING [Accessed March 2020]
[52] Roncoroni, J. A., Hembree, K. J., & Ingels, C. A. (2019). Herbicide Treatment Table. Grape Agricultural Pest Management. University of California Agriculture & Natural Resources. Available at: http://ipm.ucanr.edu/PMG/r302700311.html [Accessed March 2020]
[53] Sellmer, J., Kuhns, L., and Harpster, T. L. 2017. Controlling Weeds in Nursery and Landscape Plantings. Penn State Extension. Retrieved from: https://extension.psu.edu/controlling-weeds-in-nursery-and-landscape-plantings.
[54] USDA. 2020. USDA Response: Agency Request for Oxyfluorfen Use Patterns and Benefits for Forestry, Christmas Trees and Ornamentals. received September 2nd, 2020.
[55] Zandstra, B. & O'Donnell, J. 2018. Weed control in Christmas trees. Michigan State University Extension. Available at: https://www.canr.msu.edu/Christmas_trees/uploads/files/e3237%20wcag%202.0.pdf [Accessed June 2020].
[56] Peer, K. 2015. An introduction to growing Christmas trees in Virginia. Virginia Cooperative Extension. Available at: https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/420/420-080/420-080_pdf.pdf [Accessed June 2020]

spp.), and annual bluegrass in conifer seed beds.[55,54] There are no recommended chemical alternatives to oxyfluorfen for the control of common lambsquarters and pigweeds for use in conifer seedbeds, due to phytotoxicity concerns during establishment. As trees become larger, weeds interfere with production practices such as pruning and spraying.[55] Weed control requires spraying herbicides in early fall and/or early spring in spots around each tree or in bands along the planting row.[56,57] The area between the tree rows is usually mowed.[56,57] After trees become too tall for over-the-top boom sprayer applications, back-pack sprayers may be the most effective application method.[5555] Oxyfluorfen is rated as excellent for preemergent control of common lambsquarters and pigweeds, which are frequently observed weeds in these sites.

The Agency received information from industry professionals solicited by the USDA, which discussed oxyfluorfen as critically important in the production of conifer species such as those used for Christmas trees and forestry.[54] The USDA reported that oxyfluorfen was of high value in Christmas tree and conifer production as it exhibits a uniquely high degree of crop safety to young plants (*i.e.*, less than one year old) relative to the available alternatives. In some regions of the country, oxyfluorfen is applied several times per year (up to 3) to slightly older conifers (1-2 years old) as an important component of herbicide rotations prior to stand establishment.[54] Alternative herbicides to older conifers (more than one year old) include atrazine, flumioxazin, flufenacet, hexazinone, and indaziflam, all of which may also be used in rotations with oxyfluorfen.[54]

Hardwood seedling growth and survival can be negatively impacted by competing vegetation.[58] Use of oxyfluorfen for weed control improves seedling establishment for hardwood species such as black walnut, cherrybark oak, cottonwood, green ash, northern red oak, nuttal oak, Shumard oak, sweetgum, water oak, white ash, white oak, willow oak, and eucalyptus.[58,59] The Agency received information from industry professionals solicited by the USDA, which identified oxyfluorfen as a critically important tool in forestry throughout the country as it provides good contact and residual weed control.[54]

Coffee and Cacao

Coffee and cacao production in the United States is mostly limited to Hawaii and Puerto Rico. Oxyfluorfen is used in Hawaii in coffee and cacao production for the control of invasive, uncultivated taro root.[60] Taro root is a problem weed in these crops because it can smother plants and out compete the crop for water and nutrients.[60] The only recommended alternative to

[57] Kime, L. (2014). Christmas tree production. PennState Extension. Available at: https://extension.psu.edu/Christmas-tree-production [Accessed June 2020]
[58] Self, B. 2012. Herbaceous weed control in hardwood plantation establishment. Mississippi State University Extension Service. The Overstory, 1(4). Available at: https://www.cfr.msstate.edu/forestry_extension/newsletter/The%20Overstory1(4).pdf [Accessed June 2020].
[59] Osiecka, A. & Minogue, P. (2019). Herbicides for weed control in Eucalyptus Culture. University of Florida IFAS Extension. Available at: https://edis.ifas.ufl.edu/fr378 [Accessed June 2020].
[60] USDA. 2020. Pest Management Strategic Plan for Coffee in Hawaii. United States Department of Agriculture. Southern Integrated Pest Management Center. Retrieved from: https://ipmdata.ipmcenters.org/source_report.cfm?view=yes&sourceid=1419 [Accessed July 2020]

oxyfluorfen is glyphosate, which offers no residual control.[60] While this information describes the importance in Hawaii, EPA assumes that oxyfluorfen would have similar importance in Puerto Rico.

IV. AMENDED PROPOSED INTERIM REGISTRATION REVIEW DECISION

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

At the end of the registration review process, EPA will decide whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[61] However, the mitigation proposed in this amended PID may not be sufficient for EPA to determine that oxyfluorfen registrations continue to satisfy the FIFRA standard for registration. EPA may determine that additional mitigations or other measures are necessary in its final registration review decision. For oxyfluorfen, EPA has identified in this amended PID additional information that is needed to complete registration review and will issue a data call-in for that information, as discussed in Section IV.E.

The Agency has not made ESA effects determinations for oxyfluorfen registrations. However, EPA expects that the mitigation in this amended PID will reduce environmental exposure to oxyfluorfen and may reduce effects on listed species whose range or critical habitat co-occur with the use of oxyfluorfen. Additionally, EPA has included FIFRA IEM measures in Section IV.C, which are intended to reduce effects to nontarget organisms, including listed species.[62] The FIFRA IEM measures described in Section IV.C also meet EPA's obligations under Section 711 of the Consolidated Appropriations Act, PL-117-328 (Dec. 29, 2022). Section 711 requires EPA to "include, where applicable, measures to reduce the effect of the applicable pesticide on" listed species and designated critical habitats in any ID noticed in the *Federal Register* between December 29, 2022 and October 1, 2026 for which EPA has not "made effects determinations or completed any necessary consultation under [ESA Section 7(a)(2)]." 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

[61] 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.
[62] EPA has published and taken comment on these mitigations. *See* EPA-HQ-OPP-2022-0908.

developing the FIFRA IEM measures. EPA also requested public input on the FIFRA IEM measures described in this ID on November 16, 2022 and responded to those comments in Section I.B. Additionally, EPA received public comment from USDA regarding the oxyfluorfen PID which supported the development of this amended PID.[63] 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 oxyfluorfen. For more information, see Appendix C.

A. Risk Mitigation and Regulatory Rationale

EPA has evaluated the currently registered uses of oxyfluorfen and has identified the following risks of concern:

1. The cancer dietary risk estimate for surface water alone is of concern for most uses. The cancer dietary risk estimate for food exposure alone does not exceed levels of concern.
2. The residential cancer risk estimates are of concern for most residential handler scenarios.
3. Short-term and intermediate-term non-cancer risks of concern to occupational handlers for the following uses with baseline attire of a single layer of clothing with no gloves:
   - Mixing and loading for aerial application to high-acreage field crops,
   - Foliar applications of liquid formulations with backpack sprayers to forestry, Christmas trees, landscaping trees, bushes, and shrubs,
   - Foliar applications of liquid formulations with mechanically pressurized handguns to orchards/vineyards, Christmas tree farm, nurseries, landscaping trees/shrubs/bushes, and
   - Ground directed sprays of liquid formulations with mechanically pressurized handguns to orchards/vineyards and nurseries.
4. Cancer risks to handlers for the following use sites and equipment:
   - Mixing and loading for aerial application to high-acreage field crops,
   - Mixing and loading for sprays of liquid formulation by ground boom to high-acreage field crops including corn and cotton and soybeans, and field-grown ornamentals,[64]
   - Spray applications of liquid formulations using ground boom equipment to high acreage field crops,
   - Chemigation to orchard and vineyards,
   - Hand dispersal of granules to Christmas tree farms, landscaping with trees, shrubs, and bushes, and container grown nursery stock,
   - Backpack sprayer applications for foliar applications to orchards and vineyards, artichokes, Christmas, tree farms, and forestry, and
   - Mechanically pressurized handguns applications for all uses.
5. Both cancer and non-cancer occupational post-application risks to agricultural workers during hand-setting of irrigation pipes for nurseries.

[63] For EPA's response to USDA's comment, see Appendix E.

[64] Other high acreage field crops are agricultural fallow/idle land/conservation reserve program lands/uncultivated areas; clover; chickpeas; grasses grown for seed; mint; nonagricultural uncultivated areas/soils; and shelterbelts.

6. Chronic risks to mammals, birds, reptiles, and terrestrial-phase amphibians.
7. Chronic risk to terrestrial insects for applications to artichokes, berries, cacao, citrus, coffee, corn, cotton, forestry, garlic, grapes, onion, soybeans, pome fruits, stone fruits, and tree nuts for adults, and applications to cacao, coffee, and grapes for larvae. Uncertainties related to the quality of dataset suggest that risk may be higher than estimated in the risk assessment.
8. Chronic risks to freshwater fish and aquatic phase amphibians in clear shallow waters for applications to beans, berry, citrus, cotton, pome fruit, soybean, stone fruit, and tree nuts because of toxicity enhancement in the presence of ultraviolet light.
9. Chronic risks to estuarine/marine fish from all uses except garlic, onion, and fruiting vegetables. The risks may be greater because toxicity enhancement in the presence of ultraviolet light is expected but was not tested for all taxa.
10. Chronic risk to freshwater invertebrates from uses with three applications of 0.5 lbs a.i./A or greater, or a single application at the label rate of 1.5 lbs a.i./A, including artichoke, coffee, cacao, corn, forestry, and grape.
11. Chronic risks to estuarine/marine invertebrates for artichokes, beans, coffee, cacao, corn, cotton, forestry, and grapes.
12. Chronic risk to benthic invertebrates from all uses.
13. Risks to terrestrial plants were identified from the edge of the field at distances ranging from 102 to 584 ft, depending upon the application rate.
14. Chronic risks to vascular and non-vascular aquatic plants for all uses.

Given the extent of the risks identified, and in certain cases considering the benefits of use of oxyfluorfen, the Agency is proposing the following package of mitigation measures:

1. To mitigate cancer dietary risks from surface water source drinking water, and to reduce chronic risks to aquatic and terrestrial organisms, the Agency proposes that applications to orchards and vineyards (not including almonds, pistachios, and walnut) be made in a banded application 30% of the row width with a boom height of 2 feet or less. For almonds, pistachios, and walnuts, a single non-dormant broadcast application at 0.25 to 0.5 lb-ai/acre is proposed to be made.
2. A) To mitigate cancer dietary risks from surface water source drinking water, reduce chronic risks to aquatic and terrestrial organisms, and to in part, mitigate cancer and non-cancer risks to mixer/loaders for aerial applications to high-acreage field crops, the Agency proposes reducing the maximum annual application rates and number of applications for the following crops:
    - Beans: 2 applications at 0.25 lb-ai/acre with an annual maximum rate of 0.5 lb-ai/acre;
    - Berries: 1 application per year with an annual maximum rate of 1.0 lb-ai/acre;
    - Cacao: 1 application per year with an annual maximum rate of 1.1 lb ai acre;
    - Coffee: 1application per year with an annual maximum rate of 1.1 lb-ai/acre;
    - Corn: 1 application per year with an annual maximum rate of 0.6 lb-ai/acre;
    - Cotton: 1 application per year with an annual maximum rate of 0.5 lb-ai/acre;

- Forestry: 1 application per year with an annual maximum rate of 1.4 lb ai/acre; and
- Soybeans: 2 applications per year with an annual maximum rate of 1.0 lb-ai/acre.

B) To reduce both occupational post-application cancer and non-cancer post-application risks for hand-setting of irrigation pipes in field-grown ornamentals, the Agency proposes reducing the single application rate to 2 lb ai/acre.

3. To mitigate cancer dietary risks from surface water source drinking water, and reduce chronic risks to aquatic organisms, the Agency is proposing a 30-foot-wide vegetated filter strip be maintained between the edge of the field and any water body *except* in the states of Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming, and Texas west of I-35.
4. To mitigate cancer dietary risks from surface-water-source drinking water and reduce chronic risks to aquatic and terrestrial organisms by reducing the amount of spray which travels off-field, the Agency is proposing mandatory and advisory spray drift language on all agricultural use labels and the use of a coarse or coarser spray droplet size. The spray drift language proposed in the 2021 PID has been amended to be consistent with FIFRA IEM.
5. To mitigate cancer risks to residential handlers, the Agency proposes removing all residential uses of oxyfluorfen.
6. To mitigate non-cancer risks to occupational handlers from backpack applications, the Agency proposes to:
   - restrict the use of foliar applications by backpack sprayer (applications must be soil/ground directed) for all uses,
   - reduce the concentration of the prepared solution rate to 0.05 lb-ai/gal for orchard and vineyard crops and 0.1 lb-ai/gal for Christmas tree farms and forestry, and
   - prohibit application by backpack sprayer to landscape trees, shrubs, and bushes.
7. To mitigate cancer and non-cancer risks to occupational handlers, the Agency is proposing to prohibit the application of oxyfluorfen by mechanically pressurized handguns.
8. To mitigate cancer risk to occupational handlers, the Agency proposes prohibiting the application of granules by hand for Christmas tree farms, landscaping with trees, shrubs, and bushes, and container grown nursery stock.
9. The Agency proposes the additional personal protective equipment to mitigate the following mixer/loader risk:
   - Non-cancer and cancer risk for aerial applications to high acreage field crops from aerial applications (the Agency proposes that gloves be worn while mixing and loading for these uses).
   - Non-cancer and cancer risk for aerial applications to forestry and Christmas trees (the Agency proposes that gloves be worn while mixing and loading for these uses).
   - Ground boom applications to high acreage field crops and field grown ornamentals. The Agency proposes that gloves be worn during mixing and loading with these uses.
   - To mitigate risks to mixers/loaders using backpack sprayers the Agency proposes the use of gloves while mixing and loading oxyfluorfen for these uses.

- To ensure consistency and clarity of labeling, the Agency proposes that all glove statements be upgraded to be consistent with Chapter 10 of the Label Review Manual.

10. To reduce occupational handler cancer risks to mixer/loader/applicators the Agency proposes eliminating application of oxyfluorfen through irrigation systems, known as chemigation, to orchard and vineyard crops.
11. To mitigate risks to terrestrial invertebrates, and, in particular pollinators such as bees, the Agency proposes to include non-target organism protection advisory language. This language is also part of the FIFRA IEM measures the Agency is implementing, in part, as a framework for future endangered species mitigation.
12. To mitigate the risk of development of herbicide resistance, the Agency proposes resistance management language be included on all agricultural use labels.
13. To address chronic risks to aquatic wildlife, the Agency proposes that runoff advisory language be put on all labels.
14. To address potential impacts to the forage and habitat of non-target organisms, the Agency proposes that advisory non-target organism protection be put on all labels.
15. To ensure label consistency and clarity, the Agency proposes removing information about volumetric mean diameter from all labels where such information currently appears and use standard droplet size classes to characterize sprays.

The proposed prohibition of residential use would mean that dietary (food and drinking water) exposure would remain as the sole contributor to the aggregate risk. Drinking water is the driver for dietary risk, and thus for aggregate risk. EPA cannot consider benefits in making a safety determination about dietary risks, as the FFDCA standard requires reasonable certainty of no harm for human health. The cancer dietary risks are addressed through the proposed requirement that applications to orchard crops be made as bands, the use of 'coarse or coarser' droplet sizes for spray applications, the implementation of a 30-foot vegetated filter strip, and reduction in application rates for certain uses. Detailed discussion of each mitigation measure is provided below.

Occupational handler and non-target environmental risks are also addressed by the proposed mitigation measures. For some risks, these measures do not reduce the risk below the level of concern and the benefits of oxyfluorfen to users are considered in the Agency's decision-making as required by FIFRA, which is further discussed in the following sub-sections.

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 Amended PID. EPA sought public comment on the full suite of FIFRA Interim Ecological Mitigation measures, which is available in the ESA Workplan Docket (EPA-HQ-OPP-2022-0908-0002), at www.regulations.gov. EPA updated some of the FIFRA IEM measures after considering public comments and additional EPA and interagency review of the mitigations. The FIFRA IEM measures proposed for oxyfluorfen in this amended PID reflect these revised mitigations.

EPA developed the FIFRA IEM measures—including those that EPA proposes for oxyfluorfen based on the ecological risks—to reduce exposure to nontarget organisms, including listed species.[65] EPA is proposing the following FIFRA Interim Ecological Mitigation measures for oxyfluorfen:

- Surface water protection statement
- A vegetated filter strip of 30 feet
- Spray drift reduction measures, including a buffer around conservation areas
- Pollinator stewardship advisory language
- Ecological incident reporting label language
- Bulletins Live! Two (BLT) labeling

The proposed FIFRA IEM measures in this amended PID are not designed to fully address EPA's ESA obligations for oxyfluorfen 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 oxyfluorfen during registration review, such as mitigations developed as part of its various ESA initiatives.[66] Additional measures may also be necessary when EPA conducts effects determinations and, if necessary, consults with the Service(s) on oxyfluorfen.

C. Required Label Mitigation

1. Restricting Broadcast Application in Vineyards and Orchards

To reduce the exposure through surface-water source drinking water from applications of oxyfluorfen the Agency is proposing to restrict (not allow) broadcast applications in orchard and vineyard crops with the exception of almonds, walnuts, and pistachios, and including label requirements that the applications be made in bands. In orchards, Washington State University[67] already recommends that growers apply oxyfluorfen as a banded application to bare soil under healthy trees in orchards and avoid contact with the crop. This mitigation measure was suggested by one the registrants, Adaura, as an alternative to decreasing the application rate on grapes. In vineyards, growers apply herbicides in a narrow strip centered on the vineyard row that comprises 15% to 30% of the total vineyard area or in an area three to six feet around each vine.[68] Oxyfluorfen is used in establishment of new vineyards as well as in established vineyards

[65] *See ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions* (Nov. 2022), https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf.
[66] *Id.*
[67] Washington State University Extension, EB0419, *2021 Crop Protection Guide for Tree Fruits in Washington*, Weed Control Pome Fruit (2020), http://cpg.treefruit.wsu.edu/weed-control/seasonal-weed-control-pome-fruit/.
[68] Roncoroni, J. A., Hembree, K. J., & Ingels, C. A., University of California Agriculture & Natural Resources, UC ANR Pub. 3448, *Grape Agricultural Pest Management: Integrated Weed Management* (2016), http://ipm.ucanr.edu/PMG/r302700111.html.

and is applied as a band down the vine row or in an area three to six feet around each vine.[68] Requiring that applications to orchards and vineyards be made in bands would reduce the field area where oxyfluorfen is applied by 70% or more as compared to broadcast application without impacting the efficacy of weed prevention or substantially burdening growers.

By restricting applications to banded treatments of 30% of the row width in orchard and vineyard crops, the highest estimated concentration in drinking water changes from 5.1 ppb to 1.3 ppb. Concentrations must be below 1.97 ppb to allow both food and water combined to appropriately reduce potential cancer risks. These mitigations would also reduce, but not eliminate the chronic risks to aquatic organisms. As banding is already the prevalent practice for applying oxyfluorfen in orchards and vineyards, the Agency expects limited to no impact on growers from this mitigation option. Implementation of this mitigation, along with other mitigations in this document would result in dietary risks which are no longer of concern.

However, for almonds, walnuts, and pistachios, the Agency is proposing that a single non-dormant broadcast application at 0.25 to 0.5 lb-ai/acre can be made in-season to suppress weeds and cleanup in preparation for harvest. The broadcast application for almonds, pistachios, and walnuts is being retained since the reduced application rate used does not result in exceedance of risk thresholds.

Requiring banded applications in orchards and vineyards will not likely impose a significant burden on users since that is already common practice.

2. Reduction in Maximum Application Rates and Number for Certain Crops

To reduce drinking water concentrations of concern for cancer, the Agency is proposing to reduce the amount of oxyfluorfen applied for the 8 crops listed in Table 3. Simulations based on these application rates showed that for all the crops in Table 3, the EDWCs were at 1.5 ppb or below. At these levels, no dietary (food + water) cancer risks would not be a concern. For all uses not already specified, the Agency proposes that technical product labels be modified to limit the single maximum application rate to 1.5 lb ai/acre and the seasonal maximum application to 2 lb ai/acre, which are the maximum rates assessed in the drinking water assessment supporting this amended PID.[42] This measure is intended to ensure that future new registrations do not increase dietary risk.

As part of a proposed group of mitigations including requiring standard spray drift mitigation with a coarse or coarser droplet size, adding a 30-foot vegetated filter strip to all agricultural labels, consideration of all applications as a single set of applications rather than as separate sets of pre- and post-emergent applications, and removing use by residential handlers, the cancer dietary risk is reduced. These mitigations, discussed in detail in "*Oxyfluorfen: An Addendum to the Drinking Water Exposure Assessment for Registration Review*", reduce estimated drinking water concentrations (EDWCs) for cancer below 1.97 ppb for all crops. Concentrations below this level result in dietary cancer risks that meet the FFDCA standard of a reasonable certainty of no harm for human health.

This proposed mitigation in combination with other mitigation proposed in this document, will reduce the dietary risk from cancer from food and water so that it is not of concern. These mitigations would also reduce the risks to all aquatic and terrestrial wildlife in the vicinity of applications through reduced exposure via spray drift and runoff. In addition, these proposed mitigations, along with the addition of gloves (discussed in the 'Addition of PPE' section below) will mitigate the non-cancer and cancer risks to mixers/loaders for aerial and ground boom applications to high acreage field crops, namely corn, cotton, and soybeans.

Table 3. Proposed oxyfluorfen maximum label application rates for certain crops.

Crop (Current Maximum Number of Applications and Application Rate)	Proposed Maximum Single Application Rate	Proposed Maximum Annual Number of Applications	Proposed Maximum Annual Application Rate
beans (6 app @ 0.25 lb-ai/acre)	0.25 lb-ai/acre	2	0.5 lb-ai/acre
berries (2 app @ 1 lb-ai/acre)	1 lb-ai/acre	1	1 lb-ai/acre
cacao (2 app @ 3 lb-ai/acre)	1.1 lb-ai/acre	1	1.1 lb-ai/acre
coffee (2 app @ 3 lb-ai/acre)	1.1 lb-ai/acre	1	1.1 lb-ai/acre
corn (2 app @ 0.75 lb-ai/acre)	0.6 lb-ai/acre	1	0.6 lb-ai/acre
cotton (2 app @ 0.5 lb-ai/acre)	0.5 lb-ai/acre	1	0.5 lb-ai/acre
forestry (3 app @ 1.5 lb-ai/acre)	1.4 lb-ai/acre	1	1.4 lb-ai/acre
soybeans (3 app @ 0.5 lb-ai/acre)	0.5 lb-ai/acre	2	1 lb-ai/acre

In the document *"Oxyfluorfen Use, Usage, Benefits, and Impact Assessment"* supporting the PID, the extent of acreage affected by reducing the application rate and number of applications was assessed for all crops except cacao, coffee, and forestry. Table 4 in this amended PID presents the current and proposed maximum single application rates, the 5-year (2014 – 2018) average application rate, and the percent of oxyfluorfen-treated acres that exceed the proposed maximum single application rates for some of the crops with reduced application rates. For the most part, usage data indicate that few or no acres are treated at rates exceeding the proposed maximum application rates. Generally, strawberry, caneberries, cotton, corn, dry bean/pea, and soybean growers are not expected to be affected by the proposed application rate reductions.

Oxyfluorfen use in corn was found to be used on less than 1% of the crop. Usage data in corn[69] suggests that impacts from this mitigation would be limited as the average annual use rate of oxyfluorfen in corn during this period was just below 0.20 lbs. a.i./A (Table 4), about a third of the maximum rate the Agency is now requiring. Additionally, Table 4 shows that there were not any corn-acres treated with application rates above the potential application rate reduction.

Similarly, less than 1% of soybean acres are treated with oxyfluorfen based on the most recent review of usage data[69] The Agency expects limited impacts from this potential mitigation as the average application rate of oxyfluorfen in soybean, nationally over the past five years, is less than 0.18 lbs. a.i./A (Table 4), and less than the new maximum application rate of 0.5 lb-ai/acre.

Application rate usage information for forestry is unavailable. If application rate reductions result in oxyfluorfen no longer being efficacious for the control of target weeds in forestry, there could be impacts on users. Oxyfluorfen is critical for stand establishment for many forestry species due to oxyfluorfen's lack of phytotoxicity and ability to be sprayed over the top of saplings. If oxyfluorfen was no longer efficacious users may rely more heavily on alternatives and/or rely on hand cultivating; both of which may be more expensive.

Application rate usage information for coffee and cacao is not available. Oxyfluorfen is the only available pre-emergent herbicide available for these crops, and if the application rate reduction results in oxyfluorfen no longer being efficacious for the control of target weeds, such as taro root in coffee, yield losses are expected. Additionally, a lack of oxyfluorfen efficacy could result in increased use and over reliance on the only available post-application herbicides in these crops (glyphosate, paraquat), which offer no residual control. The over reliance on such a reduced number of active ingredients may result in the development of herbicide resistance, decreased weed control, and eventual yield losses.

Table 4. Current average application rates compared to current and proposed application rates and acres impacted, by crop (2014-2018, 5-year annual averages).[69]

Crop	Current Labeled Maximum Single Application Rate (lb a.i./A)	Proposed Maximum Rate (lb a.i./A)	Average Application Rate (lb a.i./A)	% Acres Treated at a Rate Greater than Proposed Maximum Rate
strawberry	1.00	1.00	0.32	0
caneberries	1.00	1.00	0.21	0
cotton	0.50	0.50	0.35	0
dry beans/peas	0.50	0.25	0.22	0
soybean	0.50	0.50	0.18	0
corn	0.75	0.60	0.20	0

The Agency also evaluated impacts of limiting the number of applications (Table 5). For the crops for which data are available, in all cases, the number of applications required in the ID is

[69] Oxyfluorfen Use, Usage, Benefits, and Impact Assessment, March 30, 2021

either equal to or greater than the average number of applications. Consequently, the impact of decreasing the number of applications on users or the proportion of treated acreage is expected to be limited.

Table 5. Average number of applications compared to proposed reductions in maximum number of applications, by crop (2014 – 2018, 5-year annual average)[69]

Crop	Average Number of Applications (applications/year)	Proposed Maximum Number of Applications (applications/year)
caneberries	1.00	1
cotton	1.00	1
dry beans/peas	1.00	2
corn	1.00	1
soybeans	1.00	2

The Agency only received one comment regarding changing application rates to mitigate risks. USDA agreed with that the rate changes were reasonable except for those for cacao and coffee. USDA had concerns that a reduction in maximum application rates could lead to poor weed control and may cause growers to increase use of the other available post-emergence herbicides, *i.e.*, glyphosate or paraquat.

3. Vegetated Filter Strips

The Agency is proposing that vegetated filter strips (VFS) be put on all agricultural use labels for oxyfluorfen, with the exception that this requirement does not extend to the western states with irrigated agriculture, specifically Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming, and TX west of I-35. The exception is being made for these states because rainfall which causes runoff mostly occurs during the winter and out of the growing season in these states. In addition, most agriculture in these states is irrigated and vegetated filter strips are not easily compatible with irrigated agriculture, especially flood and furrow irrigated systems. Many crops in these states are grown under contracts requiring a 'clean' (unvegetated) field border to keep contamination associated with animals (*Escherichia coli*) away from the crop. This mitigation is intended to reduce dietary and aggregate risk through drinking water, and risks to aquatic organisms.

Currently, there are two oxyfluorfen labels that include VFS: EPA Reg. Nos. 66222-28 and 62719-611. These labels require a 25-foot setback distance or vegetated buffers between treated areas and surface water such as lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries, and commercial fishponds. A well-maintained vegetated buffer could potentially intercept oxyfluorfen-laden run-off (both soluble and sediment bound) prior to reaching surface waters. In the modeled assessments for drinking water, only the effect on reducing spray drift was considered as the Agency does not have an approved tool for estimating

the reduction of loading to water bodies with runoff and eroded sediment, which can be significant.

In the recent draft Technical Support Document[70] EPA evaluated and scored numerous mitigation practices with respect to their available supporting literature and their demonstrated effectiveness for reduction of pesticides disolved in runoff and/or sorbed to eroded sediment. EPA identified a 30-foot wide vegetated filter strip (VFS) as a mitigation practice with medium efficacy and abundant literature studies supporting efficacy. The supporting literature indicates that on average, a well-maintained VFS may reduce pesticide exposures by 25 to 40% for runoff-prone pesticides, 50% for erosion-prone pesticides, and overall reductions range from 1 to 94%.[71,72,73]

Oxyfluorofen has a high potential to bind with sediment, with an average K_{oc} of 12,223 $L/kg_{o.c.}$ which places it in the category of erosion-prone pesticides mentioned above. Therefore, implementation of a 30-foot VFS has the potential to reduce oxyfluorofen exposure in aquatic systems an average of 50%. There will probably not be significant impacts from increasing the VFS width to 30 feet and the Agency expects minimal impact from this mitigation on crop producers who use oxyfluorfen.

The proposed FIFRA Interim Ecological Mitigation (IEM) discussed in EPA's November 2022 Endangered Species Act Workplan Update[74] would include a menu of possible mitigations to choose from for compounds with similar environmental fate, risk and benefit profiles to oxyfluorfen. Rather than implement the runoff/erosion mitigation menu for oxyfluorfen, the Agency has chosen to specifically require the use of vegetated filter strips. Vegetated filter strips are among the most highly effective tools for reducing pesticide movement to water with runoff and eroded sediment. There is also a more substantial body of literature regarding the efficacy of VFS than other methods on the mitigation menu. However, the Agency is proposing to increase the VFS width from 25 feet to 30 feet to be consistent with the VFS width recommended in IEM. In addition, as noted above, VFS are already on the most used oxyfluorfen product labels, and the registrants have already agreed to their inclusion on labels. Therefore, the Agency has decided to continue to propose VFS for management of oxyfluorfen movement to surface waters rather than adopt the mitigation menu approach proposed for the ESA Workplan.

[70] USEPA. 2023. Draft Technical Support for Runoff, Erosion, and Spray Drift Mitigation Practices to Protect Non-Target Plants and Wildlife. Office of Pesticide Programs. Office of Chemical Safety and Pollution Prevention. U.S. Environmental Protection Agency. Washington, D.C. June 2023.
[71] Alix, A., Brown, C., Capri, E., Goerlitz, G., Golla, B., Knauer, K., et al. 2017. Society of Environmental Toxicology and Chemistry. Mitigating the Risks of Plant Protection Products in the Environment. Proceedings of the MAgPIE Workshop. Available at: https://www.spraydriftmitigation.info/mitigation-toolbox.
[72] Reichenberger, S., Bach, M., Skitschak, A., & Frede, H.-G. 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness; A review. Science of The Total Environment, 384(1), 1-35.
[73] USDA. 2014. Agronomy Technical Note No. 5. Conservation Planning Process. February 2014. United States Department of Agriculture. Natural Resources Conservation Service.
[74] https://www.epa.gov/system/files/documents/2022-11/esa-workplan-update.pdf

4. Spray Drift Management

The Agency is proposing to add spray drift management language to oxyfluorfen labels to reduce off-target spray drift and consistently attain a baseline level of spray drift reduction across all oxyfluorfen products.[75] This mitigation is intended to reduce dietary risk through exposure through drinking water, risks to aquatic organisms, risks to non-target mammals and birds, and non-target terrestrial plants.

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

The following spray drift mitigation language is being proposed for all oxyfluorfen products applied by liquid spray application. This 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 that allow oxyfluorfen registrants to standardize all advisory spray drift language on oxyfluorfen product labels. Registrants should ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this amended ID, once effective.

This proposed language for labels with aerial applications is:

- Do not release spray at a height greater than 10 feet above the ground or vegetative canopy unless a greater application height is necessary for pilot safety.
- During application, the sustained wind speed, as defined by the National Weather Service (standard averaging period of 2 minutes) must register between 3 and 15 miles per hour.
- 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.
- For aerial applications when the windspeed is between 11-15 miles per hour, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, 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.
- If the windspeed is 10 miles per hour or less, applicators must use a minimum of ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between

[75] Reducing spray drift will decrease environmental exposure and risk to nontarget organisms. Although EPA is not making a listed species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of oxyfluorfen. For specific label language, see Appendix B.

11-15 miles per hour, applicators must use a minimum of ¾ swath displacement upwind at the downwind edge of the field.

- Applicators must not spray during temperature inversions.

This proposed language for labels with ground boom applications is:

- For applications in orchards and vineyards, use a release height no more than 2 feet above the ground. For all other crops, apply with a release height no more than 4 feet above the ground or crop canopy.
- Do not apply when wind speeds exceed 15 miles per hour at the application site.

For both ground boom and aerial applications:

- Applicators must select nozzle and pressure that deliver coarse or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 641 (ASABE S641).

The Agency is proposing to restrict droplet size because coarser droplets have been demonstrated to decrease spray drift, and therefore, reduce potential risks to non-target species. Currently, the most used products (by total acres treated) already have the restriction of coarse or coarser droplet size (*e.g.*, EPA Reg# 62719-424, 62719-447).[69] Therefore, the Agency expects limited impact from this mitigation on growers.

The Agency is proposing a release height of four feet or less for ground boom applications for all use sites and a release height of two feet or less for orchard and vineyards. Currently, the most used products (by total acres treated) already have the restriction a 4-foot release height (*e.g.*, EPA Reg# 62719-424, 62719-447). Therefore, the Agency expects limited impacts on users from the 4-ft release height requirement. However, the Agency does expect impacts on users from the 2-foot release height requirement in orchards and vineyards. Spray release height is important to minimize overlap of spray from nozzles while maintaining proper coverage. If nozzles are placed too low, they will not provide adequate coverage and could lead to portions of the orchard or vineyard not receiving the proper rate of pesticide or going untreated. This mitigation could lead to control failure in the field resulting in either greater weed competition or the need for additional herbicide applications. Improper distribution of the herbicide over the field could also lead to issues with herbicide resistance management.

In addition to the proposed mandatory spray drift management language discussed in the preceding section, the Agency is proposing the spray drift advisory language be included on all labels for agricultural use. Adding this language will provide pesticide users with information about what factors influence the off-site movement of pesticide sprays so that they can make informed decisions about how and when to apply a product while reducing impacts on non-target resources. The spray drift advisory language is not expected to have significant impacts on the benefits from the of the pesticide.

In addition to the mitigation proposed above the Agency is proposing spray drift buffers around conservation areas as FIFRA IEM as discussed in the introduction. To reduce risks to organisms that reside in conservation areas, the Agency is proposing spray drift buffers between the edge of the field and conservation areas (e.g., public lands and parks, wilderness areas, National Wildlife

Refuges, reserves, and conservation easements). The proposed spray drift buffers are as follows for applications near conservation areas.

For aerial applications: "Do not apply within 150 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.

- For ground applications: "Do not apply within 50 feet of any conservation areas (*e.g.*, public lands and parks, Wilderness Areas, National Wildlife Refuges, reserves, conservation easements) unless using a hooded spray boom. When using a hooded spray boom, do not apply within 25 feet of these protected areas."
- For both aerial and ground applications, a 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (*e.g.*, trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria:
    - The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area.
    - The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage is sufficiently dense such that the aquatic habitat is not visible on the upwind side at the time of application.
    - The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side.
    - The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application.
    - The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted.
    - The windbreak or shelterbelt must be maintained such that their functionality is not compromised.
    - A manmade structure (*e.g.*, curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application."
    - A 50% reduction in buffer distance can be made if: the application is made with a hooded sprayer; or,
    - 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."

It is reasonable to expect that a 10-foot windbreak between the edge of the field and the conservation area could substantially reduce pesticide deposition into conservation areas. Similarly, pesticides may be applied to public lands, parks, wilderness areas, national wildlife refuges, reserves, conservation easements, and other conservation areas to kill invasive species and/or to restore habitat. Buffer exemptions are needed for these types of specialized applications. EPA is proposing buffer reduction of 50% for applications near conservation areas when a 10-foot high windbreak is used, or when the application is made for conservation purposes.

A spray drift buffer around aquatic habitat is included as part of FIFRA IEM. For oxyfluorfen, the Agency has chosen instead to propose reducing the application rate on the crops with highest EECs and requiring that spray droplet sizes be of coarse or coarser droplet size. Even though oxyfluorfen moves more with eroded sediment than dissolved in runoff, movement in rainfall events is still the dominant source of loading to aquatic environments. This route of loading is being mitigated with a 30 foot VFS as described in section IV.C.3. This, in concert with the spray drift mitigation listed above along with a coarse or coarser droplet size spectrum should significantly reduce loadings to aquatic environments without the imposition of a spray drift buffer to aquatic habitats.

As part of FIFRA IEM, the Agency is considering the benefits of the use of oxyfluorfen as part of its proposal for setting spray drift buffer distances. Buffers widths are usually set for all crops on the same label, so the buffers are based on the crops with the lowest level of benefit. Because the risks for oxyfluorfen to terrestrial wildlife are high and the benefits for some crops are low, a wide buffer of 150 feet was set for aerial applications and 50 feet for ground sprays. However, the Agency is considering an alternative approach where if all the crops on the label are of higher benefits, then smaller buffers could be used. For example, most orchard crops have high benefits for the use of oxyfluorfen, so labels which only included orchard crops could have reduced buffer of 100 feet for aerial applications and 25 feet for ground applications. While this approach has not been proposed here, the Agency invites comments on the utility and feasibility of this approach for managing ecological risks.

5. Prohibition of Residential Use

The Agency is proposing that residential use be prohibited on labels to eliminate the risk from cancer from residential exposure. For the purposes of this action, residential use sites would include the application to driveways, brick walks, sidewalks, patios, parking areas, along paths, fences, curbs, and gutters; around buildings; and in decorative rock or bark landscapes; edging lawns; around the base of established trees, shrubs and ornamental plants around residences, playgrounds, parks, game fields, and ornamental beds. The Agency received five sets of comments regarding the residential uses of oxyfluorfen, with one comment supporting the prohibition of residential

use and the other comments suggesting concerns with, and potential modifications to, the Agency's proposed prohibition.[76] These comments are discussed in detail in Section I.C above.

Cancer risks were greater than $1x10^{-6}$, for all formulations and use patterns except for hose-end sprayers using the ready-to-use formulation where the cancer risk is 9.2×10^{-7}. Cancer risks ranged up to 2.6×10^{-5} for hose-end sprayer applications using the liquid formulation around buildings. Aggregate risk estimates include both residential exposures and dietary risks. If either use pattern exceeds the risk threshold individually, then there will also be an aggregate risk concern. After accounting for the mitigation measures targeting reductions of dietary risks from cancer, the contribution from residential sources of exposure still results in aggregate risks of concern. The Agency does not use PPE to mitigate residential uses (*e.g.*, homeowners) because there is no mechanism in place to ensure these users are properly trained in the use of PPE, and because it is difficult to implement and enforce. Decreases in application rates (8-fold) to help reduce the risks of concern would result in applications that would not be efficacious. Therefore, the Agency is proposing to prohibit the residential uses of oxyfluorfen.

Oxyfluorfen is registered as a garden herbicide in the U.S. homeowner market, although the usage has been minimal.[77] The Agency is proposing to prohibit residential use of oxyfluorfen for all applicators, including professional applicators, as the Agency cannot otherwise preclude residential users from using products intended for professional applicators. Licensed professional users would have access to efficacious alternatives to oxyfluorfen, including granular formulations of oxadiazon and flumioxazin, for use in residential areas. However, residential and other non-professional users would need to either hire professional applicators at increased cost, or else rely on other herbicides which may be less effective than oxyfluorfen and potentially face higher costs or reduced control of weeds[8]. However, as use of oxyfluorfen in residential settings is minimal[77], the extent of these impacts may be limited. Professional applicators would still be allowed to apply oxyfluorfen to commercial, retail, and industrial sites. EPA is also proposing to round up the 1.9 lbs a.i./A rate for non-residential ornamental sites to 2 lbs a.i./A for increased ease and consistency of measurement.

6. Restrictions for Application with Backpack Sprayers

Occupational handler risks were assessed for soil-directed sprays for a variety of fruit and nut orchard crops, Christmas tree plantations, forestry, and landscaping trees, shrubs, and bushes. Occupational handler risks were also assessed for foliar and broadcast sprays only for Christmas tree plantations, forestry, and landscaping trees, shrubs, and bushes.[78] Of these uses, risks of concern were identified for occupational handlers for either non-cancer or cancer risks with baseline PPE. The Agency is proposing three label mitigations which in combination will mitigate the non-cancer risks to below the level and concern and will reduce cancer risks of concern: 1) reduce the concentration of the prepared application solution to 0.05 lb-ai/gal for

[76] Docket IDs EPA-HQ-OPP-2014-0778-0077, EPA-HQ-OPP-2014-0778-0080), EPA-HQ-OPP-2014-0778-0085), EPA-HQ-OPP-2014-0778-0088), and (EPA-HQ-OPP-2014-0778-0076)
[77] Nonagricultural Market Research Data (NMRD). 2020. Study on consumer markets. [Accessed November 2020].
[78] Oxyfluorfen**:** Addendum to the 2019 Draft Human Health Risk Assessment for Registration Review (D445742).

orchard and vineyard crops and 0.1 lb-ai/gal for Christmas tree farms and forestry; 2) require that all backpack sprays be directed toward the ground/or soil; and 3) prohibit backpack sprays on ornamental landscaping trees bushes and shrubs. In addition, the Agency is proposing that gloves be required on all labels with forestry or Christmas tree uses. This mitigation is discussed in the PPE mitigation section below. These measures reduce the cancer risks for orchards and vineyards, Christmas tree farms, and forestry as specified in Table 6.

Table 6. Non-cancer and cancer risk estimates for occupational handlers (mixer/loaders and applicators) for soil-directed backpack applications of liquid formulations by commercial applicators with proposed mitigation (spray directions, reduced spray concentrations, and PPE[25])

Crop	Spray Direction	Spray Concentration (lb-ai/gal)	PPE*	Non-Cancer ARI	Cancer Risk
orchard & vineyards	soil-directed	0.05	SL/No-G/No-R	7.7	$1x10^{-4}$
Christmas tree farm	soil-directed	0.1	SL/No-G/No-R	3.7	$2x10^{-4}$
forestry	soil-directed	0.1	SL/G/No-R	3.7	$2x10^{-4}$

* SL/no-G: single layer of clothing, no gloves; SL/G – single layer of clothing and gloves; DL/G – double layer of clothing and gloves; No-R – no respirator

These risk estimates are upper bound estimates, and expected to be equaled on a very limited basis considering the estimates are based on maximum label rates, upper bound estimates of the area treated each day in each scenario, and based on a lifetime of exposure. After accounting for the protection provided by the proposed mitigation, the risk estimates are reduced to a level where oxyfluorfen use can be retained in orchards and vineyards, Christmas tree farms, and forestry.

The Agency is proposing to prohibit application by backpack sprayers for landscape trees, shrubs and bushes as cancer risks cannot be precluded by mitigation. Oxyfluorfen is recommended by state extension specialists for use on landscape ornamentals and selected field-grown deciduous trees.[53] Oxyfluorfen provides residual control of most broadleaf weeds and some grasses and contact control for broadleaf weeds up to 4 inches in height.[53] Oxyfluorfen is commonly recommended in premix products with prodiamine, trifluralin, pendimethalin, or oryzalin to provide increased weed spectrum. Most herbicides utilized in these sites are residual herbicides. Non-phytotoxic and effective residual control of broadleaf weeds and sedges in the production of woody ornamentals and herbaceous perennials can be difficult, especially when considering nurseries grow many different types of plants and not all genera or species are listed on labels.

According to feedback from professional applicators reported by the USDA, oxyfluorfen is a critical tool for weed control in established landscape beds.[79] Growers prefer oxyfluorfen because generally it can be used safely, based on phytotoxicity, to achieve weed control in a wide variety of ornamental crops, especially conifer seedlings.[79] Based the species being

produced and the grower's knowledge of potential phytotoxicity, the following herbicide active ingredients are possible alternatives to oxyfluorfen in ornamental production: dimethenamid-P, dithiopyr, flumioxazin, indaziflam, isoxaben, oxadiazon, pendimethalin, prodiamine, simazine, and trifluralin. The Agency does not expect significant impacts from requiring the spray to be soil or ground directed as this is likely to be the regular practice.

7. Prohibit Application by Mechanically Pressurized Handgun

Seventy-three scenarios (combinations of formulation, and PPE) using mechanically pressurized handguns were evaluated in the "*Oxyfluorfen: Addendum to the 2019 Draft Human Health Risk Assessment for Registration Review*", dated March 17, 2021. With baseline PPE (single layer of clothing including socks and shoes and no gloves) there were only 6 scenarios without non-cancer risks of concern, and there was only one scenario without cancer risks. When full PPE (double layer of clothing, chemical resistant gloves and a PF10 respirator) were assessed, most scenarios had acceptable non-cancer risks, but only three scenarios were acceptable for cancer risk concerns including foliar- and ground-directed sprays to nursery ornamentals at an application rate of 0.025 lb/acre, and landscape turf (lawns, athletic fields, and parks). Because of the widespread nature of the risk across these exposure scenarios, and the inability to sufficiently reduce risks with PPE, the Agency is proposing to prohibit application of oxyfluorfen using mechanically pressurized handguns.

Use of mechanically pressurized handguns on small acreage and/or difficult terrain may be an important oxyfluorfen use. In areas where a mechanically pressurized handguns would be most useful an applicator would have to choose a different active ingredient (if available) if applications of oxyfluorfen were not permissible using this equipment type. Alternatives may not be available for all use sites, but this has not been assessed for all use sites. However, impacts from using an alternative control option will likely take the form of increased costs as well as potential decreases in efficacy given varying spectrums of weed control between herbicides. For example, in orchard sites, growers utilizing mechanically pressurized handguns to make applications of oxyfluorfen would either be forced to utilize different equipment such as an ATV mounted sprayer or choose an alternative herbicide combination such as glyphosate or glufosinate in combination with indaziflam or rimsulfuron.

The Agency received information from industry professionals solicited by the USDA around the impacts of this mitigation in ornamentals, forestry and Christmas tree farm use sites. [54] None of these respondents to the USDA indicated that use of the mechanically pressurized handgun as typical equipment for applying oxyfluorfen in these sites. They did indicate that backpack sprayers and ATV mounted sprayers as the standard types of application equipment used in herbicide applications.[54]

8. Prohibit Hand Application of Granules

Currently, occupational hand dispersal of granules is allowed for three use sites: Christmas tree farms, landscaping with trees, shrubs, and bushes, and container grown nursery stock. In all three

cases, the commercial handler cancer risk was estimated to be $6x10^{-4}$ with baseline attire and no gloves (the currently required level of attire and PPE on product labeling), and $3x10^{-4}$ with double layer of clothing and gloves. Since these uses still present potential cancer risks of concern even with additional PPE, the Agency is proposing to prohibit this application method for these use sites.

The Agency received information from industry professionals solicited by the USDA which indicated that the use of granular formulations of oxyfluorfen currently labeled for hand dispersal are not heavily used in forestry and Christmas tree production for a number of reasons, including application efficiency and the phytotoxicity of co-formulated active ingredient (flumioxazin and oxadiazon) to young conifer seedlings.[79] However, USDA did indicate that the use of granular formulations of oxyfluorfen, not necessarily applied through hand dispersal, were important for weed control in containerized tree production and in established landscapes.[54] Since information suggests the use of granular oxyfluorfen products is not achieved through hand dispersal application in sites where the formulation is important, impacts on users from this mitigation are likely limited. The one-time cost to acquire a chest-mounted spreader would be the most likely impact of this mitigation for growers to continue the use of oxyfluorfen without hand dispersal applications.

9. Addition of Personal Protective Equipment

The Agency is proposing to add chemical resistant gloves to mitigate potential risks of concern to occupational handlers. Risks were estimated assuming single layer clothing and no gloves worn for pesticides covered by the Worker Protection Standard (WPS),[80] for:

A. Mixer/loaders for liquid formulations applied aerially to high acreage field crops, namely agricultural fallow/idle land/conservation reserve program lands/uncultivated areas; clover; corn, field; cotton; chickpeas; grasses grown for seed; mint; nonagricultural uncultivated areas/soils; shelterbelt; and soybeans. Adding gloves changes estimated non-cancer ARIs from 0.91 to 4.2 and changes the cancer risk estimate from $8x10^{-4}$ to $1x10^{-4}$.
B. Mixer/loaders for liquid formulations applied by ground-boom to field-grown ornamentals. Adding gloves changes cancer risk from $2x10^{-4}$ to $4x10^{-5}$ when assessed at the maximum rate of 4.5 lb-ai/acre.
C. Mixer/loader/applicators for ground-directed backpack sprays to forestry and Christmas tree farms. This, in concert with other mitigations discussed in the section on backpack sprayers reduces the cancer risk to $2x10^{-4}$. Benefits for the backpack sprayer use are significant as discussed in the backpack sprayer section above

The addition of chemical resistant gloves reduces the non-cancer risk for these three scenarios to below the ARI of 1 and reduces the cancer risks below $1x10^{-4}$ for all three scenarios. Gloves are currently required on all but two products which have these uses: Reg. No. 62222-157, "Zoomer" and Reg. No. 59807-12, "Biathlon." As this requirement is currently on most

[79] USDA. 2020. USDA Response: Agency Request for Oxyfluorfen Use Patterns and Benefits for Forestry, Christmas Trees and Ornamentals. Received September 2nd, 2020.
[80] 40 C.F.R. pt. 170

oxyfluorfen labels, it is not expected that extending this requirement to all labels will significantly alter benefits from the use of oxyfluorfen products.

Note that gloves statements on all labels need to be updated to be consistent with Chapter 10 of the Label Review Manual.[81] In particular, the Agency proposes to remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.

10. Restriction of Application by Chemigation

An occupational handler cancer risk of concern, $7x10^{-4}$, was estimated for the exposure scenario, mixing/loading liquid formulations for application through by chemigation assuming a single layer of clothing and no gloves. Currently chemigation is allowed for fruit and nut orchards and vineyards, pine seedlings beds, garlic, and onions. Chemigation is only allowed for garlic and onions on one label, Galligan H2O (Reg No. 66222-140). The Agency is proposing restricting this use based on the risk of concern and limited amount of chemigation used in orchards. Herbicides, particularly those that are general herbicides that can kill a range of plant types, are generally not applied as sprays in orchards, as application methods like chemigation may damage the trees. As alternative application methods are available for these crops, this proposed restriction is not expected to negatively impact growers of these crops.

11. Resistance Management

The Agency is proposing to add resistance-management language to oxyfluorfen agriculture use labels[82] to address pesticide resistance.[83] Consistent with EPA's Pesticide Registration Notice (PRN) on general pesticide resistance management.[84] EPA proposes resistance management 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—

[81] https://www.epa.gov/sites/default/files/2016-02/documents/chap-10-feb-2016.pdf
[82] For specific label language, see Appendix B.
[83] Pesticide resistance is the ability of portions of a pest population to tolerate or survive otherwise lethal doses of a pesticide through genetic or behavioral changes. EPA considers increased pesticide resistance an adverse effect that can drive increased use of pesticides. The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. Currently, there are over 250 weed species worldwide with confirmed herbicide resistance, including over 155 weed species in the United States with confirmed resistance to one or more herbicides. For more details, see PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.
[84] PRN 2017-1, "Guidance for Pesticide Registrants on Pesticide Management Labeling" (Aug. 24, 2017), available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.

including oxyfluorfen—thereby preserving the benefits of oxyfluorfen and other useful pesticides.[85]

12. Surface Water Protection Statement

Oxyfluorfen can, in some cases, be persistent in soil, with half-lives ranging from 67 to 949 days in laboratory soil metabolism studies. According to the Food and Agriculture Organization (FAO) classification scheme, oxyfluorfen is classified as slightly mobile with a mean K_{oc} of 12,223 L/kg-oc in the soil. Transport off the field via soil erosion was identified in the oxyfluorfen ecological risk assessment as a potential exposure route of concern.

To reduce the potential for transport off the field of oxyfluorfen via runoff and soil erosion and reduce risk to non-target organisms, EPA is proposing the following surface water protection statement for oxyfluorfen delivered via liquid spray to crops: "Do not apply during rain."

The surface water protection statement is intended to reduce the amount of pesticide that moves off a treated field via erosion during a rain event. Applying pesticides when it is not raining is a common-sense measure that ensures the pesticide application will be effective against the target pest while reducing ecological risks from erosion.

12. Run Off Advisory Language

The Agency is proposing that all labels include surface water advisory statements consistent with the Label Review Manual Chapter 8, Section F, to protect aquatic wildlife. Adding this language will provide pesticide users with information about what factors influence the off-site movement of pesticide with runoff following rainstorms. This language will provide users with information about oxyfluorfen's potential to move into surface water resources so that they can make informed decisions about how and when to apply a product while reducing impacts on non-target resources. This language is not expected to have significant impacts on the use of the pesticide.

13. Spray Drift Advisory Language

In addition to the mandatory language in Section IV.C.12 above, the Agency proposes adding advisory spray drift management language to labels to reduce off-target spray drift and consistently protect against a baseline level of spray drift across all oxyfluorfen products.[86]

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

[86] Reducing spray drift will decrease environmental exposure and risk to nontarget organisms. Although EPA is not making a listed species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of oxyfluorfen. For specific label language, see Appendix B.

14. Non-Target Organism Advisory Language

The Agency is proposing to add a nontarget organism advisory statement to oxyfluorfen labels. EPA prioritizes protecting pollinators, including by reducing spray drift and educating growers about potential indirect adverse effects of herbicides (including oxyfluorfen) on foliage and habitat of nontarget organisms. Based on the incomplete data available, EPA is uncertain how much risk oxyfluorfen presents to pollinators.[87] Pollinators may be exposed to oxyfluorfen from residues in pollen or nectar through spray drift. Like all herbicides, oxyfluorfen is also toxic to plants and spray drift may negatively impact forage and habitat of pollinators and other non-target organisms.

Advisory statements do not impact the risks of concern but is intended to help users understand the potential effects of the product on pollinators and make informed decisions about when, where, and how to apply the pesticide. The statement is not expected to have significant impacts on the benefits from the use of the pesticide.

15. Droplet Size Characterization on Labels

To ensure consistency and clarity in labeling, the Agency is proposing that spray droplet sizes should be characterized using standard droplet size classifications and described in ASABE S572.3. All references to volumetric mean diameter (VMD) information for spray droplets are to be removed from all oxyfluorfen labels where such information currently appears. The new language above, which cites ASABE S572.3, eliminates the need for VMD information.

16. Best Management Practices for Pollinator Protection

Best management practices (BMPs) are proposed for the protection of pollinators as part of the FIFRA Interim Ecological Mitigation because oxyfluorfen poses chronic risks to bees. The following best management practices can help reduce risk to pollinators. To protect wild and managed pollinators, the following BMPs should be implemented:

- Developing and maintaining clear communication with local beekeepers to help protect bees. To the extent possible, advise beekeepers within a 1-mile radius 48-hours in advance of the application, and confirm hive locations before spraying,
- Avoiding applications during bloom,
- Avoiding applications when bees are actively foraging,
- Applying pesticides in the evening or early morning hours when fewer bees are foraging,
- Using 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.

[87] For a detailed discussion of pollinator risks, see Section III.B, above. For a list of missing data that may clarify pollinator risks, see Sections III.B.3, above, and IV.D, below.

- Using integrated pest management to prevent or mitigate potential negative effects to pollinators, and consider multiple management options before resorting to a pesticide application,
- Avoiding applying pesticides to plants in bloom, including flowering weeds,
- Mowing understory weeds or cover crops in orchards and vineyards to prevent flowering of weeds and reduce exposure to bees where and when pesticides are applied.

The following BMPs can help promote the health and habitat of ground-nesting bees:

- For uncultivated land, leaving large undisturbed patches of land unmowed and untilled can provide nesting and forage sites.
- For uncultivated land, mowing at the highest cutting height possible (minimum of 8-10 inches if possible) can increase and diversify food sources.

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

D. Environmental Justice

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

One community which may experience disproportionate exposure to pesticides is agricultural farmworkers. EPA has conducted assessments of risks to farmworkers who handle oxyfluorfen or may be exposed to oxyfluorfen during occupational handling activities (*e.g.*, mixing, loading, application) and has found risks of concern from oxyfluorfen to farmworkers. EPA has also evaluated the risks to people living adjacent to treated fields, which may include many farmworker families, and has not found risks of concern for oxyfluorfen. In addition, the labels presently contain preventative measures such as baseline PPE, defined as a single layer of clothing consisting of a long-sleeved shirt, long pants, shoes plus socks, and no respirator. Occupational post-application exposures for farmworkers are not anticipated as workers are not expected to re-enter treated areas following application. The Agency has committed resources and expertise to the development of specialized software and models that consider exposure to other types of possible bystander exposures and farmworkers as well as lifestyle and traditional dietary patterns among specific subgroups.

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 oxyfluorfen compared to the general population or who may otherwise be disproportionately affected by the use of oxyfluorfen as a pesticide. EPA requested comments during the public

comment period for the 2021 PID but did not receive any comments concerning environmental justice. The Agency continues to seek information regarding environmental justice during the comment period for this amended PID and will consider those comments before issuing an interim decision.

E. Tolerance Actions

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

> (a) General. Tolerances are established for residues of oxyfluorfen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene].
>
> (c) Tolerances with regional registrations. Tolerances with regional registrations, are established for residues of oxyfluorfen, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only oxyfluorfen [2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene].

The Agency is proposing to convert the tolerance for bananas to an import-only tolerance as bananas are no longer a use pattern on any registered product. In addition, the Agency is revising the oxyfluorfen tolerances to include updated crop group definitions and updated tolerance levels (based on residue data submitted in response to the RED document). The tolerance revisions are presented in Table 7.

Table 7. Oxyfluorfen proposed tolerance revisions for registration review.			
Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments [*Correct Commodity Definition*]
40 C.F.R. § 180.381(a). General			
Bananas	0.05	convert to import only tolerance	there are no longer active registrations for bananas in the United States
Cattle, fat	0.01	remove	Based on recalculated dietary burden, these tolerances fall under 40 C.F.R. § 180.6(a)(3) regarding secondary residues in livestock commodities
Cattle, meat	0.01	remove	
Cattle, meat byproduct	0.01	remove	
Cotton gin-byproducts	--	0.3	Based on OECD calculator using the submitted cotton study
Egg	0.03	0.03	Based on recalculated dietary burden, tolerance for egg will remain
Fruit, pome, group 11-10	--	0.05	Crop group revision/ Commodity definition correction
Fruit, pome, group 11	0.05	remove	
Fruit, stone, group 12-12	--	0.05	Crop group revision/ Commodity definition correction.
Fruit, stone group 12	0.05	remove	
Goat, fat	0.01	remove	Based on recalculated dietary burden, these tolerances fall under 40 C.F.R. § 180.6(a)(3) regarding secondary residues in livestock commodities
Goat, meat	0.01	remove	
Goat, meat byproduct	0.01	remove	
Hog, fat	0.01	remove	
Hog, meat	0.01	remove	
Hog, meat byproduct	0.01	remove	
Horse, fat	0.01	remove	
Horse, meat	0.01	remove	
Horse, meat byproduct	0.01	remove	
Milk	0.01	remove	
Nut, tree, group 14-12	-	0.05	1) Commodity definition correction / Crop group revision. 2) Separate tolerance for pistachio is not needed as it is included in Nut, tree, group 14-12.
Nut, tree, group 14	0.05	remove	
Pistachio	0.05	remove	
Pepper, bell	--	0.05	Based on the submitted pepper study
Pepper, non-bell	--	0.05	
Peppermint, fresh leaves	--	0.05	Commodity definition correction.
Peppermint, tops	0.05	remove	
Poultry, fat	0.2	0.2	Based on recalculated dietary burden, tolerance for poultry fat will remain Poultry meat and meat byproducts fall under 40 C.F.R. § 180.6(a)(3) regarding secondary residues in livestock commodities
Poultry, meat	0.01	remove	
Poultry, meat byproduct	0.01	remove	
Sheep, fat	0.01	remove	
Sheep, meat	0.01	remove	

Table 7. Oxyfluorfen proposed tolerance revisions for registration review.			
Sheep, meat byproduct	0.01	Remove	
Spearmint, fresh leaves	--	0.05	Commodity definition correction.
Spearmint, tops	0.05	remove	
40 C.F.R. § 180.381(c) Tolerances with regional registrations			
Chickpea, dry, seed	--	0.05	Commodity definition correction.
Chickpea, seed	0.05	remove	
Grass, forage, fodder and hay, group 17, forage	--	0.05	Commodity definition correction.
Grass, forage	0.05	remove	
Grass, forage, fodder and hay, group 17, hay	--	0.05	Commodity definition correction.
Grass, hay	0.05	remove	
Grass, forage, fodder and hay, group 17, seed screening	--	0.05	Commodity definition correction.
Grass, seed screening	0.05	remove	

F. Data Requirements

The Agency has identified the need to replace the honey bee larval chronic oral toxicity study (SS-1314) and the honey bee adult chronic oral toxicity study (SS-1313), which the registrant previously submitted under GDCI-111601-1515, because those studies did not fulfill the study requirements. In addition, based on the risk assessments for terrestrial vertebrates which were called in the same GDCI must now be submitted to better characterize the risks to these organisms and especially bees. The registrant must also submit the honey bee larvae acute oral toxicity study (SS-1312), but registrants may fulfill that data requirement with either a separate submission or an adequate chronic larval bee oral study that includes lethality as an endpoint. The Agency is also working with the registrant to schedule a foliar dislodgeable residue from the same GDCI study for which a waiver request has been denied.

The Agency intends to call in a subchronic inhalation study to better characterize the human health risk from inhalation by bystanders and handlers using its authority under FIFRA.

The analytical reference standard for oxyfluorfen had an expiration of October 3, 2022 and a replacement must be submitted to EPA's National Pesticide Standards Repository (https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository).

V. NEXT STEPS AND TIMELINE

A Federal Register Notice will announce the availability of the oxyfluorfen Amended PID and open a 60-day comment period. The Agency may issue an ID after the close of this comment period if appropriate or may proceed to a final registration review decision for oxyfluorfen

without previously issuing an ID. However, a final registration review decision for oxyfluorfen will only be made after EPA (1) completes effects determinations, and (2) meets EPA's ESA section 7 obligations (*e.g.*, initiates any necessary consultation with the Services, consistent with ESA section 7(a)(2)). The Agency also intends to make a determination on its EDSP obligations under FFDCA section 408(p). Any product cancellations that may result based on the restrictions in the ID would also have to be announced in a 6(f) Federal Register Notice announcing the intent to cancel the products, subject to a 180-day public comment period.

Appendix A: Summary of Proposed Actions for Oxyfluorfen

Registration Review Case #: 2490
PC Code:111601
Chemical Type: herbicide
Chemical Family: diphenyl-ether
Mechanism of Action: protoporphyrinogen oxidase (PPO) inhibition

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment
Adults 50-99	Dietary	Ingestion	Chronic	Cancer	• Application rate reductions • Reduce maximum number of applications • Reduce maximum annual application rates • Require vegetated filter strips • Require mandatory spray drift measures • Restrict application methods • Require banded application for orchards/vineyards	
Residential Handlers	Spray and granular application	Dermal absorption	Cancer	Cancer	• Use deletion	
Occupational Handlers – backpack sprayers	Spray applications	Dermal absorption	Short- and intermediate-term cancer	Cancer	• Require additional PPE • Require application rate reductions • Restrict application method	Liquid formulations only

Occupational Handlers – mechanically pressurized handguns	Spray applications	Dermal absorption	Short- and intermediate-term cancer	Cancer	• Restrict application method	Liquid formulations only
Occupational Handlers – hand application of granules	Granular applications	Dermal absorption	Short and intermediate term	Cancer	• Restrict application method	
Occupational handler - chemigation	Chemigation applications	Dermal absorption	Cancer		• Restrict application method	
Occupational post-application Activity-handset irrigation	Residues on treated site	Dermal absorption	Cancer		• Reduce application rate	Ornamentals only
Pollinators	Residues on treated site	Ingestion	Chronic	Chronic oral – bee larvae and adults	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Precautionary statements • BMPs for pollinator protection	Only for uses with > 2 lb/acre rate
Terrestrial Plants	Aerial application	Foliar absorption	Acute	Growth, weight, biomass	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Require banded application for orchards/vineyards	

					• Spray drift buffers to conservation areas	
Birds, reptiles & aquatic phase amphibians	Residues on treated site	Ingestion	Chronic	Growth, reproduction	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Require banded application for orchards/vineyards • Spray drift buffers to conservation areas	
Mammals	Residues on treated site	Ingestion	Chronic	Growth, reproduction	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Require banded application for orchards/vineyards • Spray drift buffers to conservation areas	
Aquatic plants	Water	Foliar absorption	Acute	Growth	• Require application rate reductions • Require enforceable spray	

					drift reduction language • Spray drift advisory language • Require VFS • Surface water advisory language • Require banded application for orchards/vineyards • Do not apply during rain statement	
Freshwater fish & aquatic phase invertebrates	Water	Ingestion Respiration	Chronic	Growth	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Require VFS • Surface water advisory language • Require banded application for orchards/vineyard • Do not apply during rain statement	
Estuarine/marine fish	Water	Ingestion respiration	Chronic	Growth	• Require application rate reductions • Require enforceable spray drift reduction language	

					• Spray drift advisory language • Require VFS • Surface water advisory language • Require banded application for orchards/vineyards • Do not apply during rain statement	
Freshwater invertebrates	Water	Ingestion respiration	Chronic	Growth	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Require VFS • Surface water advisory language • Require banded application for orchards/vineyards • Do not apply during rain statement	
Estuarine/marine invertebrates	Water	Ingestion Respiration	Chronic	Growth	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language	

					• Require VFS • Surface water advisory language • Require banded application for orchards/vineyards Do not apply during rain statement	
Benthic invertebrates	Water Sediment	Ingestion Respiration	Chronic	Growth	• Require application rate reductions • Require enforceable spray drift reduction language • Spray drift advisory language • Require VFS • Surface water advisory language • Require banded application for orchards/vineyards • Do not apply during rain statement	

Appendix B: Proposed Labeling Changes for Oxyfluorfen Products

<table>
<tr><th>Description</th><th>Proposed Label Language for Oxyfluorfen Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>All Technical Products</td><td></td></tr>
<tr><td>Directions for Use</td><td>In order to help ensure that future new uses do not increase dietary risk, Label will include the following statements: “This product will not be used to formulate and end-use product with a limit single application rate greater than 1.5 lb ai/acre or an annual maximum application rate of 2 lb ai/acre.” “Not for formulation into residential use products.”</td><td></td></tr>
<tr><td></td><td>All End Use Products</td><td></td></tr>
<tr><td>Mechanism of Action Group Number</td><td>Note to registrant:
Include the name of the ACTIVE INGREDIENT in the first column
Include the word “GROUP” in the second column
Include the MODE/MECHANISM/SITE OF ACTION CODE in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is SITE OF ACTION)
Include the type of pesticide (i.e., HERBICIDE) in the fourth column.
<table><tr><td>OXYFLUORFEN</td><td>GROUP</td><td>14</td><td>HERBICIDE</td></tr></table></td><td>Front Panel, upper right quadrant.
All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.</td></tr>
<tr><td>Use Deletion</td><td>Remove any residential use sites from all labels. Residential use sites include the application to driveways, brick walks, sidewalks, patios, parking areas, along paths, fences, curbs and gutters; around buildings; and in decorative rock or bark landscapes; edging lawns; around the base of established trees, shrubs and ornamental plants around residences, playgrounds, parks, game fields, and ornamental beds.</td><td></td></tr>
<tr><td>Endangered Species Protection Requirements for all products</td><td>“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,</td><td>Directions for Use, under the heading “ENDANGERED SPECIES</td></tr>
</table>

Description	Proposed Label Language for Oxyfluorfen Products	Placement on Label
	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."	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: https://www.epa.gov/pesticide-incidents or call (registrant provided phone number)"	Directions for Use, under the heading "REPORTING ECOLOGICAL INCIDENTS"
Additional PPE For mixing and loading of all products with liquid formulations which allow aerial application to any of the following crops: agricultural fallow, idle land, conservation reserve program lands, uncultivated areas, clover, corn, cotton, chickpeas, grasses grown for seed, mint, nonagricultural uncultivated areas/soils, shelterbelts, and soybeans, forestry, and Christmas trees	All mixers/loaders must wear: • Chemical-resistant gloves The chemical resistant gloves statement must be consistent with language in the Label Review Manual for the formulation of each product (https://www.epa.gov/pesticide-registration/label-review-manual)	Precautionary Statements, in a section labeled "Personal Protective Equipment (PPE)
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. Remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and

Description	Proposed Label Language for Oxyfluorfen Products	Placement on Label
		Agricultural Use Requirements, if applicable
Water Protection Statements For all products delivered via liquid spray applications to crops that do not require production in flooded fields or streams.	**WATER PROTECTION STATEMENT** "Do not apply during rain."	Directions for Use – Under the Restriction or Use Restriction Section
Surface Water Advisory Language	Language consistent Chapter 8, Section F of the Label Review Manual "*Surface Water Advisories*" should be included on all labels: "This product may impact surface water quality due to runoff of rainwater. This is especially true for poorly draining soils and soils with shallow ground water. This product is classified as having a medium potential for reaching both surface water and aquatic sediment via runoff for several months or more after application. 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 oxyfluorfen from runoff water and sediment. Runoff of this product will be reduced by avoiding applications when rainfall or irrigation is expected to occur within 48 hours."	Environmental Hazards
Non-target Organism Advisory: Plants	"NON-TARGET ORGANISM ADVISORY: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."	Environmental Hazards
Maximum Application Rates and Number	Set the maximum annual application rates and number of applications for the following crops to: • beans: maximum of 2 applications per year; maximum single application rate of 0.25 lb a.i./acre; annual maximum application rate of 0.5 lb a.i./acre • berries: maximum of 1 application per year; annual maximum application rate of 1 lb a.i./acre	Directions for Use

Description	Proposed Label Language for Oxyfluorfen Products	Placement on Label
	• cacao: maximum of 1application per year; annual maximum application rate of 1.1 lb a.i./acre • coffee: maximum of 1 application per year; annual maximum application rate of 1.1 lb a.i./acre • corn: maximum of 1 application per year; annual maximum application rate of 0.6 lb a.i./acre • cotton: maximum of 1 application per year; annual maximum application rate of 0.5 lb a.i./acre • forestry: maximum of 1 application per year; annual maximum application rate of 1.4 lb a.i./acre • soybeans: maximum of 2 applications per year; annual maximum application rate of 1 lb a.i./acre • field-grown ornamentals: annual maximum application rate of 2 lb a.i./acre For all uses not specified above, set the maximum single application rate to 1.5 lbs a.i./acre, and annual maximum of 2.0 lbs a.i./acre	
Backpack Sprayers	In the directions of use for any product which can be applied with a backpack sprayer: "Do not use backpack sprayers for foliar applications. All applications from backpack sprayers applications should be directed at the ground."	Directions for Use
Orchard/ Vineyard Crops, Other than Almonds, Pistachios, and Walnuts	In the directions for use specific to any orchard or vineyard crop: "Spray must be applied in a band not more the 30% of the row width." "If applications are being made with backpack sprayers, the finished spray solution should not be applied at more than 0.05 lb-ai/gal."	Directions for Use
Almonds, Pistachios, and Walnuts	In the directions for use specific to almonds, pistachios, and walnuts: "For pre-emergence sprays: Spray must be applied in a band not more the 30% of the row width. For post-emergence (non-dormant) application for orchard floor cleanup before harvests: A single broadcast application of 0.25 to 0.5 lb-ai/acre" "If applications are being made with backpack sprayers, the finished spray solution should not be applied at more than 0.05 lb-ai/gal. No more than 1 application of oxyfluorfen can be made per year."	Directions for Use
Forestry and Christmas Tree Farms	In the directions for use specific to forestry uses and Christmas tree farms: "If applications are being made with backpack sprayers, the finished spray solution should not be applied at more than 0.10 lb-ai/gal."	Directions for Use

Description	Proposed Label Language for Oxyfluorfen Products	Placement on Label
Landscape Trees, Shrubs and Bushes	In the directions for use specific to any application landscape trees, shrubs or bushes: "Do not apply using backpack spray equipment."	Directions for Use
Removal of application method - Chemigation	"Oxyfluorfen may not be applied through irrigation systems." Remove any instructions pertaining to the application of oxyfluorfen through irrigation systems	Directions for Use
Mechanically Pressurized Handguns	"Do not make applications using mechanically pressurized handgun equipment."	Directions for Use
Granular Products	In the directions for use of all granular products: "Do not apply granules by hand."	Directions for Use
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: • Developing 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. • Avoiding applications during bloom. • Avoiding applications when bees are actively foraging. • Applying pesticides in the evening or early morning hours when fewer bees are foraging. • Using 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. • Using integrated pest management to prevent or mitigate potential negative effects to pollinators and consider multiple management options before resorting to a pesticide application. • Avoiding applying pesticides to plants in bloom, including flowering weeds. • Mowing understory weeds or cover crops in orchards and vineyards can prevent flowering of weeds and reduce exposure to bees where and when pesticides are applied. The following BMPs can help promote the health and habitat of ground-nesting bees: • For uncultivated land, leaving large undisturbed patches of land unmowed and untilled can provide nesting and forage sites.	Directions for Use – Under the Best Management Practices header after Resistance Management section

Description	Proposed Label Language for Oxyfluorfen Products	Placement on Label
	• 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 ."	
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action **Applies to all products delivered via liquid spray applications**	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use

Description	Proposed Label Language	Placement on Label
Spray Drift Management Application Restrictions for products that are applied as liquid with aerial equipment (except Ultra Low Volume/ULV applications for mosquitocides)	**"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 coarse 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 15 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. • If the windspeed is 10 miles per hour or less, applicators must use a minimum of ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use a minimum of ¾ swath displacement upwind at the downwind edge of the field. • If max wind speed is up to10 mph, use: The boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • If max wind speed is up to 15 mph, use: When the windspeed is between 11-15 miles per hour, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, 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. • "Do not apply within 150 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).	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, before and use-specific directions for use.

	Applications made to agricultural fields located within a conservation area are acceptable when made in accordance with an approved pesticide management plan for the conservation area and the restrictions on this label. A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (e.g., trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria: o The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area. o The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage is sufficiently dense such that the aquatic habitat is not visible on the upwind side at the time of application. o The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side. o The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application. o The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted. o The windbreak or shelterbelt must be maintained such that their functionality is not compromised. A manmade structure (*e.g.*, curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application."	
Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications – does not include orchard or vineyard uses	**"MANDATORY SPRAY DRIFT MANAGEMENT** **<u>Ground Boom Applications:</u>** • During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 15 miles per hour. • Wind speed and direction must be measured on location using a windsock or anemometer.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"

	• Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment. • Do not release spray at a height greater than 4 feet above the ground or crop canopy. • Applicators must select a nozzle and pressure that deliver coarse or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572). • Do not apply during temperature inversions 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 Management Application Restrictions for products that are applied as liquids and allow ground boom applications – orchard or vineyard uses only	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Ground Boom Applications:** • During application, the Sustained Wind Speed, as defined by the National Weather Service (standard averaging period of 2 minutes), must register between 3 and 15 miles per hour. • Wind speed and direction must be measured on location using a windsock or anemometer. • Wind speed must be measured at the release height or higher, in an area free from obstructions such as trees, buildings, and farm equipment. • Do not release spray at a height greater than 2 feet above the ground. • Applicators must select a nozzle and pressure that deliver coarse or coarser droplets in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572). • Do not apply during temperature inversions. • Do not apply within 50 feet of any conservation areas when wind is blowing toward the conservation area. Conservation areas include public lands and parks, national and state wilderness areas and wildlife refuges, national and state forests, and national and state grasslands. Any land between the conservation areas and the application area can be included in the buffer (including Conservation Reserve Program (CRP) and Agricultural Conservation Easement Program (ACEP) areas). Applications made to agricultural fields located within a conservation area are	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"

	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 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." o A 50% reduction in the wind-directional buffer distance required above can be made if a windbreak or shelterbelt (*e.g.,* trees or riparian hedgerows) between the application site and conservation area is present and meets the following criteria: o The windbreak or shelterbelt must be downwind between the pesticide application and the conservation area. o The windbreak or shelterbelt must have a minimum of one row of trees and/or shrubs that have foliage is sufficiently dense such that the aquatic habitat is not visible on the upwind side at the time of application. o The row(s) of trees and/or shrubs in the windbreak/shelterbelt must run the full length of the treated crop and must have foliage that is sufficiently dense such that the conservation area is not visible on the upwind side. o The height of the trees in the windbreak or shelterbelt must be at a height higher than the release height of the application. o The windbreak or shelterbelt must be planted according to local/regional/federal conservation program standards; however, no state or federally listed noxious or invasive trees or shrubs should be planted. o The windbreak or shelterbelt must be maintained such that their functionality is not compromised. A manmade structure (*e.g.,* curtain that is raised prior to application, building) can be used instead of a windbreak or shelterbelt. This structure must be downwind between the pesticide application and the conservation area, cover the entire distance of field adjacent to the conservation area, and higher than the release height of the application."	
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

	spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **RELEASE HEIGHT - Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* Higher release heights increase the potential for spray drift. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.	

	TEMPERATURE INVERSIONS Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **<u>Handheld Technology Applications:</u>** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Vegetated Filter Strips	"VEGETATIVE FILTER STRIPS For western irrigated agriculture, a vegetative filter strip is not required. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35). In all other states, construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds). Only apply products containing oxyfluorfen onto fields where a maintained vegetative filter strip of at least 30 feet exists between the field edge and down-gradient aquatic habitat. This minimum required width of 30 feet may be reduced or removed under the following conditions: • The vegetative filter strip requirement may be reduced from 30 feet to 15 feet if at least one of the following applies: o the area of application is considered prime farmland (as defined in 7 C.F.R. § 657.5).	Directions for Use

	○ conservation tillage is being implemented on the area of application. Conservation tillage is defined as any system that leaves at least 30% of the soil surface covered by residue after planting. Conservation tillage practices can include mulch-till, no-till, or strip-till. ○ a functional terrace system is maintained on the area of application. ○ water and sediment control basins for the area of application are functional and maintained, and/or ○ the area of application is less than or equal to 10 acres.	

Appendix C. Listed Species Assessment

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

Developing Approaches for ESA Assessments and Consultation for FIFRA Actions

In 2015, EPA, along with the Services—the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS)—and the United States Department of Agriculture (USDA) (referred to as "the agencies") released their joint Interim Approaches[88] 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.[89]

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.[90]

Consultation on Chemicals in Registration Review

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

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

malathion biological opinion[91] from FWS in February 2022 and a final biological opinion from NMFS on malathion, chlorpyrifos and diazinon in June 2022.[91] The Agency plans to implement both biological opinions according to the 18-month timeframes specified in the biological opinions.

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

EPA's New Actives Policy and the 2022 Workplan

In January 2022, EPA announced a policy[92] 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.*[93] This workplan reflects the Agency's most comprehensive thinking to date on how to create a sustainable ESA-FIFRA program that focuses on meeting EPA's ESA obligations and improving protection for listed species while minimizing regulatory impacts to pesticide users and collaborating with other agencies and stakeholders on implementing the plan.

On November 16, 2022, EPA released the *ESA Workplan Update: Nontarget Species Mitigation for Registration Review and Other FIFRA Actions*.[94] 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 actions. These measures are intended to reduce risks to nontarget organisms efficiently and consistently across pesticides with similar levels of risk. EPA expects that these mitigation measures may also reduce pesticide exposures to listed species.

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

Appendix D: Endocrine Disruptor Screening Program

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

The EDSP developed by EPA in 1998 includes human and wildlife testing for estrogen, androgen, and thyroid pathway activity and employs a two-tiered approach. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid pathways. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship for any estrogen, androgen, or thyroid effect. If EPA finds, based on that data, that the pesticide has an 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." (21 U.S.C. 346a(p)(6))[95].

Between October 2009 and February 2010, EPA issued Tier 1 test orders/data call-ins (DCIs) for its first list of chemicals ("List 1 chemicals") for EDSP screening and subsequently required submission of EDSP Tier 1 data for a refined list of these chemicals. EPA received data for 52 List 1 chemicals (50 pesticide active ingredients and 2 inert ingredients). EPA scientists performed weight-of-evidence (WoE) analyses of the submitted EDSP Tier 1 data and other scientifically relevant information (OSRI) for potential interaction with the estrogen, androgen, and/or thyroid signaling pathways for humans and wildlife.[96]

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

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

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

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

The EDSP Strategies Notice and the support documents are available on www.regulations.gov in docket number EPA-HQ-OPP-2023-0474. As explained in these documents, EPA is prioritizing its screening for potential impacts to the estrogen, androgen, and thyroid systems in humans, focusing first on conventional active ingredients. Although EPA voluntarily expanded the scope of the EDSP to screening for potential impacts to the estrogen, androgen, and thyroid systems in wildlife, EPA announced that it is not addressing this discretionary component of the EDSP at this time, taking into account its current focus on its comprehensive, long-term approach to meeting its Endangered Species Act obligations (See EPA's April 2022 ESA Workplan97 and November 2022 ESA Workplan Update[98]). However, EPA notes that for 35 of the List 1 chemicals (33 active ingredients and 2 inert ingredients), Tier 1 WoE memoranda99 indicate that available data were sufficient for FFDCA section 408(p) assessment and review for potential effects to the estrogen, androgen, or thyroid pathways for wildlife. For the remaining 17 List 1 chemicals, Tier 1 WoE memoranda made recommendations for additional testing. EPA expects to further address these issues taking into account additional work being done in concert with researchers within the EPA's Office of Research and Development (ORD).

As discussed in EPA's EDSP Strategies Notice and supporting documents, EPA will be using all available data to determine whether or what additional data are needed to meet EPA's obligations and discretionary commitments under FFDCA section 408(p). For some conventional pesticide active ingredients, the toxicological databases may already provide sufficient evaluation of endocrine potential for estrogen, androgen, and/or thyroid pathways and EPA will generally not need to obtain any additional data to evaluate those pathways. For instance, EPA has data for numerous conventional pesticide active ingredients on mammalian estrogen and androgen effects through either an acceptable two-generation reproductive study in accordance with the current guideline (referred to here as the updated two-generation reproduction study; OCSPP 870.3800 - Reproduction and Fertility Effects) or an extended one-generation

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

reproductive toxicity (EOGRT) study (OECD Test Guideline 443 - Extended One-Generation Reproductive Toxicity Study). In these cases, EPA expects to make FFDCA 408(p)(6) decisions for humans without seeking further estrogen or androgen data. However, as also explained in the EPA's EDSP Strategies Notice, where these data do not exist, EPA will assess available data for the conventional active ingredient to determine what additional data, if any, might be needed to assess the potential for impacts to estrogen, androgen, and/or thyroid pathways in humans. For more details on EPA's approach for assessing these endpoints, see EPA's EDSP Strategies Notice and related support documents.

Also described in the EPA's EDSP Strategies Notice is a framework that represents an initial approach by EPA to organize and prioritize the large number of conventional pesticides in registration review. For conventional pesticides that lack an updated two-generation reproduction study or an EOGRT study, EPA has used data from the Estrogen Receptor Pathway and/or Androgen Receptor Pathway Models to identify a group of chemicals with the highest priority for potential data collection (described in EPA's EDSP Strategies Notice as Group 1 active ingredients). For these cases, EPA sought in the FRN data and information in response to issuance of EPA's EDSP Strategies Notice to better understand the positive findings in the ToxCast™ data for the Pathway Models and committed to issuing DCIs to require additional EDSP Tier 1 data. For the remaining conventional pesticides (described in EPA's EDSP Strategies Notice as Group 2 and 3 conventional active ingredients), EPA committed to assessing the available data to determine what additional studies, if any, might be needed to assess the potential for impacts to endocrine pathways in humans. Oxyfluorfen was placed Group 3 due to the lack of bioactivity in the ToxCast™ data for the Pathway Models[100].

[100] *List of Conventional Registration Review Chemicals for Which an FFDCA Section 408(p)(6) Determination is Needed*; EPA-HQ-OPP-2023-0474-0002; https://www.regulations.gov/document/EPA-HQ-OPP-2023-0474-0002