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Prallethrin

Interim Registration Review Decision
Case Number 7418

September 2020

Approved by: _____

Elissa Reaves, Ph.D.
Acting Director
Pesticide Re-evaluation Division

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for prallethrin (PC Code 128722, case 7418), 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 prallethrin can be found in EPA's public docket (EPA-HQ-OPP-2011-1009) 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.

The EPA is issuing an ID for prallethrin 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 prallethrin prior to completing the prallethrin registration review. Likewise, the Agency will complete endocrine screening for prallethrin, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

Prallethrin is a synthetic pyrethroid insecticide useful for quick knockdown of indoor, outdoor (i.e., ant, roach, termites, fly), and animal (i.e., flea and tick) target pests. Prallethrin products are currently registered for use in food handling establishments (FHEs), as a

wide-area mosquito adulticide, and in a variety of residential uses to control pests on pets, turf, and in homes and commercial settings. Aside from the use of prallethrin in FHEs, there are no other food uses for the chemical. The first product containing prallethrin was registered in 1994. A Reregistration Eligibility Decision (RED) was not required for prallethrin because it was registered after November 1984.

Prallethrin is a member of the pyrethroids and pyrethrins class of insecticide, which share the same mode of action. The pyrethroids and pyrethrins work by altering nerve function, causing paralysis in target insect pests, 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). A screening-level cumulative risk assessment to assess human health risks 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 prallethrin ID, which describes the risk management approach for prallethrin determined to be necessary by the Agency, EPA previously published and opened a 60-day public comment periods on the following documents: *Prallethrin Proposed Interim Registration Review Decision,* which summarizes the risk assessment and proposes mitigation for prallethrin, *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 prallethrin. Those documents, as well as additional supporting documents, are located in the prallethrin docket and in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2011-1009 and EPA-HQ-OPP-2008-0331, respectively).

Having considered stakeholder comments on the prallethrin 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 prallethrin.

This document describes changes or updates since the prallethrin 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 prallethrin 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 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 March 2020, EPA published the PID for prallethrin. 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 indoor, outdoor, and mosquito adulticide 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.

There have been updates to the human health mitigation from what was proposed in the PID. In addition to this ID, the Agency will publish a *Prallethrin: Revised Updated Human Health Draft Risk Assessment in Support of Registration Review*, which resulted in some new scenarios being risks of concern and previously identified scenarios being no longer of concern. In addition to the previously identified occupational handler scenarios with combined dermal and inhalation risk estimates of concern; there are scenarios of concern associated with two microencapsulated formulation end-use products, one ready-to-use (RTU) aerosol can end-use product, and one manually pressurized handwand end-use product which were not originally identified in the PID.

In addition to the new risks of concern, the Agency also decided to no longer eliminate the use of handheld or portable foggers when applying Multicide Fogging Concentrate 2798 (Reg. No. 1021-1795) and 2922 (Reg. No. 1021-2562), in response to comments from the U.S. Department of Agriculture (USDA) and Clarke Mosquito Control Products, Inc, which the Agency addressed in the revised DRA for prallethrin. Instead, the Agency has added additional personal protective equipment (PPE) to allow for the use of these products when applied with a handheld or portable fogger.

Most risk estimates of concern will be mitigated with the use of additional PPE, such as gloves and/or a protection factor (PF) 10 respirator. The updated label language appears in Appendix B of this ID. See the response to comments in Section I.C of this document for more details.

This ID thus finalizes the Agency's draft supporting documents: *Prallethrin. Draft Human Health Risk Assessment for Registration Review, Prallethrin: Updated Human Health Draft Risk Assessment in Support of Registration Review, Prallethrin: Revised 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 prallethrin public docket.

B. Summary of Prallethrin Registration Review

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

- July 9, 2012 - The *Prallethrin Preliminary Work Plan* (PWP)*;* the *Prallethrin. Human Health Assessment Scoping Document in Support of Registration Review;* and the *Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Prallethrin* were posted to the docket for a 60-day public comment period.

- January 4, 2013 - The *Prallethrin Final Work Plan* (FWP) was issued. Several comments were received on the PWP that addressed the planned ecological and human health risk assessments and data requirements. These comments resulted in changes to the data needs for prallethrin. The Agency revised its planned data requirements to include the submission of guideline studies 850.1010 (Acute toxicity Freshwater Invertebrates, using *Hyalella azteca* as the test species) and 850.6100 (Environmental Chemistry Methods and Associated Independent Laboratory Validations for Soil, Water, and Sediment).

- April 17, 2013 - A Generic Data Call-In (GDCI-128722-1244) for prallethrin was issued for data needed to conduct the registration review risk assessments. The GDCI-128722-1244 for prallethrin has been satisfied. The registrants receiving GDCI-128722-1109 (for guideline 875.1700 product use information) 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, 2016 - The Agency announced the availability of the *Prallethrin Revised Draft Human Health Risk Assessment for Registration Review,* 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 prallethrin 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.
    - Eleven comments were received in the prallethrin docket. Of these comments, one asked for an extension of the comment period and eight addressed pyrethroids in

general and were not specific to prallethrin. 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 to Comments on the Preliminary Risk Assessments for the Pyrethroids and Pyrethrins Insecticides* (also referred to as the "EFED/PRD Response to Comments" document), which is available at http://www.regulations.gov (Docket # EPA-HQ-OPP-2008-0331). Two comments were specific to prallethrin. Upon review of the comments received, EPA modified the risk assessments but did not change the registration review timeline for prallethrin.

- August 2019 – The Agency published the *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 prallethrin.

- November 2019 – The Agency announced the availability of the following documents for public comment: (1) *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review*, and (2) *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals.* Both documents are located in the Special Docket for Pyrethroids, Pyrethrins, and Synergists at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2008-0331). The Agency accepted comments on the documents for 60 days, which began on November 12, 2019 and ended on January 13, 2020.

  The following supporting documents for the *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review* are also available in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331):

  - *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*

  Along with the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*, the following supporting documents are also available in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331):

  - *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*
  - *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review*
  - *Readers Guide – Instructions for Commenting on the Registration Review Documents in the Pyrethroids Group*

- May 2020 – The Agency announced the availability of the *Prallethrin Proposed Registration Review Interim Decision* (or the prallethrin PID) in the prallethrin registration review docket (EPA-HQ-OPP-2011-1009), for a 60-day public comment period.

  Along with the prallethrin PID, the following documents were also posted in the prallethrin registration review docket (EPA-HQ-OPP-2011-1009):

  - *Prallethrin: Updated Human Health Draft Risk Assessment in Support of Registration Review*
  - *Prallethrin: Response to Public Comments on the Prallethrin Draft Risk Assessment for Registration Review*
  - *Readers Guide – Instructions for Commenting on the Registration Review Documents in the Pyrethroids Group*

- September 2020 – The Agency has completed the prallethrin ID and will post it in the prallethrin registration review docket (EPA-HQ-OPP-2011-1009).

  - Along with the prallethrin ID, the following documents will also be available in the prallethrin registration review docket (EPA-HQ-OPP-2011-1009):

    - *Prallethrin: Revised Updated Human Health Draft Risk Assessment in Support of Registration Review,* September 2020
    - *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 2*020*

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

During the 60-day public comment period for the *Prallethrin 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 nine comments specifically for prallethrin. For prallethrin, comments were received from the United States Department of Agriculture (USDA), The Scotts Company LLC, the American Mosquito Control Association (AMCA), Clarke Mosquito Control Products, Inc., the Washington State Department of Agriculture (WSDA), 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) . Substantive comments, comments of a broader regulatory nature, and the Agency's responses to those comments are summarized 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 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 documents are available in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331) and in the prallethrin docket. Prallethrin-specific comments on these same documents and the Agency's responses are also summarized below.

Comments Submitted by USDA and Clarke Mosquito Control Products, Inc (Docket ID: EPA-HQ-OPP-2011-1009-0056) and (Docket ID: EPA-HQ-OPP-2011-1009-0060)

Comment: USDA requests that the Agency consider available PPE and other exposure mitigation options that will allow for continued use of prallethrin for applications using handheld and truck-mounted foggers. Clarke Mosquito Control Products, Inc. explains that the Agency's assumption and characterization of the handheld or portable fogger use utilizing a maximum daily amount handled rate of 40 gallons is unreasonable and suggests 5.8 gallons is an appropriate amount. Clarke further explains that a maximum daily rate of 5.8 gallons will not exceed the MOE or present an occupational exposure risk of concern.

EPA Response: The Agency thanks USDA and Clarke Mosquito Control Products, Inc. for their comments. After revising its exposure assumptions in the Revised Updated Human Health Draft Risk Assessment for prallethrin, EPA has determined that it no longer needs to eliminate the use of handheld portable foggers for products Multicide Fogging Concentrate 2798 (Reg. No.

1021-1795) and 2922 (Reg. No. 1021-2562). However, the addition of a PF10 respirator will be required for this use. Upon review of the submitted information regarding the potential amount of active ingredient handled using handheld or portable ULV equipment for mosquito and vector control, the Agency concurs with Clarke's assumptions and inputs in determining a maximum daily amount handled rate of 5.8 gallons. For a more detailed response, please see the *Prallethrin: Revised Updated Human Health Draft Risk Assessment in Support of Registration Review* (2020), which is available in the prallethrin registration review docket (EPA-HQ-OPP-2011-1009).

Comments Submitted by The American Mosquito Control Association, Clarke Mosquito Control Products, Inc, and The Scotts Company LLC (Docket ID: EPA-HQ-OPP-2011-1009-0059, Docket ID: EPA-HQ-OPP-2011-1009-0060, and Docket ID: EPA-HQ-OPP-2011-1009-0058)

Comment: AMCA and Clarke Mosquito Control Products, Inc. (Clarke) requested clarifications on which portions of the pollinator hazard statement should apply to specific use patterns, specifically on wide-area mosquito control applications. AMCA and Clarke commented that wide-area ultra-low volume (ULV) applications occur under conditions to promote drift of very fine droplets, which makes spray drift mitigation inappropriate for this use pattern; that ULV applications using pyrethroids use a fraction of application rates used in agriculture and minimize deposition onto foliage; and occur when pollinators are unlikely to be active (late evening or early morning). Both AMCA and Clarke commented that the pollinator hazard statement that directs the user to minimize drift should not apply to ULV mosquito control applications. Clarke did not object to the placement of the remaining three pollinator hazard statements, which reference best management practices, state/tribal pollinator protection plans, and information on how to report bee kills, on product labels used for ULV wide-area mosquito control. Scotts Company LLC noted that pollinator hazard statements should not apply equally to consumer products and suggested the Agency include clarifying language to exclude residential homeowner use from the pollinator hazard statement requirements.

EPA Response: EPA thanks the commenters for their suggestions and confirms that the environmental hazard statements to protect pollinators (including language on minimizing ground deposition; link to best management practices; information on state/tribal pollinator protection plans; and how to report bee incidents) do not apply to wide-area mosquito uses. Language has been added to the label tables in this document to clarify that the statements do not apply to products formulated for residential homeowner use or (ULV) wide-area mosquito control applications. While EPA appreciates the suggested pollinator protection language for residential product labels, these pollinator protection statements only apply to pyrethroids products with foliar agricultural applications.

Comment: AMCA and Clarke supported the inclusion of pesticide resistance management language on labeling, noting that pyrethroids and organophosphates are the only modes of action currently available for wide-area mosquito control. Clarke and Scotts Company LLC asked that pesticide resistance management language requirements clarify the use patterns to which the requirements apply, as well as use patterns that are excluded. Clarke also suggested that pesticide resistance management language should be recommended/advisory rather than mandatory, given

the limited modes of action available for wide-area mosquito control. Scotts LLC suggested that label tables include additional language to clarify that resistance management language does not apply to products formulated for residential use.

EPA Response: EPA thanks the contributors for their comments. As PR Notice 2017-1 states, pesticide resistance management language is "intended mainly for agricultural and certain non-crop land areas under commercial or government-sponsored pest management. In particular, this PR Notice applies to all field use agricultural pesticide products, as well as pesticides which are labeled for greenhouse production, sod farms, ornamental crops, aquatic vegetation, rights-of-way, and pest management along roadways. This guidance is not intended to apply to products labeled for use by the general consumer, such as residential use pesticides". As part of registration review, the Agency determined that resistance management labeling for most pyrethroid products is necessary to address known resistance concerns but is not meant for residential uses. The Agency agrees with the commenters that resistance management language would inform users making wide-area mosquito adulticide applications. Therefore, the Agency has added the pesticide resistance management language requirement to products intended for wide area mosquito adulticide uses. A clarifying note has been added to the description column of the label table to exclude products that are residential use products.

Comment Submitted by AMCA (Docket ID: EPA-HQ-OPP-2011-1009-0059)

Comment: AMCA suggested the respirator requirement for mixing/handling should be unnecessary for applications made using truck-mounted ULV machines with an enclosed cab.

EPA Response: The Agency thanks AMCA for their comment, but to clarify, the respirator requirement for mixing/handling is not required for truck-mounted ULV machines with an enclosed cab.

Comments Submitted by The Scotts Company LLC: Docket ID: EPA-HQ-OPP-2011-1009-0058)

Comment: The Scotts Company suggested that the Agency clarify that waterproof gloves should be sufficient for consumer labeling.

EPA Response: The Agency thanks The Scotts Company for their comment. While EPA appreciates the suggested glove language, this language will not be incorporated into the label table as the glove type depends on the product solvent. Because of this, the Agency is not able to enforce a global requirement for a specific type of gloves. Furthermore, EPA does not consider the use of personal protective equipment (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.

Comments Submitted by Clarke Mosquito Control Products, Inc. (Docket ID: EPA-HQ-OPP-2011-1009-0060)

Comment: Clarke questioned the Agency's rationale to remove information references to Volumetric Mean Diameter (VMD) from prallethrin labels.

EPA Response: The Agency thanks Clarke for their comment regarding the above, however, the mitigation the comment refers to only applies to end-use products that have urban, outdoor, non-agricultural, and agricultural uses, not wide-area mosquito adulticide uses. Mosquito products are ones where fine to very fine droplets, carefully calibrated, really are needed in order to maximize efficacy – so users may need to know the VMD info, especially if they are already used to seeing it on labels. The only label language intended for the wide-area mosquito adulticide uses in the Ecological Risk Mitigation Proposal were listed on page 61 under the heading, "This proposed language applies to products used by mosquito control districts for wide-area applications." As such, there are no changes to the VMD at this time for wide area mosquito control uses.

Comment Submitted by Washington State Department of Agriculture (Document ID: EPA-HQ-OPP-2011-1009-0079)

Comment: The Washington State Department of Agriculture (WSDA) submitted a comment on four pyrethroid PIDs, including the prallethrin PID. The comment included a summary of data that were collected by WSDA's crop mapping, pesticide usage data collection, and surface water monitoring programs.

EPA Response: EPA thanks WSDA for the data on prallethrin. The Agency will consider incorporating these data in future risk assessments, as appropriate.

Comments Submitted by Various Water Boards/Water Agencies

Comment: The National Association of Clean Water Agencies (NACWA) (EPA-HQ-OPP-2011-1009-0062), the California Stormwater Quality Association (CASQA) (EPA-HQ-OPP-2011-1009-0063), the San Francisco Bay Regional Water Quality Control Board (SFBRWQCB) (EPA-HQ-OPP-2011-1009-0057), and the Bay Area Clean Water Agencies (BACWA) (EPA-HQ-OPP-2011-1009-0061) commented on the proposed risk mitigation for prallethrin.
The water boards/agencies urged EPA to consider individualized mitigation measures for high risk pyrethroids such as deltamethrin. The water boards/agencies noted that EPA's proposed mitigation was the same across all 23 pyrethroids and pyrethrins, but the level of risk differed substantially between individual pyrethroids, as reflected in the differences in the magnitude of risk quotients (RQs) for aquatic organisms. They suggest that EPA implement targeted mitigation for the most used and higher risk pyrethroids since not all pyrethroids and pyrethrins have equal costs and benefits.

EPA Response: The agency appreciates the comments from NACWA, CASQA, SFBRWQCB, and BACWA. EPA has considered these comments and has decided not to develop unique chemical-specific risk mitigation for prallethrin at this time beyond what is already required as part of this ID. EPA concludes that deltamethrin provides high benefits for controlling pests in indoor residential areas, outdoor urban areas, in agricultural crop production, and as an adult mosquitocide to control vectors for human disease. The agency is requiring risk mitigation

primarily to address risk to non-target invertebrates and fish; however, risks may remain to non-target organisms even after mitigation. Any remaining risks are outweighed by the benefits of deltamethrin use. In addition, EPA notes that all states, including California, are authorized to restrict pesticide use according to state requirements/standards. For a more detailed response to submitted water quality comments, please see the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*.

Comments Submitted by Pyrethrin Joint Venture and Various Registrants (Docket ID: EPA-HQ-OPP-2008-0331-0085)

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, 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).

EPA 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 separate response.

II. USE AND USAGE

Prallethrin is a member of the pyrethroids and pyrethrins class of insecticides, which share the same mode of action. The pyrethroids and pyrethrins work by altering nerve function, causing paralysis in indoor, outdoor (i.e., ant, roach, termites, fly) and animal (i.e. tick and flea) target insect pests, eventually resulting in death.

Prallethrin is a synthetic pyrethroid insecticide that affects the peripheral and central nervous systems of insects. Prallethrin works by keeping sodium channels in neuronal membranes open in target insects, which initially stimulates nerve cells to repeatedly discharge resulting in paralysis initially (often called 'knockdown') and death eventually. The Insecticide Resistance Action Committee (IRAC) categorizes prallethrin and other synthetic pyrethroids as Mode of Action Group 3A.

Prallethrin products are registered for use in a variety of settings that include direct applications to animals (*e.g.*, horses, dogs), animal quarters (*e.g.*, stables, barns, poultry houses), stored grains, indoor and outdoor uses in residential and commercial areas, and for wide-area adult mosquito control. Products containing prallethrin are commonly co-formulated with other pyrethroids, pyrethrins, and/or piperonyl butoxide (a synergist).

Nationally, residential consumers purchased around 100,000 pounds (of active ingredient, or a.i.) of pyrethroid insecticides, 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 (*e.g.*, ant, cockroach, termite, fly control, and lawn and garden pest control insecticides), pet products, and insect repellents. Prallethrin has reported use on indoor residential areas and houseplants, but an estimated amount was not included in the report.[1] Recent data indicate almost 190,000 lbs a.i. of pyrethroids are used for wide-area applications for mosquito control.[2] Food handling establishments, including processing facilities, warehouses, restaurants, and other food preparation facilities, used around 200,000 lbs a.i. of pyrethroids in 2013, including less than 2,000 lbs a.i. of prallethrin.[3] 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.[4,5] Of this amount, almost 22,000 lbs a.i. of prallethrin was used, primarily for mosquito control. Industrial vegetation management, including roadways and rangeland, used around 2.5 million pounds a.i. of pyrethroids, including an unspecified amount of prallethrin used on roadways.[6] In 2016, 18,000 pounds a.i. of pyrethroids were used to control insects in grain storage facilities.[7] The figures mentioned here cover pyrethroids as a group and are not specific to prallethrin. Pet products used by commercial groomers are not captured in these data. Agricultural usage data for prallethrin applied directly to equines or within animal quarters were not available.

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 prallethrin. For additional details on the human health

[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] 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].
[3] Kline and Company. 2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities. [Accessed June 2019].
[4] Kline and Company. 2013. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2012. [Accessed June 2019].
[5] 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 professional pest control pesticide usage. [Accessed June 2019].
[6] Non-Agricultural Market Research Proprietary Data. 2017d. Studies conducted and sold by a consulting and research firm. Report on vegetation management. [Accessed June 2019.]
[7] Non-Agricultural Market Research Proprietary Data. 2017e. Studies conducted and sold by a consulting and research firm. Report on grain storage. [Accessed June 2019].

assessment for prallethrin, see the *Prallethrin: Revised Human Health Risk Assessment for Registration Review* (2016)*, Prallethrin: Updated Human Health Draft Risk Assessment in Support of Registration Review* (2019), and *Prallethrin: Revised Updated Human Health Draft Risk Assessment in Support of Registration Review* (2020), which are available in the prallethrin registration review docket (EPA-HQ-OPP-2011-1009).

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.

2. Risk Summary and Characterization

There is no dietary (food and water), residential, or aggregate risk of concern for either children or adults; however, there are risk estimates of concern for some occupational handler scenarios.

Dietary (Food and Water)

In the general U.S. population and all population subgroups, the acute and chronic risk estimates are below EPA's level of concern (i.e. <100% aPAD and <100% cPAD[8]). Prallethrin is classified as "not likely to be carcinogenic" to humans; therefore, a cancer dietary assessment was not conducted for prallethrin.

Residential Handler and Residential Post Application

[8] aPAD – acute population-adjusted dose; cPAD – chronic population-adjusted dose

In the 2016 draft risk assessment, the Agency identified risk estimates of concern for residential handlers and for residential post-application exposures. The dermal and inhalation exposures were both based on clinical signs related to neurotoxicity. However, the human equivalent concentration (HEC) for inhalation exposure was based on portal of entry effects, resulting in lower HECs then the HEC for systemic (neurotoxicity) effects. Therefore, the portal of entry HEC was considered protective of neurotoxic systemic effects and handler inhalation and dermal routes of exposure were not combined. Inhalation risk estimates of concern were identified for two handler exposure scenarios (adult inhalation level of concern (LOC) is 30): (1) mixing/loading/applying liquid solutions for treating horses using a trigger-spray bottle (margins of exposure (MOE) = 12); and (2) mixing/loading/applying liquid solutions to treat horse stables using a manually pressurized handwand (MOE = 13). Residential dermal, inhalation and incidental oral post-application residential exposure from the indoor surface direct spray, indoor and outdoor aerosol space sprays, and pet (*i.e.*, small dogs) use products resulted in risk estimates of concern for adults and children with MOEs below the respective LOCs (adult dermal LOC 100; adult inhalation LOC = 30; children's dermal and incidental oral LOC = 300)

In the updated human health risk assessment that was completed in September 2019, the Agency refined the inhalation risk estimates by incorporating the revised vapor pressure and inhalation point of departure (POD). As a result of the revised inhalation POD, the dermal and inhalation routes of exposure for residential handler and post-application exposure as well as occupational handler exposure scenarios should have been combined but were not. As a result, there are no risk estimates of concern associated with residential adult handler or post-application exposure. However, there remained several occupational handler scenarios with risk estimates of concern identified in the 2016 prallethrin DRA.

In the revised updated human health risk assessment that was completed in September 2020, the Agency revised the risk estimates using the aggregate risk index (ARI) since the LOCs for dermal exposure (100) and inhalation exposure (30) are different. All representative scenarios resulting in an ARI $\geq$ 1 are not of concern. In consideration of the previous reduction of the FQPA SF to 1X, there continue to be no residential risk estimates of concern for the existing residential uses of prallethrin.

Aggregate

Acute aggregate exposure and risk estimates are equivalent to the dietary (food and water) exposure and risk estimates which are not of concern.

The short-term aggregate risk estimates for children and adults resulted in ARIs > 1 and are not of concern. The short-term aggregate risk assessment resulted in an ARI of 1.5 for adults 20 to 49 years of age, for applying an end-use product with a sponge to horses. Post-application exposure to children 1 to 2 years old from an outdoor aerosol spray resulted in an ARI of 1.2. As a result, the short-term aggregate risk estimates are not of concern for the general U.S. population or any population subgroup.

Occupational

The Agency identified several occupational handler scenarios in the 2016 prallethrin draft risk assessment, in the 2019 updated human health draft risk assessment, and in the 2020 revised updated human health draft risk assessment. This ID includes four scenarios that were not previously identified in the PID. These include the handwand application scenario associated with Farnam X5306-98 (Reg. No. 270-326), the ready-to-use (RTU) aerosol can scenario associated with TC-312 (Reg. No. 499-559), and two additional indoor surface scenarios associated with MGK Formula 2964 Microencapsulated Suspension Concentrate Insecticide (Reg. No. 1021-2574). Scenarios resulting in an ARI ≥ 1 or inhalation MOE ≥ 30 are not of concern.

The following occupational handler scenario remains a risk of concern with baseline attire and additional PPE:

Multicide Fogging Concentrate 2651 (Reg. No. 1021-1812)

- Mixing/loading/applying an ***undiluted*** liquid formulation using mechanically pressurized handgun to treat indoor food handling establishments, warehouses, schools, hospitals etc. resulted in an ARI of 0.002 using baseline attire and no respirator. Even with the use of double layer clothing, gloves, and the use of a PF10 respirator, the ARI is 0.019 and remains a risk of concern.

The following occupational handler scenarios are no longer of concern with the use of additional PPE:

Farnam X5306-98 (Reg. No. 270-326)

- Applying a liquid formulation with a sponge to horses resulted in an ARI of 0.67 using baseline attire (*i.e.*, single layer clothing consisting of long pants, long sleeved shirt, socks and shoes) and no PPE (*i.e.*, no gloves or respirator). Use of double layer clothing and gloves resulted in an ARI of 1.5; and
- Mixing/loading/applying liquid solution with manually pressurized handwand to treat horse barns and poultry houses resulted in an ARI of 0.17 using baseline attire and no PPE. Use of single layer clothing, gloves and a protection factor (PF)10 respirator resulted in an ARI of 7.2
- Mixing/loading/applying liquid solution with mechanically pressurized handgun to treat horse barns and poultry houses resulted in an ARI of 0.24 using baseline attire and no PPE. Use of single layer clothing and a PF10 respirator resulted in an ARI of 2.

TC-312 (Reg. No. 499-559) ready-to-use (RTU) aerosol can

- Applicators applying space spray and surface direct spray for indoor crack and crevice application results in an ARI of 0.69 using baseline clothing and no respirator. Use of a PF10 respirator resulted in an ARI of 3. The registered label currently requires applicators using handheld foggers in enclosed areas to wear a half face, full face, or hood style NIOSH-approved respirator.

Multicide Fogging Concentrate 2651 (Reg. No. 1021-1812)

- Mixing/loading/applying liquid using stationary, handheld or portable foggers to treat indoor food handling establishments, warehouses, schools, hospitals etc. resulted in an inhalation MOE of 29 (inhalation LOC = 30) with no respirator (*study did not measure dermal exposure; therefore, no dermal unit exposure values available*). The use of a respirator with a PF10 resulted in an MOE of 290.

Multicide Fogging Concentrate 2798 (Reg. No. 1021-1795) and 2922 (Reg. No. 1021-2562)

- Mixing/loading/applying a liquid using handheld or portable foggers for mosquitocide/larvicide/vector control resulted in an inhalation MOE of 17 with no respirator (study did not measure dermal exposure; therefore, no dermal unit exposure values available). The use of a PF10 respirator resulted in an inhalation MOE of 170, with a LOC =30.

MGK Formula 2964 Microencapsulated Suspension Concentrate Insecticide (Reg. No. 1021-2574)

- Mixing/loading/applying a microencapsulated formulation using mechanically pressurized handgun for broadcast treatment of indoor food handling establishments, warehouses, schools, hospitals etc. resulted in an ARI of 0.33 using baseline attire and no respirator. Use of single layer clothing and a PF10 respirator resulted in an ARI of 2.7.
- Mixing/loading/applying a microencapsulated formulation using manually pressurized handwand to treat indoor cracks and crevices in food handling establishments, warehouses, schools, hospitals etc. resulted in an ARI of 0.58 using baseline attire and no respirator. Use of single layer clothing and a PF10 respirator resulted in an ARI of 4.7.

Occupational Post-Application

A dermal post-application exposure assessment was performed to determine potential indirect exposure for re-entry workers in agricultural fields under the airspace receiving public health mosquito vector control treatment with prallethrin. The dermal post-application exposure scenario resulted in MOEs significantly higher than the LOC (MOE $\geq$100) and are not of concern.

Although a quantitative occupational post-application inhalation exposure assessment was not performed, an inhalation post-application exposure assessment resulting from mosquito vector control applications was performed for residential bystanders. The residential bystander exposure assessment is considered to be protective of most occupational post-application inhalation exposure scenarios. If new policies or procedures are put into place, the Agency might revisit the need for a quantitative occupational post-application inhalation exposure assessment for prallethrin.

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 prallethrin, refer to the *Prallethrin: Draft Human Health Risk Assessment for Registration Review*, *Prallethrin: Updated Human Health Draft Risk Assessment in Support of Registration Review*, and *Prallethrin: Revised Updated Human Health Draft Risk Assessment in Support of Registration Review*, which are available in the prallethrin public docket (EPA-HQ-OPP-2011-1009).

3. Human Incidents and Epidemiology

Prallethrin incidents were previously reviewed in 2016 (E. Evans and S. Recore, 3/17/16, D432314). At that time, based on the low severity of prallethrin incident cases reported to the Incident Data System (IDS), NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides, and the National Pesticide Information Center (NPIC), further investigation was not warranted.

In the current IDS incident analyses from February 11, 2016 to January 6, 2020, 143 prallethrin incidents were reported to Main IDS. One hundred and thirty-nine incidents involved multiple active ingredients and four incidents involved the single active ingredient, prallethrin. Fifteen incidents were classified as major severity, 122 incidents were classified as moderate severity, five incidents were classified as minor severity, and one incident had no or unknown effects.

From February 11, 2016 to January 6, 2020, 1,783 prallethrin incidents were reported to Aggregate IDS. Eleven incidents had no or unknown effects and 1,772 incidents were classified as minor severity.

An updated query of SENSOR-Pesticides from 2013-2015 identified 88 incidents involving prallethrin. Of these 88 cases, 71 were low in severity and 17 were moderate to severity. All 88 cases involved multiple active ingredients.

4. Tolerances

Existing prallethrin tolerances are established under 40 CFR § 180.545. The currently established tolerance of 1.0 ppm for all commodities is adequate to cover the use of prallethrin in food handling establishments and as a wide-area mosquito adulticide. There are no other tolerance considerations. There are no Codex or Canadian maximum residue limits (MRLs) for prallethrin; hence, there are no harmonization issues with respect to either the residue definition or MRLs.

5. Human Health Data Needs

The Agency does not anticipate any further human health data needs for the prallethrin registration review. The registration review GDCI-128722-1244 for prallethrin has been satisfied. The registrants receiving GDCI-128722-1109 (for guideline 875.1700 product use information) 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.

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;[9] risks from outdoor residential, commercial, turf, and nursery uses; risks from agricultural (crop production) 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

[9] "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.

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 prallethrin, risks of concern were identified for aquatic invertebrates and fish from indoor; outdoor residential, commercial, and turf; and wide-area mosquito adulticide uses.

Terrestrial Invertebrates (Honey Bees)

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, RQs 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 honey bees (TGAI)
850.3030	Honey bee toxicity of residues on foliage (TGAI)
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity (TGAI)
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity (TGAI)
Non-Guideline	Honey bee adult chronic oral toxicity (TGAI)
Non-Guideline	Honey bee larvae chronic oral toxicity (TGAI)
Tier 2[†]	
Non-Guideline	Field trial of residues in pollen and nectar (TEP)
Non-Guideline (OECD 75)	Semi-field testing for pollinators (TEP)
Tier 3[†]	
850.3040	Full-Field testing for pollinators (TEP)

[†] 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 may reassess risk to pollinators and consider any additional mitigation changes for prallethrin.

1. Ecological and Environmental Fate Data Needs

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

C. Benefits Assessment

Pyrethroids and pyrethrins are the most common active ingredients labeled for a wide variety of equine pests.[10] Prallethrin and products containing prallethrin are recommended by university extension specialists and the American Association of Equine Practitioners (AAEP), as they provide knockdown protection from several nuisance and/or mechanical vectors (*e.g.*, face flies, stable flies) and disease-vectoring pests (*e.g.*, mosquitoes, fleas, ticks).[10,11] Prallethrin products may be applied as a surface spray, fog, or mist treatment within animal quarters (*e.g.*, barn, stable) or directly to equines. Prallethrin fog or mist applications stay airborne longer and increase the likelihood of pests contacting the treatment. Space treatments are an effective control option for pests with life cycles completed within animal quarters. Direct application of prallethrin to the animal provides constant protection for several days and may be advantageous as pest breeding sites and other pest sources outside of the quarters may be difficult to manage.[10]

Alternatives to prallethrin depend on the target pest and application method which may be applied to animals or structures in addition to products formulated as baits or feed-through additives. These products include other pyrethroids and pyrethrins, carbamates (e.g., methomyl), diflubenzuron, methoprene, neonicotinoids (*e.g.*, dinotefuran, imidacloprid), organophosphates (*e.g.*, coumaphos, DDVP, tetrachlorvinphos, trichlorfon), and spinosad. Additionally, fly traps and sanitation or exclusion practices may reduce or control pest populations.

Prallethrin is also co-formulated with d-phenothrin (also called sumithrin) to reduce adult mosquito populations (*i.e.*, as a mosquito 'adulticide'). It appears that the main benefit of prallethrin in this context is as a causative agent of 'excitation', described as an increase in flight speed and duration.[12] This results in increased exposure to the insecticide mixture, and thus

[10] Townsend, L. 2012. Insect Control for Horses, Horse Barns, and Stables- 2013. University of Kentucky Cooperative Extension Services. https://entomology.ca.uky.edu/files/efpdf3/ef513.pdf. [Accessed October 2019]
[11] American Association of Equine Practitioners (AAEP). 2016. External Parasite and Vector Control Guidelines. https://aaep.org/sites/default/files/Guidelines/AAEP-ExternalParasites071316Final.pdf. [Accessed October 2019].
[12] Cooperband, M.F., F.V. Golden, G.G. Clark, W. Jany, and S.A. Allan. 2010. Prallethrin-Induced Excitation Increases Contact Between Sprayed Ultralow Volume Droplets and Flying Mosquitoes (Diptera: Culicidae) in a Wind Tunnel. J. Med. Entomol. 47(6): 1099-1106.

increased mortality of adult mosquitoes.[12,13] While insecticides containing prallethrin are not the only adulticides available to mosquito control agencies in the U.S., it is one that is mentioned as an effective option along with other pyrethroids and some organophosphates for areas that require suppression of the adult life stages.[13]

For more information on the usage of prallethrin, refer to the *Usage Characterization and Alternatives Summary for Synthetic Pyrethroids Used in Residential Lawns and Outdoor Vegetative Spot Treatments* and *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito Adulticides in Support of Registration Review* (available in the public docket (EPA-HQ-OPP-208-0331). 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 is no dietary (food and water), residential or aggregate risk of concern associated with the registered uses of prallethrin; however, prallethrin poses potential risks of concern to occupational handlers. As a result, the Agency is requiring additional mitigation measures beyond those needed to clarify, update, and improve consistency of product labeling. In addition, the Agency identified potential risks for various taxa (freshwater and terrestrial invertebrates, and fish), with the major potential risks of concern focusing on aquatic invertebrates from indoor, outdoor, and mosquito adulticide uses. Mitigation to address risks to aquatic and terrestrial invertebrates will benefit the other taxa to the extent that there is any risk.

The residential indoor products containing pyrethroids are expected to result in ecological risks of concern from the use of pet shampoos; pyrethroid-impregnated or treated textiles being laundered; and indoor household treatments (*e.g.*, carpet, furniture, or bedding) to control bed bugs, fleas, and other pests with public health significance. Under these use patterns, 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

[13] Lloyd, A.M., C.R. Connelly, and D.B. Carlson (Eds.). 2018. Florida Coordinating Council on Mosquito Control. Florida Mosquito Control: The state of the mission as defined by mosquito controllers, regulators, and environmental managers. Vero Beach, FL: University of Florida, Institute of Food and Agricultural Sciences, Florida Medical Entomology Laboratory. Available on the web at https://fmel.ifas.ufl.edu/ [Accessed November 2019].

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.

Applications of pyrethroids for wide-area adult mosquito control also are expected to result in potential risks of concern to aquatic invertebrates and fish. However, these mosquito control applications are made to control mosquito-borne diseases and have high benefits for public health. The Agency has determined that label revisions to improve consistency and clarity of labels for wide-area mosquitocide products used are necessary, but potential risks of concern to aquatic invertebrates and fish may remain. The Agency concludes that the importance of pyrethroids as a pest control option in wide-area mosquito control programs outweighs the remaining potential risks.

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 prallethrin labels and updates to glove and respirator language is necessary, where applicable.

1. Mitigation Measures to Promote Proper Usage and Reduce Indoor and Inadvertent 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 required 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 appropriate 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 an image 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 that could result in 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 found that in order to protect aquatic environments from risks posed by pyrethroids, a reduction in the application footprint of these pesticides is appropriate. 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 decided 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 required 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 appropriate. These include:

C. 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.)."

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 appropriate. 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.[14] 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."

3. Mitigation Measures for Wide-Area Mosquito Adulticide Uses

EPA has determined that label changes to reduce off-target spray drift and establish consistent labeling across all mosquito adulticide products is appropriate. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target species. The required mitigation measures are intended to reduce the overall amount of pyrethroids that enters waterbodies and outdoor drainage systems. The Agency has determined that pesticide resistance management information is necessary for products with wide-area mosquito adulticide use and has added this requirement for these labels.

Wide-area Mosquito Adulticide Label Consistency and Clean Up

[14] 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

Mitigation measures and application measures differ for products with conventional mosquito control uses and products with wide-area mosquito adulticide public health uses. The Agency recommends separate labels be generated for the public health wide-area mosquito adulticide uses – either sub labels, or mosquito adulticide only registrations. This would reduce confusion for the applicators and reduce misapplications.

Required label statements intended to reduce potential risk to aquatic organisms are as follows:

Wind Speed Statements

- "Apply when ground wind speeds are equal to or greater than 1 mph.

- All types of applications should be conducted when temperatures at ground level are at or above 50°F."

Release Height Statement

"For Ground applications:

- Create an optimum swath when possible. An optimum swath width can be achieved when [product name] is applied from a truck that is being driven perpendicular to the wind direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area.

- FOR BEST RESULTS treat when mosquitoes or insects are most active and weather conditions are conducive to keeping the spray cloud in the air column close to the ground.

- An inversion of air temperatures and a light breeze is preferable. Application during the cooler hours of the night or early morning is recommended."

"For Aerial Applications:

- Do not apply by fixed wing aircraft at a nozzle height less than 100 feet (30.5 m) above ground or canopy, or by helicopter at a height less than 75 feet (22.9 m) above the ground or canopy, unless specifically approved by the state or tribe based on public health needs."

Environmental Hazard Statements:

EPA has determined that limiting adult mosquito control applications to trained personnel is appropriate. Therefore, the following label statement is required for non-Restricted-Use Products (non-RUPs) for wide-area adult mosquito control:

"Adult mosquito control applications should be limited to trained personnel.

- For use only by federal, state, tribal or local government officials responsible for public health or vector control or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult

mosquito control applications, or by persons under their supervision, or as allowed by state regulations for persons treating private property.

- This pesticide is [toxic/extremely toxic][15] to aquatic organisms. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to aquatic organisms.

- Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material beyond the body of water to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or wash waters.

- Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.

- Do not treat a site with more than (X amount)* of each a.i., per acre in a single application or in any 24-hour period. Do not exceed (X amount)* of a.i. in any site in one year. More frequent applications may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease-causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort."

*Note to registrants: X amount must be on the previously approved label

4. Human Health

The Agency is requiring the following mitigation measures to address the occupational handler scenarios with risks of concern (see Section III.A.2). The registrants agreed with the Agency's mitigation measures.

Elimination of Uses and Application Methods

The EPA is eliminating the following uses and application methods to mitigate potential dermal and inhalation risks to occupational handlers:

- Use of a clean cloth or sponge to treat horses (EPA Reg. No. 270-326)

[15] Registrants should follow EPA's guidance in Chapter 8 of EPA Label Review Manual to determine which version of this statement is appropriate.

- Use of a mechanically pressurized handgun using undiluted liquid to treat indoor areas (EPA Reg. No. 1021-1812)

The EPA does not know how common these uses are. The Agency acknowledges that eliminating these uses may require users of prallethrin products to use another product or application method which may be more expensive or less effective for users.

Gloves and Respirator Requirement for Mixers, Loaders, and Applicators for Handwand Application of Farnam X5306-98 (EPA Reg. No. 270-326)

- To mitigate the potential dermal and inhalation risks for handlers of liquid solution using a manually pressurized handwand to treat horse barns, EPA is requiring that handlers (mixers, loaders, and applicators) of the product wear gloves and a PF10 respirator.

Respirator Requirement for Several Application Methods

To mitigate potential inhalation risk to occupational handlers, the Agency is requiring a PF10 respirator for the following:

- Mixers and loaders applying liquid solution Farnam X5306-98 (EPA Reg. No. 270-326) with mechanically pressurized handgun to treat horse barns and poultry houses.
- Mixers and loaders of liquid solution (EPA Reg. No. 1021-1812) using stationary, handheld or portable foggers to treat enclosed areas (such as commercial apartments, food handling establishments, food processing plant, warehouses, schools, hospitals etc.),
- Mixing and loaders applying a liquid Multicide Fogging Concentrate 2798 (Reg. No. 1021-1795) and 2922 (Reg. No. 1021-2562) using handheld or portable foggers for mosquitocide/larvicide/vector control.
- Mixers and loaders applying MGK Formula 2964 *Microencapsulated Suspension Concentrate Insecticide (Reg. No. 1021-2574) using mechanically pressurized handgun for broadcast indoor treatment and manually pressurized handwand for treatment of indoor cracks and crevices in food handling establishments, warehouses, schools, hospitals etc.

With the exception of horse barns and poultry houses, handlers in most of these scenarios would likely be professional applicators and are therefore likely to be using respirators as part of their work. The impact of these requirements for those handlers will be low. If a prallethrin product handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler's employer. Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Alternatively, users could hire a commercial firm to make applications or use other products.

In addition to potential monetary costs of respirators, the use of a respirator can reduce productivity of workers wearing a respirator. Workers wearing respirators may need to take more

frequent breaks in certain situations (*e.g.*, high temperatures) than those not wearing a respirator.[16] Individuals will respond differently to the use of a respirator, depending on the fitness level of the individual and the conditions in which the respirator is used. The requirement of a respirator may decrease productivity, which could increase the time required to mix and load the tanks, which could increase costs. Alternatively, applicators may choose to use an alternative to prallethrin that does not require a respirator.

The EPA acknowledges that requiring a respirator places a burden on handlers or employers. In estimating the inhalation risks, and the risk reduction associated with different respirators, EPA's human health risk assessments assume NIOSH protection factors (*i.e.*, respirators are used according to Occupational Safety and Health Administration's (OSHA) standards). If the respirator does not fit properly, use of prallethrin may cause unreasonable adverse effects on the pesticide handler.

5. 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 prallethrin 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.

6. Update Glove and Respirator Language

The Agency is updating the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, the Agency is removing the reference to specific categories in

[16] Johnson, A.T. 2016. Respirator masks protect health but impact performance: a review. Journal of Biological Engineering 10:4, DOI 10.1186/s13036-016-0025-4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4748517/pdf/13036_2016_Article_25.pdf, last accessed July 2018.

EPA's chemical-resistance category selection chart and is instead specifying the appropriate glove types to use on the labels. 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

As stated in Section III. A.4., no changes to the tolerance levels, crop listings, or the tolerance expression are necessary at this time.

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 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 prallethrin, 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 prallethrin. The Agency's final registration review decision for prallethrin 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 pollinator data listed under Section III.B. is required, and EPA will issue a DCI for the data. The registrants receiving GDCI-128722-1109 (for guideline 875.1700 product use information 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.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this ID for prallethrin. A final decision on the prallethrin 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 ESA Section § 7 consultation with the Services.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the prallethrin 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 in the docket.

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 prallethrin 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 prallethrin 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 Marisa Wright at one of the following addresses, as 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

Docket Number EPA-HQ-OPP-2011-1009
www.regulations.gov

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 Prallethrin

Registration Review Case #: 7418 PC Code: 128722 Chemical Type: Insecticide Chemical Family: Pyrethroid Mode of Action: Axonic excitotoxins (alter nerve function)					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions
Human Health					
Occupational handler	Applying liquid formulation with a sponge to treat horses	Dermal	Short-term dermal (1 to 30 days)	Dermal toxicity	Removal of application method
Occupational handler	Mixing/loading/applying a liquid solution with manually pressurized handwand to treat horse barns and poultry houses	Dermal and Inhalation	Short-term dermal and inhalation (1 to 30 days)	Dermal and Inhalation toxicity	Additional PPE
Occupational handler	Mixing/loading/applying a liquid solution with mechanically pressurized handgun to treat horse barns and poultry houses	Inhalation	Short-term dermal (1 to 30 days)	Inhalation toxicity	Additional PPE
Occupational handler	Mixing/Loading/Applying liquid using stationary, handheld or portable foggers to treat commercial apartments, food handling establishments, food processing plants, warehouses, schools, hospitals, etc.	Inhalation	Short-term inhalation (1 to 30 days)	Inhalation toxicity	Additional PPE

Occupational handler	Mixing/Loading/Applying undiluted liquid formulation using mechanically pressurized handgun to treat indoor food handling establishments, warehouses, schools, hospitals, etc.	Dermal and Inhalation	Short-term dermal and inhalation (1 to 30 days)	Dermal and Inhalation toxicity	Prohibit application method
Occupational handler	Mixing/Loading/Applying liquid using handheld or portable foggers for mosquitocide/larvicide vector control	Inhalation	Short-term inhalation (1 to 30 days)	Inhalation toxicity	Additional PPE
Occupational handler	Mixing/loading/applying a microencapsulated formulation using mechanically pressurized handgun for broadcast treatment of indoor food handling establishments, warehouses, schools, hospitals etc.	Inhalation	Short-term inhalation (1 to 30 days)	Inhalation toxicity	Additional PPE
Occupational handler	Mixing/loading/applying a microencapsulated formulation using manually pressurized handwand to treat indoor cracks and crevices in food handling establishments, warehouses, schools, hospitals etc.	Inhalation	Short-term inhalation (1 to 30 days)	Inhalation toxicity	Additional PPE

Ecological					
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

Appendix B: Required Labeling Changes for Prallethrin Products

Description	Required Label Language for Prallethrin End Use Products	Placement on Label
	All Prallethrin End Use Products (unless specified otherwise)	
Mode of Action Group Number *Applies only to products with wide-area mosquito uses*	**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. **Prallethrin** | **GROUP** | **3A** | **INSECTICIDE**	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.
Resistance-management labeling statements for insecticides *Applies only to products with wide-area mosquito uses*	Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops
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
Updated Respirator Language	If your label currently contains respirator requirements, update the language based on https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment.	In the Personal Protective Equipment (PPE) within the Precautionary Statements

	[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 and 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.	
Additional Required Labelling Action. *Applies to all products delivered via liquid spray applications (except those with mosquito use)*	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
	Label-Specific Requirements	
	EPA Reg. No. 270-326	
Removal of application method EPA Reg. No. 270-326	Remove the application method using a clean cloth or sponge to treat horses by deleting the sentence, "As a wipe, apply liberally with a clean cloth or sponge"	Directions for Use
PPE Requirement – Gloves and PF10 Respirator	Add the following statements:	In the Personal Protective Equipment (PPE) within Precautionary Statements

EPA Reg. No. 270-326	"All mixers and loaders using manually pressurized handwands in an enclosed area must wear long-sleeved shirt, long pants, shoes and socks, [INSERT APPROPRIATE TYPE] gloves, and a respirator." **Note to registrant:** Refer to Chapter 10 of the Label Review Manual for guidance on what types of gloves need to be included on the label. Choose the appropriate respirator language from the following: **[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 and 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. For more information, refer to https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment.	and Agricultural Use Requirements, if applicable
PPE Requirement – PF10 Respirator **EPA Reg. No. 270-326**	Add the following statement: "All mixers and loaders using mechanically pressurized handguns in an enclosed area must wear long-sleeved shirt, long pants, shoes and socks, and a respirator." Choose the appropriate respirator language from the following:	In the Personal Protective Equipment (PPE) within Precautionary Statements and Agricultural Use Requirements, if applicable

	[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 and 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. For more information, refer to https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment.	
	EPA Reg. No. 1021-1812	
PPE Requirement – PF10 Respirator EPA Reg. No. 1021-1812	Add the following statement: "All mixers and loaders using handheld or portable foggers in an enclosed area must wear long-sleeved shirt, long pants, shoes and socks, and a respirator." Choose the appropriate respirator language from the following: **[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."	In the Personal Protective Equipment (PPE) within Precautionary Statements and Agricultural Use Requirements, if applicable

	*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 and 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. For more information, refer to https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment.	
Application Method Restriction **EPA Reg. No. 1021-1812**	Add the following restriction: "Do not use a mechanically pressurized handgun when applying undiluted spray in indoor areas."	In Use Restrictions within Directions for Use
	EPA Reg. Nos. 1021-1812 and 1021-2562	
PPE Requirement – PF10 Respirator **EPA Reg. Nos. 1021-1812 and 1021-2562**	Add the following statement: "All mixers and loaders using handheld or portable foggers for mosquitocide/larvicide/vector control must wear long-sleeved shirt, long pants, shoes and socks, and a respirator." Choose the appropriate respirator language from the following: **[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.	In the Personal Protective Equipment (PPE) within Precautionary Statements and Agricultural Use Requirements, if applicable

	[Note to registrant: For respiratory protection from organic vapor and 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. For more information, refer to https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment.	
	EPA Reg. No. 1021-2574	
PPE Requirement – PF10 Respirator **EPA Reg. No. 1021-2574**	Add the following statement: "All mixers and loaders applying a microencapsulated formulation using a manually pressurized handwand or mechanically pressurized handgun in an enclosed area must wear long-sleeved shirt, long pants, shoes and socks, and a respirator." Choose the appropriate respirator language from the following. **[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 and particulates (or aerosols), use the following language:]**	In the Personal Protective Equipment (PPE) within Precautionary Statements and Agricultural Use Requirements, if applicable

	"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. For more information, refer to https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment.	
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
Steward-ship statement that	Note to registrants: If adding stewardship statements on end-use consumer products, the following language is required and must be placed in a prominent location:	Directions for Use

includes a Spanish translation (Stewardship statement not required for products applied to pets)	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 .25 square inches unless this size is greater than 10% of the size of the label). **Use the following pictogram on product labels:** 	
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	"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;	Directions for Use

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.]**	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."	
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." "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 after application to the point of runoff."	Directions for Use
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 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."	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 wide-area mosquito uses		
Enforceable Spray Drift Management Language for products that allow aerial applications	• Apply when ground wind speeds are equal to or greater than 1 mph. • All types of applications should be conducted when temperatures at ground level are at or above 50°F. "For Ground Applications: • Create an optimum swath when possible. An optimum swath width can be achieved when [product name] is applied from a truck that is being driven perpendicular to the wind direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area. • FOR BEST RESULTS treat when mosquitoes or insects are most active and weather conditions are conducive to keeping the spray cloud in the air column close to the ground. • An inversion of air temperatures and a light breeze is preferable. Application during the cooler hours of the night or early morning is recommended."	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ultra Low Volume Applications"

	"For Aerial Applications: • Do not apply by fixed wing aircraft at a nozzle height less than 100 feet (30.5 m) above ground or canopy, or by helicopter at a height less than 75 feet (22.9 m) above the ground or canopy, unless specifically approved by the state or tribe based on public health needs."	
Enforceable Spray Drift Management Language for products that allow aerial applications	"Adult mosquito control applications should be limited to trained personnel. • For use only by federal, state, tribal or local government officials responsible for public health or vector control or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their supervision, or as allowed by state regulations for persons treating private property". • This pesticide is [toxic/extremely toxic][17] to aquatic organisms. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to aquatic organisms. • Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material beyond the body of water to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or wash waters. • Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist. • Do not treat a site with more than (X amount)* of each a.i., per acre in a single application or in any 24-hour period. Do not exceed (X amount)* of a.i. in any site in one year. More frequent applications may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease-causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort." *Note to registrants: X amount must be on the previously approved label	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ultra Low Volume Applications"

[17] Registrants should follow EPA's guidance in Chapter 8 of EPA Label Review Manual to determine which version of this statement is appropriate.