Docket Number EPA-HQ-OPP-2010-0384
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Bifenthrin

Interim Registration Review Decision
Case Number 7402

September 2020

Approved by: _____

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Date: 09/29/2020

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for bifenthrin (PC Code 128825, case 7402), 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 bifenthrin, can be found in EPA's public docket (EPA-HQ-OPP-2010-0384) at www.regulations.gov.

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

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

Bifenthrin, first registered in 1989, is a broad-spectrum non-systemic pyrethroid insecticide/miticide registered for use in a variety of indoor and outdoor residential and commercial areas, including use in food handling establishments and as a pet shampoo, as well as on a variety of agricultural and livestock settings. Bifenthrin was not subject to reregistration since it was registered after 1984. Based on data from 2008 to 2017, the greatest amount of

agricultural use of bifenthrin, in terms of average pounds applied annually, is on corn and cotton. In terms of average annual percent crop treated, fresh beans (55%), strawberries (55%), cantaloupes (50%), and caneberries (45%) are among the top crops treated with bifenthrin.[1] Bifenthrin is formulated as ready-to-use-sprays, aerosols, shampoos, dusts, emulsified concentrates, wettable powders, granules, flowable concentrates, and as seed treatment. Bifenthrin can be applied by a wide range of application equipment, including aerial, ground boom, air blast, belly grinder, push-type spreader, low/high pressure handwand, paint roller, and foggers. Bifenthrin controls a variety of insects including aphids, ants and wasps, maggots and flies, caterpillars and moths, beetles, grasshoppers, mites, spiders, ticks, thrips, fleas, and other arthropod pests.

Bifenthrin 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 this bifenthrin ID, which describes the risk management approach for bifenthrin determined to be necessary by the Agency, EPA previously published and opened a 60-day public comment periods on the following documents: the *Bifenthrin Proposed Interim Registration Review Decision,* which summarizes the risk assessment and proposes mitigation for bifenthrin, the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*, which summarizes the ecological risk assessment approach and outlines EPA's proposed mitigation to address potential ecological risks for pyrethroids as a whole, and 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 bifenthrin. Those documents, as well as additional supporting documents, are located in the bifenthrin docket and in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at http://www.regulations.gov (Docket #: EPA-HQ-OPP-2010-0384 and EPA-HQ-OPP-2008-0331, respectively).

Having considered stakeholder comments on the bifenthrin Proposed Interim Decision (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

[1] Bifenthrin Usage Analysis in Support of Human Health Risk Assessment for Registration Review (Revised), 2020. https://www.regulations.gov/document/EPA-HQ-OPP-2010-0384-0276

human health and ecological risk management and mitigation measures in this Interim Registration Review Decision for bifenthrin.

This document describes changes or updates since the bifenthrin PID and is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why bifenthrin is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Interim Registration Review Decision*, which describes the mitigation measures necessary to address risks of concern and the regulatory rationale for EPA's ID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Updates since the Proposed Interim Decision was Issued

In May 2020, EPA published the PID for bifenthrin. In this ID, there are several updates to what was proposed in the PID. The updates include changes made to the ecological risk mitigation as proposed in the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*. Label language has been revised for indoor, outdoor, agricultural, and mosquito adulticide uses to improve clarity and consistency. The vegetative filter strip (VFS) requirement 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. 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, which may be disproportionately impacted by the expanded VFS requirements. See the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals,* for a detailed discussion of the changes made to the proposed mitigation. There have been updates to the human health mitigation from what was proposed in the PID, but no updates to the draft risk assessments (DRAs). The requirement for granular applications to lawn and turf to be immediately watered-in has been changed. Only turf granular applications at a rate of 0.34 lb ai/A or higher are required to be immediately watered-in. The Agency has also updated the status of the bifenthrin GDCI-128825-902, the current outstanding data gaps are: direct photolysis rate of parent and degradates in water (guideline 835.2240); aerobic soil metabolism on one additional soil (guideline 835.4100); aerobic aquatic metabolism (guideline 835.4300); an independent laboratory validation in water which is a part of the aquatic field dissipation requirement (guideline 835.6200). This ID thus finalizes the Agency's draft supporting documents: *Bifenthrin. Draft Human Health Risk Assessment for Registration Review, Bifenthrin: Updated Human Health Draft Risk Assessment in Support of Registration Review, Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins,* and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review,* which are available in the bifenthrin public docket.

B. Summary of Bifenthrin Registration Review

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

- June 2010- The *Bifenthrin Summary Document*, *Bifenthrin Human Health Assessment Scoping Document in Support of Registration Review*, and *Environmental Fate and Ecological Risk Assessment Problem Formulation in Support of Registration Review for Bifenthrin* were posted to the docket for a 60-day public comment period.

- January 2011 - The *Bifenthrin Final Work Plan Registration Review* was issued. Many comments were received that facilitated changes to the *Environmental Fate and Ecological Risk Assessment Problem Formulation in Support of Registration Review for Bifenthrin*. The Agency revised its risk hypothesis, revised its conceptual model, and evaluated the extent to which ecological risk from bifenthrin from application of biosolids to land should be addressed for the ecological risk assessment. The *Revised EFED Registration Review Problem Formulation for Bifenthrin* and the *Response to Public Comments on the EFED Registration Review Problem Formulation for Bifenthrin* were posted to the docket along with the final work plan. No comments impacted the timeline set in the preliminary work plan.

- June 2011- An *Amended Final Work Plan* was issued along with the *Bifenthrin Revised Human Health Assessment Scoping Document in Support of Registration Review*. The updated work plan added two additional toxicology studies and removed two ecological effects studies from the list of data needed for registration review. The Agency also removed the UV/visible light absorption study from the data requirements.

- January 2012- *Bifenthrin Generic Data Call Ins* (GDCI-128825-902 and GDCI-128825-1159*)* were issued for various human health, environmental fate, and ecological effects data needed to conduct the registration review risk assessments. GDCI-128825-902 and GDCI-128825-1159 have not been satisfied. Refer to Section III.B.1 for a complete list of all outstanding data requirements. GDCI-097805-1100 (for guideline 875.1700 product use information) is partially satisfied; EPA has received and accepted data from the companies who represent the Residential Exposure Joint Venture. EPA continues to evaluate data submitted from companies comprising the Generic Residential Exposure Task Force (GRETF) and is partially satisfied. EPA continues to evaluate data submitted from companies comprising the GRETF and will update the status of this DCI when the review is completed.

- November 2012 – A *Bifenthrin Generic Data Call In* (GDCI-128825-1158) was issued for the submission of a developmental neurotoxicity study. This GDCI has been satisfied.

- September 2015 – The Agency issued its Endocrine Disruptor Screening Program evaluation for bifenthrin in the *EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals* and determined that there was no convincing evidence of potential interaction with the estrogen, androgen, or thyroid pathways.

- November 2016 – The Agency announced the availability of the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* (also referred to as the "Ecological Risk Assessment") and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* (also referred to as the "Rationale Document") in the bifenthrin docket for a 60-day public comment period. The same FR Notice (81 FR 85952) also announced the availability of the risk assessments for several other pyrethroids, the Ecological Risk Assessment, and the Rationale Document in the individual pyrethroid dockets. The comment period was extended from January until July 2017.
    - During the public comment period, EPA received over 1,400 public comments across all the dockets of the pyrethroids. These comments and the Agency's responses can be found in the *Joint Response from OPP's Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for the Pyrethroids and Pyrethrins Insecticides* which can be found at http://www.regulations.gov (Docket # EPA-HQ-OPP-2008-0331).

- December 2017 – The Agency announced the availability of *Bifenthrin: Human Health Draft Risk Assessment for Registration Review, and Section 3 Risk Assessment* to the bifenthrin docket for a 60-day public comment period which was extended until March 2018. There were 15 bifenthrin-specific comments received in the bifenthrin docket.

- 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 bifenthrin.

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

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

- *Pyrethroids: Tier II Epidemiology Report*

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

    - *Joint Response from OPP's Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for Pyrethroids and Pyrethrins Insecticides*
    - *Updated Ecological Incidents Search for the Pyrethroids and Pyrethrins*
    - *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroids Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*
    - *Review of USDA's Assessment of the Benefits of Pyrethroids*
    - *Review of Estimated Benefits of Pyrethroids in U.S. Agriculture from "The Value of Pyrethroids in U.S. Agriculture and Urban Settings" Prepared by AgInfomatics, LLC for the Pyrethroid Working Group*
    - *Biological and Economic Analysis Division (BEAD) Summary of Public Comments Related to Benefits of Pyrethroids Submitted in Response to the Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins*
    - *Review of "Economic Benefits of Pyrethroids Insecticides for Select California Crops," Report Prepared by ERA Economics for the Pyrethroids Working Group*
    - *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito Adulticides in Support of Registration Review*
    - *Readers Guide – Instructions for Commenting on the Registration Review Documents in the Pyrethroids Group*

- May 2020 – The Agency opened a 60-day public comment period for the bifenthrin PID in the bifenthrin registration review docket (EPA-HQ-OPP-2010-0384).
    - Along with the bifenthrin PID, the following documents were also posted in the bifenthrin registration review docket (EPA-HQ-OPP-2010-0384):
        - *Bifenthrin: Updated Human Health Draft Risk Assessment in Support of Registration Review*
        - *Bifenthrin Revised Occupational and Residential Exposure and Risk Assessment for Registration Review*
        - *Bifenthrin: Response to Public Comments on the Draft Human Health Risk Assessment for Registration Review*

- September 2020 – The Agency has completed the bifenthrin ID and will post it in the bifenthrin registration review docket (EPA-HQ-OPP-2010-0384).

- Along with the bifenthrin ID, the following documents will also be available in the bifenthrin registration review docket (EPA-HQ-OPP-2010-0384):
  - *Pyrethroids: Health Effects Division Response to Public Comments Submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists [EPA-HQ-OPP-2008-0331]*, September 2020
  - *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals,* September 2020

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

During the 60-day public comment period for the *Bifenthrin Proposed Interim Registration Review Decision*, which opened on May 5, 2020 and closed on July 6, 2020, the Agency received 65 substantive comments from various stakeholders on the pyrethroids as a group and 13 comments specifically for bifenthrin. The FMC Corporation (FMC) and the Bifenthrin Task Force (BTF) commented that some studies in the data needs section of the PID have been previously satisfied. The Northwest Horticultural Council (NHC) supported the label changes and mitigation proposed in the PID. The United States Department of Agriculture (USDA) supported the overall proposed label language and mitigation with additional concerns that are addressed in detail below. The National Agricultural Aviation Association (NAAA) commented on the temperature inversion label language for aerial application of pyrethroid products. The Scotts Company LLC (Scotts) submitted a comment asking for clarification on label language for updated glove statement, pollinator environmental hazard statements, and clarifying if the Mode of Action Group Number is to be applied to applications by residential users. The Washington State Department of Agriculture submitted water monitoring and usage data for bifenthrin. The National Pest Management Association (NPMA), Bay Area Clean Water Agencies (BACWA), San Francisco Bay Regional Water Quality Control Board (SFBRWQCB), National Association of Clean Water Agencies (NACWA), and California Stormwater Quality Association (CASQA) submitted comments relating to pyrethroids in general and bifenthrin specifically.

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

Comments Submitted by FMC (EPA-HQ-OPP-2010-0384-0289) and BTF (EPA-HQ-OPP-2010-0384-0286)

Comments: FMC and BTF commented that they have satisfied the ecological and environmental fate data needs that were noted as outstanding in the Bifenthrin PID. The studies that FMC and BTF stated they have satisfied include: leachability from treated wood (non-guideline, MRIDs 47454101 and 47454102), direct photolysis rate of parent and degradates in water (guideline 835.2240, MRID 48882501), aerobic soil metabolism (guideline 835.4100, MRID 48882502), anaerobic soil metabolism (guideline 835.4200, MRID 48882503), aerobic aquatic metabolism (guideline 835.4300, MRID 48882504), aquatic invertebrate acute toxicity-freshwater daphnids (guideline 850.1010, MRID 48593601), and fish early-life stage toxicity (guideline 850.1400, MRID 49412101).

FMC commented on the proposed pollinator data requirements and requested that EPA consider approaches to utilize existing data and streamline data generation prior to issuing a DCI for pollinator data.

FMC and BTF suggest that the Mode of Action Group Number be changed from 3 to the IRAC subgroup 3B for agricultural use labels. They believe this is a more specific annotation for the mode of action.

FMC also notes that turf granular products applied at an application rate of 170 lbs product/A (0.34 lbs active ingredient (a.i.) /Acre (A)) or less should not be required to be watered-in after application. FMC refers to the revised bifenthrin human health risk assessment, which notes that episodic granule ingestion is not a risk of concern at the 0.34 lbs a.i./A rate. FMC suggests watering in of granule bifenthrin product applications to turf only be required if the application rate is above 0.34 lbs a.i./A.

FMC also notes that for above ground pests, watering granule applications immediately after application could impact efficacy.

EPA Response: The Agency appreciates FMC and BTF's comment on the ecological effects and environmental fate data needs for bifenthrin. The Agency's response to each study requirement from GDCI-128825-902 is below:

- Leachability from treated wood (Non-guideline): The Agency agrees with FMC and BTF that MRIDs 47454101 and 47454102 have been reviewed and deemed acceptable, therefore this data requirement is satisfied.
- Direct photolysis rate of parent and degradates in water (guideline 835.2240): The submitted study, MRID 48882501, was classified as supplemental due to the study being conducted above the solubility limit and because the length of the experiment was not able to capture the pattern of decline for *trans*-bifenthrin. This study did not satisfy the requirement for guideline 835.2240 and this data gap is still outstanding.

- Aerobic soil metabolism (guideline 835.4100): The submitted study, MRID 48882503, was classified as supplemental due to the exaggerated application rate and levels of unextracted radioactivity exceeding 18% Applied Radioactivity in latter test intervals. This study partially fulfills the data requirement, but another study with at least one additional soil is needed to fully fulfill the requirement.
- Anaerobic soil metabolism (guideline 835.4200): The Agency agrees with FMC and BTF that the study MRID 48882503 has been reviewed and deemed acceptable, therefore this data requirement is satisfied.
- Aerobic aquatic metabolism (guideline 835.4300): The study MRID 48882504 was classified as supplemental due to the limited test duration and sample treatment exceeding the solubility limit. This study did not satisfy the requirement for guideline 835.4300 and this data gap is still outstanding.
- Aquatic invertebrate acute toxicity-freshwater daphnids (guideline 850.1010): The Agency disagrees with the rationale provided by FMC and BTF. The submitted study, MRID 48593601, a guideline 850.1735 spiked sediment exposure test on *Hyalella azteca*, would not satisfy the requirement for guideline 850.1010, a water column exposure study. However, there is an existing guideline 850.1020 *Hyalella azteca* water column study (MRID 49552201) which can be used to fulfill this requirement, therefore this data requirement is considered satisfied.
- Fish early-life stage toxicity (guideline 850.1400): The Agency agrees with FMC and BTF that the submitted study, MRID 49412101, has been reviewed and deemed acceptable, therefore this data requirement is satisfied.

For the pollinator data requirements, EPA has been in discussion with the Pyrethroid Working Group on the possibility of bridging pollinator data across the pyrethroids to streamline data generation efforts. Registrants are strongly encouraged to submit proposals for bridging pyrethroid exposure and effects data to EPA for review and comment prior to their implementation. A bridging proposal should incorporate several underlying principles, including but not limited to:

a. generating sufficient empirical data to demonstrate the predictability of the bridging approach being proposed,
b. addressing the presumed greater uncertainty of bridged data relative to empirical data, and
c. addressing data gaps should the intended bridging approach be considered unreliable (e.g., using a conservative approach such as lower 95th confidence limit on observed toxicity).

Please see the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals* for additional considerations for pollinator data bridging.

EPA intends to issue Data Call-Ins for pollinator data for each pyrethroid with outdoor uses based on the data needs outlined in the pyrethroid DRAs and PIDs. As with all DCIs, registrants

will be able to cite existing data and/or request data waivers (for example, as a result of any data bridging) in response to the DCIs.

EPA also has changed the labeling for turf granular products to note that watering in after application is only required if the application rate is greater than 0.34 lbs a.i./A. This will allow for greater flexibility to applicators and also address residential post-application risks to children.

The Agency disagrees with FMC that the mode of action group number 3B should be used for bifenthrin. According to the Insecticide Resistance Action Committee's (IARC) mode of action classification scheme[2], insecticides in subgroup 3B consist of DDT and methoxychlor. Subgroup 3A comprises the pyrethroids and pyrethrins. To be consistent with other pyrethroid product labels, the EPA will use the mode of action group number 3A for bifenthrin.

Comment Submitted by Washington State Department of Agriculture (EPA-HQ-OPP-2014-0051-0065)

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

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

Comment Submitted by USDA (EPA-HQ-OPP-2010-0384-0287)

Comment: The USDA encourages EPA to evaluate the potential for Codex MRL harmonization to the greatest extent possible or provide detailed, risk-based explanations for not harmonizing when U.S. tolerances are lower than the Codex MRLs. In addition, USDA encourages EPA to consider a more comprehensive approach to 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.

EPA Response: EPA thanks the USDA for its comments and will take them into consideration. 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 should be sent to the Registration Division Product Manager for bifenthrin.

[2] https://irac-online.org/modes-of-action/

Comment Submitted by the Scotts Company (EPA-HQ-OPP-2010-0384-0285)

Comment: The Scott's Company sought clarification on the required labeling for residential consumer products. Scotts noted that the boscalid PID stated that residential consumer product labels are excluded from the requirement to list the mode of action group number. Scotts noted it was also unclear whether the following pollinator labeling measures were meant to be excluded from residential homeowner 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. Scotts suggested the updated glove statement have a sentence added that registrants of consumer products should review the label review manual Chapters 7 and 10 to determine if waterproof gloves are applicable.

EPA Response: EPA thanks The Scotts Company for its feedback on the bifenthrin PID. The Agency confirms that the requirement to list the mode of action group number and other resistance management labeling and pollinator labeling are not intended for residential products. 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. EPA is not changing the updated glove statement language as waterproof gloves may not be appropriate for every product and urges each registrant to choose the appropriate glove type(s) to list on their label based on the current guidance in the Label Review Manual.

Comment Submitted by NAAA (EPA-HQ-OPP-2010-0384-0291)

Comment: NAAA noted the overall importance of aerial applications and the advantages of aerial applications over other forms of application. While NAAA supports the proposed spray drift mitigation language for aerial applications, NAAA described the need for clear label language regarding the specific altitude above which temperature inversions are not of concern. NAAA states it is currently collaborating with the USDA-ARS Aerial Application Technology Research Unit to conduct a literature review on the matter.

EPA Response: EPA thanks NAAA for the comments and for its work with USDA-ARS to conduct a literature review. The Agency will review any additional information submitted regarding the altitude of temperature inversions as it relates to pesticide applications. At this time EPA is not changing the temperature inversion label restriction proposed in the bifenthrin PID.

Comments Submitted by Various Water Boards/Water Agencies

Comments: The National Association of Clean Water Agencies (NACWA) (EPA-HQ-OPP-2010-0384-0290), the California Stormwater Quality Association (CASQA) (EPA-HQ-OPP-2010-0384-0292), the San Francisco Bay Regional Water Quality Control Board (SFBRWQCB) (EPA-HQ-OPP-2010-0384-0294), and the Bay Area Clean Water Agencies (BACWA) (EPA-HQ-OPP-2010-0384-0295) commented on the proposed risk mitigation for bifenthrin.
The water boards/agencies urged EPA to consider individualized mitigation measures for high risk pyrethroids such as bifenthrin. 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 RQs for aquatic organisms. They suggest that EPA implement targeted mitigation for the most used and higher risk pyrethroids, like bifenthrin, since not all pyrethroids and pyrethrins have equal costs and benefits. BACWA also urged the cancelation of bifenthrin pet shampoo products, and NACWA stated the benefits of these products do not justify the risks. CASQA and SFBRWQCB commented that the outdoor urban use of bifenthrin should be ended or further restricted due to its impacts on aquatic life and costs to municipal agencies, and that its benefits can be replaced from the use of less harmful pyrethroids.

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 bifenthrin at this time beyond what is already required as part of this ID. EPA concludes that bifenthrin 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 bifenthrin use. In addition, EPA notes that all states, including California, are authorized to restrict pesticide use according to state requirements/needs. For a more detailed response to these comments, please see the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*.

Comments Submitted by Pyrethrin Joint Venture and Various Registrants

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

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

II. USE AND USAGE

Bifenthrin is registered for use in a wide variety of settings including numerous agricultural crops, indoor and outdoor residential and commercial areas, and pet shampoo and collars, and for wide area mosquito control.

Nationally, residential consumers purchased around 100,000 lbs of pyrethroid insecticides (as a group), for indoor use and around 2 million lbs a.i. of pyrethroids for residential outdoor uses in 2016, 98% of which is bifenthrin.[3] These amounts include household insecticides for use both indoor and outdoor (e.g., ant, cockroach, termite, fly control, and lawn and garden pest control insecticides), pet products, and insect repellents.

Recent data also indicate that pyrethroids are used in other non-agricultural areas. Recent data also indicate that pyrethroids are used in other non-agricultural areas. Almost 190,000 lbs a.i. of pyrethroids are used for wide-area applications for mosquito control; however, there are no reports of bifenthrin use in this area.[4] Food handling establishments, including processing facilities, warehouses, restaurants, and other food preparation facilities, used around 200,000 lbs a.i. of pyrethroids, including 80,000 lbs a.i. of bifenthrin in 2013.[5] Professional pest management companies and horticultural companies used over 3 million lbs a.i. of pyrethroids for control of various nuisance and public health pests both in and around residential and commercial buildings. Bifenthrin accounted for 600,000 lbs a.i. of this total in professional pest management and 1.4 million lbs a.i. in turf and horticultural companies.[6,7] Industrial vegetation management, including roadways and rangeland, used around 56,000 lbs of pyrethroids, 8,000 lbs of which is bifenthrin usage.[8]

Usage in agriculture averages about 1 million lbs a.i. of bifenthrin used to treat over 14 million acres of cropland per year between 2014-2018.[9] Corn, soybeans, and cotton account for about 80% of that usage. About 5% of corn and soybeans and 15% of cotton acres are treated with bifenthrin. However, while low in overall treated acres, between 35-45% for artichokes, cantaloupes, strawberries, and pistachios are treated with bifenthrin. For more information, see the Screening Level Usage Analysis[10] available in this docket.

[3] Non-Agricultural Market Research Proprietary Data (NMRD). 2017a. Studies conducted and sold by a consulting and research firm. Report on consumer pesticide usage. Accessed June 2019.
[4] Kline and Company. 2017. Mosquito Control 2016: U.S. Market Analysis and Opportunities. Accessed June 2019.
[5] Kline and Company. 2014. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2013: U.S. Market Analysis and Opportunities. Accessed June 2019.
[6] Kline and Company. 2013. Professional Turf and Ornamental Markets for Pesticides and Fertilizers 2012. Accessed June 2019.
[7] Non-Agricultural Market Research Proprietary Data (NMRD). 2017c. Studies conducted and sold by a consulting and research firm. Report on professional pest control pesticide usage. Accessed June 2019.
[8] Non-Agricultural Market Research Proprietary Data (NMRD). 2017d. Studies conducted and sold by a consulting and research firm. Report on vegetation management. Accessed June 2019.
[9] Kynetec USA, Inc. 2019, The AgroTrak Study, Database Subset: 2014-2018.
[10] Environmental Protection Agency (EPA). (2019). Screening Level Usage Analysis (SLUA) of Bifenthrin.

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 bifenthrin. For additional details on the human health assessment for bifenthrin, see the *Bifenthrin: Human Health Draft Risk Assessment for Registration Review, and Section 3 Risk Assessment* and *Bifenthrin: Updated Draft Human Health Risk Assessment for Registration Review*, which are available in the public docket.

1. Pyrethroids FQPA Safety Factor Determination

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

2. Risk Summary and Characterization

There are no dietary, residential handler, aggregate, or non-occupational spray drift risks of concern for bifenthrin. There are residential post-application risks of concern from exposures from high contact activities on treated turf for adults and children at maximum labeled rates for liquid formulations (2.3 lbs a.i./A). Since comments from bifenthrin registrants note that the 2.3 lb ai/A rate assessed is incorrect, the Agency also evaluated a lower application rate of 0.23 lb ai/A for liquid/spray formulations of bifenthrin used on residential turf. There were no risk

estimates of concern for adults and children from exposure following liquid applications of bifenthrin at a rate of 0.23 lbs ai/A.

There are also residential post application risks from episodic ingestion of granules, assuming the maximum amount of bifenthrin in registered granular formulations (0.2%), a maximum application rate of 200 lbs product/A (0.4 lbs a.i./A[11]), and ingestion rates adjusted for bifenthrin-specific application rates. This scenario is not of concern assuming a maximum application rate of 170 lbs product/A (0.34 lbs a.i./A) in granular formulations. Two scenarios result in occupational handler risk estimates of concern assuming baseline attire (long-sleeved shirts, long pants, shoes, and socks) but are not of concern with the addition of chemical-resistant gloves.

Dietary (Food and Water) Risks

In the general U.S. population and all population subgroups, the acute dietary risk estimates are below the EPA's level of concern (*i.e.*, <100% aPAD). Bifenthrin is classified as a "possible human carcinogen." Quantification of human cancer dietary risk is not required since the acute reference dose (RfD) will adequately account for all repeated exposure/chronic toxicity, including carcinogenicity, which could result from exposure to bifenthrin.

Residential Handler Risks

All residential handler inhalation and dermal risks estimates are not of concern as margins of exposure (MOEs) are greater than the levels of concern (LOCs) of 30 and 100, respectively. Dermal and inhalation risk estimates were combined in the bifenthrin human health risk assessment, since the toxicological effects for these exposure routes were the same. A total aggregate risk index (ARI) was used but there were no risks of concern since the MOE exceeded the LOC of 1.

Residential Post-Application Risks

None of the residential post-application exposures result in risk estimates of concern, except the following scenarios:

- High contact activities following liquid application to lawns/turf at an application rate of 2.3 lbs a.i./A (for children the dermal MOE = 35, for adults the dermal MOE = 69, LOC = 100).
- Hand-to-mouth exposures for children 1 to < 2 years old following liquid application to lawns/turf at an application rate of 2.3 lbs a.i./A (MOE = 32, LOC = 100).
- Combined dermal and hand-to-mouth exposures for children 1 to < 2 years old years old following liquid application to lawns/turf at an application rate of 2.3 lbs a.i./A (MOE = 17, LOC = 100).

[11] The revised DRA incorrectly identifies this rate as 0.5 lb ai/A, but based on the label (EPA Reg. #279-3343), the correct rate should be 0.4 lb ai/A.

- Episodic granular ingestion following application to lawns/turf for children 1 to < 2 years old assuming maximum % bifenthrin in registered granular formulations (0.2%), a maximum application rate of 200 lbs product (0.4 lb a.i./A), and ingestion rates adjusted for bifenthrin-specific application rates[12] (acute/episodic ingestion MOE = 85, LOC = 100). This scenario is not of concern assuming a maximum application rate of 170 lbs product/A (0.34 lbs a.i./A; acute/episodic ingestion MOE = 100, LOC = 100).

Due to public comments received noting that the application rate used for liquid/spray formulations of bifenthrin on residential turf (2.3 lbs a.i./A) was incorrect, EPA also evaluated residential post application risk at a corrected rate of 0.23 lbs a.i./A (as suggested by bifenthrin registrants). For the lower application rate of 0.23 lbs a.i./A, there were no risks of concern (all MOEs are greater than the LOC of 100).

Aggregate Risks

The acute aggregate risk assessment combines exposures to bifenthrin in food and drinking water only and is equivalent to the acute dietary assessment. There are no acute aggregate risks of concern.

Short-term aggregate risks for bifenthrin were estimated. The short-term residential exposure and average dietary (food and water) exposure for adults and children was aggregated. Residential exposures that were of concern were not aggregated. However, because of a possible discrepancy in the label rates, an aggregate assessment was performed for treated turf assuming a lower maximum application rate of 0.23 lbs a.i./A for liquid/spray formulations of bifenthrin on residential turf. There are no short-term aggregate risks of concern for the scenarios assessed.

Non-occupational Spray Drift

Non-occupational spray drift risk estimates reflect exposures for children and adults who have contact with turf where residues are assumed to be deposited via spray drift. There were no dermal or combined dermal and incidental oral risks of concern for non-occupational spray drift (all MOEs were greater than the LOC of 100).

Occupational Handler Risks

Occupational handlers are individuals who are involved in the pesticide application process (including mixers, loaders, and applicators). Handlers are assumed to have baseline personal attire, which consists of long-sleeved shirt, long pants, and shoes plus socks. Engineering controls are assumed for aerial applicators. Exposure data for workers loading/applying, performing multiple activities, and planting treated seed is only available for occupational handlers wearing gloves. The majority of occupational handler dermal, inhalation, and

[12] The assumed ingestion rate for dry pesticide formulations (e.g., pellets and granules) is 0.3 gram/day for children 1 < 2 years old. It is assumed that if 150 pounds of product were to be applied to a ½ acre lawn, the amount of product per square foot would be approximately 3 g/ft^2 and a child would consume one-tenth of the product available in a square foot. This rate has been refined with product-specific information to reflect the amount of product applied on a per area basis (200 lb product applied per acre to result in an ingestion rate of 0.2 g/day).

combined (dermal + inhalation) risk estimates were not of concern (dermal MOEs ≥ 100, inhalation MOEs ≥ 30, and ARI ≥ 1) with baseline attire for the registered uses of bifenthrin.

The scenarios that result in risk estimates of concern with baseline attire are

1) mixing/loading liquids for aerial ultra-low volume application to cotton (0.1 lb a.i./A; dermal MOE = 79, Dermal LOC = 100; ARI = 0.75, ARI LOC = 1.0),
2) mixing/loading/applying liquids with a mechanically pressurized handgun for soil at-plant applications to tuberous and corm vegetables (0.03 lb a.i./gallon; Dermal MOE = 72, Dermal LOC =100; ARI = 0.67, ARI LOC = 1.0), and
3) mixing/loading/applying liquids with a mechanically pressurized handgun for soil at-plant applications to tobacco (dermal MOE=54, dermal LOC=100; ARI = 0.51, ARI LOC = 1.0).

If all the labels were to require use of chemical-resistant gloves for the scenarios above, there would be no risks of concern.

Occupational Post-Application Risks

Post-application exposure describes exposures that occur when individuals are present in an environment that has been previously treated with bifenthrin and includes activities such as scouting for pests or hand-harvesting. The occupational dermal post-application MOEs are not of concern (MOEs ≥ 100, LOC = 100) on the day of application for the registered uses of bifenthrin. The occupational post-application MOEs representing the worst-case activity scenario for each crop range from 320 to 320,000 on the day of application (LOC = 100).

Bifenthrin is classified under the Worker Protection Standard (WPS) for Agricultural Pesticides as acute toxicity categories III via dermal exposure and IV for acute eye irritation. Under this standard, bifenthrin is assigned a 12-hour REI. There are no dermal post-application risks of concern on the day of application for bifenthrin; therefore, the current label-specified REI of 12 hours is adequate.

Cumulative Risks

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

For more information on the human health risks conclusions for bifenthrin, refer to the *Bifenthrin: Human Health Draft Risk Assessment for Registration Review, and Section 3 Risk Assessment* and *Bifenthrin: Updated Draft Human Health Risk Assessment for Registration Review*, which are available in the bifenthrin public docket (EPA-HQ-OPP-2010-0384).

3. Human Incidents and Epidemiology

The Agency conducted a search for human incidents and epidemiology reports attributed to bifenthrin in 2017. The following sources were searched:

1) the Office of Pesticide Programs' Incident Data System (covering incidents from 2009 to 2014),
2) the Center for Disease Control (CDC)/NIOSH Sentinel Event Notification System for Occupational Risk (SENSOR-Pesticides, covering incidents from 1998 to 2011),
3) the Agency-sponsored National Pesticide Information Center (NPIC, covering incidents from 2009 to 2014),
4) California's Pesticide Incident Surveillance Program (PISP, covering incidents from 2007 to 2011), and
5) epidemiological studies [Agricultural Health Study (AHS)].

The acute health effects reported for bifenthrin are consistent among the databases queried and are primarily neurological, respiratory, dermal, and gastrointestinal effects.

The available incident data from IDS, NPIC, SENSOR-Pesticides and California PISP suggest that most of the reported bifenthrin incidents involve homeowner and residential exposures. The majority of these incidents are from post-application exposures. Although most bifenthrin cases reported to the SENSOR-Pesticides and California PISP databases were residential, both datasets did have several occupational incidents reported involving bifenthrin. Both SENSOR-Pesticides and PISP reported that most occupational incidents occurred while conducting routine work, including fieldwork. The Agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern. For more information, see the *Bifenthrin: Updated Tier I Review of Human Incidents and Epidemiology for Draft Risk Assessment.*

The Agricultural Health Study (AHS) is a high quality, prospective epidemiology study evaluating the link between pesticide use and various health outcomes including cancer. Bifenthrin is included in the AHS, so this study provides information specific to bifenthrin. An epidemiological report was developed to assess the association between exposure to the pyrethroids in humans and adverse carcinogenic and non-carcinogenic outcomes, as well as select individual pyrethroids, including bifenthrin. Overall, the epidemiological report found little substantive evidence to suggest a clear, associative, or causal relationship between exposure to pyrethroids and cancer and non-cancer health endpoints in the available studies, including the AHS publications reported. For further information, please see the *Pyrethroids: Tier II Epidemiological Report*[13] dated April 30, 2019.

4. Tolerances

Existing tolerances for bifenthrin residues, including its metabolites and degradants, are established under 40 CFR §180.442. During registration review, EPA implements crop group

[13] https://www.epa.gov/sites/production/files/2019-08/documents/tier-ii-epidemiology-report.pdf

conversions and commodity definition revisions for existing tolerances resulting in changes to pesticide crop grouping regulations. The following crop group conversions are anticipated:

1) brassica head and stem subgroup 5A (except cabbage) to vegetable head and stem brassica group 5-16;
2) brassica leafy greens subgroup 5B to brassica leafy greens subgroup 4-16B;
3) caneberry subgroup 13A to caneberry subgroup 13-07A;
4) leafy petioles subgroup 4B to leaf petiole vegetable subgroup 22B;
5) citrus fruit group 10 to citrus fruit group 10-10; and
6) tree nut group 14 to tree nut group 14-12.

The Agency also anticipates correcting the commodity definitions for cilantro, milk, grass forage, and grass hay.

There are several crops with U.S. tolerance levels that are different than Canada and/or Codex maximum residue limits. For the purpose of harmonization, the U.S tolerances for bifenthrin, which are lower than those established by Canada and/or Codex, are anticipated to be increased.

The Agency intends to undertake these tolerance actions pursuant to its FFDCA authority. The following established tolerances are anticipated to be revised to be consistent with the Organization for Economic Co-operation and Development (OECD) rounding class practice: almond hulls at 2 ppm, globe artichoke at 1 ppm, avocado at 0.5 ppm, cattle fat at 1 ppm, coriander seed at 5 ppm, field corn forage at 3 ppm, pop corn stover at 5 ppm, sweet corn forage at 3 ppm, sweet corn stover at 5 ppm, hog fat at 1 ppm, horse fat at 1 ppm, okra at 0.5 ppm, pomegranate at 0.5 ppm, sheep fat at 1 ppm, soybean hulls at 0.5 ppm, soybean refined oil at 0.3 ppm, and root vegetable subgroup 1B at 0.1 ppm.

Table 1 lists the anticipated changes to the tolerances for bifenthrin.

Table 1. Anticipated Tolerance Revisions for Bifenthrin (40 CFR §180.442(a) General).

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Almond, hulls	2.0	2	Corrected value to be consistent with OECD Rounding Class Practice.
Artichoke, globe	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Beet, garden, leaves	-	15	Commodity definition revision.
Beet, garden, tops	15	remove	
Beet, garden, roots	0.45	0.5	Harmonization with Canada.
Broccoli, chinese	0.6	4	Crop group conversion/revision.[1,2] Harmonization with Canada.
Brassica, leafy greens, subgroup 4-16B	-	4	Crop group conversion/revision.[1] Harmonization with Canada.
Brassica, leafy greens, subgroup 5B	3.5	remove	
Bushberry, subgroup 13-07B	1.8	3	Harmonization with Codex and Canada.
Cabbage	4.0	7	Harmonization with Canada.
Caneberry subgroup 13-07A	-	1	Crop group conversion/revision. Corrected value to be consistent with OECD Rounding Class Practice.
Caneberry subgroup 13A	1.0	remove	

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Cattle, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Cattle, meat byproducts	0.10	0.2	Harmonization with Codex.
Cattle, meat	0.5	3	Harmonization with Codex.
Celtuce	-	3	Crop group conversion/revision.[1,3]
Cilantro, dried leaves	-	25	Commodity definition revision.
Coriander, dried leaves	25	remove	
Cilantro, fresh leaves	-	6	Commodity definition revision.
Coriander, fresh leaves	6.0	remove	Corrected value to be consistent with OECD Rounding Class Practice.
Coriander, seed	5.0	5	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, field, forage	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, field, stover	5.0	15	Harmonization with Codex.
Corn, pop, stover	5.0	5	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, sweet, forage	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Corn, sweet, stover	5.0	5	Corrected value to be consistent with OECD Rounding Class Practice.
Egglant	0.05	0.3	Harmonization with Codex.
Fennel, florence, fresh leaves and stalk	-	3	Crop group conversion/revision.[1,3]
Fruit, citrus, group 10-10	-	0.05	Crop group conversion/revision.
Fruit, citrus, group 10	0.05	remove	
Goat, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Goat, meat byproducts	0.10	0.2	Harmonization with Codex.
Goat, meat	0.5	3	Harmonization with Codex.
Grape	0.2	0.3	Harmonization with Codex.
Hog, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Hog, meat byproducts	0.10	0.2	Harmonization with Codex.
Hog, meat	0.5	3	Harmonization with Codex.
Hop, dried cones	10.0	20	Harmonization with Codex.
Horse, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Horse, meat byproducts	0.10	0.2	Harmonization with Codex.
Horse, meat	0.5	3	Harmonization with Codex.
Kohlrabi	-	3	Crop group conversion/revision.[1,3]
Leaf petiole vegetable subgroup 22B	-	3	Crop group conversion/revision.[1,3]
Leafy petioles subgroup 4B	3	remove	
Lettuce, head	3.0	4	Harmonization with Canada.
Mayhaw	1.4	1.5	Harmonization with Canada.
Milk	0.1	0.2	Commodity definition revision. Harmonization with Codex.
Milk, fat	1.0	3	Commodity definition revision. Harmonization with Codex.
Milk, fat (reflecting 0.1 ppm in whole milk)			
Nut, tree, group 14-12	-	0.05	Crop group conversion/revision.

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Nut, tree, group 14	0.05	remove	
Pistachio	0.05	remove	
Okra	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.
Pear	0.5	0.9	Harmonization with Canada.
Sheep, fat	1.0	1	Corrected value to be consistent with OECD Rounding Class Practice.
Sheep, meat byproducts	0.1	0.2	Harmonization with Codex.
Sheep, meat	0.5	3	Harmonization with Codex.
Soybean, hulls	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.
Soybean, refined oil	0.30	0.3	Corrected value to be consistent with OECD Rounding Class Practice.
Spinach	0.2	0.3	Harmonization with Canada.
Strawberry	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice.
Swiss chard	-	3	Crop group conversion/revision.[1,3]
Turnip, greens	3.5	remove	Crop group conversion/revision.[1]
Tomato	0.15	0.3	Harmonization with Codex.
Vegetable, brassica, head and stem, group 5-16	-	0.9	Crop group conversion/revision.[1] Harmonization with Canada.
Brassica, head and stem, subgroup 5A	0.6	remove	
Vegetable, cucurbit, group 9	0.4	0.5	Harmonization with Canada.
Vegetable, legume, edible podded, subgroup 6A	0.6	0.8	Harmonization with Canada.
Vegetable, root, subgroup 1B, except sugar beet and garden beet	0.10	0.1	Corrected value to be consistent with OECD Rounding Class Practice.

[1] The proposed conversion of existing tolerances in/on crop subgroup 4B to crop subgroup 22B (leafy petioles), crop subgroup 5B to crop subgroup 4-16B (*Brassica* leafy greens), and crop subgroup 5A to crop group 5-16 (vegetable, *Brassica*, head and stem), kohlrabi, and Chinese broccoli are consistent with the document entitled, "Attachment - Crop Group Conversion Plan for Existing Tolerances as a Result of Creation of New Crop Groups under Phase IV (4-16, 5-16, and 22)" dated 11/3/2015.

[2] The Agency is proposing individual tolerances of 0.6 ppm for broccoli, chinese and kohlrabi based on the currently established tolerance for these commodities as part of crop group 5A.

[3] for the Agency is proposing individual tolerances of 3 ppm for celtuce, florence fennel, and swiss chard based on the currently established tolerance for these commodities as part of crop subgroup 4B.

For the 40 CFR §180.442(b) *Section 18 emergency exemption* tolerances, the anticipated revisions are summarized below in Table 2.

Table 2. Anticipated Tolerance Revisions for Bifenthrin (40 CFR §180.442(b) *Section 18 Emergency Exemptions*).

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Avocado	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.
Pomegranate	0.50	0.5	Corrected value to be consistent with OECD Rounding Class Practice.

For the 40 CFR §180.442(c) *Tolerances with regional registration*, the anticipated revisions are

summarized below in Table 3.

Table 3. Anticipated Tolerance Revisions for Bifenthrin (40 CFR §180.442(c) *Tolerances with Regional Registration*).

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Anticipated Tolerance (ppm)	Comments
Grass, forage, fodder and hay, group 17, forage	-	4	Commodity definition correction. Corrected value to be consistent with OECD Rounding Class Practice.
Grass, forage	4.0	remove	
Grass, forage, fodder and hay, group 17, hay	-	15	Commodity definition correction.
Grass, hay	15	remove	

5. Human Health Data Needs

The Agency does not anticipate any further data needs for the registration review of bifenthrin at this time. GDCI-097805-1100 (for guideline 875.1700 product use information) is partially satisfied; EPA has received and accepted data from the companies who represent the Residential Exposure Joint Venture. EPA continues to evaluate data submitted from companies comprising the Generic Residential Exposure Task Force (GRETF) and is partially satisfied. EPA continues to evaluate data submitted from companies comprising the GRETF and will update the status of this DCI 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, esfenvalerate, fenpropathrin, permethrin, and pyrethrins. The 2016 risk assessment was divided into five sections: risks from indoor "down the drain" uses;[14] 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. Bifenthrin has uses that fall into all five categories. The Agency primarily focused on potential effects to aquatic organisms (for all uses) as well as terrestrial invertebrates (for agricultural uses). A quantitative assessment was conducted for these nine pesticides, for which the Agency had a relatively large amount of data. A companion piece, titled the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* or the Rationale Document, summarized potential risk concerns for the remaining pyrethroids and was

[14] "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.

published at the same time. The pesticides covered in the Rationale Document are: cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, esfenvalerate, and tetramethrin. The Rationale Document describes EPA's approach in using the quantitative assessment of the nine cases to serve as a basis for making risk management and regulatory decisions for all 23 affected pesticides currently undergoing registration review. Potential risks that were identified for the eight pyrethroids and pyrethrins assessed in 2016 were determined to be representative of the risks for the other pyrethroids also undergoing registration review. For additional details on the ecological assessment for the pyrethroids, see the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review*, which are available in the public docket.

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

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

Terrestrial Invertebrates (honeybees)

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

For bifenthrin, acute risk to bees was identified from the agricultural uses. Risk to bees from outdoor residential use and from the wide-area adult mosquito control use was not assessed. The potential impacts of bifenthrin on bees and non-target terrestrial invertebrates in residential settings is uncertain.

The Agency did not have sufficient information to assess chronic risk to bees or effects on honeybee colonies. EPA concludes that additional pollinator data are necessary to fully evaluate risks to bees from use of the pyrethroids/pyrethrins. The Agency has determined the full suite of pollinator studies for the pyrethroids/pyrethrins that may impact pollinators is necessary, where

such data are not currently available. EPA will issue a Data Call-In (DCI) for the pollinator studies listed in Table 4.

Table 4. Pollinator Data Requirements

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

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

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

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

1. Ecological and Environmental Fate Data Needs

The following studies are outstanding for bifenthrin from the registration review GDCI-128825-902:

- Direct photolysis rate of parent and degradates in water (guideline 835.2240)
- Aerobic soil metabolism on one additional soil (guideline 835.4100)
- Aerobic aquatic metabolism (guideline 835.4300)
- Independent laboratory validation in water as a part of the aquatic field dissipation requirement (guideline 835.6200)
    - There is currently an independent laboratory validation for wastewater study (MRID 49347501) for multiple pyrethroids including bifenthrin in review which may fulfill this data requirement if determined to be acceptable

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

Sufficient data were available for conducting the risk assessments and making in interim registration review decision. These data will be used to inform future risk assessments.

C. Benefits Assessment

As a synthetic pyrethroid, bifenthrin affects the nervous systems of insects by keeping sodium channels in neuronal membranes open which initially stimulates nerve cells to repeatedly discharge, resulting in paralysis (also called "knockdown") and eventually death. The knockdown effect is often a desirable feature for crop growers, because it prevents affected insect pests from feeding even before death occurs. Pyrethroids are widely used in agriculture to control a variety of pests that disrupt crop production. In terms of total acres treated and particularly in terms of the variety of crops that use them, pyrethroids have largely surpassed the organophosphate and carbamate insecticides as the preferred options by growers for cost-effective and broad-spectrum insect control.

Bifenthrin is recommended by university extension specialists for the control of pests in many agricultural crops, as well as in turfgrass and ornamental plants, nursery production, and human and livestock structures.[15,16,17] The Agency previously determined that bifenthrin was one of the most heavily used insecticides and beneficial for to users producing blueberries, corn, cotton, grapes, soybeans, tree nuts, and numerous vegetables including brassica, cucurbits, fruiting vegetables (*e.g.*, tomato and peppers), and sweet corn as it provides efficacious control of a variety of economically important pests.[18] Bifenthrin is commonly included in extension recommendations to control a wide variety of taxa that includes pests such as caterpillars and borers (*e.g.*, bollworms, cutworms, corn borers, grape berry moth, orange navel worm), plant bugs (*e.g.*, lygus bugs, tarnished plant bugs), stink bugs (*e.g.*, green stink bug, brown marmorated stinkbug, brown stink bug), leaf-footed bugs, flies (*e.g.*, spotted-wing drosophila, seedcorn maggot, walnut husk flies), and various beetles (*e.g.*, corn rootworms or cucumber beetles, Japanese beetles). [22,23,24] Generally, EPA found that alternatives to bifenthrin that have similar broad-spectrum pest activity include other pyrethroid insecticides, neonicotinoids, organophosphates, and carbamates.

[15] Haviland, D.R., R.A. Baldwin, K.J. Hembree, T.J. Michailides, B.B. Westerdahl, R.H. Beede, K.M. Daane, T.A. Fukuda, C.E. Kallsen, A. Shrestha, J.P. Siegel, and G.B. Weinberger. 2019. UC IPM Pest Management Guidelines: Pistachio. UC ANR Publication 3461. Oakland, CA. https://www2.ipm.ucanr.edu/agriculture/pistachio/. Accessed January 2020.
[16] North Dakota State University Extension. 2019. North Dakota Field Crop Insect Management Guide (2020). 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 January 2020.
[17] University of Arkansas Extension. 2019. Insecticide Recommendations for Arkansas. University of Arkansas Division of Agriculture Research and Extension MP 144. https://www.uaex.edu/publications/MP144.pdf. Accessed January 2020.

Bifenthrin is also used in indoor/outdoor residential settings to deter fleas and ticks. In residential settings, it may also 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, cockroaches, and bedbugs. As such, bifenthrin provides benefits as one of several options to suppress pests of public health concern.

For all these uses, while bifenthrin generally offers effective pest control, various alternatives with similar efficacy also exist in the marketplace, many are other pyrethroids. Depending on the use setting and target pest, other chemistries are also effective. 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 bifenthrin.

For pests that affect pets such as dogs, several types of products (*e.g.*, shampoos) contain bifenthrin; similar products containing other pyrethroids are also available. 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, benefits, and alternatives of bifenthrin, refer to the following documents (available in the public docket EPA-HQ-OPP-2008-0331):

- *Usage Characterization and Alternatives Summary for Synthetic Pyrethroids Used in Residential Lawns and Outdoor Vegetative Spot Treatments*,
- *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito Adulticides in Support of Registration Review*,
- *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroid Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*, and
- *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*.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

The Agency has determined that there are potential residential post-application and occupational handler risks of concern associated with the registered uses of bifenthrin for several scenarios. As a result, EPA is requiring additional mitigation measures to reduce risk to adults, children, and handlers, in addition to other changes needed to clarify, update, and improve consistency of product labeling. The Agency identified potential risks for various taxa (freshwater and terrestrial invertebrates, and fish), with the major potential risks of concern focusing on aquatic invertebrates from (indoor, outdoor, agricultural, mosquito adulticide uses) and terrestrial invertebrates, from agricultural uses of bifenthrin. Mitigation to address risks to aquatic and terrestrial invertebrates will benefit the other taxa to the extent that there is any risk.

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

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

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.

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

1. Mitigation Measures for Residential Post-Application Risks

a. Application Rate Clarification for Turf

There are potential residential post-application risks of concern from exposures from high contact activities on treated turf for adults and children at maximum labeled rates for turf liquid formulations (2.3 lbs a.i./A). During the public comment period on the Draft Human Health Risk Assessment, registrants noted inconsistencies between the labeled maximum rates on bifenthrin liquid turf products and the rates assessed for risk assessment and requested that EPA assess the maximum turf rate of 0.23 lbs a.i./A. At this revised rate, there are no potential residential post-application risks of concern. Therefore, EPA is adding a rate clarification for turf: labels must reflect the correct maximum application rate of 0.23 lbs a.i./A for all liquid turf products. The following turf products containing bifenthrin currently allow up to the 2.3 lbs a.i./A rate: EPA Reg. Nos. 279-3169, 279-3152, 279-9547, and 228-494. EPA is currently working with registrants to update these labels with the correct lower maximum application rates and is requiring any other product labels that may contain the 2.3 lbs ai/A rate be changed.

b. Watering In for Turf Granular Formulations

There are potential residential post-application risks of concern from episodic ingestion of granules following application to lawns/turf for children 1 to < 2 years old, assuming the

maximum percent bifenthrin in registered granular formulations (0.2%) at a maximum application rate of 0.4 lb ai/A and ingestion rates adjusted for bifenthrin-specific application rates. The acute/episodic ingestion MOE is 85 (where MOEs below the LOC of 100 are of concern). This scenario is not of concern assuming a maximum application rate of 170 lbs product/A (0.34 lb ai/A) in turf granular formulations (acute/episodic ingestion MOE = 100, LOC = 100). In the risk assessment, the assumed ingestion rate for dry pesticide formulations (*e.g.*, pellets and granules) is 0.3 gram/day for children 1 < 2 years old. It is assumed that if 150 pounds of product were to be applied to a ½ acre lawn, the amount of product per square foot would be approximately 3 g/ft^2 and a child would consume one-tenth of the product available in a square foot. This rate has been refined with product-specific information to reflect the amount of product applied on a per area basis (200 lbs product applied per acre to result in an ingestion rate of 0.2 g/day; 170 lbs product applied per acre to result in an ingestion rate of 0.17 g/day).

The current maximum application rate for turf granular products is 0.4 lb ai/A. For granular applications at rates above 0.34 lb ai/A (or 170 lb product/A), requiring watering in after application would significantly reduce the potential risk from episodic ingestion of granular products. Therefore, EPA is requiring watering in after application for all turf granular applications at rates above 0.34 lb ai/A (170 lb product/A).

2. Mitigation Measures for Occupational Handlers

There are potential risks of concern for handlers for some uses and activities. The scenarios that result in risk estimates of concern at baseline attire are mixing/loading liquids for aerial ultra-low volume application to cotton (0.1 lbs a.i./A; dermal MOE = 79, dermal LOC = 100; ARI = 0.75, ARI LOC = 1.0), mixing/loading/applying liquids with a mechanically pressurized handgun for soil at-plant applications to tuberous and corm vegetables (0.03 lbs a.i./gallon; Dermal MOE = 72, Dermal LOC =100; ARI = 0.67, ARI LOC = 1.0), and mixing/loading/applying liquids with a mechanically pressurized handgun for soil at-plant applications to tobacco (0.04 lbs a.i./gallon; Dermal MOE = 54, Dermal LOC =100; ARI = 0.51, ARI LOC = 1.0). For these scenarios, there were no risks of concern when chemical resistant gloves were used along with the baseline attire. The use of chemical resistant gloves is not a requirement on all labels for the scenarios above. Therefore, EPA is requiring the addition of chemical-resistant gloves for mixers and loaders supporting aerial applications to cotton and handlers (mixers, loaders, and applicators) using mechanically pressurized handguns for applications to tuberous and corm vegetables, and tobacco.

3. 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 result in potential down-the-drain exposure are necessary to help mitigate this potential risk.

To reduce the potential for aquatic risks from improper use and disposal of pyrethroids down indoor drains and storm drains, EPA has determined that measures to inform consumers about the appropriate use sites for the pyrethroid products they purchase are necessary, as well as the

importance of proper disposal of leftover pesticides and their containers. These product stewardship measures include clear, simple language about whether the product is meant to be used indoors or outdoors, as well as consistent label language and graphic imagery to encourage proper disposal.

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

a. Indoor and Outdoor Use Site Clarification

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

b. Disposal/Stewardship Statement and Pictogram

- Labels must include the following statement on the product label unless labeled for use directly inside pipes/sinks.
    - "Do not pour or dispose down the drain or sewer. Call your local solid waste agency for local disposal options."
- Include a pictogram of a diagonal strikethrough over a drain on all end-use consumer product containers. Place pictogram in a prominent location. The pictogram must be legible (i.e. no smaller than 1.5 square centimeters or 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.

4. Mitigation Measures for Outdoor Urban Uses

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

In order to reduce the potential load of pyrethroids in surface water attributed to urban uses, the Agency has determined that a reduction in distance from building foundations that can be treated with pyrethroids from 10 feet to 7 feet is necessary. The Agency considered reducing the distance to 3 feet from the building foundation, but found the 3-foot distance to be too restrictive to allow for effective use of pyrethroids throughout various building environments. Commenters have suggested limiting to this distance could impact the efficacy of treatments in certain areas. However, the Agency finds that in order to protect aquatic environments from risks posed by pyrethroids, a reduction in the application footprint of these pesticides is necessary. The Agency has 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 indoors only, outdoors only, or both indoors and outdoors (as described in the previous section).

B. Revised General Outdoor Application Statement

The Agency is revising the general outdoor statement for all outdoor spray applications, which includes a maximum horizontal perimeter treatment of 7 feet from the base of a structure and a reduction from 3 feet to 2 feet for vertical applications to man-made structures. Current pyrethroid product labels specify the vertical and horizontal distance that may be treated with a pyrethroid; the vertical distance is measured from the ground upward and the horizontal distance is measured outward, away from the side of a man-made structure. Due to varying use sites and target pests, it is difficult to determine a single effective vertical and horizontal specification across all products. Insects need to come into contact or ingest a lethal dose of insecticide to be effectively controlled. However, reduction of the area that can be treated at the same application rate represents a load reduction for each pyrethroid treatment, which represents a clear reduction in the amount of pyrethroid material that can be transported from a treated area to nearby waterbodies. The Agency has determined that the vertical application distance may extend up to 2 feet above ground level, rather than "3 feet above grade" as previously stated on labels. The horizontal application distance is restricted to 7 feet or less from the base of a man-made structure to pervious surfaces (e.g., grass, mulched groundcover, planted areas).

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

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

5. Applications to vertical surfaces (such as the side of a man-made structure) directly above impervious surfaces (e.g., driveways, sidewalks, etc.), up to 2 feet above ground level;

6. Applications to vertical surfaces directly above pervious surfaces, such as soil, lawn, turf, mulch or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters."

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

C. Spot Treatment Guidance Statement

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

D. Buffer from Water Statement

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

E. Water Protection Statements

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

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

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

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

F. Rain-Related Statements

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

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

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

G. Statements for Ornamental/Recreational Turf

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

H. Statements for Outdoor Applications at Commercial Nurseries

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

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

The Agency does not know how efficacy may be impacted when droplet sizes are determined to be necessary for various insecticides in commercial nurseries. Pyrethroids are contact insecticides which require thorough coverage of the treated surface for effective pest control. University extension recommendations for contact insecticides such as pyrethroids are for ASABE droplet sizes of fine to medium (Wolf and Bretthauer, 2009[19]). For foliar applications, insect control would likely be negatively impacted given the requirement for a medium or larger droplet size. Growers may be driven to use higher rates, mix with another insecticide, make additional applications per season, or increase application volume with larger droplet sizes to achieve the same efficacy they were able to with finer droplet sizes. However, many pyrethroid products are already subject to droplet size restrictions and buffers to water bodies, so impacts may be limited.

I. Statements for Crack and Crevice Treatments

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

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

5. <u>Mitigation Measures for Agricultural Use Products</u>

Vegetative Filter Strip (VFS) Language

To reduce the amount of pyrethroids that enter waterbodies from runoff, EPA has determined that an increase to the existing vegetative filter strip (VFS) for agricultural products to 25 feet is necessary. EPA is concerned that sediment from agricultural land, with which pyrethroids bind, erodes into aquatic habitats exposing aquatic organisms susceptible to these pesticides. Pyrethroid monitoring data have been collected in water and sediment across the United States,

[19] 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

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 products, already have a 10-foot VFS requirement on the labels. VFS 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. [20] 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 are required to include a minimum 25-foot VFS. However, the 25-foot VFS requirement may be reduced to 15 feet if other soil conservation practices are used. Areas that qualify for a reduced 15-feet VFS are: areas considered prime farmland, areas where conservation tillage is implemented, areas with a functional terrace system, areas where water and sediment control basins are present and maintained, and areas that are less than or equal to 10 acres. Prime farmland, as defined in 7 CFR § 657.5, is not excessively erodible and pyrethroids binding to soil particles are less likely to enter adjacent waterways. Conservation tillage also works to reduce soil erosion, because remaining crop residues remain on the field. Terrace farming and the presence of water and sediment control basins also reduce soil erosion. Additionally, based on public comments on the Ecological Risk Mitigation Proposal, the VFS requirement is reduced to 15 feet, if the area of application is less than or equal to 10 acres—this reduces the impact on small-scale operations that are not primary contributors to runoff. These added criteria for a reduced VFS are intended to allow more flexibility for stakeholders.

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

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

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.[21]

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.

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

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

Required Statements for Aerial Applications

- "Do not release spray at a height greater than 10 feet above the vegetative canopy, unless a greater application height is necessary for pilot safety.
- Applicators are required to select nozzle and pressure that deliver 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."

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."

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.

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.

6. 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.

Wide-area Mosquito Adulticide Label 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:

Wind Speed Statements

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

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

Release Height Statement

"For Ground applications:

- Create an optimum swath when possible. An optimum swath width can be achieved when [product name] is applied from a truck that is being driven perpendicular to the wind

direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area.

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

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

"For Aerial Applications:

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

Environmental Hazard Statements:
EPA has determined that limiting adult mosquito control applications to trained personnel is 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][22] 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.

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

- 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

7. Pollinator Risk Mitigation

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

1) inexpensive, effective, and broad-spectrum pest control,
2) importance in resistance management programs in rotation with other insecticides,
3) convenience and ease of use due to short restricted entry intervals, and
4) effective management of key pests in crops such as alfalfa, cotton, corn, wheat, 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)[23] 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[24].

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:

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

[24] https://www.epa.gov/pollinator-protection

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.[25]

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 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;

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

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

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

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

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

d. Pollinator Incident Reporting

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

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

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

8. 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 bifenthrin 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.

9. Update Glove and Respirator Language

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

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

B. Tolerance Actions

Changes to the tolerance levels, crop listings, or the tolerance expression are needed at this time. The tolerance expression for bifenthrin in 40 CFR §180.442 (a), §180.442 (b), and §180.442 (c) are required to be revised. Updates are needed for tolerances for multiple crop groups. For additional details, refer to Section III.A.4. The Agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances.

C. Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the Agency is issuing this ID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA)

components of this case, the Agency has made the following interim decision: (1) additional pollinator data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV. A and Appendices A and B of this document, as well the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals* (EPA-HQ-OPP-2008-0331).

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of bifenthrin, nor is it making a complete endangered species finding. Although the Agency is not making a complete endangered species finding at this time, the necessary mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of bifenthrin. The Agency's final registration review decision for bifenthrin 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

There are several environmental fate studies that are outstanding from GDCI-128825-902, please refer to section III.B.1. for a detailed list. EPA has determined that pollinator data listed under Section III.B are necessary and will issue a DCI for the data. GDCI-097805-1100 (for guideline 875.1700 product use information) is partially satisfied; EPA has received and accepted data from the companies who represent the Residential Exposure Joint Venture. EPA continues to evaluate data submitted from companies comprising the Generic Residential Exposure Task Force (GRETF) and is partially satisfied. EPA continues to evaluate data submitted from companies comprising the GRETF and will update the status of this DCI when the review is completed.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

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

B. Implementation of Mitigation Measures

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

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

"I certify that this amendment satisfies the requirements of the Bifenthrin 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 Bifenthrin 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 Andrew Muench 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 Bifenthrin

Registration Review Case#: 7402 PC Code: 128825 Chemical Type: Insecticide Chemical Family: Pyrethroid Mode of Action: Neurotoxic					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions
Residential Post-Application	• Residues on lawn/turf	• High Contact Activities on lawn/turf • Hand-To-Mouth • Episodic Granular Ingestion	• Short	• Dermal toxicity • Episodic ingestion	• Correcting labels with a maximum lawn/turf application rate of 2.3 a.i./A to a maximum lawn/turf application rate of 0.23 lbs a.i./A • Require watering-in of granule products when applying at rates above 0.34 lb ai/A (170 lbs product/A)
Occupational Handler Risks	Mixing/Loading/Application for: • aerial ultra-low volume (ULV) application to cotton • mechanically pressurized handgun for soil at-plant applications to tuberous and corm vegetables • mechanically pressurized handgun for soil at-plant applications to tobacco	• Dermal • Combined Dermal and Inhalation	• Short Term • Intermediate Term	• Dermal toxicity • Combined dermal and inhalation toxicity	• Require chemical resistant gloves for these uses
Aquatic invertebrates	• Water (non-dietary) • Residues (at/on site of treatment)	• Contact • Ingestion	• Acute • Sub-chronic • Chronic	• Growth • Mortality	• Label clarity and consistency • Advisory storage and disposal statements • Reduced perimeter treatments • Defined spot treatment size

					• Rain statements • Buffers to water bodies • Spray drift management language • Precautionary statements • Increased width of vegetative filter strips
Fish	• Water (non-dietary) Residues (at/on site of treatment)	• Contact • Ingestion	• Acute • Sub-chronic • Chronic	• Growth • Mortality	• Label clarity and consistency • 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 Bifenthrin Products

<table>
<tr><th>Description</th><th>Required Label Language for Bifenthrin End-Use Products</th><th>Placement on Label</th></tr>
<tr><td></td><td>All Bifenthrin 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 uses</td><td>Note to registrant:
• Include the name of the ACTIVE INGREDIENT in the first column
• Include the word “GROUP” in the second column
• Include the MODE/MECHANISM/SITE OF ACTION CODE in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is SITE OF ACTION)
• Include the type of pesticide (i.e., INSECTICIDE) in the fourth column.

<table><tr><td>Bifenthrin</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 uses</td><td>Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)</td><td>Directions for Use, prior to directions for specific crops</td></tr>
<tr><td>Updated Gloves Statement</td><td>Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.</td><td>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use</td></tr>
</table>

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
		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 **and** particulates (or aerosols), use the following language: "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges and combination N*, R, or P filters; OR a NIOSH-approved gas mask with OV canisters; OR a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." **Note to registrant:** For products requiring protection for organic vapor only, use the following language:] "Wear a minimum of a NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
PPE for products containing directions for: • aerial ultra-low volume (ULV) application to cotton • mechanically pressurized	"Mixers and loaders supporting aerial applications to cotton must wear at a minimum: -long-sleeved shirt and long pants, - chemical-resistant gloves, - shoes plus socks" "Mixers, loaders, and applicators using mechanically pressurized handguns for applications to tuberous and corm vegetables must wear at a minimum: -long-sleeved shirt and long pants, - chemical-resistant gloves,	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
handgun for soil at-plant applications to tuberous and corm vegetables • mechanically pressurized handgun for soil at-plant applications to tobacco	- shoes plus socks" "Mixers, loaders, and applicators using mechanically pressurized handguns for applications to tobacco must wear at a minimum: -long-sleeved shirt and long pants, - chemical-resistant gloves, - shoes plus socks"	
Additional Required Labeling Action. Applies to all products delivered via liquid spray applications (except those with mosquito use)	Remove information about volumetric mean diameter from all labels <u>delivered via liquid spray application, except from products with mosquito adulticide use,</u> where such information currently appears.	Directions for Use
Rate clarification for liquid products applied to lawns and turf	All liquid products containing directions for use on turf and lawns must be updated to reflect a maximum label rate of 0.23 lbs a.i./A (expressed as both the product rate and active ingredient rate).	Directions for Use
Watering in statement for all granule products with directions for use on lawns, parks, recreational areas, and other turf sites children may visit	"For applications at rates above 0.34 lb ai/A (170 lbs product/A), users must water the treated area immediately after application."	Directions for Use
Directions for mixing/loading for products packaged in water soluble bags	Instructions for Introducing Water Soluble Packages Directly into Spray tanks: "Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your	Directions for Use

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 CFR 170.607(d)]. Handling Instructions Follow these steps when handling pesticide products in WSPs. 1.Mix in spray tank only. 2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 3. Keep the WSP in outer packaging until just before use. 4. Keep the WSP dry prior to adding to the spray tank. 5. Handle with dry gloves and according to the label instructions for PPE. 6. Keep the WSP intact. Do not cut or puncture the WSP. 7. Reseal the WSP outer packaging to protect any unused WSP(s). Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions. 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 3. Stop adding water and stop any agitation. 4. Place intact/unopened WSP into the tank. 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP. 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.	

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label. ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as in case of a spill or equipment break-down."	
Label clarification for EPA Reg. No. 1021-1858	Include the maximum single application rate for all uses on this label. Clarification of contradictory statements noting whether the product can be used on mattresses and bedding.	Directions for use
End-use products formulated with indoor residential uses		
For all products that have indoor uses only	Add the following language: "For indoor use only."	Front Label Panel and/or Directions for Use
For all products that have both indoor and outdoor uses	Add the following language: "For both indoor and outdoor use."	Front Label Panel and/or Directions for Use

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
For all products used on pets	Add the following language: "Application of product on pets must only be done indoors."	Directions for Use
Required disposal statement for products not labeled for use directly into drains and sewers.	"Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options."	Storage and Disposal
Stewardship statement that includes a Spanish translation (Stewardship statement not required for products applied to pets)	Note to registrants: If adding stewardship statements on end-use consumer products, the following language is required and must be 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

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
End-use products formulated with outdoor, urban, non-agricultural uses		
For all products that have outdoor uses only	Add the following language: "For outdoor use only."	Front Label Panel and/or Directions for Use
For all products that have both indoor and outdoor uses	Add the following language: "For both indoor and outdoor use."	Front Label Panel and/or Directions for Use
General Outdoor Application Statement to replace existing general outdoor statement **[Registrants may not add new uses from items 1-6 which are not currently on the existing label. Registrants are required to choose only the uses from items 1-6 which apply to their product.]**	"All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses: 1. Application to pervious surfaces such as soil, lawn, turf, and other vegetation; 2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (*e.g.*, soil, mulch, or lawn); 3. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure; 4. Applications around potential exterior pest entry points into man-made structures such as doorways and windows, when limited to a band not to exceed one inch; 5. Applications to vertical surfaces (such as the side of a man-made structure) directly above impervious surfaces (e.g., driveways, sidewalks, etc.), up to 2 feet above ground level; 6. Applications to vertical surfaces directly above pervious surfaces, such as soil, lawn, turf, mulch or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters."	Directions for Use
Spot Treatment Guidance Statement	"Spot treatments must not exceed two square feet in size (for example, 2 ft. by 1 ft. or 4 ft. by 0.5 ft.)."	Directions for Use

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
Buffer from Water Statement	"For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for Use
Water Protection Statements	"Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur." "Do not allow the product to enter any drain during or after application." "Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment." "Do not apply or irrigate to the point of runoff."	Directions for Use
Rain-Related Statements (except for products that require watering-in)	"Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours)." "Rainfall within 24 hours after application may cause unintended runoff of pesticide application."	Directions for Use
Wind speed requirement for ornamental/ recreational turf applications	"Do not apply when the wind speed is greater than 15 mph."	Directions for Use
Spray drift management for commercial nurseries	For outdoor applications to commercial nurseries: • "Do not apply when the wind speed is greater than 15 mph." • "Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572)." • "For soil or foliar applications, do not apply by ground equipment within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for Use
Crack and crevice treatments	• "Treat surfaces to ensure thorough coverage but avoid runoff."	Directions for Use

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	• "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."	
End-use products formulated with 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"

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
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	Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	• Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. TEMPERATURE AND HUMIDITY • When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. TEMPERATURE INVERSIONS • Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. WIND • Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. • Applicators need to be familiar with local wind patterns and terrain that could affect spray drift. NON-TARGET ORGANISM ADVISORY STATEMENT (Environmental Hazards): • This product is highly toxic to bees and other pollinating insects exposed to direct treatment or to residues in/on blooming crops or weeds. Protect pollinating insects by following label directions intended to minimize drift and reduce pesticide risk to these organisms.	
Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies	**"SPRAY DRIFT ADVISORIES** **Handheld Technology Applications:** • Take precautions to minimize spray drift."	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
Vegetative Filter Strips Note: This requirement is separate and in addition to buffer zones to aquatic areas, which are still required if a vegetative filter strip is present.	"VEGETATIVE FILTER STRIPS Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds). Only apply products containing (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"	Directions for Use
Buffer Zones to Water Bodies	Ground Application	Directions for Use

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	• "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 • "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 exclusively 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 exclusively for residential use and/or Ultra*	"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

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
Low Volume (ULV) wide area 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 exclusively 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 exclusively 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 formulated with wide-area mosquito uses		
Enforceable Spray Drift Management Language for products that allow aerial applications	• Apply when ground wind speeds are equal to or greater than 1 mph. • All types of applications should be conducted when temperatures at ground level are at or above 50°F. "For Ground Applications:	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ultra Low Volume Applications"

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	• 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."	
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][26] 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	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ultra Low Volume Applications"

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

Description	Required Label Language for Bifenthrin End-Use Products	Placement on Label
	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	