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Tetramethrin

Interim Registration Review Decision
Case Number 2660

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 tetramethrin (PC Code 069003, case 2660), 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 tetramethrin, can be found in EPA's public docket (EPA-HQ-OPP-2011-0907) 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 tetramethrin 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 tetramethrin prior to completing the tetramethrin registration review. Likewise, the Agency will complete endocrine screening for tetramethrin, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

Tetramethrin is a synthetic pyrethroid insecticide. The first product containing tetramethrin was registered in 1968. Tetramethrin is a broad-spectrum, non-systemic insecticide registered for use to control insects, especially urban and nuisance pests such as cockroaches, wasps, flies and ants indoors and outdoors in residential, institutional (*e.g.*, hotels, theaters, restaurants), and industrial settings (*e.g.*, buildings, warehouses). Tetramethrin products are also registered for use on

companion animals as well as in animal quarters and kennels. EPA Reg No. 1021-2576 also previously allowed use of tetramethrin in automated barn misting systems, however this use was recently voluntarily cancelled.[1] Indoor application methods include direct broadcast, spot, crack and crevice aerosol or trigger spray, and aerosol space spray total release fogger. Outdoor application methods include direct or spot spray to buildings and household perimeters as well as landscapes and lawns via aerosol cans, and handheld equipment. Outdoor applications can also be made via ultra-low volume thermal foggers. There are no registered agricultural uses for tetramethrin.

Tetramethrin was subject to reregistration and a Reregistration Eligibility Decision (RED) for tetramethrin was published in June 2008.

Tetramethrin 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, categorizes 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 risk 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/pyrethrins, published on November 9, 2011 (available at http://www.regulations.gov; EPA-HQ-OPP-2011-0746).

In addition to this tetramethrin ID document, which describes the risk management approach for tetramethrin determined to be necessary by the Agency, EPA previously published and opened 60-day public comment periods for the following documents: *Tetramethrin Proposed Interim Registration Review Decision*, which summarizes the risk assessment and proposes mitigation for tetramethrin, *Pyrethroid 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 tetramethrin. Those documents, as well as additional supporting documents, are located in the tetramethrin docket and Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2011-0907 and EPA-HQ-OPP-2008-0331, respectively).

[1]As stated in the cancellation notice, the effective cancellation date for this product is October 1, 2020, which allows the registrant to continue to sell and distribute existing stocks of this product until October 1, 2021. Thereafter, the registrant is prohibited from selling or distributing this product within the United States. https://www.federalregister.gov/documents/2019/08/21/2019-17992/cancellation-order-for-certain-pesticide-registrations-and-amendments-to-terminate-uses

Having considered stakeholder comments on the tetramethrin Proposed Interim Decision (PID), the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals, the 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 tetramethrin.

This document describes changes or updates since the tetramethrin 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 tetramethrin 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 September 2019, EPA published the PID for tetramethrin. In this ID, there are some 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 indoor and outdoor uses to improve clarity and consistency. 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 made to the proposed mitigation. In addition, the insecticide resistance management language proposed in the PID has been removed since no products containing tetramethrin are registered for agricultural or wide area mosquito use. There have not been updates to the human health mitigation from what was proposed in the PID, nor any additional updates to the draft risk assessment (DRA). This ID thus finalizes the Agency's draft supporting documents: *Tetramethrin Draft Human Health Risk Assessment for Registration Review, Tetramethrin: Updated Human Health Risk Assessment for 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 tetramethrin public docket.

B. Summary of Tetramethrin Registration Review

Pursuant to 40 CFR § 155.50, EPA formally initiated registration review for tetramethrin 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 tetramethrin.

- December 2011- The *Tetramethrin Preliminary Work Plan (PWP);* the *Human Health Assessment Scoping Document in Support of Registration Review;* the *Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for tetramethrin*; were posted to the docket for a 60-day public comment period.

- February 2012- A Generic Data Call-in Notice (GDCI-069003-1110) was issued for guideline 875.1700 product use information. GDCI-069003-1110 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.

- May 2012 - The *Final Work Plan* (FWP) for tetramethrin was issued. Several comments were received on the PWP; however, the comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.

- January 2013 - *A Generic Data Call-In Notice* (GDCI-069003-1150) for tetramethrin was issued for data needed to conduct the registration review risk assessments. The GDCI-069003-1150 for tetramethrin has been satisfied.

- November 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 tetramethrin docket for a 60-day 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.
    - Five comments were received in the tetramethrin docket (EPA-HQ-OPP-2011-0907) during the comment period. None of these comments addressed tetramethrin specifically and all comments were posted to other pyrethroid dockets. These 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 on 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 tetramethrin.

- November 2016 – The Agency announced the availability of the *Tetramethrin Draft Human Health Risk Assessment for Registration Review* for a 60-day public comment period. No comments were received in the tetramethrin docket during the comment period.

- 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 tetramethrin.

- November 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 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 Pyrethroid 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*
    - *Review of "Economic Benefits of Pyrethroid Insecticides for Select California Crops," Report Prepared by ERA Economics for the Pyrethroids 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*
    - *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*

- November 2019 – The Agency opened a 60-day public comment period for the tetramethrin PID in the tetramethrin registration review docket (EPA-HQ-OPP-2011-0907). The following document is also available in this docket:
  - *Tetramethrin: Updated Human Health Risk Assessment for Registration Review*

- September 2020 – The Agency has completed the tetramethrin ID and will post it in the tetramethrin registration review docket (EPA-HQ-OPP-2011-0907). The following documents will also be available in this docket:
  - *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

In response to multiple stakeholder requests, the initial 60-day public comment period (beginning November 12, 2019) was extended for an additional 30 days (until February 12, 2020) for all chemicals covered in the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*, including for the PID for tetramethrin. The Agency received 65 substantive comments from various stakeholders on the pyrethroids as a group and two specifically for tetramethrin. One public comment advocated for stronger protections against the effects of pyrethroids in general to pollinators. A comment from Beyond Pesticides, submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331), specifically references tetramethrin and is addressed below.

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 tetramethrin docket. The comments from Beyond Pesticides and the Pyrethrin Joint Venture and the Agency's responses are summarized below.

Comment received from Beyond Pesticides and signatories (EPA-HQ-OPP-2008-0331-0144):

Beyond Pesticides (BP) and multiple signatories[2], commenting on five pyrethroid pesticides (cyphenothrin, flumethrin, imiprothrin, momfluorothrin, and tetramethrin) stated that EPA underestimated risks based on potential synergistic and adverse effects, health risks to children and pets, and did not adequately consider the use of safer alternatives. Beyond Pesticides called for the suspension of these five pesticides, or short of suspension, that all outdoor uses of these pesticides be classified as Restricted Use. On tetramethrin specifically, BP indicated that even though the Agency classified most incidents as minor in severity, users should be directed to wear additional personal protective equipment (PPE).

Agency Response: EPA thanks Beyond Pesticides for its comments. Please see the documents *Pyrethroids: Health Effects Division Response to Public Comments Submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists* and *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals* in the Special Docket for responses to BP's concerns on synergistic and adverse effects. EPA does not consider the use of PPE, such as gloves and respirators, to be appropriate for consumer use products. The Agency assesses exposure in its human health risk assessments under the assumption that residential applicators do not use PPE; under this assumption, no residential handler risks of concern were identified for tetramethrin.

EPA further notes that while a comparative assessment of pet incidents across all registered pet products based on usage data is not available, the Agency is aware of and continually monitors incidents involving pets. Information on the ongoing efforts to better monitor and evaluate companion animal incidents with pyrethroids and other active ingredients in spot-on products is available on the Agency's website: https://www.epa.gov/pesticides/implementation-guidance-enhanced-reporting-registrants-pet-spot-products. EPA has engaged with stakeholders on a variety of different actions to address potential risks to pets from the use of pet spot-on products; additional information on this project can be found here: https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects. As additional information is gathered through this project, EPA will determine whether additional changes are needed to pet product registrations more generally.

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

[2] Signatories include Friends of Animals, Northeast Organic Farming Association – Massachusetts Chapter, Occidental Arts and Ecology Center, Food and Water Action, Friends of the Earth, Maryland Pesticide Education Network, Women's Voices for the Earth, Pesticide Action Network, Northwest Coalition for Alternatives to Pesticides, Toxic Free NC, Environmental Justice Health Alliance, Farmworker Association of Florida, and Center for Food Safety.

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

Tetramethrin is a synthetic pyrethroid insecticide which acts to prevents sodium channels in an organism's neuronal membranes from closing, resulting in paralysis and eventual death. The Insecticide Resistance Action Committee categorizes tetramethrin and other synthetic pyrethroids in "Mode of Action" (MOA) Group 3A.

Tetramethrin is registered in the United States for indoor and outdoor uses in residential and commercial settings. It is also registered for use in animal quarters, such as kennels, and may be used on companion animals. Formulations currently include liquid sprays and foggers or misters. Outdoors, it may be applied as a perimeter or spot treatment, including lawns and ornamentals. There are no agricultural uses.

Nationally, residential consumers purchased around 100,000 pounds active ingredient (a.i.) of pyrethroid insecticides (as a group) for indoor use, and around 2 million pounds a.i. of pyrethroids for residential outdoor uses in 2016.[3] These amounts include household insecticides for use both indoor and outdoor (e.g., ant, cockroach, termite, fly control, and lawn and garden pest control insecticides), pet products. Consumers purchased 22,000 pounds a.i. of tetramethrin for residential outside uses in 2016.[4] Tetramethrin also accounted for a portion of indoor residential usage by consumers, but the specific amount is not available.[8]

Recent data also indicate that pyrethroids are used in other non-agricultural areas. Almost 190,000 pounds a.i. of pyrethroids are used for wide-area applications for mosquito control.[5] Food handling establishments, including processing facilities, warehouses, restaurants, and other food preparation facilities, used around 200,000 pounds a.i. of pyrethroids in 2013.[6] Professional

[3] 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.]

[4] 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.]

[5] Non-Agricultural Market Research Proprietary Data. 2017b. Studies conducted and sold by a consulting and research firm. Report on mosquito control pesticide usage. [Accessed June 2019.]

[6] Kline and Company. 2014. Pest Control in Food- Handling Establishments: U.S. Market Analysis and Opportunities. [Accessed June 2019.]

pest management companies used over 3 million pounds a.i. of pyrethroids for control of various nuisance and public health pests both in and around residential and commercial buildings.[7,8] Industrial vegetation management, including roadways and rangeland, used around 56,000 pounds of pyrethroids.[9] However, there are no reports of tetramethrin use in any of the above areas. Over 1.4 million pounds a.i. of pyrethroids were also reported to be used in the turf and ornamental market; tetramethrin was reported to be used in institutional turf but the exact amounts are not available.[7]

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 tetramethrin. For additional details on the human health assessment for tetramethrin, see the *Tetramethrin Draft Human Health Risk Assessment for Registration Review*, and *Tetramethrin: Updated Human Health Risk Assessment for Registration Review,* which are available in the tetramethrin registration review docket (EPA-HQ-OPP-2011-0907).

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-

[7] Non-Agricultural Market Research Proprietary Data. 2017c. Studies conducted and sold by a consulting and research firm. Report on professional pest management markets for pesticides. [Accessed June 2019.]

[8] Kline and Company. 2014. Report on professional turf and ornamental plants and professional pest control pesticide usage. 2013. [Accessed June 2019.]

[9] Non-Agricultural Market Research Proprietary Data. 2017c. Studies conducted and sold by a consulting and research firm. Report on professional turf and ornamental plants and p

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.

2. Risk Summary and Characterization

Tetramethrin is a non-food use chemical as it is not registered for application to agricultural crops. Occupational and residential handler exposures are anticipated from the application of tetramethrin. Residential post-application exposures are expected based on the use pattern of the chemical; however, occupational post-application exposures are not expected since re-entry activities are not likely based on the use pattern of tetramethrin. All aggregate exposures are equivalent to the residential exposure estimates since there are no dietary exposures for tetramethrin. A non-occupational spray drift assessment was not conducted because tetramethrin is not used in agricultural fields and any direct exposure from residential turf, the most conservative residential use pattern, is not of concern. The only potential risk of concern that has been identified is with the use of tetramethrin in automated barn misting systems, which is discussed below as a potential residential post-application risk.

Residential Handler Risks

All residential handler inhalation risks estimated are not of concern as margins of exposure (MOEs) are greater than the level of concern (LOC) of 30.

Residential Post-Application Risks

The Agency identified potential risks of concern for adults (inhalation exposure) and children ages 3 to < 6 years old (combined hand-to-mouth and inhalation exposures) following treatment of animal barns with tetramethrin through an automated misting system. These risks are associated with a single label, EPA Reg No. 1021-2576. However, the registrant requested to voluntarily cancel the product identified to have a potential risk: the product cancellation was recently finalized with an effective date of October 1, 2020.[10]

Occupational Exposures and Risk

In the 2016 DRA, a screening-level approach was used for assessment of occupational exposures by evaluation of the maximum application rate for all possible occupational exposure scenarios of tetramethrin. All occupational handler inhalation risks estimated are not of concern (*i.e.*, MOE > 30). No changes to the occupational assessment have occurred since the time of the 2016 DRA, except for the removal of the mixing/loading/applying exposure scenario relating to the automated (animal barn) misting system due to product cancellation.

Occupational post-application exposures are not anticipated for tetramethrin based on the manner in which it is applied. Further, restricted entry intervals (REIs) are not included on tetramethrin

[10] https://www.federalregister.gov/documents/2019/08/21/2019-17992/cancellation-order-for-certain-pesticide-registrations-and-amendments-to-terminate-uses

product labeling as the registered uses are not covered by the Worker Protection Standard (WPS), that is, no tetramethrin uses are involved in the production of agricultural plants on a farm, forest, nursery, or greenhouse. Therefore, there are no WPS-related personal protective equipment (PPE) or REI statements required on the registered labels.

Cumulative Risks

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 tetramethrin, refer to the *Tetramethrin Draft Human Health Risk Assessment for Registration Review*, and *Tetramethrin: Updated Human Health Risk Assessment for Registration Review*, which are available in the tetramethrin public docket (EPA-HQ-OPP-2011-0907).

3. Tolerances

Tetramethrin currently has no registered food uses and there are no tolerances for specific raw agricultural commodities. Tetramethrin is not registered for direct application to agricultural crops, livestock animals, or livestock premises where livestock are used for food.

4. Human Health Data Needs

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

The GDCI-069003-1110 (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;[11] 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 tetramethrin, potential risks of concern were identified for aquatic organisms, in particular for aquatic invertebrates, from indoor and outdoor use in residential and commercial settings.

1. Ecological and Environmental Fate Data Needs

The Agency does not anticipate calling in additional ecological and environmental fate data for tetramethrin at this time.

C. Benefits Assessment

Tetramethrin is among the first synthetic pyrethroids developed. It has better knockdown (paralytic) effects on insects than other older pyrethroids, such as pyrethrins. Like these older pyrethroids, tetramethrin is susceptible to quick degradation in sunlight.

[11] "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.

While many of the arthropods for which tetramethrin can be used in residential/institutional settings are nuisance pests, a few (such as some ant species and cockroaches) are considered public health pests. Alternatives to tetramethrin for most target pests are likely to be other synthetic pyrethroids since they often target the same insects, and some are long-standing options for insect control in residential and commercial settings. For ants and cockroaches, non-pyrethroid alternatives also exist, such as hydramethylnon, indoxacarb, and abamectin. For some professional pest control operators, tetramethrin is probably one of several insecticides used to control pests over an extended period of time.

For use on companion animals and animal living quarters, tetramethrin is registered for use to suppress fleas and biting flies. Likely alternatives include fly baits impregnated with *N*-methyl carbamates (*e.g.*, methomyl) or spinosyns (*e.g.*, spinosad); space sprays containing pyrethroids (*e.g.*, cypermethrin); and topical applications of other pyrethroids (*e.g.*, permethrin). For flea and tick control, other pyrethroids (*e.g.*, cyphenothrin) may be used, as can many other active ingredients, including neonicotinoids (*e.g.*, imidacloprid), spinosad, nitenpyram, and amitraz. Some products can be given to animals orally, others require topical applications, and a few can be used as shampoos.

For more information on the usage of tetramethrin, refer to the *BEAD Chemical Profile for Registration Review: Tetramethrin (PC Code: 069003)*, which is available in the public docket (EPA-HQ-OPP-2011-0907). 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

Potential residential post-application risks of concern were identified for a use of tetramethrin in automated barn misting systems, which is permitted on one tetramethrin label only (EPA Reg. No. 1021-2576); however, this product was voluntarily cancelled with an effective date of October 1, 2020.[12] The Agency has determined that there are no other human health risks of concern associated with the registered uses of tetramethrin, which include indoor and outdoor urban uses. While there are no remaining human health risks of concern, the Agency identified potential risks of concern for aquatic organisms, primarily invertebrates, from indoor and outdoor urban uses of tetramethrin. Mitigation to address risks to aquatic organisms will benefit the other taxa to the extent that there is any risk.

The residential indoor products containing pyrethroids are expected to result in risks of concern from the use of pet shampoos, pyrethroid-impregnated or treated textiles being laundered, and

[12] https://www.federalregister.gov/documents/2019/08/21/2019-17992/cancellation-order-for-certain-pesticide-registrations-and-amendments-to-terminate-uses

indoor household treatments (e.g., carpet, furniture, bedding) to control bed bugs, fleas, and other pests with public health significance. Under this use pattern, the wastewater that goes down-the-drain contains pyrethroid residues and is treated in wastewater treatment plants (WWTPs) or publicly owned treatment works (POTWs) and then discharged to waterbodies. A portion of the pyrethroid residues remains in the water discharged to the outdoor waterbodies and results in potential risks to aquatic invertebrates and fish. Mitigation to address risks from the indoor use of products containing these chemicals focuses on reducing the amount of residues being poured down the drain. The potential ecological risks, which are expected to be reduced with the mitigation, are outweighed by the high benefits associated with the use of pyrethroids for the control of pests with public health significance.

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.

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). To address generic labeling requirements, EPA has determined that updates to glove language on tetramethrin labels are necessary where applicable.

1. Mitigation Measures to Promote Proper Usage and Reduce Indoor and Storm Drain Disposal of Pyrethroids

To address concerns for residues in wastewater discharges, the Agency has determined that advisory label language and graphics on indoor pyrethroid products that have uses that could end up down-the-drain are necessary to help mitigate this potential risk.

To reduce the potential for aquatic risks from improper use and disposal of pyrethroids down indoor drains and storm drains, EPA has determined that measures to inform consumers about the appropriate use sites for the pyrethroid products they purchase are necessary, as well as the importance of proper disposal of leftover pesticides and their containers. These product stewardship measures include clear, simple language about whether the product is meant to be used indoors or outdoors, as well as consistent label language and graphic imagery to encourage proper disposal.

The products that are subject to these necessary amendments are those with any indoor or outdoor use in a residential or commercial setting. Note that all products registered for indoor residential and commercial uses are included, not just the those with indoor down-the-drain uses,

because the potential for improper use or disposal is present for any household pyrethroid product. The specific measures are necessary to reduce the potential for runoff and drain disposal, and subsequent potential aquatic risk, and are outlined below.

a. Indoor and Outdoor Use Site Clarification

- Label language must explicitly state whether the product is allowed to be applied indoors only, outdoors only, or both indoors and outdoors. For example, label text for a product that is only used indoors could state, "For indoor use only."
- For applications to pets, the label must have the following statement to ensure products are applied indoors.
    - "Application of product on pets must only be done indoors."

b. Disposal/Stewardship Statement and Pictogram

- Labels must include the following statement on the product label unless labeled for use directly inside pipes/sinks.
    - "Do not pour or dispose down the drain or sewer. Call your local solid waste Agency for local disposal options."
- Include a pictogram of a diagonal strikethrough, over a drain on all end-use consumer product containers. Place pictogram in a prominent location. The pictogram must be legible (i.e. no smaller than 1.5 square centimeters or .25 square inch unless this size is greater than 10% of the size of the label). Below is an example graphic of an indoor drain image:

c. Advisory Statements

- Labels must include the following statements on all end-use consumer product containers in a prominent location. The only exception is for pet products, as residues from these products may be expected to be released down indoor or outdoor drains as a result of standard pet care:
    - "Do not allow to enter indoor or outdoor drains." and also include the Spanish translation, "No permita la entrada a desagües internos o externos." For products with down-the-drain uses, use the following variation - "Do not allow to enter indoor or outdoor drains unless labeled for drain treatments." and the Spanish translation, "No permita la entrada a desagües internos o externos a menos que el etiquetado indique que está permitido el uso del producto para tratamiento de desagües."
    - "Follow proper disposal procedures on this label." and also include the Spanish translation, "Siga las indicaciones del etiquetado para el desecho apropiado del producto."

The Agency does not expect that this mitigation would have an adverse impact to pesticide users. Directions are intended to promote proper disposal after use of the product.

2. 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 offsite-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."

The Agency has not assessed the impact of 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[13]). 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.

H. 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."

3. Update Glove 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.

B. Tolerance Actions

No tolerance actions are necessary for tetramethrin because no tolerances are established. See Section III.A.3 for more information.

C. Interim Registration Review Decision

[13] 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

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) no additional 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 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 tetramethrin, 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 tetramethrin. The Agency's final registration review decision for tetramethrin 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

The GDCI-069003-1110 (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 tetramethrin. A final decision on the tetramethrin 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 tetramethrin 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 Tetramethrin 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 Tetramethrin 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 Anna Romanovsky at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

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

APPENDICES

Appendix A: Summary of Required Actions for Tetramethrin

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions
• Children 3 to <6	Residential post-application - automated (animal barn) misting	• Hand-to-mouth • Inhalation	Short-Term (1-30 days)	• Hand-to-mouth: Decreased body weight • Inhalation: respiratory, liver, and kidney toxicity	Registrant has voluntarily cancelled this use[14]
• Adults	Residential post-application - automated (animal barn) misting	• Inhalation	Short-Term (1-30 days)	• Inhalation: respiratory, liver, and kidney toxicity	Registrant has voluntarily cancelled this use[9]
• Aquatic invertebrates	• Water (non-dietary) • Residues (at/on site of treatment)	• Contact • Ingestion	• Acute • Sub-chronic • Chronic	• Growth • Mortality	• Label clarity and consistency • Advisory storage and disposal statements • Reduced perimeter treatments • Defined spot treatment size • Rain statements • Buffers to water bodies
• Fish	• Water (non-dietary) Residues (at/on site of treatment)	• Contact • Ingestion	• Acute • Sub-chronic • Chronic	• Growth • Mortality	• Label clarity and consistency • Advisory storage and disposal statements • Reduced perimeter treatments • Defined spot treatment size • Rain statements • Buffers to water bodies

[14] https://www.federalregister.gov/documents/2019/08/21/2019-17992/cancellation-order-for-certain-pesticide-registrations-and-amendments-to-terminate-uses

Appendix B: Required Labeling Changes for Tetramethrin Products

Description	**Required Label Language for Tetramethrin End Use Products**	Placement on Label
	All Tetramethrin End Use Products (Unless specified otherwise)	
Updated Gloves Statement	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	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirement
End-use products with indoor residential uses		
For all products that have indoor uses only	Add the following language: "For indoor use only."	Front Label Panel and/or Directions for Use
For all products that have both indoor and outdoor uses	Add the following language: "For both indoor and outdoor use."	Front Label Panel and/or Directions for Use
For all products used on pets	Add the following language: "Application of product on pets must only be done indoors."	Directions for Use
Required disposal statement for products not labeled for use directly into drains and sewers.	"Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options."	Storage and Disposal

Stewardship statement that includes a Spanish translation (stewardship statement not required for products applied to pets)	Note to registrants: If adding stewardship statements on end-use consumer products, the following language is required and placed in a prominent location: For products without drain treatment uses: "Do not allow to enter indoor or outdoor drains" *"No permita la entrada a desagües internos o externos."* For products with drain treatment uses: "Do not allow to enter indoor or outdoor drains unless labeled for drain treatments." *"No permita la entrada a desagües internos o externos a menos que el etiquetado indique que está permitido el uso del producto para tratamiento de desagües."* For products with and without drain treatment uses: "Follow proper disposal procedures on this label" *"Siga las indicaciones del etiquetado para el desecho apropiado del producto."* Graphic on the product package showing an image of a diagonal strikethrough over a drain. The pictogram must be legible (i.e. no smaller than 1.5 square centimeters or 0.25 square inches unless this size is greater than 10% of the size of the label). **Use the following pictogram on product labels:** 	Directions for Use
End-use products with outdoor, urban, non-agricultural uses		
For all products that have outdoor uses only	Add the following language: "For outdoor use only."	Front label panel and/or Directions for Use
For all products that have both indoor and outdoor uses	Add the following language: "For both indoor and outdoor use."	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, 2 ft. 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, permanent 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." "Do not allow the product to enter any drain during or after application."	Directions for Use

	"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
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