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Deltamethrin

Interim Registration Review Decision
Case Number 7414

September 2020

Approved by: _____

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

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Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for deltamethrin (PC Code 097805, case 7414), 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 deltamethrin, can be found in the EPA's public docket (EPA-HQ-OPP-2009-0637) 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 the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

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

Deltamethrin is a pyrethroid acaricide/insecticide registered for use to control a broad spectrum of pests (including cockroaches, mosquitos, bed bugs, mites, ants, weevils, and beetles) in both

agricultural and non-agricultural settings. Agricultural uses for deltamethrin include cotton, sorghum, pears, artichokes, and other vegetables, fruits, and tree nut crops. Non-agricultural uses include indoor and outdoor perimeter treatments to control pests such as cockroaches, silverfish, mosquitos, bedbugs, and other flying and crawling insects in residential and industrial settings. Deltamethrin is also registered for use as a pet collar to control fleas and ticks. The first product containing deltamethrin was registered in 1994 and deltamethrin was not subject to the reregistration requirements of FIFRA.

Deltamethrin is a member of the pyrethroids and pyrethrins class of insecticides, which share the same mode of action. These insecticides work by altering nerve function, causing paralysis in target insect pests (also called "knockdown"), and eventually resulting in death. The Agency has determined that the pyrethroids and pyrethrins belong to a common mechanism group (http://www.regulations.gov; EPA-HQ-OPP-2008-0489-0006), and the Insecticide Resistance Action Committee (IRAC), composed of industry and university scientists, categorizes them together in Mode of Action Group 3A, since they all have the same site of action in affected insects. A screening-level cumulative risk assessment to assess human health risks from this group of pesticides was completed in 2011. This analysis did not identify cumulative risks of concern for children and adults. For further information, please see Section III. 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 the *Deltamethrin Proposed Interim Registration Review Decision* (PID), which describes the Agency's proposed human health and ecological risk management approach for deltamethrin, EPA previously published and opened a 60-day public comment period on the following documents: *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*, which summarizes the ecological risk management approach and outlines EPA's required mitigation to address all other potential ecological risks for the pyrethroids as a whole, and the *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 deltamethrin. Those documents, as well as additional supporting documents, are located in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2008-0331).

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

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

context with a discussion of risk characterization; the *Interim Registration Review Decision*, which describes the mitigation measures necessary to address risks of concern and the regulatory rationale for the EPA's ID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Updates since the Proposed Interim Decision was Issued

In May 5, 2020, EPA published the PID for deltamethrin. In this ID, there are several updates to what was required 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, agricultural, and mosquito adulticide uses to improve clarity and consistency. The vegetative filter strip (VFS) requirements for the agricultural uses of pyrethroids has been revised to add flexibility for users. For Western irrigated agriculture, EPA is allowing use of a sediment control basin in lieu of constructing and maintaining a VFS. In addition, the Agency is also adding an allowance for treatment areas of 10 acres or less to retain a 15-foot VFS. The Agency considers the use of sediment control basins for Western irrigated agriculture as effective as a VFS in retaining sediment and minimizing runoff, without the burden of constructing and maintaining a VFS. The allowance for treatment areas of 10-acres or less to retain a smaller VFS will alleviate some of the impact on small scale operations, who may be disproportionately impacted by the expanded VFS requirements. See the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals,* for a detailed discussion of the changes made to the required mitigation. There have not been updates to the human health mitigation from what was required in the ID, nor any updates to the draft risk assessment (DRA). This ID thus finalizes the Agency's draft supporting documents: the *Deltamethrin Draft Human Health Risk Assessment for Registration Review,* the *Deltamethrin: Revised Human Health Draft Risk Assessment in Support of Registration Review,* 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.

B. Summary of Deltamethrin Registration Review

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

- March 2010 - The *Deltamethrin Summary Document;* the *Deltamethrin Human Health Assessment Scoping Document in Support of Registration Review;* and the *Environmental Fate and Ecological Risk Assessment Problem Formulation in Support of Registration Review for Deltamethrin,* were posted to the docket for a 60-day public comment period. Several comments were submitted by the California Stormwater Quality Association, two municipal water boards, and Bayer CropScience. The comments prompted the addition of

two new data requirements in the deltamethrin FWP: the publicly owned treatment works effluent monitoring study and the treatability study.

- September 2010 - The *Deltamethrin Final Work Plan* (FWP) was issued.

- October 2011 – A Generic Data Call-In Notice (GDCI-097805-899) for deltamethrin was issued for environmental fate and ecological effects data needed to conduct the registration review risk assessments. The registrants have submitted studies in response to every guideline requirement; however, not all submitted studies have been reviewed and some environmental fate data gaps remain. EPA is still reviewing the submitted studies.

- February and August 2012 – Two GDCIs (GDCI-097805-1210 and GDCI-0907805-1100) were issued for additional data needed to conduct registration review risk assessment for deltamethrin. GDCI-097805-1210 (for pet collar residue data) is satisfied. GDCI 097805-1100 (for product use information) is partially satisfied; EPA has received and accepted data from companies who represent the Residential Exposure Joint Venture. EPA continues to evaluate data submitted from companies comprising the Generic Residential Exposure Task Force and will update the status of this DCI when the review is completed.

- November 2016 - The Agency announced the availability of the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* (referred to as the "Ecological Risk Assessment" hereafter), and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* (referred to as the "Rationale Document" hereafter) for a 60-day public comment period.
    - The comment period was extended for the Ecological Risk Assessment and the Rationale Document from January until July 2017.
        - During the public comment period, EPA received over 1,400 public comments across all the dockets of the pyrethroids.
        - 11 comments were received in the deltamethrin docket. Of these comments, only one addressed deltamethrin specifically. All other comments addressed pyrethroids in general and were not specific to deltamethrin. 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 Pyrethroids and Pyrethrins Insecticides*, which can be found in the Special Docket for Pyrethroids, Pyrethrins, and Synergists docket, EPA-HQ-OPP-2008-0331.

- August 2017 - The Agency announced the availability of *Deltamethrin. Draft Human Health Draft Risk Assessment for Registration Review* for a 60-day public comment period.
    - 31 comments were received in the deltamethrin docket during the comment period. Of these comments one addressed deltamethrin specifically. The other 29 comments addressed pyrethroids in general and were not specific to deltamethrin. Comments did not result in changes to the risk assessments for deltamethrin.

- November 2018 – The Agency released *Final Report External Peer Review of EPA S Physiologically-based Pharmacokinetic (PBPK) Model for Deltamethrin and Permethrin and PBK-Pharmacodynamic (PBK-PD) Model for Carbaryl* in the deltamethrin registration review docket EPA-HQ-OPP-2009-0637.

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

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

- November 2019 – The Agency opened a 60-day public comment period for the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals.* This document is in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (located at www.regulations.gov, docket EPA-HQ-OPP-2008-0331).

    - Along with the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*, the following 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 Pyrethroid 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*
  - *Instructions for Commenting on the Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals and the Proposed Interim Registration Review Decisions (PIDs) for 5 Pyrethroids* (also posted in the deltamethrin registration review docket, EPA-HQ-OPP-2009-0637)

- May 2020 – The Agency announced the availability of the deltamethrin PID in the deltamethrin registration review docket (EPA-HQ-OPP-2009-0637) for a 60-day public comment period.
  - Along with the deltamethrin PID, the following documents were posted in the deltamethrin registration review docket (EPA-HQ-OPP-2009-0637):
    - *Deltamethrin: Revised human health Risk Assessment in Support of Registration Review*
    - *Deltamethrin. Response to Public Comments on the Deltamethrin Draft Risk Assessment for Registration Review*

- September 2020 – The Agency has completed the deltamethrin ID and intends to post it in the deltamethrin registration review docket (EPA-HQ-OPP-2009-0637). Twelve comments were received from various stakeholders during the public comment period on the PID. Comments resulted in minor editorial changes to the required labeling for deltamethrin.
  - Along with the deltamethrin ID, the following documents will also be posted in the deltamethrin registration review docket (EPA-HQ-OPP-2009-0637):
    - *Pyrethroids: Health Effects Division Response to Public Comments Submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists [EPA-HQ-OPP-2008-0331]*, September 2020
    - *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals, September 2020*

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

The 60-day public comment period for the *Deltamethrin Proposed Interim Registration Review Decision* 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, including the

Pyrethroid Working Group, the Pyrethroid Joint Venture, various registrants, states, local municipalities, non-governmental organizations, growers, pesticide industry groups, and other stakeholders. Twelve public comments were received for deltamethrin specifically, which are addressed in this document. One comment was not substantive, and eleven comments related to deltamethrin specifically. In total, the following stakeholders submitted comments to the deltamethrin docket in response to the PID: anonymous commenter (docket ID: EPA-HQ-OPP-2009-0637-0100), United States Department of Agriculture (EPA-HQ-OPP-2009-0637-0101), the Scott's Company (EPA-HQ-OPP-2009-0637-0102), American Mosquito Control Association (EPA-HQ-OPP-2009-0637-0103), National Association of Clean Water Agencies (EPA-HQ-OPP-2009-0637-0104), California Stormwater Quality Association (EPA-HQ-OPP-2009-0637-0105), National Pest Management Association (EPA-HQ-OPP-2009-0637-0106), Bayer CropScience (EPA-HQ-OPP-2009-0637-0107), San Francisco Bay Regional Water Quality Control Board (EPA-HQ-OPP-2009-0637-0108), Bay Area Clean Water Agencies (EPA-HQ-OPP-2009-0637-0109), the Washington State Department of Agriculture (EPA-OPP-HQ-2009-0637-0111), and Clarke Mosquito Control Products (EPA-HQ-OPP-2009-0637-0112).

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 issues, and pet health and pet health concerns, and the Agency's responses, are addressed in detail in the document 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 deltamethrin docket. Substantive deltamethrin-specific comments and the Agency's responses are summarized below.

Comments Submitted by United States Department of Agriculture (EPA-HQ-OPP-2009-0637-0101)

Comment: In general, the United States Department of Agriculture (USDA) supported the Agency's proposed resistance management labeling, and advisory language for the protection of pollinators. USDA concluded that the Agency's proposed label changes will not negatively impact growers and will enhance the clarity of deltamethrin product labels for users.

USDA expressed concerns regarding the proposed droplet size language for ground boom and aerial applications. Because spray nozzles are often marketed with specifications directly for droplet size control, USDA proposed the following revision: "*Applicators are required to select nozzles and pressure that deliver medium or coarser droplets as indicated in manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572.1 (ASABE §572.1).*"

In addition, USDA encouraged EPA to consider a more comprehensive approach to international maximum residue limit (MRL) harmonization by evaluating not only existing U.S. tolerances, but also cases where Codex has established an MRL and EPA has no corresponding tolerance.

The USDA Animal and Plant Health Inspection Service (APHIS) also commented on the benefits of deltamethrin. APHIS noted that deltamethrin, along with various other pyrethroids, are used to treat nursery stock in quarantine programs to prevent the spread of Asian citrus psyllid, the vector for citrus greening disease. Deltamethrin is also recommended to control adult Japanese beetle in integrated pest management handbooks provided to homeowners. Surface, perimeter, spot, crack and crevice, or mist applications of deltamethrin are also used to treat the khapra beetle at ports and other hitchhiker pests in containers, ships, or on aircraft.

EPA Response: EPA thanks USDA for its comments and has taken them into consideration. EPA is revising the droplet size text for ground boom and aerial application to note that applicators are required to select the nozzle and pressure that will deliver the appropriate droplet size. See Appendix B of this document for the revised droplet size language.

Regarding the potential for additional harmonization with Codex MRLs, EPA attempts to harmonize existing US tolerances with Codex MRLs where feasible. However, harmonization is not possible in some cases due to a difference in tolerance expression (*e.g.*, a difference in metabolites covered), a difference in commodity definition (*e.g.*, livestock meat versus livestock fat), or a difference in use pattern (*e.g.*, in season versus post-harvest). Additionally, the Agency does not establish new tolerances in the registration review process other than those that might result from crop group updates. Any petition to establish a new tolerance for deltamethrin should be sent to the Registration Division Product Manager for deltamethrin. Lastly, EPA does not routinely harmonize US tolerances for pesticide residues in/on livestock feed commodities with Codex MRLs.

EPA thanks APHIS for information submitted on the specific benefits of deltamethrin and acknowledges the general benefits of pyrethroids use in many settings.

Comments Submitted by the Scott's Company and the American Mosquito Control Association

Comment: The Scott's Company (EPA-HQ-OPP-2009-0637-0102) sought clarification on the required labeling for residential consumer products. Citing PR Notices 2017-1 and 2, Scotts noted that residential consumer product labels should be excluded from the requirement to list the mode of action group number and other resistance management labeling. The Scott's Company noted that it was also unclear whether the following pollinator labeling measures were meant to be excluded from residential consumer labels: the link to pollinator best management practices, the information on state managed pollinator protection plans, and information on how to report bee incidents. Scotts also proposed its own pollinator labeling for consumer labels.

The American Mosquito Control Association (AMCA) (EPA-HQ-OPP-2009-0637-0103) also submitted comments on resistance management and pollinator labeling. AMCA mentioned their support of the pesticide resistance management labeling for mosquito adulticide ULV products, as the inclusion of resistance management labeling can help minimize potential pest resistance to pyrethroids as well as pyrethroid alternatives such as organophosphates. AMCA notes that wide area ultra low volume (ULV) broadcast applications to control adult mosquitoes require suitable conditions that promote drift of very fine droplets at a fraction of the dosage used in agriculture.

Wide area ULV applications is performed in the late evening or early morning hours when mosquitos are active, but most pollinators are not, which minimizes potential exposure. AMCA proposed alternative pollinator statements for products with ULV mosquitocide uses.

EPA Response: EPA thanks the Scott's Company and AMCA for its feedback on the deltamethrin PID. The Agency confirms that resistance management labeling are not intended for residential use products. While PR Notices 2017-1 and 2 excludes residential use labels, it does not exclude public health mosquito adulticide labels, therefore resistance management labeling is required for mosquito ULV products. The proposed pollinator statements are intended for liquid agricultural outdoor use products only. The Agency has made modifications to the Appendix B label table so that it is clear to users and stakeholders which statements are required for residential use products.

Comments Submitted by Various Water Boards/Water Agencies

Comment: The National Association of Clean Water Agencies (NACWA) (EPA-HQ-OPP-2009-0637-0104), the California Stormwater Quality Association (CASQA) (EPA-HQ-OPP-2009-0637-0105), the San Francisco Bay Regional Water Quality Control Board (SFBRWQCB) (EPA-HQ-OPP-2009-0637-0108), and the Bay Area Clean Water Agencies (BACWA) (EPA-HQ-OPP-2009-0637-0109) commented on the proposed risk mitigation for deltamethrin. 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 deltamethrin 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 Bayer CropScience (EPA-HQ-OPP-2009-0637-0107)

Comment: Bayer CropScience supported the corrections in the revised deltamethrin human health risk assessment. Bayer also supported the EPA's proposed pollinator labeling. Bayer sought clarification concerning EPA's proposal to increase the US tolerance for poultry fat to 0.1 ppm, to harmonize with the Codex Maximum Residue Levels (MRL) for meat fat. According to the BCI MRL database, there are no Codex MRLs for poultry fat or cattle fat.

EPA noted in the PID that the following study was outstanding: guideline 850.6100, environmental chemistry methods (ECM) and associated independent laboratory validation (ILV) for soil/sediment and water for the isomers of deltamethrin. The submitted study (MRID 49263805) was classified as supplemental and Bayer proposed an approach to satisfy this requirement. Analysis of pyrethroids at very low levels is difficult because of issues with binding to glass as well as low detection limits. Both the soil and water ILVs performed using Bayer's methods were satisfactory using the primary ion. The water ILV failed for the secondary ion in the final test. For the soil ILV, the secondary ion had to be removed due to inadequate sensitivity. The secondary ion was not tested in later attempts because it was questionable if the ILV would have been successful. Dues to the difficulties with soil and water ILV testing for the secondary ion, Bayer recommends that EPA rely on the Pyrethroid Working Group (PWG) methods for both soil and water. The soil method was submitted by PWG: MRID 47053001 (soil method), MRID 47053002 (soil method validation), MRID 48935001 (soil ILV). An ILV for the water method was also submitted by PWG (MRID 49310901). Since the PWG methods are multi-residue methods covering several pyrethroids, both the Bayer and PWG methods for deltamethrin provides the sum of deltamethrin and its two isomers. Bayer believes this approach would satisfy this data requirement.

EPA Response: EPA attempts to harmonize existing US tolerances with Codex MRLs where feasible. The BCI MRL database (*i.e.*, global MRL), lists a Codex MRL of 0.1 ppm for "chicken, meat." However, there is a commodity note that states: "MRL applies to the fat of meat." Deltamethrin is a fat-soluble compound with a high octanol/water partition coefficient. Residues are much more likely to be found in the fat than the meat. The US tolerance for poultry fat is 0.05 ppm, whereas the tolerance for poultry meat is 0.02 ppm. As a result of the fact that the Codex MRL for "chicken, meat" applies to the fat of the meat, EPA continues to recommend that the US tolerance for poultry, fat be increased from 0.05 ppm to 0.1 ppm to harmonize with Codex. The result is that the US will have a tolerance of 0.1 ppm for poultry fat, and Codex will have an MRL of 0.1 ppm for the fat of chicken meat.

The Global MRL database also lists a Codex MRL of 0.5 ppm for "meat (from mammals other than marine mammals)." The commodity database states: "The MRL/EMRL applies to the fat of meat." Again, the Codex MRL applies to the fat of meat rather than the meat itself. The MRL for the fat of mammalian meat isn't relevant in this case, however, since poultry is classified as a bird, rather than a mammal.

EPA agrees that the PWG sediment method (MRIDs 47053001/47053002 (ECM); 48935001 (ILV)) could be used to fulfil the 850.6100 guideline requirement for deltamethrin in soil/sediment. EPA is reviewing the PWG study MRID 49310901 and the corresponding ILV

(MRID 49347501) to determine whether these are acceptable to fulfill the guideline 850.6100 data gap for the water matrix.

Comments submitted by the Washington State Department of Agriculture (EPA-OPP-HQ-2009-0637-0111)

Comment: The Washington State Department of Agriculture (WSDA) provided a summary of data that were collected by WSDA's crop mapping, pesticide usage data collection, and surface water monitoring programs for the following pyrethroids dockets: bifenthrin, deltamethrin, phenothrin, and prallethrin.

EPA Response: The Agency thanks WSDA for submitting this information to the deltamethrin docket and will use it to inform future risk assessments, as appropriate.

Comments Submitted by Clarke Mosquito Control Products, Inc (EPA-OPP-HQ-2009-0637- 0112)

Comment: Clarke Mosquito Control Products, Inc submitted comments regarding the proposed mitigation in the deltamethrin, prallethrin, and phenothrin PIDs. Clarke expressed concerns with the Agency's proposed resistance management labeling, the proposed removal of volumetric mean diameter (VMD) information on the labels, and the proposed pollinator statements.

Clarke contested a statement in the deltamethrin PID noting that deltamethrin is one of the few mosquitos adulticides that maintains its efficacy across distance up to 300 ft. Clarke stated that a 300 ft swath is the standard measure of performance for all wide-area mosquito adulticides.

Clarke also noted that certain resistance management measures as mentioned in PR Notice 2017-1, are excessively restrictive to the mosquito control community, particularly measures that require that a discreet number of applications in the same season be listed on the label. Clarke stated that alternative mosquito adulticide products are limited to certain pyrethroids and a small number of organophosphates, and until such time as there are ample alternatives, any labeling instructions for rotation in wide-area mosquito control should be advisory, rather than mandatory.

Additionally, Clarke expressed their concern with the Agency's proposal to remove VMD information from all labels, as they believe that VMD information is necessary for ULV applications. Mosquito adulticides use ultra-low volume nozzles which suspend the product in the air for a longer duration. The Agency's proposal to remove VMD information conflicts with the requirements of PR Notice 2005-1, which recommended that specific VMD specifications be noted on mosquito adulticide labels.

Lastly, Clarke recommended that the Agency clarify which types of applications are pertinent for pollinator labeling statements and sought clarification whether these statements applied for mosquito ULV applications. Clarke expressed concern about the fluid nature of eternal referenced best management practices resources on EPA's pollinator website and noted concerns that the statements/guidelines in those resources might be worded in such a way as to become

enforceable labeling. Clarke asks if the proposed inclusion of a reporting link for bee incidents bypass and diminish similar reporting instructions in the state managed pollinator protection plans (MP3s) and interfere with the ability of local resources to investigate bee incidents in a timely manner. Clarke asks if the Agency will be coordinating a response to reported bee kills with state agencies.

EPA Response: The Agency thanks Clarke for its comments on the deltamethrin PID.

In response to Clarke's comments, the Agency acknowledges that all mosquito adulticides are tested for mortality efficacy against mosquitoes. EPA's statement in the PID referencing efficacy at 300 ft from the spray line was in reference to efficacy data submitted by Bayer which suggested that deltamethrin performed significantly better at that distance as compared to other registered alternatives. However, EPA did not intend to suggest that the alternatives tested did not meet EPA's minimum efficacy standards.

The Agency disagrees with Clarke that the resistance management labeling for pyrethroids products is excessively restrictive to the mosquito control community. Public comments from the mosquito control community (e.g., the American Mosquito Control Association) indicates there is support from mosquito control districts for resistance management labeling. Although PR Notice 2017-1 excludes products meant for general consumer use, such as residential use products, it does not exclude products formulated for mosquito adulticide uses. Mosquito ULV products were not exempted because mosquito pests have already shown resistance to pyrethroids on a local basis. The Agency is requiring resistance management labeling for mosquito ULV products in order to provide mosquito control officials resistance management guidance via the label. However, EPA notes that registrants have flexibility to define the maximum number of applications of their products per season.

The proposal to remove VMD instructions from spray drift labeling for agricultural products is not meant to apply to mosquito ULV products. The Agency has added text in the label table (Appendix B) to add clarity for stakeholders.

The pollinator statements as proposed in the deltamethrin PID are not applicable for mosquito ULV applications and the agency has modified the appendix B label table to reflect this clarification. The label link to EPA's pollinator website, which contains externally referenced best management practices resources, is meant to provide additional information for applicators/users. Best management practices noted on the website and externally references resources are not intended to be mandatory enforceable measures. The labeling merely notes that following best management practices can help reduce risk to terrestrial pollinators, it does not state that following best management practices is mandatory. EPA will work with external stakeholders to update any referenced resources as needed.

The proposed labeling containing information on how to report bee incidents is not intended to bypass any reporting recommendations/requirements as noted in state MP3s or interfere with the states' ability to investigate bee incidents. Ideally, pollinator incidents should be reported to both the states (who are responsible for incident investigations) and the EPA. EPA has added clarification in the bee incident reporting text to note this, see Appendix B for revised labeling.

Comments Submitted by Pyrethrin Joint Venture and Various Registrants

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

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

II. USE AND USAGE

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

Deltamethrin is registered for use in a wide variety of use settings including indoor and outdoor uses in residential and commercial areas, wide-area mosquito control, stored grains, and both crop and livestock production.

Nationally, residential consumers purchased around 100,000 lbs. of pyrethroid insecticides (as a group), by active ingredient (a.i.), for indoor use, and around 2 million pounds (lbs.) a.i. of pyrethroids for residential outdoor uses in 2016 including 4,000 lbs. a.i. of deltamethrin for outdoor uses.[1] Professional pest control management companies used over 3 million lbs. a.i. of pyrethroids, including nearly 30,000 lbs. a.i. of deltamethrin, for control of various household pests such as bedbugs and cockroaches, both in and around residential and commercial buildings.[2] In the turf and ornamental markets, professional pest control firms also use over 1.4 million lbs. a.i. of pyrethroids for lawn care, on golf courses, for landscape protection, and in horticultural nurseries, there are no reports of deltamethrin use in the turf and ornamental

[1] Non-agricultural Research Market Data. 2017. Consumer Markets for Pesticides and Fertilizers 2016. [Accessed July 2019].
[2] Non-agricultural Research Market Data. 2017. Professional Pest Management Markets for Pesticides 2016. [Accessed July 2019].

market.[3] Food handling establishments, including processing facilities, warehouses, restaurants, and other food preparation facilities, use around 200,000 lbs. a.i. of pyrethroids, including over 10,000 lbs. a.i. of deltamethrin.[4]

Recent data indicate almost 190,000 lbs. a.i. of pyrethroids are used for wide-area applications for mosquito control.[5] Usage of deltamethrin is not included in this estimate due to its recent registration for this use. Usage was reported in California in 2016. For more details, see *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito in Support of Registration Review* available in the deltamethrin docket.

Nearly 10,000 lbs. a.i. of pyrethroids are reported to be used for insect control in stored grains, of which 1,600 lbs. a.i. are deltamethrin.[6] [7]

Usage in agriculture averages about 7,600 lbs. a.i. of deltamethrin to treat over 450,000 acres of cropland.[8] Sunflower has an average of 5 percent of its crop treated with deltamethrin, while artichoke has an average of 45 percent of its crop treated. The percent of the crop treated for the remainder of the crops treated with deltamethrin is lower. For more information, see the deltamethrin Screening Level Usage Analysis (2019). Data on usage of deltamethrin in livestock production are not available.

Nearly 10,000 lbs. a.i. of pyrethroids are reported to be used for insect control in stored grains, of which 1,600 lbs. a.i. are deltamethrin.[9] [10] Recent data indicate almost 220,000 lbs. a.i. of pyrethroids are used for wide area applications for mosquito control, covering nearly 60 million acres, accounting for multiple applications.[11] [12] [13] Usage of deltamethrin is not included in this estimate due to its more recent registration for this use. Usage was reported in California in 2016. For more details, see *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito in Support of Registration Review* available in the deltamethrin docket.

[3] Non-agricultural Research Market Data.2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities.
[4] Non-agricultural Research Market Data. 2015. Pest Control in Food Handling Establishments 2014: U.S. Market Analysis and Opportunities. [Accessed July 2019].
[5] Non-Agricultural Market Research Proprietary Data. 2017b. Studies conducted and sold by a consulting and research firm. Report on mosquito control pesticide usage. [Accessed June 2019.]
[6] Non-agricultural Research Market Data. 2016. Stored Grain Insect Control 2015: United States market Analysis and Opportunities. [Accessed July 2019].
[7] Non-agricultural Research Market Data. 2018. Stored Grain Insect Control 2017: United States Market Analysis and Opportunities. [Accessed July 2019].
[8] Agricultural Market Research Data Collected and Sold by Private Market Research Firm. 2013-2016. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States.
[9] Non-agricultural Research Market Data. 2016. Stored Grain Insect Control 2015: United States market Analysis and Opportunities. [Accessed July 2019].
[10] Non-agricultural Research Market Data. 2018. Stored Grain Insect Control 2017: United States Market Analysis and Opportunities. [Accessed July 2019].
[11] Non-agricultural Research Market Data. 2013. Global Mosquito Control Markets 2012: United States market Analysis and Opportunities. [Accessed July 2019].
[12] Non-agricultural Research Market Data. 2016. Stored Grain Insect Control 2015: United States market Analysis and Opportunities. [Accessed July 2019].
[13] Non-agricultural Research Market Data. 2017. Mosquito Control 2016: United States Market Analysis and Opportunities. [Accessed July 2019].

Usage in agriculture averages about 7,600 lbs. a.i. of deltamethrin to treat over 450,000 acres of cropland.[14] Corn, soybean, and sunflower account for about 80 percent of the usage. Except for artichoke, the percent of crops treated is generally low. For more information, see the Screening Level Usage Analysis (2019) available in the deltamethrin docket. Data on usage in livestock production are 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 deltamethrin. For additional details on the human health assessment for deltamethrin, see the *Deltamethrin. Draft Human Health Draft Risk Assessment for Registration Review* and the *Deltamethrin: Revised Human Health Risk Assessment in Support of Registration Review* which are available in the deltamethrin registration review docket EPA-HQ-OPP-2009-0637.

1. Pyrethroid FQPA Safety Factor Determination

The FQPA 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.

[14] Agricultural Market Research Data Collected and Sold by Private Market Research Firm. 2013-2016. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States.

EPA's full evaluation, *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review* (June 2019), is available in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331.

2. Risk Summary and Characterization

There are no human health risks of concern (i.e., dietary, residential, bystander, aggregate, occupational) for deltamethrin. Cancer risk is not of concern for deltamethrin because it is classified as "not likely to be carcinogenic to humans." Since the 2017 *Deltamethrin Draft Human Health Risk Assessment for Registration Review,* the 3X FQPA Safety Factor was reduced to 1X for children less than 6 years old. Because few risks of concern were identified in the 2017 risk assessment, the change in the FQPA SF further reduces risk estimates for children. Revised risk estimates reflecting this change are summarized in the *Deltamethrin: Revised Human Health Risk Assessment in Support of Registration Review*. There have been no changes to risk assessment endpoints or points of departure. In 2019 a new residential handler assessment was performed to assess exposure from a new indoor surface broadcast treatment to carpets, floors, mattresses, and other surfaces. Furthermore, in 2020 an occupational handler exposure assessment was performed for a new granular formulation of deltamethrin to control pests in stored grains.

Dietary (Food + Water)

The Agency conducted dietary (including food and drinking water) exposure assessments, for all population subgroups, including those comprised of infants and children.

The acute dietary risk estimates identified for deltamethrin are not of concern for the general U.S. population or any of the population subgroups. The Agency is concerned when risk estimates exceed 100% of the population adjusted dose (PAD). Children between the ages of 3-5 are likely to be the most exposed population subgroup, with a risk estimate of 29% of the acute PAD (aPAD).

Chronic dietary risk estimates were not calculated due to lack of increased hazard from repeated exposure to deltamethrin. The risk estimates derived from the acute dietary assessment are protective of risk from repeated exposures.

Residential Handler

The deltamethrin product labels with residential use sites, including lawns, ornamentals, indoor environments, garden and trees, and pets, have been considered in the residential handler assessment. These deltamethrin product labels do not require personal protective equipment (PPE) or specific clothing such as a long sleeve shirt or long pants; therefore, a residential handler assessment is necessary.

There were no risk estimates of concern for residential handlers. Dermal risk estimates were not assessed since a dermal hazard has not been identified for deltamethrin. All residential handler scenarios, including the 2019 indoor broadcast surface treatment of carpets, resulted in inhalation risk estimates that are not of concern, with MOEs that ranged from 1,000 to 850,000 (MOEs below the LOC of 100 are of concern).

Residential Post-Application

EPA assessed the potential for post-application exposure to deltamethrin for individuals who enter an environment that has been treated. Dermal risk estimates were not assessed since a dermal hazard was not identified for deltamethrin. Residential post-application risk estimates are driven by inhalation exposure and were generated for mosquito vector control truck mounted fogger uses, indoor and outdoor surface direct spray applications, pet collars, paint applications, and lawn/turf uses. Residential post-application risk estimates range from MOE of 290 to 1.5 million and are not of concern.

The 2017 risk assessment also identified potential risks of concern for children from incidental ingestion of granules (MOE=120, the LOC from 2017 assessment was 300). However, based on updates in the revised deltamethrin assessment, the MOE for this scenario is 1,700 and is not a risk of concern (the revised LOC for children is 100).

Residential Spray Drift

A quantitative spray drift assessment is not required for any deltamethrin products since the existing residential turf assessment is considered protective of exposure and risk from residential spray drift. There are no risks of concern from residential spray drift exposure.

Aggregate

Aggregate risk assessment considers risks from three sources: food, drinking water, and residential exposure. For deltamethrin, acute aggregate exposures and risk estimates are equivalent to the acute dietary (food and drinking water) exposure and risk estimates and are not of concern.

Short-term aggregate risk estimates were not of concern for the general U.S. population or any population subgroup (children MOE = 240 and adult MOE = 860; children and adult LOC = 100.

Cumulative

The Agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has determined that the pyrethroids and pyrethrins share a common mechanism group (http://www.regulations.gov; EPA-HQ-OPP-2008-0489-0006). The members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was

published on Nov. 9, 2011[15] and is available at http://www.regulations.gov docket EPA-HQ-OPP-2011-0746. No cumulative risks of concern were identified.

For information regarding EPA's efforts to evaluate the risk of exposure to pyrethroids, refer to http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html. After all the chemical-specific interim decisions have been completed for the pyrethroid class of pesticides, the Agency will determine if an update of the cumulative risk assessment needs to be performed in association with registration review.

Occupational Handler

Occupational handler exposure from deltamethrin, including the use of deltamethrin to control pests in stored grains, was assessed and risk estimates were not of concern (MOEs were equal to or greater than 100; the LOC equals 100). Assuming handlers wear baseline attire (single layer clothing with no gloves or respirator), inhalation MOEs ranged from 350 to 15,000,000.

Occupational Post-Application

For agricultural and commercial outdoor uses, a quantitative occupational post-application inhalation exposure assessment was not performed. However, it is expected that the occupational handler inhalation exposure estimates would be protective of occupational post-application exposure, because handler exposure is greater than post-application exposure. Since occupational handler risk estimates are not of concern, occupational post-application risk estimates are not of concern.

For indoor commercial uses, an occupational post-application risk assessment was not performed since it is atypical for commercial applicators to return to the deltamethrin treated areas after an indoor application.

Systemic toxicity via the dermal route of exposure is not anticipated; therefore, a quantitative dermal occupational post-application assessment was not required.

The current human health risk assessment supports a 12-hour restricted entry interval (REI). The current REI of 12 hours listed on the agricultural labels is adequate to protect agricultural workers from post-application exposures to deltamethrin.

For more information on the human health risks conclusions for deltamethrin, see the *Deltamethrin. Draft Human Health Draft Risk Assessment for Registration Review* and the *Deltamethrin: Revised Human Health Risk Assessment in Support of Registration Review*, which are available in the deltamethrin registration review docket.

[15] *Pyrethroid Cumulative Risk Assessment* https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0746-0003

3. Human Incidents and Epidemiology

The Agency reviewed human incidents involving deltamethrin in 2009. The OPP Incident Data System (IDS) and the Centers for Disease Control and Prevention/National institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR) databases were searched. In the 2009 search, there were 118 deltamethrin related incidents reported to Main IDS that occurred from 2002 to 2008, and 120 reported cases to NIOSH SENSOR-Pesticides. Most of these incidents involving deltamethrin were of low severity, with no notable trends or patterns recognized amongst the reported cases.

In 2016, an updated search for newer human incidents was conducted covering incidences that occurred from January 1, 2011 to August 25, 2016. There were 128 incidents reported to the Main IDS involving deltamethrin only, and 61 incidences reported involving multiple pesticides, including deltamethrin. In Aggregate IDS, there were 1,296 incidents of minor severity reported and 12 incidents reported with no or unknown affects.

The Agency also searched the NIOSH SENSOR Pesticides database for deltamethrin related incidents. There were 380 deltamethrin related incidents reported, with 239 of these incidents involving deltamethrin only. Of the cases reported, six were high in severity, 51 were moderate in severity, and 323 were low in severity.

Several deltamethrin incidents were reported in aggregate IDS, including 1296 incidents of minor severity and 12 incidents with no or unknown effects. Most of the incidents (93%) were either classified as minor severity or had no/unknown effects. EPA will continue to monitor the incident information and, if a concern is prompted, will conduct additional analysis.

4. Tolerances

Existing tolerances for deltamethrin residues are established under 40 CFR §180.435. Adequate data have been submitted to support the established tolerances for residues of deltamethrin in or on food commodities. There are no outstanding data needs with respect to tolerances.

There are multiple Codex Maximum Residue Limits (MRLs) established for deltamethrin commodities. For the commodities with both U.S. tolerances and Codex MRLs, the MRLs are harmonized in some cases, but not in others. In general, harmonization is not possible when the U.S. tolerances are higher, because the tolerances are based on field trials that resulted in residues that required a higher tolerance limit. However, there are several commodities in which the U.S. tolerances are lower than the Codex MRLs where harmonization is possible: tomato; cattle, goat, horse, and sheep meat; cereal grains; poultry meat; and poultry fat. The Federal Food Drug and Cosmetic Act requires the Agency to harmonize tolerances with Codex MRLs when possible. Please refer to Table 1. to view the required tolerance harmonization for these commodities. The Agency will use its FFDCA rulemaking authority to harmonize tolerances where possible.

Table 1. Anticipated Tolerance Harmonization for Deltamethrin			
Commodities	**Established U.S. Tolerance (ppm)**	**Codex MRLs (ppm)**	**Anticipated Tolerance Harmonization**
Tomato	0.2	0.3	U.S. tolerances are anticipated to be increased to harmonize with the Codex MRLs.
Cattle, meat; Goat meat; Horse, meat; and Sheep, meat	0.02	0.5	
Cereal grains	1.0	2	
Poultry fat	0.05	0.1 (poultry meat fat)	U.S. tolerances for poultry fat are anticipated to be increased to 0.1 to harmonize with the Codex MRLs for meat fat.

5. Human Health Data Needs

The Agency does not anticipate any further human health data needs for deltamethrin registration review at this time. Guideline 875.1700—product use information (required in GDCI-097805-1100) is partially satisfied; EPA has received and accepted data from companies who represent the Residential Exposure Joint Venture. EPA continues to evaluate data submitted from companies comprising the Generic Residential Exposure Task Force and will update the status of this data requirement when the review is completed.

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, fenpropathrin, permethrin, and pyrethrins. The 2016 risk assessment was divided into five sections, all of which pertain to deltamethrin: risks from indoor "down the drain" uses;[16] risks from outdoor residential, commercial, turf, and nursery uses; risks from agricultural uses; risks from mosquito adulticide uses; and an assessment of risk to bees from agricultural uses of pyrethroids and pyrethrins. The Agency primarily focused on potential effects to aquatic organisms (for all uses) as well as terrestrial invertebrates (for agricultural uses). A quantitative assessment was conducted for these nine pesticides, for which the Agency had a relatively large amount of data. A companion piece, titled the *Ecological Risk Management*

[16] "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.

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, deltamethrin, and tetramethrin. The Rationale Document describes EPA's approach in using the quantitative assessment of the nine cases to serve as a basis for making risk management and regulatory decisions for all 23 affected pesticides currently undergoing registration review. Potential risks that were identified for the eight pyrethroids and pyrethrins assessed in 2016 were determined to be representative of the risks for the other pyrethroids also undergoing registration review.

For additional details on the ecological assessment for the pyrethroids, see the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review*, which are available in the public docket.

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

For deltamethrin, risks of concern were identified for aquatic invertebrates, fish, and terrestrial invertebrates from indoor, outdoor, agricultural, and wide area mosquito adulticide use.

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, risk quotients indicate a potential for adverse effects on bees from acute exposure from particular uses of pyrethroids/pyrethrins. Reported bee mortality incidents from spray drift support these risks of concern.

For deltamethrin, exposure to bees would be expected from the agricultural use and this risk was assessed in the 2016 Ecological Risk Assessment. However, risk to bees from residential urban use and from the wide-area adult mosquito control use were not assessed. The potential impacts of deltamethrin on bees and non-target terrestrial invertebrates is uncertain, given the lack of data. Given the uncertainties surrounding potential risks to bees, the EPA has concluded that additional data are necessary to fully evaluate risks to non-target terrestrial invertebrates,

especially pollinators. The EPA will issue a Data Call-In (DCI) for the pollinator studies listed in Table 2.

Table 2: Pollinator Data Requirements

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

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

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

For additional details on the ecological risk 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.

1. Ecological and Environmental Fate Data Needs

Various studies were submitted in fulfillment of the deltamethrin registration review GDCI (GDCI-0907805-899). Guideline 850.6100 environmental chemistry methods (ECM) and associated independent laboratory validation (ILV) for soil/sediment and water (for the isomers of deltamethrin) is considered outstanding. The Agency will review the water ECM (MRID 49310901) and the corresponding ILV (MRID 49347501) to determine if these studies will satisfy this requirement.

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

C. Benefits Assessment

Pyrethroids are widely used in agriculture to control a wide variety of pests that impact crop production and in urban pest control programs for several public-health pests. In terms of the total acres treated and particularly in the variety of crops that depend on them, pyrethroids have largely surpassed the organophosphate and carbamate classes as the preferred options by growers for cost-effective and broad-spectrum insect control.

Deltamethrin is an effective control tool for a several economically important agricultural and public-health pests. Deltamethrin is recommended by university extension specialists for control of pests in many agricultural crops, barns and stables housing livestock, turfgrass and ornamentals, and structures.[17] While registered for use in many crops, the Agency determined deltamethrin was one of the market-leading insecticides and one of the most beneficial for sunflower production as it provides efficacious control of several economically important pests such as sunflower seed and stem weevils, sunflower moths, and grasshoppers.[18]

For adult mosquito control, deltamethrin is one of several insecticides registered for use in the U.S. Other insecticides, including permethrin, d-phenothrin, malathion and naled (both organophosphates) are among the most highly used adulticides in the U.S. according to an analysis done by EPA.[19] Like deltamethrin, most of these are used at very low application rates. However, deltamethrin is one of only a few that maintains its efficacy across distances up to 300 feet. In addition, it has low acute mortality effects on beneficial insects such as ladybeetles and lacewings that occur in areas subject to wide-area mosquito control. This, along with deltamethrin's lower susceptibility to degradation in sunlight, makes it a better choice in IPM-oriented mosquito programs that want to minimize non-target impacts and repeated applications.[20]

To protect commodities against insects such as weevils and moth larvae that can infest harvest stored long-term, deltamethrin is registered for use on stored grain (*e.g.*, wheat, barley, oats, rice, and sorghum) and in bin and warehouse applications. It is one of several insecticides registered for such uses. Other examples include fumigants such as sulfuryl fluoride and phosphine, other pyrethroids such as cyfluthrin, insect growth regulators (methoprene), and organophosphates (malathion).

Not all of these are exact substitutes for deltamethrin uses for stored grain protection. For example, deltamethrin (mixed with an organophosphate, chlorpyrifos-methyl), can be used on both empty grain bins and directly on some commodities (wheat, barley, oats, grain sorghum,

[17] North Dakota State University Extension. 2018. North Dakota Field Crop Insect Management Guide (2019). North Dakota State University Extension Entomology. https://www.ag.ndsu.edu/publications/crops/north-dakota-field-crop-insect-management-guide/2019-insecticide-guide-online-version-4.pdf. [Accessed August 2019].
[18] Mallampalli, N., C. Cook, and C. Myers. 2015. *Qualitative Overview of Alternatives for Selected Use Patterns of Pyrethroids Being Assessed for a Down-the-Drain Risk Assessment*. Docket ID EPA-HQ-OPP-2008-0331
[19] Mallampalli, N. and D. Berwald. 2014. Minor Use Determination of Deltamethrin as a Mosquito Adulticide under FIFRA2(11)(2) (DP# 423118, DP# 427246). Official Record of the Biological and Economic Analysis Division, U.S. EPA.
[20] Mallampalli, N. and D. Berwald. 2014. Minor Use Determination of Deltamethrin as a Mosquito Adulticide under FIFRA2(11)(2) (DP# 423118, DP# 427246). Official Record of the Biological and Economic Analysis Division, U.S. EPA.

rice, seeds with storage tolerances), while cyfluthrin can only be used on empty bins.[21] While effective alternatives appear to exist, deltamethrin (available as a premix with chlorpyrifos-methyl) is one of the options recommended for stored grain protection against insects. Given that these pests can cause serious post-harvest yield and quality losses, deltamethrin offers growers and processors benefits in this context.

Deltamethrin is also used in indoor/outdoor residential settings and in pet collars to control fleas and ticks. In residential settings, it may be used to target various arthropods, including nuisance pests such as houseflies, crickets, and centipedes, pests that damage turf and gardens (*e.g.*, aphids, beetles, caterpillars, etc.), and public health pests, such as fire ants, mosquitoes, cockroaches, and bedbugs. As such, deltamethrin provides benefits as one of several options to suppress pests of public health concern.

For all these uses, while deltamethrin generally offers effective pest control, various alternatives with efficacy also exist in the marketplace. Many are other pyrethroids. Depending on the use setting, other chemistries are also available. For example, some organophosphates (*e.g.*, malathion), carbamates (*e.g.*, carbaryl), and neonicotinoids (*e.g.*, imidacloprid) are available for outdoor residential uses. For indoor residential uses, hydramethylnon, indoxacarb, and boric acid can control many of the pests targeted by deltamethrin.

For pests that affect pets such as dogs, pet collars are available that contain tetrachlorovinphos (an organophosphate), propoxur (a carbamate), insect growth regulators (such as methoprene), or amitraz. These pet collars sometimes also contain pyrethroids as co-formulated active ingredients. Non-pyrethroid active ingredients in "spot-on" treatments include fipronil, indoxacarb, or imidacloprid. These active ingredients are often co-formulated with insect growth regulators, *e.g.*, pyriproxyfen or s-methoprene, which provide specific efficacy against flea eggs and larvae. In addition, the U.S. Food and Drug Administration also registers pet medications that control fleas and ticks. These include the non-pyrethroid active ingredients fluralaner, afoxolaner, cythiolate, lufenuron, selamectin, nitenpyran, milbemycin oxime, s-methoprene, and spinosad. Some of these products require veterinary licensing for use and some products may not be stand-alone treatments – *i.e.*, they require the use of additional treatments or pest exclusion tactics to be fully effective.

For more information on the usage and general benefits of deltamethrin in agricultural settings, refer to the *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroids Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*. For information on the benefits and alternatives of the mosquitocide uses of the pyrethroids, including deltamethrin, refer to the *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito Adulticides in Support of Registration Review*. These support documents are available in the public docket (EPA-HQ-OPP-2008-0331).

[21] Bellinger, R. 2015. Farm-Stored Grain Insect Management. A chapter of the South Carolina Pest Management Handbook for Field Crops. https://johnston.ces.ncsu.edu/wp content/uploads/2012/06/farmstoredgraininsectmanagementPMH2015.pdf?fwd=no. [Accessed August 2019].

IV. INTERIM REGISTRATION REVIEW DECISION

A. Required Risk Mitigation and Regulatory Rationale

The Agency has determined that there are no human health risks of concern from registered deltamethrin uses. The Agency identified potential risks of concern for aquatic invertebrates, fish, and terrestrial invertebrates. Potential risks of concern are primarily for aquatic invertebrates (from indoor, outdoor, agricultural use, and mosquito adulticide use) and terrestrial invertebrates (from agricultural uses). Mitigation to address risks to aquatic and terrestrial invertebrates and fish will benefit the other taxa to the extent that there is any risk.

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

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

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 the 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 deltamethrin labels where applicable.

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

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

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

The products that are subject to these necessary amendments are those with any indoor or outdoor use in a residential or commercial setting. Note that all products registered for indoor residential and commercial uses are included, not just those with indoor down-the-drain uses, because the potential for improper use or disposal is present for any household pyrethroid product. The specific measures are necessary to reduce the potential for runoff and drain disposal, and subsequent potential aquatic risk, and are outlined below.

a. Indoor and Outdoor Use Site Clarification

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

b. Disposal/Stewardship Statement and Pictogram

- Labels must include the following statement on the product label unless labeled for use directly inside pipes/sinks.

  - "Do not pour or dispose down the drain or sewer. Call your local solid waste agency for local disposal options."
- Include a pictogram of a diagonal strikethrough over a drain on all end-use consumer product containers. Place pictogram in a prominent location. The pictogram must be legible (*i.e*. no smaller than 1.5 square centimeters or 0.25 square inch unless this size is greater than 10% of the size of the label). Below is an example graphic of an indoor drain image:

c. Advisory Statements

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

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

2. Mitigation Measures for Outdoor Urban Uses

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

In order to reduce the potential load of pyrethroids in surface water attributed to urban uses, the Agency has determined that a reduction in the distance from building foundations that can be treated with pyrethroids from 10 feet to 7 feet is necessary. The Agency considered reducing the

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

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

a. Statements for Outdoor Label Consistency and Clean-up

The Agency has determined that several label changes for consistency with other products and current policy (*e.g.*, EPA's January 10, 2013 letter *Revisions to Environmental Hazard and General Labeling for Pyrethroid Non-Agricultural Outdoor Products*) is necessary.

Labels must explicitly say whether particular products are to be applied outdoors only or both indoors and outdoors (as described in the previous section).

b. Revised General Outdoor Application Statement

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

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

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

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

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

c. Spot Treatment Statement

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

d. Buffer from Water Statement

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

e. Water Protection Statements

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

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

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

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

f. Rain-Related Statements

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

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

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

g. Statements for Ornamental/Recreational Turf

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

h. Statements for Outdoor Applications at Commercial Nurseries

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

- "Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572)."

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

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

The Agency does not know how efficacy may be impacted when droplet sizes are determined to be necessary for various insecticides in commercial nurseries. Pyrethroids are contact

insecticides which require thorough coverage of the treated surface for effective pest control. University extension recommendations for contact insecticides such as pyrethroids are for ASABE droplet sizes of fine to medium.[22] For foliar applications, insect control would likely be negatively impacted given the requirement for a medium or coarser 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 Agricultural Use Products

a. Vegetative Filter Strips (VSF) Language

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

Currently, all pyrethroid products, except etofenprox and pyrethrins, already have a 10-foot VFS requirement on the labels. VSF are somewhat expensive to implement and maintain, and they must be maintained or they will lose efficacy and cause channelized flow across the VFS after a few years. VFS are most effective at removing non-source point pollutants (e.g., pesticides) from runoff water sources. However, the effectiveness of a VFS is influenced by various land management practices (*e.g.*, flood and furrow irrigated fields) which may impact their utility. [23]

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[22] 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

[23] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175

The Agency has considered several additional sources of research which contextualize the benefits of VFS and has determined that increasing the use of VFS is appropriate mitigation to reduce pyrethroid residues in aquatic habitats.

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

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

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

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

"Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).

Only apply products containing (name of pyrethroid) onto fields where a maintained vegetative filter strip of at ***least 25 feet*** *exists between the field edge and where a down gradient aquatic habitat exists. This minimum required width of 25 feet may be reduced or removed under the following conditions:*
For Western irrigated agriculture, a maintained vegetative filter strip of at least 10 feet wide is required. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35).

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

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

- *The area of application is considered prime farmland (as defined in 7 CFR § 657.5).*
- *Conservation tillage is being implemented on the area of application. Conservation tillage is defined as any system that leaves at least 30% of the soil surface covered by residue after planting. Conservation tillage practices can include mulch-till, no-till, or strip-till.*
- *A functional terrace system is maintained on the area of application.*
- *Water and sediment control basins for the area of application are present, functional, and maintained.*
- *The area of application is less than or equal to 10 acres.*

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

Potential VFS Mitigation Impacts

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

Estimates of losses from increasing the size of the VFS for the 10th percentile and the median field size by crop are available in EPA document "Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroid Insecticides for Selected Crops and Impacts

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

In addition to any reduced crop production, growers would need to manage the space taken out of production and put into a VFS. Costs would differ across states and regions, and also vary according to the size and shape of the field. In addition to the cost of establishing the VFS, the cost of annual maintenance must also be considered. Yearly maintenance costs are estimated to be $40 to $240 per acre (for four mowing or weed control applications). Maintenance costs could be higher if additional operations are required such as additional mowing or weed control expenses, reseeding of disturbed areas, or regrading of the filter strip with reseeding if sediment deposition were to jeopardize its function.[24]

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

b. Spray Drift Reduction Measures

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

The Agency has determined that the following spray drift mitigation language to be included on all product labels for the pesticide addressed in this interim decision is necessary. The required spray drift language is mandatory, enforceable statements and supersede any existing language

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

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

c. Required Statements for Aerial Applications

- "Do not release spray at a height greater than 10 feet above the vegetative canopy, unless a greater application height is necessary for pilot safety.
- Applicators are required to select nozzle and pressure that deliver medium or coarser droplets (ASABE S641).
- Do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters.
- If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field.
- Do not apply during temperature inversions."

d. Required Statements for Airblast Applications

- "Sprays must be directed into the canopy.
- Do not apply when wind speeds exceed 15 mph at the application site.
- User must turn off outward pointing nozzles at row ends and when spraying outer row.
- Do not apply during temperature inversions."

e. Ground Boom Applications

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

EPA does not expect the requirements for release height to impact users since they largely correspond to current practice and recommendations. Due to the varying use sites and target pests of pyrethroids it is difficult to assess the impacts of a droplet size restriction across all crops. Components of applications, including droplet size, are complex, but essentially insects need to come into contact with, or ingest, a lethal dose of insecticide to be effectively controlled

which requires proper coverage throughout the plant. Pyrethroids are contact insecticides and require a certain amount of coverage for efficacy. For foliar applications, insect control would likely be negatively impacted by requiring a medium droplet size or larger. Growers may be driven to use higher rates, mix with another insecticide, make additional applications per season, or increase gallons applied per acre with larger droplet sizes to achieve the same efficacy they were able to with finer droplet sizes.

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

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

a. Required Updates to Spray Drift Buffers

In addition to the spray drift mitigation measures above, EPA is updating the buffers to water already on labels. The following revised language reflects current spray drift reduction language limiting the amount of spray drift that enters waterbodies. These required clarifications will establish a baseline level of protection for waterbodies against spray drift that is consistent across all products affected by this interim decision. Reducing the overall amount of spray drift that reaches waterbodies will reduce the extent of environmental exposure and risk to aquatic organisms. Required label updates encompass the following statements:

- "For ground applications, do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).
- For non-ultra-low volume (ULV) aerial applications, do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds).
- For ULV aerial applications, do not apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds). Applications made by mosquito control districts and other public health officials are exempt from this requirement."

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

4. 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 necessary. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target species. The necessary 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.

a. Wide-area Mosquito Adulticide Consistency and Clean Up

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:

b. 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."

c. 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."

d. Environmental Hazard Statements

EPA has determined that limiting adult mosquito control applications to trained personnel is necessary. 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][25] 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

5. Pollinator Risk Mitigation

Although the Agency has identified potential acute risks of concern to bees and other terrestrial invertebrates from use of the pyrethroids/pyrethrins, risk to invertebrates is expected from use of

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

insecticides, in general. The potential acute risk to bees is considered along with the benefits of pyrethroids/pyrethrins in agriculture. Pyrethroids/pyrethrins benefits were assessed in the *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroid Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*. Benefits include the following:

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

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

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

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

a. Pollinator Environmental Hazard

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

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

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

b. Pollinator Stewardship – Promoting Pollinator Best Management Practices

In addition to establishing both advisory and compulsory language for product labels, EPA's registration review process provides an opportunity to inform stakeholders and the general public about opportunities to minimize potential ecological risks and promote pollinator health more generally. Beyond the necessary mitigation measures above, voluntary stewardship activities and

use of best management practices (BMPs)[26] to protect pollinators can be effective in further reducing pesticide exposure to non-target organisms. Examples of these activities include:

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

Habitat loss is a significant issue with negative impacts on the health of bees. With access to a healthy and diverse diet through a thriving habitat, bees may be better able to tolerate stressors, such as pests, disease, and exposure to pesticides. As a healthy diet is crucial to maintaining flourishing pollinator populations, and the protection of pollinator habitat is not something that can be directly addressed on a pesticide product label, EPA and other federal/state/tribal and local government agencies and non-government organizations (NGOs) promote pollinator habitat through active education and outreach programs. Helpful guidance on pollinator protection can be found on EPA's pollinator protection webpage[27].

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

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

Other things the public can do to minimize potential exposure of pollinators are listed on EPA's *What You Can Do to Protect Honey Bees and Other Pollinators* webpage.[28]

The Agency encourages strong pollinator protection stewardship in both the public and private sector in creating tools and fostering effective communication to help reach applicators and educate them on practices that can reduce risks to the environment. EPA will continue to work with its partners at the federal, state, tribal, and local levels, along with non-governmental organizations to promote pollinator protection, education, and outreach. This includes coordinating with states and tribes on managed pollinator protection plans (MP3), coordinating

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

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

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

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

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

c. Promoting State Managed Pollinator Protection Plans (MP3s)

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

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

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

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

> "**Managed pollinator protection plans** are developed by states/tribes to promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees to pesticides. If available, visit state plans for additional information on how to protect pollinators."

d. Pollinator Incident Reporting

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

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

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

6. 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 deltamethrin, 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.

7. Updated Glove and Respirator Language

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

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

B. Tolerance Actions

The Agency anticipates revising deltamethrin tolerances to harmonize with Codex MRLs for several commodities. Refer to Section III.A.4 for more details.

C. Interim Registration Review Decision

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

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of deltamethrin, nor is it making a complete endangered species finding. The Agency's final registration review decision for deltamethrin will be dependent upon the result of the Agency's ESA assessment and any needed § 7 consultation with the Services and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

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

Various studies were submitted in fulfillment of the deltamethrin registration review GDCI (GDCI-0907805-899). Guideline 850.6100 ECM and associated ILV for soil/sediment and water

(for the isomers of deltamethrin) is considered outstanding. The Agency will review the water ECM (MRID 49310901) and the corresponding ILV (MRID 49347501) to determine if these studies will satisfy this requirement.

GDCI 097805-1100 (for product use information) is partially satisfied; EPA has received and accepted data from companies who represent the Residential Exposure Joint Venture. EPA continues to evaluate data submitted from companies comprising the Generic Residential Exposure Task Force and will update the status of this DCI when the review is completed.

The pollinator data listed under Section III.B. are required and the EPA intends to issue a DCI for the data.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

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

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, deltamethrin registrants must submit amended labels that include the label changes described in Appendices A and B, which supersede existing label requirements. Registrants must ensure that any existing language on labels does not contradict or modify the new statements required in this ID. 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 Deltamethrin 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 Deltamethrin 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 Samantha Thomas at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

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

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

Appendix A: Summary of Required Actions for Deltamethrin

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

Appendix B: Required Labeling Changes for Deltamethrin Products

<table>
<tr><th>Description</th><th>Required Label Language for Deltamethrin End Use Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>All Deltamethrin End Use Products (unless specified otherwise)</td><td></td></tr>
<tr><td>Mode of Action Group Number

Applies only to products with agricultural and/or wide area mosquito use</td><td>Note to registrant:
Include the name of the ACTIVE INGREDIENT in the first column
Include the word “GROUP” in the second column
Include the MODE/MECHANISM/SITE OF ACTION CODE in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is SITE OF ACTION)
Include the type of pesticide (i.e., INSECTICIDE) in the fourth column.
<table><tr><td>Deltamethrin</td><td>GROUP</td><td>3A</td><td>INSECTICIDE</td></tr></table></td><td>Front Panel, upper right quadrant.
All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.</td></tr>
<tr><td>Resistance-management labeling statements for insecticides
Applies only to products with agricultural and/or wide area mosquito use</td><td>Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)</td><td>Directions for Use, prior to directions for specific crops</td></tr>
</table>

Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Updated Respirator Language	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products. [**Note to registrant:** For respiratory protection from organic vapor a**nd** particulates (or aerosols), use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." [**Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Additional Required Labeling Action. Applies to all products delivered	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

via liquid spray applications (except those with mosquito adulticide use)		
End-use products formulated for 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 uses."	Front Label Panel and/or Directions for Uses
For all products used on pets	Add the following language: "Application of product on pets must only be done indoors."	Directions for Uses
Required disposal statement for products not labeled for use directly into drains and sewers.	"Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options."	Storage and Disposal

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

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

	"Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment." "Do not apply or irrigate to the point of runoff."	
Rain-Related Statements (except for products that require watering-in)	"Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours)." "Rainfall within 24 hours after application may cause unintended runoff of pesticide application."	Directions for Use
Wind speed requirement for ornamental/ recreational turf applications	"Do not apply when the wind speed is greater than 15 mph."	Directions for Use
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 formulated for agricultural uses		
Enforceable Spray Drift Management Language for products that allow aerial applications	Aerial Applications: • Do not release spray at a height greater than 10 feet above the vegetative canopy, unless a greater application height is necessary for pilot safety. • Applicators are required to select nozzle and pressure that deliver medium or coarser droplets (ASABE S641). • Do not apply when wind speeds exceed 15 mph at the application site. If the wind speed is greater than 10 mph, the boom length must be 65% or less of the wingspan for fixed wing aircraft and 75% or less of the rotor diameter for helicopters. Otherwise, the boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters. • If the windspeed is 10 miles per hour or less, applicators must use ½ swath displacement upwind at the downwind edge of the field. When the windspeed is between 11-15 miles per hour, applicators must use ¾ swath displacement upwind at the downwind edge of the field. • Do not apply during temperature inversions.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Aerial Applications" Placement for these statements should be in general directions for use, before the use-specific directions for use.
Enforceable Spray Drift Management Language	Airblast Applications: • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 15 mph at the application site. • User must turn off outward pointing nozzles at row ends and when spraying outer row. • Do not apply during temperature inversions.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Airblast Applications"
Enforceable Spray Drift Management Language for products that allow ground boom applications	Ground Boom Applications: • User must only apply with the nozzle height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to select nozzle and pressure that deliver medium or coarser droplets (ASABE S572). • Do not apply when wind speeds exceed 15 mph at the application site. • Do not apply during temperature inversions.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"

Advisory Spray Drift Management Language for all products that allow aerial and ground boom uses	**THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.** **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. Controlling Droplet Size – Ground Boom • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. Controlling Droplet Size – Aircraft • Adjust Nozzles - Follow nozzle manufacturers recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. BOOM HEIGHT – Ground Boom • For ground equipment, the boom should remain level with the crop and have minimal bounce. RELEASE HEIGHT - Aircraft • Higher release heights increase the potential for spray drift. SHIELDED SPRAYERS • Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. TEMPERATURE AND HUMIDITY	Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”

	• When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. TEMPERATURE INVERSIONS • Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. WIND • Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. • Applicators need to be familiar with local wind patterns and terrain that could affect spray drift. NON-TARGET ORGANISM ADVISORY STATEMENT (Environmental Hazards): • This product is highly toxic to bees and other pollinating insects exposed to direct treatment or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and reduce pesticide risk to these organisms.	
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **<u>Handheld Technology Applications:</u>** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"
Vegetative Filter Strips Note: This requirement is separate and in addition to buffer	"VEGETATIVE FILTER STRIPS Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).	Directions for Use

zones to aquatic areas, which are still required if a vegetated filter strip is present.	Only apply products containing (name of pyrethroid) onto fields where a maintained vegetative filter strip of at **least 25 feet** exists between the field edge and where a down gradient aquatic habitat exists. This minimum required width of 25 feet may be reduced or removed under the following conditions:
	• For Western irrigated agriculture, a maintained vegetative filter strip of at least 10 feet wide is required. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35).
	  o For Western irrigated agriculture, if a sediment control basin is present, a vegetative filter strip is not required.
	• In all other areas, a vegetative filter strip with a minimum width of 25 feet is required, unless the following conditions are met. The vegetative filter strip requirement may be reduced from 25 feet to 15 feet if at least one of the following applies:
	  o The area of application is considered prime farmland (as defined in 7 CFR § 657.5).
	  o Conservation tillage is being implemented on the area of application. Conservation tillage is defined as any system that leaves at least 30% of the soil surface covered by residue after planting. Conservation tillage practices can include mulch-till, no-till, or strip-till.
	  o A functional terrace system is maintained on the area of application.
	  o Water and sediment control basins for the area of application are functional and maintained.
	  o The area of application is less than or equal to 10 acres.
	For further guidance on vegetated filter strips, refer to the following publication for information on constructing and maintaining effective buffers: Conservation Buffers to Reduce Pesticide Losses. Natural Resources Conservation Services. https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175"	

Buffer Zones to Water Bodies	Ground Application • "Do not apply within 25 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)." Ultra Low Volume (ULV) Aerial Application • "Do not apply within 450 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds). Applications made by mosquito control districts and other public health officials are exempt from this requirement." Non-ULV Aerial Application	Directions for Use

	• "Do not apply within 150 feet of aquatic habitats (such as, but not limited to, lakes, reservoirs, rivers, streams, marshes, ponds, estuaries, and commercial fish ponds)."	
New text to include under Environmental Hazard statements: (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential use and/or Ultra Low Volume (ULV) wide area mosquito control applications*	Update the Environmental Hazard with the bolded statement: "This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. **Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms."**	Environmental Hazard
Link to pollinator best management practices (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential use and/or Ultra Low Volume (ULV) wide area*	"Following best management practices can help reduce risk to terrestrial pollinators. Examples of best management practices include applying pesticides in the evening and at night when pollinators are not foraging and checking to confirm hive locations before spraying. For additional resources on pollinator best management practices, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators."	Directions for Use, prior to crop specific directions

mosquito control applications		
Information on state managed pollinator protection plans (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential use and/or Ultra Low Volume (ULV) wide area mosquito control applications*	"**Managed pollinator protection plans** are developed by states/tribes to promote communication between growers, landowners, farmers, beekeepers, pesticide users, and other pest management professionals to reduce exposure of bees to pesticides. If available, visit state plans for additional information on how to protect pollinators."	Directions for Use, prior to crop specific directions
Information on how to report bee incidents (For liquid products formulated for outdoor foliar applications to agricultural row crops.) *Excludes products formulated for residential use and/or Ultra Low Volume (ULV) wide area mosquito control applications*	**"How to Report Bee Kills** It is recommended that users contact both the state lead agency and the U.S. Environmental Protection Agency to report bee kills due to pesticide application. Bee kills can be reported to EPA at beekill@epa.gov. To contact your state lead agency, see the current listing of state pesticide regulatory agencies at the National Pesticide Information Center's website: http://npic.orst.edu/reg/state_agencies.html"	Directions for Use, prior to crop specific directions

End use products with wide area mosquitocide 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." "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."	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ultra Low Volume Applications"

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][29] 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"

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