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www.regulations.gov

Tau-fluvalinate

Interim Registration Review Decision
Case Number 2295

September 2020

Approved by: _____

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for tau-fluvalinate (PC Code 109302, case 2295), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on tau-fluvalinate can be found in EPA's public docket (EPA-HQ-OPP-2010-0915) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an ID for tau-fluvalinate so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). The Agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, "the Services") to improve the consultation process for threatened and endangered (listed) species for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although EPA has not yet fully evaluated risks to federally-listed species, the Agency will complete its listed species assessment and any necessary consultation with the Services for tau-fluvalinate prior to completing the tau-fluvalinate registration review. Likewise, the Agency will complete endocrine screening for tau-fluvalinate, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

Tau-fluvalinate is a synthetic pyrethroid insecticide and miticide registered for the control of a variety of pests in a number of agricultural, and non-agricultural and residential settings. Tau-fluvalinate does not have any indoor uses and is not used in wide-area mosquito control. Agricultural use sites include beehives and non-food use seed crops (carrots, brassica, cole crops) under a FIFRA Section 24c Special Local Need registration. Non-agricultural and

residential use sites include ornamentals (outdoor and container-grown, greenhouse, interior plantscapes, dip for cuttings), building surfaces/perimeters, and ant mounds. Products containing tau-fluvalinate were first registered in 1988 and were subject to the reregistration requirements of FIFRA. The tau-fluvalinate reregistration eligibility decision (RED) was completed in 2005.

Tau-fluvalinate is a member of the pyrethroids and pyrethrins class of insecticides, which share the same mode of action. These insecticides work by altering nerve function, causing paralysis in target insect pests (also called 'knockdown'), and eventually resulting in death. The Agency has determined that the pyrethroids and pyrethrins belong to a common mechanism group (http://www.regulations.gov; EPA-HQ-OPP-2008-0489-0006), and the Insecticide Resistance Action Committee (IRAC), composed of industry and university scientists, categorize them together in Mode of Action Group 3A since they all have the same site of action in affected insects. A screening-level cumulative risk assessment to assess human health risks from this group of pesticides was completed in 2011. This analysis did not identify cumulative risks of concern for children and adults. For further information, please see Section III. A 2. of this document and the cumulative risk assessment for the pyrethroids and pyrethrins, published on November 9, 2011 (available at http://www.regulations.gov; EPA-HQ-OPP-2011-0746).

In addition to this tau-fluvalinate ID, which describes the risk management approach for tau-fluvalinate determined to be necessary by the Agency, EPA previously published and opened a 60-day public comment periods on the following documents: *Tau-fluvalinate Proposed Interim Registration Review Decision,* which summarizes the risk assessment and proposes mitigation for tau-fluvalinate, *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*, which summarizes the ecological risk assessment approach and outlines EPA's proposed mitigation to address potential ecological risks for pyrethroids as a whole, and *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review*, which discusses the data and rationale underlying the Agency's decision to remove the 10X FQPA safety factor for the pyrethroids, including tau-fluvalinate. Those documents, as well as additional supporting documents, are located in the tau-fluvalinate docket and in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2010-0915 and EPA-HQ-OPP-2008-0331, respectively).

Having considered stakeholder comments on the tau-fluvalinate Proposed Interim Decision (PID), the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals,* and *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review*, EPA has consolidated the necessary human health and ecological risk management and mitigation measures in this interim decision document for tau-fluvalinate.

This document describes changes or updates since the tau-fluvalinate PID and is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why tau-fluvalinate is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Interim Registration Review Decision*, which

describes the mitigation measures necessary to address risks of concern and the regulatory rationale for EPA's ID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Updates since the Proposed Interim Decision was Issued

In May 2020, EPA published the PID for tau-fluvalinate. In this ID, there are several updates to what was proposed in the PID. The updates include changes made to the ecological risk mitigation as proposed in the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*. Label language has been revised for outdoor and agricultural uses to improve clarity and consistency. The vegetative filter strip (VFS) requirements for the agricultural uses of pyrethroids has been revised to add flexibility for users. For Western irrigated agriculture, EPA is allowing use of a sediment control basin in lieu of constructing and maintaining a VFS. In addition, the agency is adding an allowance for treatment areas of 10 acres or less to retain a 15-foot VFS. The Agency considers the use of sediment control basins for Western irrigated agriculture as effective as a VFS in retaining sediment and minimizing runoff, without the burden of constructing and maintaining a VFS. The allowance for treatment areas of 10-acres or less to retain a smaller VFS will alleviate some of the impact on small-scale operations, which may be disproportionately impacted by the expanded VFS requirements. See the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*, for a detailed discussion of the changes since the proposed mitigation. There have not been updates to the human health mitigation from what was proposed in the PID, nor any updates to the draft risk assessments (DRA). This ID thus finalizes the Agency's draft supporting documents: *Tau-fluvalinate: Draft Human Health Risk Assessment for Registration Review, Tau-fluvalinate: Updated Human Health Draft Risk Assessment in Support of Registration Review, Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins,* and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review,* which are available in the tau-fluvalinate public docket.

B. Summary of Tau-fluvalinate Registration Review

Pursuant to 40 CFR § 155.50, EPA formally initiated registration review for tau-fluvalinate with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of tau-fluvalinate.

- December 22, 2010 - The *Tau-fluvalinate Summary Document Registration Review: Initial Docket (Preliminary Work Plan (PWP)); the Tau-fluvalinate. Human Health Assessment Scoping Document in Support of Registration Review;* and the *Registration Review - Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Tau-fluvalinate* were posted to the docket for a 60-day public comment period.

- July 13, 2011 - The *Tau-fluvalinate Final Work Plan* (FWP) was issued. Seven comments were received on the PWP; however, the comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.

- February 1, 2012- A *Generic Data Call-In-Notice GDCI-109302-1096* for tau-fluvalinate was issued for Guideline 875.1700 (product use information).

- The registrants receiving *GDCI-109302-1096* are all members of the Residential Exposure Joint Venture (REJV), and the GDCI is satisfied. EPA has received and accepted data from companies who represent the REJV.

- November 29, 2012 - *A Generic Data Call-In Notice* (GDCI-109302-1031) for tau-fluvalinate was issued for data needed to conduct the registration review risk assessments. This GDCI is satisfied.

- November 29, 2016 - The Agency announced the availability of the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* (also referred to as the "Ecological Risk Assessment") and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* (also referred to as the "Rationale Document") in the tau-fluvalinate docket for a 60-day public comment period. The same FR Notice (81 FR 85952) also announced the availability of the risk assessments for several other pyrethroids, the Ecological Risk Assessment, and the Rationale Document in the individual pyrethroid dockets. The comment period was extended from January until July 2017.

    - During the public comment period, EPA received over 1,400 public comments across all the dockets of the pyrethroids.
    - Eight comments were received in the tau-fluvalinate docket (EPA-HQ-OPP-2010-0915) during the comment period. None of these comments addressed tau-fluvalinate specifically and all comments were posted to other pyrethroid dockets. The generic pyrethroid comments and the Agency's responses can be found in the *Joint Response from OPP's Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for the Pyrethroids and Pyrethrins Insecticides*, which can be found at http://www.regulations.gov (Docket # EPA-HQ-OPP-2008-0331). The comments did not change the ecological risk assessment or registration review timeline for tau-fluvalinate.

- September 2017 - The Agency announced the availability of *Tau-fluvalinate. Draft Human Health Risk Assessment for Registration Review and for Establishment of a Tolerance with No U.S. Registrations for Residues in Wine Grapes* for a 60-day public comment period. After a 30-day extension, the agency received public comments from two sources. Comments specific to the tau-fluvalinate human health assessment were submitted by Wellmark International. Comments regarding the human health risk

assessments for tau-fluvalinate, pyrethrins, and permethrin were submitted by the Environmental Working Group (EWG). The Agency's response to Wellmark International and EWG's comments can be found in the tau-fluvalinate registration review docket (EPA-HQ-OPP-2010-0915) in documents titled *Tau-fluvalinate: Response to Comments on the Data Evaluation Review (DER) for the Study, "A Nose-Only Inhalation Exposure Neurotoxicity Study of Tau-fluvalinate in Rats"* and *"Pyrethroids: Response to Comments from the Environmental Working Group (EWG)"*, respectively. The comments did not change the human health risk assessment or the registration review timeline for tau-fluvalinate.

- August 2019 – The Agency published *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review* on the webpage *https://www.epa.gov/sites/production/files/2019-08/documents/2019-pyrethroid-fqpa-caphra.pdf,* which discusses the data and rationale underlying the Agency's decision to remove the 10X FQPA safety factor for the pyrethroids, including tau-fluvalinate.

- November 12, 2019 – The Agency opened a 60-day public comment period for *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review*. This document is located in the Special Docket for Pyrethroids, Pyrethrins, and Synergists at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2008-0331). The following supporting documents are also available in this docket:

    - *Pyrethroids: Documentation of Systematic Literature Review Conducted in Support of Registration Review*
    - *cis-Permethrin: Statistical Analysis of PBPK Simulated Data for DDEF*
    - *Pyrethroids: Tier II Epidemiology Report*

- November 12, 2019 – The Agency opened a 60-day public comment period for the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals.* This document is located in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2008-0331). The comment period was extended an additional 30 days, due to multiple requests for an extension. The following supporting documents are also available in this docket:

    - *Joint Response from OPP's Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for Pyrethroids and Pyrethrins Insecticides*
    - *Updated Ecological Incidents Search for the Pyrethroids and Pyrethrins*
    - *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroids Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*
    - *Review of USDA's Assessment of the Benefits of Pyrethroids*

- *Review of Estimated Benefits of Pyrethroids in U.S. Agriculture from "The Value of Pyrethroids in U.S. Agriculture and Urban Settings" Prepared by AgInfomatics, LLC for the Pyrethroid Working Group*
- *Biological and Economic Analysis Division (BEAD) Summary of Public Comments Related to Benefits of Pyrethroids Submitted in Response to the Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins*
- *Review of "Economic Benefits of Pyrethroids Insecticides for Select California Crops," Report Prepared by ERA Economics for the Pyrethroids Working Group*
- *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito Adulticides in Support of Registration Review*
- *Readers Guide – Instructions for Commenting on the Registration Review Documents in the Pyrethroids Group*

- May 2020 – The Agency opened a 60-day public comment period for the tau-fluvalinate PID in the tau-fluvalinate registration review docket (EPA-HQ-OPP-2010-0915).
    - Along with the tau-fluvalinate PID, the following documents were also posted in the tau-fluvalinate registration review docket (EPA-HQ-OPP-2010-0915):
        - *Tau-fluvalinate: Updated Human Health Draft Risk Assessment for Registration Review*
        - *Tau-fluvalinate: Response to Comments on the Data Evaluation Review (DER) for the Study, "A Nose-Only Inhalation Exposure Neurotoxicity Study of Tau-fluvalinate in Rats"*
        - *"Pyrethroids: Response to Comments from the Environmental Working Group (EWG)"*

- September 2020 – The Agency has completed the tau-fluvalinate ID and will post it in the tau-fluvalinate registration review docket (EPA-HQ-OPP-2010-0915).
    - Along with the tau-fluvalinate ID, the following documents are also available in the registration review tau-fluvalinate docket (EPA-HQ-OPP-2010-0915):
        - *Pyrethroids: Health Effects Division Response to Public Comments Submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists [EPA-HQ-OPP-2008-0331]*, September 2020
        - *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*, September 2020

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

During the 60-day public comment period for the *Tau-fluvalinate Proposed Interim Registration Review Decision*, which opened on May 5, 2020 and closed on July 6, 2020, the Agency received 65 substantive comments from various stakeholders on the pyrethroids as a group and one comment specifically for tau-fluvalinate. The United States Department of Agriculture (USDA)

supported the overall proposed label language and mitigation but questioned the applicability of certain label language on one specific tau-fluvalinate product that is addressed in detail below. The Bay Area Clean Water Agencies (BACWA), San Francisco Bay Regional Water Quality Control Board (SFBRWQCB), National Association of Clean Water Agencies (NACWA), and California Stormwater Quality Association (CASQA) submitted comments relating to pyrethroids in general that were not specific to tau-fluvalinate.

Public comments pertaining to overarching pyrethroid ecological concerns and the Agency's responses are addressed in the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*. Public comments pertaining to overarching pyrethroid human health and pet health concerns and the Agency's responses are addressed in detail in the documents titled *Pyrethroids: Health Effects Division Response to Public Comments Submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists* (EPA-HQ-OPP-2008-0331). Both of these documents are available in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331) and in the tau-fluvalinate docket.

Comments Submitted by USDA (Docket ID: EPA-HQ-OPP-2010-0915-0042)

Comment: The USDA supports the tau-fluvalinate label updates and pollinator mitigation proposed by EPA. However, USDA notes that one product (EPA Reg. No. 2724-406) is registered for use in beehives to control parasitic mites, where it is applied via impregnated plastic strips. USDA claims that tau-fluvalinate is not toxic to bees in its solid state and asks EPA to confirm whether or not the proposed advisory bee statements are necessary for this product.

Agency Response: The pollinator labeling language is required for liquid formulation products for outdoor agricultural use. This labeling is intended to provide information to applicators to help reduce potential exposure to pollinators from applications related to crop production. The required labeling for those uses do not apply to the tau-fluvalinate impregnated plastic strips that are used in beehives and should not be added to those products. Clarification that this requirement is only for liquid formulations has been added to the required label language.

Comments Submitted by Pyrethrin Joint Venture and Various Registrants

Comment: Pyrethrin Joint Venture (PJV) (posting in the pyrethroids special docket, EPA-HQ-OPP-2008-0331), Bayer CropScience LP (posting in the deltamethrin docket, EPA-HQ-OPP-2009-0637), and Valent (posting in the esfenvalerate docket, EPA-HQ-OPP-2009-0301) submitted comments requesting additional time for label submission (following the Interim Decision) and/or additional time to complete implementation of updated labels on containers. Bayer and Valent request an additional 60 days for a total of 120 days for registrants to submit revised labels following the issuance of the Interim Decisions. In addition, the PJV and Valent requested 18-24 months following EPA's approval of these amended labels for registrants to begin selling and distributing product containers reflecting these new amended labels. PJV believes the 18-month implementation timeline to be in accordance with 40 CFR 152.130(c).

Agency Response: EPA thanks the submitters for their comments and has determined that an extension to the 60-day timeframe is acceptable based on the number of pyrethroid labels that will be revised and submitted to the Agency. EPA agrees to extend the label submission deadline to 120 days following the issuance of the IDs. The Office of Pesticide Programs is currently looking into the timing concerns raised related to label implementation (i.e., 40 CFR 152.130(c)) as an overall issue for the program and will consider the comments received before issuing a response.

II. USE AND USAGE

Tau-fluvalinate is a synthetic pyrethroid insecticide which acts to prevent sodium channels in an organism's neuronal membranes from closing, resulting in paralysis and eventual death. The Insecticide Resistance Action Committee (IRAC) categorizes tau-fluvalinate and other synthetic pyrethroids in mode of action (MOA) Group 3A, mainly for resistance management purposes.

Tau-fluvalinate is registered in the United States for outdoor uses in residential and commercial areas. In commercial and residential settings, it may be applied as a perimeter treatment, crack and crevice treatment, and directly to ant mounds. It is also registered for agricultural sites, including crops grown for seed, nursery production, and beehives. In agriculture, tau-fluvalinate may be applied via aerial or ground equipment. Formulations currently include liquids and impregnated materials. In landscape ornamentals and nursery settings, tau-fluvalinate may be applied as a spray or as a dip treatment. Tau-fluvalinate may also be used in beehives via an impregnated strip. Tau-fluvalinate does not have any indoor uses and is not used in wide-area mosquito control.

Nationally, residential consumers purchased around 100,000 pounds (lbs.) active ingredient (a.i.) of pyrethroid insecticides (as a group) for indoor use, and around 2 million lbs a.i. of pyrethroids for residential outdoor uses in 2016.[1] These amounts include household insecticides for use both indoor and outdoor scenarios (e.g., ant, cockroach, termite, fly control, and lawn and garden pest control), and pet products. There are no reports of usage of tau-fluvalinate.

Professional pest management companies used over 3 million lbs a.i. of pyrethroids for control of various nuisance and public health pests both in and around residential and commercial buildings.[2][3] Data do not report usage of tau-fluvalinate.

[1] Non-Agricultural Market Research Proprietary Data. 2017a. Studies conducted and sold by a consulting and research firm. Report on consumer pesticide usage. [Accessed June 2019.]
[2] Kline and Company. 2013. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2012. [Accessed June 2019.]
[3] Non-Agricultural Market Research Proprietary Data. 2017c. Studies conducted and sold by a consulting and research firm. Report on consumer pesticide usage. [Accessed June 2019.]

Tau-fluvalinate is used in horticultural nurseries and greenhouses, with 5,000 lbs a.i. applied in 2013 in the U.S.[4]

There are no national level tau-fluvalinate usage data available for beehives or specific to crops grown for seed.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the Agency's human health risk assessment is presented 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 tau-fluvalinate. For additional details on the human health assessment for tau-fluvalinate, see the *Tau-fluvalinate: Draft Human Health Risk Assessment for Registration Review and Establishment of a Tolerance with No U.S Registrations for Residues in Wine Grapes* and *Tau-fluvalinate: Updated Draft Human Health Risk Assessment for Registration Review*, which are available in the tau-fluvalinate registration review docket (EPA-HQ-OPP-2010-0915).

1. Pyrethroids FQPA Safety Factor Determination

The Food Quality Protection Act (1996) requires EPA to apply a ten-fold margin of safety (10X FQPA safety factor) for infants, children, and women of child-bearing age to account for potential juvenile sensitivity to pesticides, unless there are reliable data to reduce this safety factor. The Agency considers the FQPA safety factor as having two components: 3X assigned to pharmacokinetic (PK) differences and 3X to pharmacodynamic (PD) differences. In conjunction with registration review for the synthetic pyrethroid active ingredients, EPA previously used a 3X safety factor based on concerns for pharmacokinetic differences between adults and children. In 2019, EPA re-evaluated the need for an FQPA Safety Factor for human health risk assessments for pyrethroid pesticides. The previous conclusion that the PD contribution to the FQPA factor is 1X remains the same. Based on a review of the available guideline and literature studies as well as data from the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA) program, EPA concluded that the PK contribution to the FQPA factor is also 1X for adults, including women of child-bearing age, and children. Therefore, the Agency concluded the total FQPA safety factor for pyrethroids can be reduced to 1X for all populations. This conclusion was supported by two documents posted to the Agency's website and the Special Docket for Pyrethroids, Pyrethrins and Synergists (EPA-HQ-OPP-2008-0331): 1) "Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review," December 12, 2019; and 2) "Pyrethroids: Current Use and Potential Applications of a Generic Physiologically-Based Pharmacokinetic (PBPK) Model", December 17, 2019.

[4] Kline and Company. 2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities. [Accessed June 2019.]

2. Risk Summary and Characterization

There are no human health risks of concern for tau-fluvalinate.

An acute dietary (food and drinking water) assessment was conducted for tau-fluvalinate using the established tolerances for residues in honey and wine grapes. No acute dietary risks of concern were identified. No dermal endpoint of concern was identified for tau-fluvalinate therefore, all residential handler, residential post-application, occupational handler, and occupational post-application scenarios were based on inhalation exposures only. All inhalation scenarios resulted in margins of exposure (MOEs) greater than the level of concern (LOC) and are not of concern. Acute and short-term aggregate assessments were conducted, and no aggregate risks of concern were identified. Tau-fluvalinate is registered for use on carrots, brassica vegetables, and cole crops grown for seed and can be applied aerially or via groundboom. These application scenarios may result in spay drift exposure to bystanders. The agency conducted a quantitative non-occupational spray drift assessment and found no risks of concern at the edge of the treated field or past the field edge for all application scenarios.

Cumulative

The Agency has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity group (http://www.regulations.gov; EPA-HQ-OPP-2008-0489-0006) with respect to human health. A 2011 cumulative risk assessment for the pyrethroids and pyrethrins did not identify cumulative risks of concern. After all chemical-specific interim decisions have been completed for all pyrethroids and pyrethrins, an update of the cumulative risk assessment may be performed in association with registration review.

For more information on the human health risks conclusions for tau-fluvalinate, refer to the *Tau-fluvalinate: Draft Human Health Risk Assessment for Registration Review and Establishment of a Tolerance with No U.S Registrations for Residues in Wine Grapes* and *Tau-fluvalinate: Updated Draft Human Health Risk Assessment for Registration Review*, which are available in the tau-fluvalinate public docket (EPA-HQ-OPP-2010-0915).

3. Tolerances

There are two tolerances (honey and wine grapes) currently established under 40 CFR §180.427 for residues of tau-fluvalinate. The wine grape tolerance is not associated with a U.S. registration. No changes to the existing tolerances are needed at this time.

4. Human Health Data Needs

The Agency does not anticipate any further human health data needs for tau-fluvalinate registration review at this time.

The *GDCI-109302-1096* (for guideline 875.1700 product use information) was issued to registrants who formed the Residential Exposure Joint Venture (REJV) and is satisfied. EPA has received and accepted data from companies who represent the REJV.

B. Ecological Risks

The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of the pyrethroids and pyrethrins. EPA's 2016 *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* is a quantitative ecological assessment of nine cases: bifenthrin, cyfluthrin (beta-cyfluthrin), cyhalothrins (lambda-cyhalothrin and gamma-cyhalothrin), cypermethrin (alpha-cypermethrin and zeta-cypermethrin), deltamethrin, esfenvalerate, fenpropathrin, permethrin, and pyrethrins. The 2016 risk assessment was divided into five sections: risks from indoor "down the drain" uses;[5] risks from outdoor residential, commercial, turf, and nursery uses; risks from agricultural uses; risks from mosquito adulticide uses; and an assessment of risk to bees from agricultural uses of pyrethroids and pyrethrins. The Agency primarily focused on potential effects to aquatic organisms (for all uses) as well as terrestrial invertebrates (for agricultural uses). A quantitative assessment was conducted for these nine pesticides, for which the Agency had a relatively large amount of data. A companion piece, titled the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* or the Rationale Document, summarized potential risk concerns for the remaining pyrethroids and was published at the same time. The pesticides covered in the Rationale Document are: cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, esfenvalerate, and tetramethrin. The Rationale Document describes EPA's approach in using the quantitative assessment of the nine cases to serve as a basis for making risk management and regulatory decisions for all 23 affected pesticides currently undergoing registration review. Potential risks that were identified for the eight pyrethroids and pyrethrins assessed in 2016 were determined to be representative of the risks for the other pyrethroids also undergoing registration review. For additional details on the ecological assessment for the pyrethroids, see the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review*, which are available in the public docket.

For registration review, the Agency issued a single ecological risk mitigation proposal to address the potential ecological risks of concern for the 23 pyrethroids and pyrethrins, based on their common insecticidal mode of action and similar potential ecological risks of concern (*i.e.*, risk to aquatic invertebrates). This ecological risk mitigation proposal (*Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals* found in EPA-HQ-OPP-2008-0331) ensured a consistent approach to mitigating potential ecological risk and provided equity to stakeholders when implementing regulatory changes for pesticides in this group.

For tau-fluvalinate, potential risks of concern were identified for fish; however, the major potential risks of concern were for aquatic invertebrates (outdoor urban and agricultural uses) and terrestrial invertebrates (agricultural uses).

[5] "Down the drain" uses refer to indoor uses of pesticides that may be discharged as residues in domestic wastewater from indoor drains and then enter into publicly-owned treatment works, potentially resulting in releases to water bodies.

Terrestrial Invertebrates (honeybees)

Risks to bees were assessed for the agricultural uses of certain pesticides in the Agency's *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins*: bifenthrin, cyfluthrins, cyhalothrins, cypermethrins, deltamethrin, esfenvalerate, fenpropathrin, permethrin, and pyrethrins. The Agency's pollinator risk assessment was limited by the scarcity of bee data available across the pyrethroids/pyrethrins. Only honeybee (*Apis mellifera*) adult acute contact and acute oral toxicity studies are available for a select number of pyrethroids/pyrethrins. Based on the available data, risk quotients indicate a potential for adverse effects on bees from acute exposure from particular uses of pyrethroids/pyrethrins. Reported bee mortality incidents from spray drift support these risks of concern.

The Agency did not have sufficient information to assess chronic risk to bees or effects on honeybee colonies. EPA concludes that additional pollinator data are necessary to fully evaluate risks to bees from use of the pyrethroids/pyrethrins. The Agency has determined the full suite of pollinator studies for the pyrethroids/pyrethrins that may impact pollinators is necessary, where such data are not currently available. EPA will issue a Data Call-In (DCI) for the pollinator studies listed in Table 1.

Table 1: Pollinator Data Requirements

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

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

EPA will consider proposals from registrants to bridge pollinator datasets across pyrethroids. When available EPA will share any additional guidance on the underlying principles to consider when designing a bridging proposal in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2008-0331).

Once adequate pollinator data are received and reviewed, the Agency will reassess risk to pollinators and consider any additional mitigation changes for tau-fluvalinate.

1. Ecological and Environmental Fate Data Needs

As noted previously, additional pollinator data are necessary to fully evaluate risks to bees from use of tau-fluvalinate. EPA will issue a DCI for the necessary pollinator studies.

C. Benefits Assessment

Tau-fluvalinate can be used in various non-agricultural and residential sites to control numerous insect and mite pests. These include aphids, whiteflies, mites (e.g., clover mite, *Varroa* mite), thrips, leaf-feeding caterpillars (e.g., gypsy moth, tent moth, bagworm), ticks, fleas, ants, cutworms, armyworms, springtails, adelgids, mosquitoes, earwigs, and glassy-winged sharpshooters. While many of these insects are serious agricultural pests, they are likely to be of most concern in plant nurseries that supply trees to farmers and residences, as nursery operators want to provide a pest-free stock. Other pyrethroids, such as permethrin and bifenthrin, are among the likely alternatives with similar efficacy, as are carbamates such as carbaryl. Depending on which pest is considered, insecticides with other modes of action are also alternatives.

In seed crops, the targets pests are mites and lygus bugs, a piercing/sucking insect. Lygus bugs suck the sap from the plant tissue, including the developing seeds. Lygus bugs can severely damage the carrot seed crop by reducing seed yield and germination. Likely alternative chemicals that can be used to control lygus bugs are carbaryl and pyrethrins, though these insecticides lack the level of knockdown (paralytic) effect that tau-fluvalinate provides.

In beehives, a tau-fluvalinate-impregnated PVC resin formulation is used for the control of *Varroa* mites in honeybee colonies. This is a serious parasite of honeybees that reduces survival not only through direct feeding on bees but also through transmission of bee-specific viruses. Tau-fluvalinate cannot be used when honey is being produced. A limited set of alternatives is registered for mite control in the U.S. These include botanical products, such as thymol and eucalyptus oil, and synthetic pesticides, such as amitraz and coumaphos (an organophosphate). The efficacy of these compounds relative to tau-fluvalinate is unclear.

For additional information on the benefits of pyrethroids in general, refer to the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals* and the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*, also available in the public docket (EPA-HQ-OPP-2008-0331).

IV. INTERIM REGISTRATION REVIEW DECISION

A. Required Risk Mitigation and Regulatory Rationale

The Agency has determined that there are no human health risks of concern associated with the registered uses of tau-fluvalinate. While there are no human health risks of concern, tau-fluvalinate poses potential risks of concern for aquatic organisms (outdoor urban and agricultural

uses) and terrestrial invertebrates (agricultural uses). Mitigation to address risks to aquatic and terrestrial invertebrates will benefit the other taxa to the extent that there is any risk.

Outdoor urban uses of pyrethroids and pyrethrins are expected to result in potential risks of concern for aquatic invertebrates and fish as a result of urban runoff, spray drift or improper disposal of pyrethroid products. The potential for this risk to occur in the environment is supported by pyrethroid monitoring data from urban settings at levels that would be expected to result in potential risk to aquatic invertebrates. There has been a substantial concern from municipalities and states, particularly California, that urban pyrethroid usage adversely impacts water quality and, in the case of California, contributes to Total Maximum Daily Load (TMDL) exceedances. As a result, EPA has determined that measures to reduce the urban footprint of the pyrethroid group are necessary while still allowing flexibility for the user community and retaining the benefits of efficacious pest control.

Agricultural uses of the pyrethroids are expected to result in potential risks of concern to aquatic invertebrates and fish, primarily from runoff and spray drift. However, the benefits of pyrethroids in agricultural crop production outweigh the risks, and the necessary mitigation is expected to allow continued use of pyrethroids in agricultural settings while putting reasonable measures in place to reduce risk to non-target organisms from runoff and spray drift. The VFS requirement has been expanded in some cases but the Agency has added flexibility for Western irrigated agriculture and areas where soil conservation practices are being used. The Agency has also identified potential risks of concern to terrestrial invertebrates from the foliar applications of pyrethroids in agricultural areas. The Agency has determined that mitigation to address potential terrestrial invertebrate risks is necessary and has revised the terrestrial invertebrate Environmental Hazard Statement, adding information on stewardship and best management practices, promoting State Managed Pollinator Protection Plans (MP3s), and adding information on Pollinator Incident Reporting.

For a detailed discussion of the mitigation to address risks to aquatic and terrestrial invertebrates, refer to the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals* (EPA-HQ-OPP-2008-0331). In keeping with the Agency's current approach for insecticides and to address generic labeling requirements, EPA has determined that the addition of insect resistance management language to tau-fluvalinate labels and updates to glove and respirator language are necessary, where applicable.

1. Mitigation Measures for Outdoor Urban Uses

EPA has determined that mitigation measures for outdoor urban uses in residential and commercial settings (i.e., structural, turf, ornamental, nursery) are appropriate. To mitigate potential risks to aquatic organisms, it is the goal of the Agency to reduce runoff into water bodies from treated urban environments. By reducing the total amount of chemicals applied to an area, there is less potential for runoff into water bodies.

In order to reduce the potential load of pyrethroids in surface water attributed to urban uses, the Agency has determined that a reduction in distance from building foundations that can be treated

with pyrethroids from 10 feet to 7 feet is necessary. The Agency considered reducing the distance to 3 feet from the building foundation but found the 3-foot distance to be too restrictive to allow for effective use of pyrethroids throughout various building environments. Commenters have suggested limiting to this distance could impact the efficacy of treatments in certain areas. However, the Agency finds that in order to protect aquatic environments from risks posed by pyrethroids, a reduction in the application footprint of these pesticides is necessary. The Agency has determined it is necessary to reduce the allowable treated distance from 10 feet to 7 feet. The decrease in the area that can be treated at the same application rate amounts to a load reduction for each pyrethroid treatment, which represents a clear reduction in the amount of pyrethroid material that can be transported from a treated area. The Agency acknowledges that the biggest driver of pyrethroid transport is runoff from impervious surfaces rather than permeable surfaces. However, bare soil in cultivated areas near a home can still be transported to permeable surfaces and eventually enter surface waters during large storm events, which have been more prevalent in recent years. The purpose of this mitigation is load reduction, which is consistent with the kind of remedy built into TMDLs that California commenters say have become necessary because pyrethroid residues have caused them to declare some urban streams to be impaired.

The mitigation measures to reduce the perimeter treatment area and increase label clarity and consistency are intended to reduce the overall amount of pyrethroids in the urban environment that enters waterbodies and outdoor drainage systems. Specific measures are intended to ensure areas sprayed are permeable and less runoff-prone, reduce offsite-drift to waterbodies, increase distances between the area treated and waterbodies, as well as to reduce the potential for over-spraying. Although potential risks to aquatic organisms are expected to remain after the implementation of the measures, these required label changes are directionally correct with respect to reducing the amount of environmental exposure to pyrethroids in urban areas.

A. Statements for Outdoor Label Consistency and Clean-up

The Agency has determined that several label changes for consistency with other products and current policy (e.g., EPA's January 10, 2013 letter *Revisions to Environmental Hazard and General Labeling for Pyrethroid Non-Agricultural Outdoor Products*) is necessary. Labels must explicitly say whether particular products are to be applied outdoors only or both indoors and outdoors (as described in the previous section).

B. Revised General Outdoor Application Statement

The Agency is revising the general outdoor statement for all outdoor spray applications, which includes a maximum horizontal perimeter treatment of 7 feet from the base of a structure and a reduction from 3 feet to 2 feet for vertical applications to man-made structures. Current pyrethroid product labels specify the vertical and horizontal distance that may be treated with a pyrethroid; the vertical distance is measured from the ground upward and the horizontal distance is measured outward, away from the side of a man-made structure. Due to varying use sites and target pests, it is difficult to determine a single effective vertical and horizontal specification across all products. Insects need to come into contact or ingest a lethal dose of insecticide to be effectively controlled. However, reduction of the area that can be treated at the same application rate represents a load reduction for each pyrethroid treatment, which represents a clear reduction

in the amount of pyrethroid material that can be transported from a treated area to nearby waterbodies. The Agency has determined that the vertical application distance may extend up to 2 feet above ground level, rather than "3 feet above grade" as previously stated on labels. The horizontal application distance is restricted to 7 feet or less from the base of a man-made structure to pervious surfaces (e.g., grass, mulched groundcover, planted areas).

It is necessary that the following language replace the current general outdoor application statement:

> "All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:
>
> 1. Application to pervious surfaces such as soil, lawn, turf, and other vegetation;
>
> 2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (*e.g.*, soil, mulch, or lawn);
>
> 3. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure;
>
> 4. Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch;
>
> 5. Applications to vertical surfaces (such as the side of a man-made structure) directly above impervious surfaces (e.g., driveways, sidewalks, etc.), up to 2 feet above ground level;
>
> 6. Applications to vertical surfaces directly above pervious surfaces, such as soil, lawn, turf, mulch or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters."

The Agency also has determined that several specific mitigation measures to reduce the amount of runoff entering waterbodies and drainage systems are necessary. These include:

C. Spot Treatment Guidance Statement

- "Spot treatments must not exceed two square feet in size (for example, 2 ft by 1 ft. or 4 ft. by 0.5 ft.)."

D. Buffer from Water Statement

- "For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."

E. Water Protection Statements

- "Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur."

- "Do not allow the product to enter any drain during or after application."

- "Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment."

- "Do not apply or irrigate to the point of runoff."

F. Rain-Related Statements

- "Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours)."

- "Rainfall within 24 hours after application may cause unintended runoff of pesticide application."

The Agency has determined that mitigation measures for specific industry sectors to reduce off-site drift to waterbodies, increase distances between the area treated and waterbodies, as well as to reduce the potential for over-spraying are necessary. These include:

G. Statements for Ornamental/Recreational Turf

- "Do not apply when the wind speed is greater than 15 mph."

H. Statements for Outdoor Applications at Commercial Nurseries

- "Do not apply when the wind speed is greater than 15 mph."
- "Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572)."
- "For soil or foliar applications, do not apply by ground equipment within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."

The Agency has not assessed the impact the application wind speed restriction of no greater than 15 mph for these industry sectors; however, it is likely to decrease the number of days available for applications. However, high wind speeds interfere with proper dispersion of the pesticide, so relatively few applications may be affected by the prohibition.

The Agency does not know how efficacy may be impacted when droplet sizes are determined to be necessary for various insecticides in commercial nurseries. Pyrethroids are contact insecticides which require thorough coverage of the treated surface for effective pest control. University extension recommendations for contact insecticides such as pyrethroids are for

ASABE droplet sizes of fine to medium (Wolf and Bretthauer, 2009[6]). For foliar applications, insect control would likely be negatively impacted given the requirement for a medium or larger droplet size. Growers may be driven to use higher rates, mix with another insecticide, make additional applications per season, or increase application volume with larger droplet sizes to achieve the same efficacy they were able to with finer droplet sizes. However, many pyrethroid products are already subject to droplet size restrictions and buffers to water bodies, so impacts may be limited.

I. Statements for Crack and Crevice Treatments

- "Treat surfaces to ensure thorough coverage but avoid runoff."

- "To treat insects harbored in voids and cracks-and-crevices, applications must be made in such a manner to limit dripping and avoid runoff onto untreated structural surfaces and plants."

2. Mitigation Measures for Agricultural Use Products

Vegetative Filter Strip (VFS) Language

To reduce the amount of pyrethroids that enter waterbodies from runoff, EPA has determined that an increase to the existing vegetative filter strip (VFS) for agricultural products to 25 feet is necessary. EPA is concerned that sediment from agricultural land, with which pyrethroids bind, erodes into aquatic habitats exposing aquatic organisms susceptible to these pesticides. Pyrethroid monitoring data have been collected in water and sediment across the United States, with pyrethroid detections widespread that are directly related to agricultural uses. Data supported by the PWG and USDA have shown that VFS can be an effective method of reducing sediment transport into aquatic systems when designed with field specific factors and are well maintained. EPA concludes that the expansion of the VFS size will reduce risk to aquatic organisms. Based on public comments, EPA is now providing greater flexibility for Western irrigated agriculture and for areas where soil erosion control practices are already present. This flexibility will still reduce risk to aquatic organisms while better preserving the agricultural benefits pyrethroids provide.

Currently, all pyrethroid products, except etofenprox and pyrethrins, already have a 10-foot VFS requirement on the labels. VFSs are somewhat expensive to implement and maintain, and they must be maintained, or they will lose efficacy and cause channelized flow across the VFS after a few years. VFS are most effective at removing non-source point pollutants (e.g., pesticides) from runoff water sources. However, the effectiveness of a VFS is influenced by various land management practices (*e.g.*, flood and furrow irrigated fields) which may impact their utility. [7] The Agency has considered several additional sources of research which contextualize the

[6] Wolf, R., and S. Bretthauer. 2009. Droplet Size Calibration: A New Approach to Effective Spraying. Kansas State University Agricultural Experiment Station and Cooperative Extension Service. MF 2869. https://www.bae.ksu.edu/faculty/wolf/PDF/MF2869%20Droplet%20Calibration.pdf
[7] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175

benefits of VFS and has determined that increasing the use of VFS is appropriate mitigation to reduce pyrethroid residues in aquatic habitats.

Product labels are required to include a minimum 25-foot VFS. However, the 25-foot VFS requirement may be reduced to 15 feet if other soil conservation practices are used. Areas that qualify for a reduced 15-feet VFS are: areas considered prime farmland, areas where conservation tillage is implemented, areas with a functional terrace system, areas where water and sediment control basins are present and maintained, and areas that are less than or equal to 10 acres. Prime farmland, as defined in 7 CFR § 657.5, is not excessively erodible and pyrethroids binding to soil particles are less likely to enter adjacent waterways. Conservation tillage also works to reduce soil erosion, because remaining crop residues remain on the field. Terrace farming and the presence of water and sediment control basins also reduce soil erosion. Additionally, based on public comments on the Ecological Risk Mitigation Proposal, the VFS requirement is reduced to 15 feet, if the area of application is less than or equal to 10 acres—this reduces the impact on small-scale operations that are not primary contributors to runoff. These added criteria for a reduced VFS are intended to allow more flexibility for stakeholders.

Further, the Agency has determined that the burden on the arid parts of the country that rely on irrigation to grow agricultural crops (Western irrigated agriculture), to develop and maintain a VFS would be too impractical and therefore has determined that an increase of the existing 10-foot VFS in those areas is not necessary. A larger VFS would be more expensive to maintain, and runoff is less likely in these drier, more arid parts of the country. These areas would likely need irrigation to maintain a VFS, and on fields where water is managed carefully there is less likely to be runoff and erosion into a waterbody, so the existing 10-foot wide VFS is appropriate. These Western states, referred to as "Western irrigated agriculture" include WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35).

Since sediment control basins may be installed in Western irrigated agriculture to collect runoff and improve drainage, and may fulfill similar functions as a VFS, the Agency revised the VFS requirement for Western irrigated agriculture: if a functioning sediment control basin is already present, the Agency has determined that creating or maintaining a 10 foot VFS will no longer be necessary. In many situations a sediment control basin is as effective at controlling runoff and erosion for this type of agriculture. EPA decided to promote the use of sediment control basins for Western irrigated agriculture by allowing growers in these areas to use sediment control basins in lieu of creating and maintaining a VFS when pyrethroids are used. This exception will also reduce the amount of water Western growers will be required to use to maintain a VFS.

The following mitigation measures apply to all pyrethroids with agricultural uses (except pyrethrins). They are determined to be necessary and are separate from the spray drift buffer zones described later in this ID; spray drift buffer zones are still necessary if a vegetated filter strip is present. The vegetative filter strip requirement reads as follows:

"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 tau-fluvalinate onto fields where a maintained vegetative filter strip of at ***least 25 feet*** *exists between the field edge and where a down gradient aquatic habitat exists. This minimum required width of 25 feet may be reduced or removed under the following conditions:*
For Western irrigated agriculture, a maintained vegetative filter strip of at least 10 feet wide is 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).

- *For Western irrigated agriculture, if a sediment control basin is present, a vegetative filter strip is not required.*

In all other areas, a vegetative filter strip with a minimum width of 25 feet is required, unless the following conditions are met. The required vegetative filter strip may be reduced from 25 feet to 15 feet if at least one of the following applies:

- *The area of application is considered prime farmland (as defined in 7 CFR § 657.5).*
- *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 present, functional, and maintained.*
- *The area of application is less than or equal to 10 acres.*

For further guidance on vegetated filter strips, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services.
https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175

Potential VFS Mitigation Impacts

The impact of the VFS mitigation can be highly localized and depends critically on the size and shape of a field. When growing areas are adjacent to water bodies, vegetative filter strips may require growers to remove land from production thus decreasing revenue while imposing costs to maintain the filter strips. These impacts will disproportionally affect growers producing crops from small acreage fields. As a result of comments on the proposed mitigation, the Agency will allow application on areas of 10 acres or less to maintain a VFS of 15 feet instead of 25 feet. The reduction in VFS size for areas of application 10 acres or less is intended to lessen the burden on small scale agricultural practices which will likely be using less pyrethroids than larger farms and agricultural operations.

Estimates of losses from increasing the size of the VFS for the 10th percentile and the median field size by crop are available in EPA document "Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroid Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks." These impact estimates vary widely by crop. As an example for a smaller crop on a smaller field, the 25 foot VFS loss estimate for the 10th percentile cabbage field is almost $1,800 per acre, although the 10th percentile field size is only 0.2 acres. The highest losses estimated were for strawberries and peppers with losses of almost $3,500 per acre on the median strawberry field, and over $1,300 per acre for the median pepper field from an increase in the VFS to 25 feet, and much higher losses for smaller fields. In general, increasing the VFS will have higher losses per acre for relatively high value crops, like strawberries, peppers, pears, celery and apples. For high acreage crops, the impacts of increasing the VFS is smaller on a per acre basis, because the per acre value of the crop is lower and fields tend to be larger. These losses are only estimates and would not apply to fields where an increase in the width of the VFS is not needed.

In addition to any reduced crop production, growers would need to manage the space taken out of production and put into a VFS. Costs would differ across states and regions, and also vary according to the size and shape of the field. In addition to the cost of establishing the VFS, the cost of annual maintenance must also be considered. Yearly maintenance costs are estimated to be $40 to $240 per acre (for four mowing or weed control applications). Maintenance costs could be higher if additional operations are required such as additional mowing or weed control expenses, reseeding of disturbed areas, or regrading of the filter strip with reseeding if sediment deposition were to jeopardize its function.[8]

These additional costs could lead growers to substitute an alternative insecticide to replace pyrethroids. If the necessary mitigation prevent growers from using pyrethroids, they will most likely replace pyrethroid applications with other insecticides, such as organophosphates and carbamates, which could lead to declining yields and/or increased production costs for growers if the alternatives are less effective, more expensive or not available.

Spray Drift Reduction Measures

Most pyrethroids and pyrethrins labels currently have spray drift language to reduce the potential for the pesticides to drift off-target. EPA has determined that label clarifications to bring all labels up to date with the latest existing spray drift language, to reduce off-target spray drift and establish a baseline level of protection that is consistent across all affected products for this interim decision are necessary. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the Agency is not making an endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use areas of the pyrethroids.

[8] Lynch and Tjaden, 2003 and Solano and Yolo Co. Resource Conservation. Dist., 2006

The Agency has determined that the following spray drift mitigation language to be included on all product labels for the pesticide addressed in this interim decision is necessary. The required spray drift language is mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. In addition, the Agency is providing language that will allow the registrants to standardize all advisory spray drift language on the product labels (see Appendix B for required advisory language). Registrants must ensure that any existing advisory language left on labels does not contradict or modify the mandatory spray drift statements required in this interim decision once effective.

Required Statements for Aerial Applications

- "Do not release spray at a height greater than 10 feet above the vegetative canopy, unless a greater application height is necessary for pilot safety.
- Applicators are required to select nozzle and pressure that deliver a medium or coarser droplet size (ASABE S641).
- Do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, 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 ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- Do not apply during temperature inversions."

Ground Boom Applications

- "User must only apply with the nozzle height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy.
- Applicators are required to select nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572).
- Do not apply when wind speeds are sustained above 15 miles per hour at the application site.
- Do not apply during temperature inversions."

EPA does not expect the requirements for release height to impact users since they largely correspond to current practice and recommendations. Due to the varying use sites and target pests of pyrethroids it is difficult to assess the impacts of a droplet size restriction across all crops. Components of applications, including droplet size, are complex, but essentially insects need to come into contact with, or ingest, a lethal dose of insecticide to be effectively controlled which requires proper coverage throughout the plant. Pyrethroids are contact insecticides and require a certain amount of coverage for efficacy. For foliar applications, insect control would likely be negatively impacted by requiring a medium droplet size or larger. Growers may be driven to use higher rates, mix with another insecticide, make additional applications per season, or increase gallons applied per acre with larger droplet sizes to achieve the same efficacy they were able to with finer droplet sizes.

The application wind speed restriction of no greater than 15 mph for ground applications and the prohibition on applications during temperature inversions will decrease the number of days available during the growing season for applications and thus result in additional burdens to the grower, lack of pest control, and potentially yield loss depending on the crop. Because such weather conditions are variable, growers may be unable to apply when planned, but may also not be able to apply alternatives if, for example, tanks are already mixed with pyrethroids. Moreover, temperature inversions may be highly localized, and growers or applicators may not be aware they exist.

If the mitigation prevents growers from using pyrethroids, they will most likely replace pyrethroid applications with other insecticides, such as organophosphates and carbamates, which could lead to declining yields and/or increased production costs for growers if the alternatives are less effective, more expensive or not available.

Required Updates to Spray Drift Buffers

In addition to the spray drift mitigation measures above, EPA is updating the buffers to water already on labels. The following revised language reflects current spray drift reduction language limiting the amount of spray drift that enters waterbodies. These required clarifications will establish a baseline level of protection for waterbodies against spray drift that is consistent across all products affected by this interim decision. Reducing the overall amount of spray drift that reaches waterbodies will reduce the extent of environmental exposure and risk to aquatic organisms. All pyrethroids labels currently require these buffers to water, except for pyrethrins and etofenprox products. As mentioned previously, pyrethrins are less persistent than the synthetic pyrethroids in most environments, and as such they also do not have the monitoring detects as other chemicals in this group. The Agency is not requiring these spray drift buffers to water for products containing pyrethrins. However, products containing etofenprox do not currently contain these spray drift buffers to water and based on the potential risks identified in the assessment for etofenprox EPA is requiring the addition of these spray drift buffers to those labels. Required label updates encompass the following statements:

- "For ground applications, do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).
- For non-ultra low volume (ULV) aerial applications, do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).
- For ULV aerial applications, do not apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."

Many pyrethroid products are already subject to droplet size restrictions and buffers to water bodies, so impacts may be limited. As with VFS, impacts could include yield losses in untreated portions of fields.

3. Pollinator Risk Mitigation

Although the Agency has identified potential acute risks of concern to bees and other terrestrial invertebrates from use of the pyrethroids/pyrethrins, risk to invertebrates is expected from use of insecticides, in general. The potential acute risk to bees is considered along with the benefits of pyrethroids/pyrethrins in agriculture. Pyrethroids/pyrethrins benefits were assessed in the *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroid Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*. Benefits include the following:

1) inexpensive, effective, and broad-spectrum pest control;
2) importance in resistance management programs in rotation with other insecticides;
3) convenience and ease of use due to short restricted entry intervals; and
4) effective management of key pests in crops such as alfalfa, cotton, corn, wheat, rice, soybean, sunflower, tree nuts, citrus, blueberries, grapes, and many vegetables.

Alternatives for pyrethroids/pyrethrins, in general, include organophosphates, carbamates and/or neonicotinoid insecticides. These alternatives have their own risk and resistance issues.

In order to educate pesticide users on the importance of pollinator protection and stewardship, the Agency has determined that addition of the following labeling elements to pyrethroids/pyrethrins products formulated for outdoor agricultural use are necessary:

a) updated pollinator environmental hazards language;
b) information on pollinator stewardship/best management practices;
c) information on state managed pollinator protection plans; and
d) information on pollinator incident reporting.

a. Pollinator Environmental Hazard

EPA has determined that expansion of the existing Pollinator Environmental Hazard language to include a statement referring the reader to the spray drift management section of the label is necessary. The revised statement serves to warn users of potential risk to bees and pollinating insects from outdoor foliar applications to agricultural crops as well as to educate users on the importance of spray drift management. This language is only required for pyrethroid and pyrethrins labels with foliar agricultural uses and excludes products formulated for residential use and Ultra Low Volume (ULV) wide area mosquito control applications, which will be indicated in the label clarifications column of the label table.

The following sentence is required to be added to the existing Pollinator Environmental Hazard on the label:

> *"Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms."*

b. Pollinator Stewardship – Promoting Pollinator Best Management Practices

In addition to establishing both advisory and compulsory language for product labels, EPA's registration review process provides an opportunity to inform stakeholders and the general public

about opportunities to minimize potential ecological risks and promote pollinator health more generally. Beyond the necessary mitigation measures above, voluntary stewardship activities and use of best management practices (BMPs)[9] to protect pollinators can be effective in further reducing pesticide exposure to non-target organisms. Examples of these activities include:

- promoting the creation of additional pollinator habitat;
- improving pesticide users' understanding of and adherence to label directions that advise users on measures to reduce drift and minimize exposure to pollinators;
- promoting integrated pest management (IPM) solutions; and
- increasing awareness of potential impacts of pesticides through education (*i.e.*, training courses, pamphlets, workshops/conferences, and through television, radio, social media and other communication platforms).

Habitat loss is a significant issue with negative impacts on the health of bees. With access to a healthy and diverse diet through a thriving habitat, bees may be better able to tolerate stressors, such as pests, disease, and exposure to pesticides. As a healthy diet is crucial to maintaining flourishing pollinator populations, and the protection of pollinator habitat is not something that can be directly addressed on a pesticide product label, EPA and other federal/state/tribal and local government agencies and non-government organizations (NGOs) promote pollinator habitat through active education and outreach programs. Helpful guidance on pollinator protection can be found on EPA's pollinator protection webpage[10].

There are several precautions users can employ to minimize potential exposure to pollinators while using pyrethroid/pyrethrin products. First, try to avoid applying pyrethroid/pyrethrin products when bees and other pollinators are actively foraging on pollinator-attractive plants during bloom. Secondly, consider a pesticide's ability to drift to other non-target areas and be aware of the presence of bee colonies or highly bee-attractive plants nearby an application site. Some examples of best management practices (BMPs) to promote pollinator health include:

1. Applying pesticides in the evening and at night when pollinators are not foraging,
2. Improved communication between beekeepers and growers,
3. Identifying and confirming hive locations before spraying,
4. Maintaining buffers between treated areas and hives or foraging habitat, and
5. Controlling blooming weeds, such as dandelions, in or near treatment areas.

Other things the public can do to minimize potential exposure of pollinators are listed on EPA's *What You Can Do to Protect Honey Bees and Other Pollinators* webpage.[11]

The Agency encourages strong pollinator protection stewardship in both the public and private sector in creating tools and fostering effective communication to help reach applicators and educate them on practices that can reduce risks to the environment. EPA will continue to work with its partners at the federal, state, tribal, and local levels, along with non-governmental

[9] https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators

[10] https://www.epa.gov/pollinator-protection
[11] https://www.epa.gov/pollinator-protection/what-you-can-do-protect-honey-bees-and-other-pollinators

organizations to promote pollinator protection, education, and outreach. This includes coordinating with states and tribes on managed pollinator protection plans (MP3), coordinating with stakeholders on the implementation of, and education around, existing BMPs, and continued education and outreach to the public on pollinator protection. This language is only required for pyrethroid and pyrethrins labels with foliar agricultural uses and excludes products formulated for residential use and Ultra Low Volume (ULV) wide area mosquito control applications, which will be indicated in the label clarifications column of the label table.

In order to promote pollinator BMPs, the Agency has determined that adding the following text to pyrethroid/pyrethrin labels is necessary:

> "Following best management practices can help reduce risk to terrestrial pollinators. Examples of best management practices include applying pesticides in the evening and at night when pollinators are not foraging and checking to confirm hive locations before spraying. For additional resources on pollinator best management practices, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators."

c. Promoting State Managed Pollinator Protection Plans (MP3s)

The Agency supports state, tribal, and other local efforts to protect pollinators. EPA has been working with states and tribes to encourage the development of MP3s. Although MP3s are voluntary, approximately 80% of states have developed MP3s to promote pollinator protection efforts. The MP3s are developed through open communication among key stakeholders (including beekeepers, growers, landowners, pesticide applicators, and pest control operators). The MP3s vary from state to state according to each state's needs, and represent a more tailored, localized approach to pollinator protection. EPA engaged with states in the development of MP3s in order to give states and tribes the flexibility to do the following:

- adopt a regulatory or voluntary approach;
- expand protection efforts to address other pesticide-related issues;
- include other factors impacting pollinator health (such as habitat creation); and
- expand the scope to address wild bees and other types of pollinators.

In order to promote awareness of MP3s, EPA has determined that adding a statement to pyrethroid/pyrethrin labels to educate pesticide users on the existence of MP3s and to encourage users to follow their state plans is necessary. This language is only required for pyrethroid and pyrethrins labels with foliar agricultural uses and excludes products formulated for residential use and Ultra Low Volume (ULV) wide area mosquito control applications, which will be indicated in the label clarifications column of the label table.

The Agency has determined that the following text to pyrethroid/pyrethrin labels is necessary:

> "**Managed pollinator protection plans** are developed by states/tribes to promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other

pest management professionals to reduce exposure of bees to pesticides. If available, visit state plans for additional information on how to protect pollinators."

d. Pollinator Incident Reporting

EPA considers incident reporting data as a line of evidence to inform pesticide regulatory decisions. Information from these reports can help the Agency identify patterns of bee kills associated with specific uses and specific pesticides or classes of pesticides. EPA has determined that adding incident reporting information to pyrethroid/pyrethrin labels to encourage users to report bee kill incidents to the Agency is necessary. This language is only required for pyrethroid and pyrethrins labels with foliar agricultural uses and excludes products formulated for residential use and Ultra Low Volume (ULV) wide area mosquito control applications, which will be indicated in the label clarifications column of the label table.

The Agency has determined that adding the following text to pyrethroid/pyrethrin labels is necessary:

> **"How to Report Bee Kills** - It is recommended that users contact both the state lead agency and the U.S. Environmental Protection Agency to report bee kills due to pesticide application. Bee kills can be reported to EPA at beekill@epa.gov. To contact your state lead agency, see the current listing of state pesticide regulatory agencies at the National Pesticide Information Center's website: http://npic.orst.edu/reg/state_agencies.html."

4. Insecticide Resistance Management

Pesticide resistance occurs when genetic or behavioral changes enable a portion of a pest population to tolerate or survive what would otherwise be lethal doses of a given pesticide. The development of such resistance is influenced by several factors. One important factor is the repeated use of pesticides with the same mode (or mechanism) of action. This practice kills sensitive pest individuals but allows less susceptible ones in the targeted population to survive and reproduce, thus increasing in numbers. These individuals will eventually be unaffected by the repeated pesticide applications and may become a substantial portion of the pest population. An alternative approach, recommended by resistance management experts as part of integrated pest management (IPM) programs, is to use pesticides with different chemical modes (or mechanisms) of action against the same target pest population. This approach may delay and/or prevent the development of 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.

EPA has determined that resistance-management labeling, as listed in Appendix B, for products containing tau-fluvalinate is necessary in order to provide pesticide users with easy access to important information to help end users delay or even avoid the development of resistance and maintain the effectiveness of useful pesticides. Additional information on EPA's guidance for resistance management can be found at the following website: https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management.

5. Update Glove and Respirator Language

The Agency has determined that updating the gloves statements to be consistent with Chapter 10 of the Label Review Manual is necessary. In particular, the Agency has determined that removing the reference to specific categories in EPA's chemical-resistance category selection chart and specifying the appropriate glove types to use on the labels are necessary. For example, the chemical-resistant glove statements in the label should remove "such as" language and not state the solvent category, but rather add all acceptable glove types that provide high-level chemical resistance for the solvent category as mentioned in Table 3 of Chapter 10 of the Label Review Manual. This minor clarification does not fundamentally change the personal protective equipment that workers are currently required to use.

The Agency is requiring an update to the respirator statement currently on labels. The new respirator language does not fundamentally change the personal protective equipment that workers needs to use, and therefore should impose no impacts on users.

B. Tolerance Actions

No changes to the tolerance levels, crop listings or the tolerance expression are necessary at this time. Refer to Section III.A.3 for details.

C. Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the Agency is issuing this ID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the Agency has made the following interim decision: (1) additional pollinator data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV. A and Appendices A and B of this document, as well as the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals* (EPA-HQ-OPP-2008-0331).

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of tau-fluvalinate, nor is it making a complete endangered species finding. Although the Agency is not making a complete endangered species finding at this time, the necessary mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of tau-fluvalinate. The Agency's final registration review decision for tau-fluvalinate will be dependent upon the result of the Agency's ESA assessment and any needed § 7 consultation with the Services, and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

EPA has determined that pollinator data listed under Section III.B is necessary and will issue a DCI for the data.

The *GDCI-109302-1096* (for guideline 875.1700 product use information) was issued to registrants who formed the Residential Exposure Joint Venture (REJV) and is satisfied. EPA has received and accepted data from companies who represent the REJV.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this interim decision for tau-fluvalinate. A final decision on the tau-fluvalinate registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination and (2) an endangered species determination under the ESA and any needed § 7 consultation with the Services.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the tau-fluvalinate registrants must submit amended labels that include the label changes described in Appendices A and B. The revised labels and requests for amendment of registrations must be submitted to the Agency for review within 120 days following issuance of the Interim Registration Review Decision.

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels. Two copies for each label must be submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

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

Within the required timeframe, registrants must submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) using the following link: https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Alexander Hazlehurst at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

Docket Number EPA-HQ-OPP-2010-0915
www.regulations.gov

VIA US Mail

USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
Mail Code 7508P
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

VIA Courier

Pesticide Re-evaluation Division
c/o Front End Processing
Room S-4910, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Appendix A: Summary of Required Actions for Tau-fluvalinate

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions
Aquatic invertebrates	• Water (non-dietary) • Residues (at/on site of treatment)	• Contact • Ingestion	• Acute • Sub-chronic • Chronic	• Growth • Mortality	• Label clarity and consistency • Reduced perimeter treatments • Defined spot treatment size • Rain statements • Buffers to water bodies • Spray drift management language • Precautionary statements • Increased width of vegetative filter strips
Fish	• Water (non-dietary) Residues (at/on site of treatment)	• Contact • Ingestion	• Acute • Sub-chronic • Chronic	• Growth • Mortality	• Label clarity and consistency • Reduced perimeter treatments • Defined spot treatment size • Rain statements • Buffers to water bodies • Spray drift management language • Precautionary statements • Increased width of vegetative filter strips
Pollinators	• Residues (at/on site of treatment	• Contact • Ingestion	• Acute	• Mortality	• Stewardship information • Incident reporting information • Pollinator data requirements

Appendix B: Required Labeling Changes for Tau-fluvalinate Products

<table>
<tr><th colspan="3">Required Label Language for Tau-fluvalinate End Use Products</th></tr>
<tr><td>Description</td><td>All Tau-fluvalinate End Use Products (unless specified otherwise)</td><td>Placement on Label</td></tr>
<tr><td>Mode of Action Group Number
Applies only to products with agricultural uses</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., INSECTICIDE) in the fourth column.
<table><tr><td>Tau-fluvalinate</td><td>GROUP</td><td>3A</td><td>INSECTICIDE</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>Resistance-management labeling statements for insecticides
Applies only to products with agricultural uses</td><td>Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)</td><td>Directions for Use, prior to directions for specific crops</td></tr>
<tr><td>Updated Gloves Statement</td><td>Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.[i]</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use</td></tr>
</table>

		Requirements, if applicable
Updated Respirator Language	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products. [**Note to registrant:** For respiratory protection from organic vapor a**nd** particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.[ii]	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Additional Required Labeling Action. Applies to all products delivered via liquid spray applications	Remove information about volumetric mean diameter from all labels delivered via liquid spray application, except from products with mosquito adulticide use, where such information currently appears.	Directions for Use
End-use products with outdoor, urban, non-agricultural uses[iii]		

For all products	Add the following language: "For outdoor use only."	Front Label Panel and/or Directions for Use
General Outdoor Application Statement to replace existing general outdoor statement **[Registrants may not add new uses from items 1-6 which are not currently on the existing label. Registrants are required to choose only the uses from items 1-6 which apply to their product.]**	"All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: 1. Application to pervious surfaces such as soil, lawn, turf, and other vegetation; 2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (*e.g.*, soil, mulch, or lawn); 3. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure; 4. Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch; 5. Applications to vertical surfaces (such as the side of a man-made structure) directly above impervious surfaces (e.g., driveways, sidewalks, etc.), up to 2 feet above ground level; 6. Applications to vertical surfaces directly above pervious surfaces, such as soil, lawn, turf, mulch or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters."	Directions for Use
Spot Treatment Guidance Statement	"Spot treatments must not exceed two square feet in size (for example, 2ft. by 1 ft. or 4 ft. by 0.5 ft.)"	Directions for Use
Buffer from Water Statement	"For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for Use
Water Protection Statements	"Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur."	Directions for Use

	"Do not allow the product to enter any drain during or after application." "Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment." "Do not apply or irrigate to the point of runoff."	
Rain-Related Statements (except for products that require watering-in)	"Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours)." "Rainfall within 24 hours after application may cause unintended runoff of pesticide application."	Directions for Use
Wind speed requirement for ornamental/ recreational turf applications	"Do not apply when the wind speed is greater than 15 mph."	Directions for Use
Spray drift management for commercial nurseries	For outdoor applications to commercial nurseries: • "Do not apply when the wind speed is greater than 15 mph." • "Applicators are required to select the nozzle and pressure that delivers a medium or coarser droplet size (ASABE S572)." • "For soil or foliar applications, do not apply by ground equipment within 25 feet of lakes, reservoirs, rivers, streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for Use
Crack and crevice treatments	• "Treat surfaces to ensure thorough coverage but avoid runoff." • "To treat insects harbored in voids and cracks-and-crevices, applications must be made in such a manner to limit dripping and avoid runoff onto untreated structural surfaces and plants."	Directions for Use
End-use products with agricultural uses[iv]		
Enforceable Spray Drift Management Language for	Aerial Applications: • Do not release spray at a height greater than 10 feet above the vegetative canopy, unless a greater application height is necessary for pilot safety.	Directions for Use, in a box titled "Mandatory Spray Drift Management"

products that allow aerial applications	• Applicators are required to select nozzle and pressure that deliver a medium or coarser droplet size (ASABE S641). • Do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, 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 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 ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply during temperature inversions.	under the heading "Aerial Applications" Placement for these statements should be in general directions for use, before the use-specific directions for use.
Enforceable Spray Drift Management Language for products that allow ground boom applications	Ground Boom Applications: • User must only apply with the nozzle height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to select nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572). • Do not apply when wind speeds exceed 15 mph at the application site. • Do not apply during temperature inversions.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"
Advisory Spray Drift Management Language for all products that allow aerial and ground boom uses	**THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT.** **BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.** **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. Controlling Droplet Size – Ground Boom • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift.	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Controlling Droplet Size – Aircraft

- 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

- For ground equipment, the boom should remain level with the crop and have minimal bounce.

RELEASE HEIGHT - Aircraft

- 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. Avoid applications during temperature inversions.

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.

NON-TARGET ORGANISM ADVISORY STATEMENT (Environmental Hazards):

	• This product is highly toxic to bees and other pollinating insects exposed to direct treatment or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and reduce pesticide risk to these organisms.	
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"
Vegetative Filter Strips Note: This requirement is separate and in addition to buffer zones to aquatic areas, which are still required if a vegetated filter strip is present.	"VEGETATIVE FILTER STRIPS 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 tau-fluvalinate onto fields where a maintained vegetative filter strip of at **least 25 feet** exists between the field edge and where a down gradient aquatic habitat exists. This minimum required width of 25 feet may be reduced or removed under the following conditions: • For Western irrigated agriculture, a maintained vegetative filter strip of at least 10 feet wide is 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). o For Western irrigated agriculture, if a sediment control basin is present, a vegetative filter strip is not required. • In all other areas, a vegetative filter strip with a minimum width of 25 feet is required, unless the following conditions are met. The vegetative filter strip requirement may be reduced from 25 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 CFR § 657.5). o 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. o A functional terrace system is maintained on the area of application. o Water and sediment control basins for the area of application are functional and maintained. o The area of application is less than or equal to 10 acres.	Directions for Use

	For further guidance on vegetated filter strips, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175"	
Buffer Zones to Water Bodies	Ground Application • "Do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)." Ultra Low Volume (ULV) Aerial Application • "Do not apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)." Non-ULV Aerial Application • "Do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."	Directions for Use
New text to include under Environmental Hazard statements: (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area*	Update the Environmental Hazard with the bolded statement: "This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. **Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms.**"	Environmental Hazard

mosquito control applications		
Link to pollinator best management practices (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area mosquito control applications*	"Following best management practices can help reduce risk to terrestrial pollinators. Examples of best management practices include applying pesticides in the evening and at night when pollinators are not foraging and checking to confirm hive locations before spraying. For additional resources on pollinator best management practices, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators."	Directions for Use, prior to crop specific directions
Information on state managed pollinator protection plans (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area*	"**Managed pollinator protection plans** are developed by states/tribes to promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees to pesticides. If available, visit state plans for additional information on how to protect pollinators."	Directions for Use, prior to crop specific directions

mosquito control applications		
Information on how to report bee incidents (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area mosquito control applications*	**"How to Report Bee Kills** It is recommended that users contact both the state lead agency and the U.S. Environmental Protection Agency to report bee kills due to pesticide application. Bee kills can be reported to EPA at beekill@epa.gov. To contact your state lead agency, see the current listing of state pesticide regulatory agencies at the National Pesticide Information Center's website: http://npic.orst.edu/reg/state_agencies.html."	Directions for Use, prior to crop specific directions

[i] The updated glove language was inadvertently omitted from the text of the PID and Appendix B. It has now been added in this ID. It is label clarification.
[ii] The updated respirator language was inadvertently omitted from the text of the PID and Appendix B. It has now been added in this ID. It is label clarification.
[iii] The updated label language for outdoor, urban, non-agricultural uses does not apply to end-use products formulated as impregnated plastic strips for use in beehives.
[iv] The updated label language for agricultural uses does not apply to end-use products formulated as impregnated plastic strips for use in beehives.