

Cyfluthrin and *Beta*-Cyfluthrin Interim Registration Review Decision Case Number 7405

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for cyfluthrin and *beta*-cyfluthrin, hereafter referred to collectively as cyfluthrins, (PC Code 128831 [cyfluthrin], 118831 [*beta*-cyfluthrin], case 7405), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is 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 cyfluthrins can be found in EPA's public docket (EPA-HQ-OPP-2010-0684) at <u>www.regulations.gov</u>.

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 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 registration.

EPA is issuing an ID for cyfluthrins 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 cyfluthrins prior to completing the cyfluthrins, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review.

Cyfluthrin and *beta*-cyfluthrin are non-systemic synthetic pyrethroid insecticides (i.e., they are effective against target pests only through direct contact or ingestion by individual insects). The Insecticide Resistance Action Committee (IRAC), composed of industry and university scientists, categorizes pyrethroids and pyrethrins together in Mode of Action Group 3A since they all have the same site of action in affected insects. Products containing cyfluthrin were first

registered in 1986 whereas products containing *beta*-cyfluthrin were first registered in 1995. Cyfluthrin and *beta*-cyfluthrin are both mixtures of four isomers of the same compound: cyfluthrin is composed of comparable percentages of the four isomers, and *beta*-cyfluthrin is an enrichment of the two most efficacious isomers. Products containing cyfluthrins are currently registered for use on a wide variety of food/feed crops, including use as a seed treatment. Products containing cyfluthrins are also registered for use in a variety of commercial settings (e.g., food handling establishments) or residential settings (e.g., apartments). Products containing cyfluthrins may be applied to agricultural crops via aerial, ground, chemigation, and hand-held equipment (e.g. manually-pressurized handwands). Hand-held equipment is also used to apply cyfluthrin and *beta*-cyfluthrin end-use products inside and around commercial and residential areas.

Cyfluthrins are members of the pyrethroids and pyrethrins class of insecticides, which share the same mode of action. These insecticides work by altering nerve function initially, 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. A. 2. of this document and the cumulative risk assessment for the pyrethroids and pyrethrins, published on November 9, 2011 (available at http://www.regulations.gov; EPA-HQ-OPP-2011-0746).

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

Having considered stakeholder comments on the cyfluthrins Proposed Interim Decision (PID), the Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals, and USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review, EPA has consolidated the appropriate

human health and ecological risk management and mitigation measures in this interim decision document for cyfluthrins.

This document describes changes or updates since the cyfluthrins 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 cyfluthrins 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 appropriate 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 cvfluthrins. In this ID, there are several updates to what was proposed in the PID. The updates include changes made to the ecological risk mitigation as proposed in the Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals. Label language has been revised for indoor, outdoor, and agricultural 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, in addition, EPA is allowing use of a sediment control basin in lieu of constructing and maintaining a VFS, and the Agency is adding an allowance for treatment areas of 10 acres or less to retain a 15-foot VFS. The Agency considers the use of sediment control basins for Western irrigated agriculture as effective as a VFS in retaining sediment and minimizing runoff, without the burden of constructing and maintaining a VFS. The allowance for treatment areas of 10-acres or less to retain a smaller VFS will alleviate some of the impact on small scale operations, which may be disproportionately impacted by the expanded VFS requirements. See the Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals, for a detailed discussion of the changes made to the proposed mitigation.

There have been updates to the human health mitigation from what was proposed in the PID. Several occupational handler scenarios have been refined based on public comments. Thus, the Agency is no longer requiring respirators to mitigate occupational risks for those use patterns. For the remaining scenarios of concern for granular formulations, the Agency is requiring prohibition of certain application methods. Since respirators are no longer needed, removing precautionary statements is no longer necessary. This ID thus finalizes the Agency's draft supporting documents: *Cyfluthrins. Draft Human Health Risk Assessment for Registration Review, Cyfluthrins: 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 cyfluthrins public docket.*

B. Summary of Cyfluthrins Registration Review

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

- September 2010 The Cyfluthrins Summary Document, dated September 2010; the Cyfluthrin and Beta-Cyfluthrin. Human Health Assessment Scoping Document in Support of Registration Review, dated July 1, 2010; the EFED Registration Review Problem Formulation for Cyfluthrin and Beta-cyfluthrin, dated July 29, 2010; Usage/Use Report Package in Support of Registration Review for Cyfluthrin (128831); CYFLUTHRIN (128831) Screening Level Usage Analysis (SLUA); Cyfluthrins: Review of Human Health Incidents; and Cyfluthrins Summary Document were posted to the docket for a 60-day public comment period.
- April 2011- The Cyfluthrins Final Work Plan (FWP); Response to Public Comments on the Registration Review Problem Formulation for Ecological Risk, Environmental Fate, Endangered Species, and Drinking Water Assessments for Cyfluthrin and Beta-cyfluthrin; and Cyfluthrin and Beta-Cyfluthrin. Response to Comments on the Human Health Assessment Scoping Document and Preliminary Workplan for cyfluthrins were issued. Several comments were received on the PWP; however, the comments did not change the schedule, risk assessment needs, or anticipated data requirements in the FWP.
- December 2011- A Generic Data Call-In (GDCI) for *beta*-cyfluthrin (GDCI-118831-1054) was issued for data needed to conduct the registration review risk assessments. The GDCI for *beta*-cyfluthrin has been satisfied.
- January 2012 A Generic Data Call-in Notice (GDCI-128831-1105 (cyfluthrin) and GDCI-118831-1119 (*beta*-cyfluthrin)) was issued for guideline 875.1700 product use information. GDCI-128831-1105 (cyfluthrin) and GDCI-118831-1119 (*beta*-cyfluthrin) was issued to registrants who formed the Residential Exposure Joint Venture (REJV) and is satisfied. EPA has received and accepted data from companies who represent the REJV.
- February 2012 A GDCI for cyfluthrin (GDCI-128831-1106) was issued for data needed to conduct the registration review risk assessments. The GDCI for cyfluthrin has been satisfied.
- November 2016 The Agency announced the availability of the *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins* (also referred to as the "Ecological Risk Assessment") and the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* (also referred to as the "Rationale Document") in the cyfluthrins 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.

- The comment period was extended for the Ecological Risk Assessment and the Rationale Document from January until July 2017.
 - During the public comment period, EPA received over 1,400 public comments across all the dockets of the pyrethroids.
- 66 comments and 3 mass comments were received in the cyfluthrins docket (EPA-HQ-OPP-2010-0684) during the comment period.
 - Of these comments, several addressed pyrethroids in general and were not specific to cyfluthrins. These comments and the Agency's responses can be found in the *Joint Response from OPP's Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for Pyrethroids and Pyrethrins Insecticides*, which can be found in EPA-HQ-OPP-2008-0331. Several comments were specific to cyfluthrins. Substantive comments and the Agency's responses are summarized in section I.B. below. The comments did not change the risk assessments or registration review timeline for cyfluthrins.
- December 2017 The Agency announced the availability of the *Cyfluthrin and Beta-Cyfluthrin. Draft Human Health Risk Assessment for Registration Review* for a 60-day public comment period.
 - 8 comments were received on the *Cyfluthrin and Beta-Cyfluthrin. Draft Human Health Risk Assessment for Registration Review.* Substantive comments and the Agency's responses are summarized in section I.B. below. The comments did change the risk assessments and registration review timeline for cyfluthrins.
 - Of these comments, two addressed pyrethroids in general and were not specific to cyfluthrins. These comments and the Agency's responses can be found in the EFED/PRD Response to Comments document, which can be found in EPA-HQ-OPP-2008-0331. Six comments were specific to cyfluthrins. Comments on the Cyfluthrin and Beta-Cyfluthrin. Human Health Draft Risk Assessment in Support of Registration Review were received from the National Cotton Council (NCC), Bayer CropScience, S.C. Johnson and Son, Inc., United States Department of Agriculture Office of Pest Management Policy (USDA OPMP), and anonymous sources. These comments and the Agency's responses are summarized in the document titled Cyfluthrins: Response to Public Comments on the Human Health Draft Risk Assessment for Registration Review. The comments resulted in changes to the human health risk assessment for cyfluthrins, as noted in the Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration Review.

- 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 <u>https://www.epa.gov/sites/production/files/2019-08/documents/2019-pyrethroid-fqpa-caphra.pdf</u>, which discusses the data and rationale underlying the Agency's decision to remove the 10X FQPA safety factor for the pyrethroids, including cyfluthrins.
- 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 <u>http://www.regulations.gov</u> (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 (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
- USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review
- Readers Guide Instructions for Commenting on the Registration Review Documents in the Pyrethroids Group
- May 2020 The Agency opened a 60-day public comment period for the cyfluthrins PID in the cyfluthrins registration review docket (EPA-HQ-OPP-2010-0684).
 - Along with the cyfluthrins PID, the following document were also posted in the cyfluthrins registration review docket (EPA-HQ-OPP-2010-0684):
 - Cyfluthrins: Response to Public Comments on the Human Health Draft Risk Assessment for Registration Review
 - Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration Review
- September 2020 The Agency has completed the ID for cyfluthrins.
 - Along with the cyfluthrins ID, the following documents are also available in the cyfluthrins registration review docket (EPA-HQ-OPP-2009-0301):
 - 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
 - Cyfluthrin. Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment

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

During the 60-day public comment period for the *Cyfluthrin and Beta-Cyfluthrin Proposed Interim 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 eight comments specifically for cyfluthrins. Comments specific to cyfluthrins were submitted by Bayer CropScience LP and the National Pest Management Association (NPMA). 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 Bay Area Clean Water Agencies (BACWA), San Francisco Bay Regional Water Quality Control Board (SFBRWQCB), National Association of Clean Water Agencies (NACWA), and California Stormwater Quality Association (CASQA) submitted comments relating to pyrethroids in general that were not specific to cyfluthrins. The Pyrethroid Working Group (PWG) commented

on proposed label changes to protect pollinators and on EPA's indication that it plans to issue a Data Call-In (DCI) for additional pollinator data.

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

<u>Comments Submitted by Bayer CropScience LP and the National Pest Management</u> <u>Association (Docket ID: EPA-HQ-OPP-2010-0684-0128) and (Docket ID: EPA-HQ-OPP-2010-0684-0124)</u>

Comment: Bayer CropScience LP (Bayer) commented on multiple topics in the PID including extending the deadline of revised labels after the ID and tolerance harmonization. NPMA and Bayer both commented with refinements to EPA's assumptions for maximum application volumes for several scenarios. Bayer also suggested alternative mitigations to the proposed respirator requirements. Bayer suggested application method prohibitions for granular applications to mounds by hand or spoon. Bayer also suggested risk assessment refinements and utilization of alternative data provided in studies submitted to the Agency or, if appropriate, additional restriction label statements for manually- and mechanically-pressurized handwand/gun applications. In addition, Bayer commented on several topics in the *Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration Review*, including revisions to application rates, additional studies that may support registration review, and data to support refinements of assumptions for the occupational handler assessment.

EPA Response: The Agency has responded to Bayer and NPMA's comments in the *Cyfluthrin*. *Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment* document which may be found in the cyfluthrins docket. EPA has addressed registrants' request for an extended deadline for revised labels after the ID in Section 5 of this document. The Agency agrees that prohibition of hand or spoon application methods for granular applications to mounds would sufficiently reduce the risk to occupational handlers without the addition of a respirator. The Agency refined the risk assessment for manually- and mechanically-pressurized handwand/gun scenarios based on the use and usage information provided by Bayer and NPMA which resulted in no risks of concern. As a result, EPA has updated the mitigation in Section 4 and Appendices A and B. The Agency has reviewed or is currently reviewing the studies submitted by Bayer. At this time, the new information has not changed the risk assessment.

The study referenced by the registrant (MRID 49511802), is currently under review and, once the review is complete, the Agency will determine whether the new data will be used in future

assessments. Until then, the Pesticide Handlers Exposure Database (PHED version 1.1) will continue to be used. The Agency has also reviewed Bayer's suggestions for more realistic assumptions when calculating occupational exposure. The Agency acknowledges the conservative nature of the assumptions in both the cattle and poultry house scenarios and has revised the occupational risk assessment.

<u>Comments Submitted by the United Stated States Department of Agriculture (USDA)</u> (Docket ID: EPA-HQ-OPP-2010-0684-0120)

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 U.S. 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 cyfluthrins.

USDA recommended harmonizing tolerances for several animal meats with the Codex MRL for Meat (MRLs are an abbreviation for 'Maximum Residue Levels', which are the international analog to the U.S. term 'tolerances'). Both Codex and the US have established tolerances for animal fats, not meat. U.S. tolerances are higher than the Codex MRLs for these fats. As mentioned in USDA's comment, in the DRA, EPA pointed out the potential to harmonize with Codex on citrus fruit and hog meat byproducts. EPA recommends that the U.S. tolerance for citrus fruit increase to 0.3 ppm to harmonize with the Codex MRL. The Agency also recommends that the U.S. tolerance for Hog, meat byproducts increase to 0.02 ppm to harmonize with the Codex MRL for Edible offal (mammalian).

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

Comment: The Pyrethrin Joint Venture (PJV) group (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

As mentioned earlier, the cyfluthrins are a member of the pyrethroids and pyrethrins class of insecticides, which share the same mode of action. The Insecticide Resistance Action Committee (IRAC) categorizes synthetic pyrethroids in Mode of Action Group 3A. Cyfluthrin and *beta*-cyfluthrin are registered for both indoor and outdoor uses in residential and commercial areas, including residential lawns and other turf. Cyfluthrin is registered for use in agriculture, including both crop and livestock sites.

Nationally, residential consumers purchased around 100,000 lbs of pyrethroid insecticides, by active ingredient (a.i.), for indoor use, and around 2 million lbs a.i. of pyrethroids for residential outdoor uses in 2016¹. Both cyfluthrin and *beta*-cyfluthrin were applied for residential outdoor uses in 2016 but the exact amounts are not available.²

Professional pest management companies used over 3 million lbs a.i. of pyrethroids for control of general insects, and various nuisance and public health pests both in and around residential and commercial buildings, including 45,000 lbs of beta-cyfluthrin and 5,000 lbs of cyfluthrin.² Industrial vegetation management, including roadways and rangeland, used around 56,000 lbs of all pyrethroids; however, there are no reports of cyfluthrin use in this area.³ Over 1.4 million lbs a.i. of pyrethroids were also reported to be used in the turf and ornamental market; cyfluthrins were also reported to be used but the exact amounts are not available.⁵

Food handling establishments, including processing facilities, warehouses, restaurants, and other food preparation facilities, used around 200,000 lbs a.i. of pyrethroids in 2013⁴. Food handling establishments applied around 28,000 lbs of cyfluthrin and 6,000 lbs of *beta*-cyfluthrin in 2014⁴.

¹ 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.

² 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.

³ 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.

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

According to Kynetec⁵, on average, over 130,000 lbs of cyfluthrins by active ingredient (a.i.) are used annually in agriculture to treat almost 6.6 million acres, including acres that are treated multiple times. In terms of total amount used, corn and soybean account for about 72,000 lbs a.i. and almost 4.1 million acres⁶. Growers of citrus, hazelnuts, and peaches are some of the biggest users of cyfluthrin with 16 to 25 percent of the crop-acres treated⁶. In 2016, 100 lbs of *beta*-cyfluthrin were applied on rangeland and 15,000 lbs of cyfluthrin were used to treat stored grain^{7,6}. Seed treatment usage data for sugarbeets are not available.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the Agency's human health risk assessment is presented below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of cyfluthrins. For additional details on the human health assessment for cyfluthrins, see the *Cyfluthrins: Draft Human Health Risk Assessment for Registration Review, Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration,* and *Cyfluthrin. Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment which are available in the cyfluthrins registration review docket EPA-HQ-OPPP-2010-0684.*

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 FOPA 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

 ⁵ Kynetec, Inc (AgroTrak). 2013-2017. Data Collected and Sold by a Private Market Research Firm. Data Collected on Pesticide Use for About 60 Crops by Annual Surveys of Agricultural Users in the Continental United States. Survey Methodology Provides Statistically Valid Results, Typically at the State Level. Accessed July 2019.
 ⁶ Non-Agricultural Market Research Proprietary Data (NMRD). 2017e. Studies conducted and sold by a consulting and research firm. Report on stored grain. Accessed June 2019.

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

Dietary Exposure

The acute dietary exposure assessment in the original DRA was refined using Pesticide Data Program (PDP) monitoring data, tolerance level residues, crop field trial data for a limited number of commodities, and monitoring data as appropriate. Residue levels for some commodities were modified, the maximum percent crop treated estimates were used, and water solubility of 2 ppb for the acute estimated drinking water concentration (EDWC) was used. The Agency revised the dietary exposure assessment further based on comments received on the dietary exposure assessment in the original DRA. The acute dietary risk estimates for the cyfluthrins are not of concern for the general U.S. population or any population subgroup, including those comprised of infants and children. The most highly exposed population subgroup is Adults 20-49 years of age, which uses 83% of the acute Population Adjusted Dose (aPAD).

The chronic dietary exposure analysis was also highly refined. The chronic assessment was conducted to obtain estimates of background levels of dietary exposure for estimating aggregate risk. The Agency did not calculate chronic dietary risk estimates as the acute dietary risk estimates were protective for chronic dietary risk. Cancer risk is not of concern for cyfluthrin because the compound is classified as "not likely to be carcinogenic to humans."

Residential Exposure and Risk Assessment

There are no residential handler risk estimates of concern. All residential handler scenarios resulted in dermal and inhalation risk estimates greater than their respective LOCs (dermal LOC = 100 and inhalation LOC = 30) and are not of concern.

In the original DRA, the Agency identified several post-application scenarios of concern for children 1 to <2 years old. The scenarios of concern were liquid end-use products used indoors as broadcast and perimeter/ spot/bedbug treatments, with combined MOEs (dermal/incidental oral exposures) of 140 and 220 (LOC=300), respectively. There was also a risk of concern from outdoor aerosol space sprays, with an inhalation MOE of 40 (LOC=100) and an acute dietary concern for episodic ingestion of granules (MOE=43; LOC=300). In the revised DRA, the Agency reduced the default 10X FQPA Safety Factor to 1X for all populations for the pyrethroid pesticides. Previously, the factor was reduced to 1X for youth and adults, and to 3X for children less than six years of age. Although the risk estimates did not change in the revised DRA, the removal of the 3X safety factor for children <6 years of age resulted in risk estimates above the respective levels of concern (dermal LOC=100, inhalation LOC=30), and are not of concern.

While EPA does expect by stander exposure to drift from sprays applied to agricultural areas, spray drift was not assessed. There are registered turf uses of cyfluthrin and *beta*-cyfluthrin that result in worst-case exposure estimates for children (1 < 2 years) and adults from treated lawns;

these risk estimates are not of concern and are considered protective of exposure from spray drift.

Aggregate Exposure and Risk Assessment

The acute aggregate risk estimates are equivalent to the corresponding dietary (food plus water) risk estimates, which the 2017 DRA determined were not of concern. The short-term aggregate risk assessment is based on background dietary exposure from food and drinking water and potential residential exposure for adults (dermal) and children (dermal and incidental oral). In the 2017 DRA, several aggregate scenarios for children 1-2 were of concern. With the removal of the 3X FQPA safety factor, the revised DRA found that all risk estimates are no longer of concern.

Occupational Exposure and Risk Assessment

In the 2017 DRA, there were several occupational handler scenarios that resulted in risk estimates of concern. Dermal and inhalation exposures were not combined in this assessment. because the toxicological effects for these exposure pathways are different. Based on comments and additional information, the Agency has revised the occupational handler assessment to reflect updated amount handled/area treated inputs as well as updated unit exposures. The Agency has also updated the inhalation human-equivalent doses and concentrations used in the risk assessment, which revised the occupational handler values, and is currently updating select Pesticide Handlers Exposure Database (PHED) exposure scenarios to refine the breathing rate assumption and the use of the arithmetic mean approach for calculating the unit exposure. In the Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration Review, the Agency revised the area treated/amount handled assumptions for several scenarios. Even with these refinements, several scenarios remained of concern with baseline PPE; however, based on additional refinements received in comments submitted on the 2020 PID, only one scenario remains of concern: granular applications to mounds by hand or spoon. For more information regarding specific updates, please refer to the Cvfluthrin. Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment, dated December 18, 2019, which can be found in the cyfluthrins docket.

Based on a review of the Agricultural Handler Exposure Task Force (AHETF) survey, the Agency has refined two factors (gallons of solution handled and scenario frequency) in occupational exposure assessments for applications to greenhouses and nurseries with backpack and handheld sprayers. According to the survey, approximately 10% of users apply on a daily basis and the average daily gallons handled for the respondents who indicate use on a daily basis ranges from 4 to 2,000 gallons. Within that frequency-refined distribution and in the context of targeting the high-end in the distribution of overall short-/intermediate-term exposures, 300 gallons (equivalent to the 50th percentile of the 10% "daily user" respondents or the 95th percentile of the frequency-refined distribution) is assumed for gallons handled for nursery scenarios. Similarly, for greenhouse scenarios, the Agency is changing its default assumption to 175 gallons.

For cyfluthrins, the *Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration Review* and *Cyfluthrin. Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment assessed nursery and greenhouse scenarios using the assumption that 1000 gallons, 700 gallons, or 245 gallons would be handled, based on 1) the current HED assumptions; 2) the amount handled values at which risk estimates would be at the LOC; and 3) the amount handled values required by Bayer in their comment on the original risk assessment. The MOEs calculated in the revised risk assessment were 21 (for 1000 gallons), 29 (for 700 gallons), and 84 (for 245 gallons). Therefore, with the new HED assumptions of 300 gallons handled for nurseries and 175 gallons handled for greenhouses, there are no longer risks of concern.*

For mound/nest treatments, the Agency assessed this scenario at 10 mounds treated/day and 100 mounds treated/day (inhalation MOEs = 20, 79, and 200 (LOC=30) with a PF10 respirator). For this scenario, the higher-end assumptions used for risk assessment are very conservative and risk estimates are not of concern using the lower-end assumptions, which might be more representative of worker practices.

In the *Cyfluthrins. Revised Human Health Draft Risk Assessment for Registration Review,* treating structures with wettable powders (including in water-soluble packets (WSP)) via mechanically pressurized handgun, resulted in an MOE of 18 (with baseline PPE); however, the Agency identified an updated inhalation unit exposure for structural applications using mechanically-pressurized handguns (79 μ g/lb ai to 45.5 μ g/lb ai). In addition, the Agency used application rates from products that were cancelled in 2018 to calculate MOEs for treating structures with both wettable powders and liquids via mechanically pressurized handgun. Based on calculations with the updated rate of 0.009 lb ai/gal, the Agency does not expect any risks of concern for liquid applications to structures, at the current amount handled of 1000 gallons for mechanically-pressurized handguns.

In addition, the Agency has further refined occupational scenarios for treating residential living spaces with liquids via a manually pressurized handwand. The Agency re-evaluated labels used to establish the application rate for indoor-residential living spaces. While the Agency still finds that one of the labels specifying residential indoor uses (EPA Reg # 432-1299) allows for application rates of 0.04 lb ai/gallon, respectively, EPA agrees that applying 40 gallons/day at the labelled rate is not feasible (this amount would cover 200,000 sq ft). The Agency assessed the manually pressurized handwand scenario using 5, 10, and 40 gallons. The Agency also determined that the MOE reaches 31 (LOC=30) when assuming 10 gallons handled per day. At 40 gallons/day, the MOE is 7.7. Assuming 5 gallons per day results in an MOE of 62.

All occupational post-application scenarios are not of concern.

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 risk conclusions for cyfluthrins, refer to the *Cyfluthrins: Draft Human Health Risk Assessment for Registration Review, Cyfluthrin. Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment, which are available in the public docket.*

3. Tolerances

Tolerances for cyfluthrin (including *beta*-cyfluthrin) are established at 40 CFR §180.436. The tolerance expression for cyfluthrin in 40CFR §180.436(a)(1) need to be revised to state: "Tolerances are established for residues of cyfluthrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only cyfluthrin, (cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2dimethyl-cyclopropane-carboxylate, in or on the commodity."

The tolerance expression for residues of cyfluthrin resulting from application in food and feed handling establishments should be consolidated into one section. The CFR entries for cyfluthrin residues resulting from application in food and feed handling establishments contain label directions that do not need to be included in the 40 CFR entry. As a result, the label directions in 40CFR §180.436(a)(2)(i), (ii), and (iii) as well as those in 40CFR §180.436(a)(3) (i), (ii), and (iii), need to be deleted and the tolerance expression for cyfluthrin in 40CFR §180.436(a)(2) need to be revised to state: "A tolerance of 0.05 ppm is established for residues of cyfluthrin, including its metabolites and degradates, in or on all food and feed items when cyfluthrin is used in food or feed handling establishments. Compliance with the tolerance level specified is to be determined by measuring only cyfluthrin, (cyano(4-fluoro-3phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2dimethyl-cyclopropane-carboxylate, in or on the commodity." Section 180.436(a)(3) need to be detend.

The tolerance expression for *beta*-cyfluthrin in 40CFR §180.436(a)(4) need to be revised to state: "Tolerances are established for residues of *beta*-cyfluthrin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of *beta*-cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate [mixture comprising the enantiomeric pair (R)- α -cyano-4-fluoro-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-4-fluoro-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate with theenantiomeric pair (R)- α -cyano-4-fluoro-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-4-fluoro-3-phenoxybenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-4-fluoro-3-phenoxybenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)- α -cyano-4-fluoro-3-phenoxybenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate], in or on the commodity."

The Agency anticipates deleting tolerances that are already covered by a crop group tolerance and updating tolerances based on crop group revisions.

There are numerous Codex MRLs for cyfluthrin. U.S. tolerances are in effect for some of these commodities. When there are both U.S. tolerances and Codex MRLs for the same commodity, the MRLs are generally not harmonized. The U.S. tolerances are usually higher than the Codex MRLs. In these cases, harmonization might not be feasible because the tolerances are based on residue trials that resulted in residues that necessitated the higher residue limit. In two cases, however, the U.S. tolerances are lower than the Codex MRLs. These MRLs are the citrus fruit tolerance of 0.2 ppm and the hog, meat byproduct tolerance of 0.01 ppm. The Agency recommends that these tolerances be harmonized with the Codex MRLs of 0.3 ppm for citrus fruit and 0.02 ppm for hog meat byproducts.

Canada's Pest Management Regulatory Agency (PMRA) has also established cyfluthrin MRLs for several commodities. None of the MRLs are harmonized with the U.S. tolerances, with one exception (egg at 0.01 ppm).

In addition, the 2017 DRA recommended changes to various tolerance levels to conform with the Agency's rounding practice (i.e., adding a trailing zero) at that time. The revised DRA did not alter these changes. Since the risk assessment was issued, the Agency has decided to follow the OECD rounding class practice, which does not recommend adding a trailing zero.

The Agency will use its FFDCA rulemaking authority to make these changes.

Table 1: Summary of Anticipated Tolerance Actions

Cyfluthrin and <i>beta</i> -Cyfluthrin 40 CFR §	180.436: Sur	nmary of An	nticipated Tolerance Actions
	Established		
Commodity		Tolerance	Comments
		(ppm)	
Brassica, head and stem, group 5-16	None	2.5	Updated crop group tolerance
Brassica, leafy greens, subgroup 4-16B	None	7	Updated crop group tolerance
Fruit, citrus, group 10-10	None	0.3	Updated crop group tolerance;
		0. -	Codex harmonization
Fruit, pome, group 11-10	None	0.5	Updated crop group tolerance
Fruit, stone, group 12-12	None	0.3	Updated crop group tolerance
Leafy greens, subgroup 4-16A	None	6	Updated crop group tolerance
Nut, tree, group 14-12		0.01	Updated crop group tolerance
Stalk, stem, and leaf petiole vegetable, subgroup 22B	None	6	New crop group tolerance
Vegetable, fruiting, group 8-10	None	0.5	Updated crop group tolerance
Celtuce	None	6	Now in subgroup 22A (no subgroup
			tolerance)
Fennel, Florence	None	6	Now in subgroup 22A (no subgroup
			tolerance)
Kohlrabi	None	2.5	Now in subgroup 22A (no subgroup
			tolerance)
Brassica, head and stem, subgroup 5A	2.5	None	Revoke tolerance, concomitant with
			establishment of new crop group
Brassica, leafy greens, subgroup 5B	7.0	None	Revoke tolerance, concomitant with
			establishment of new crop group
Fruit, citrus, group 10	0.2	None	Revoke tolerance, concomitant with
			establishment of new crop group
Fruit, pome, group 11	0.5	None	Revoke tolerance, concomitant with
			establishment of new crop group
Fruit, stone, group 12	0.3	None	Revoke tolerance, concomitant with
	0.01)) j	establishment of new crop group
Nut, tree, group 14	0.01	None	Revoke tolerance, concomitant with
Vegetable finiting group 9	0.5	Nana	establishment of new crop group
Vegetable, fruiting, group 8	0.5	None	Revoke tolerance, concomitant with
Vagatable lasty avaant Dragging group 4	6.0	Nera	establishment of new crop group
Vegetable, leafy, except Brassica, group 4	0.0	None	Revoke tolerance, concomitant with establishment of new crop group
Mustard greens	7.0	None	Revoke tolerance, concomitant with
	7.0	INUIIC	establishment of new crop group
Hog, meat byproducts	0.01	0.02	Codex harmonization
riog, meat byproducts	0.01	0.02	

These tolerance revisions need to be made to both 40CFR \$180.436(a)(1) (cyfluthrin) and \$180.436(a)(4) (*beta*-cyfluthrin).

4. Human Health Data Needs

The Agency does not anticipate any further human health data needs for cyfluthrins registration review.

The GDCI-128831-1105 (cyfluthrin) and GDCI-118831-1119 (*beta*-cyfluthrin) (for guideline 875.1700 product use information) was issued to registrants who formed the Residential Exposure Joint Venture (REJV) and is satisfied. EPA has received and accepted data from companies who represent the REJV.

B. Ecological Risks

The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of the pyrethroids and pyrethrins. EPA's 2016 Preliminary Comparative Environmental Fate and Ecological Risk Assessment for Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins is a quantitative ecological assessment of nine cases: bifenthrin, cyfluthrin (beta-cyfluthrin), cyhalothrins (lambda-cyhalothrin and gamma-cyhalothrin), cypermethrin (alpha-cypermethrin and zetacypermethrin), deltamethrin, esfenvalerate, fenpropathrin, permethrin, and pyrethrins. The 2016 risk assessment was divided into five sections: risks from indoor "down the drain" uses;⁷ risks from outdoor residential, commercial, turf, and nursery uses; risks from agricultural uses; risks from mosquito adulticide uses; and an assessment of risk to bees from agricultural uses of pyrethroids and pyrethrins. The Agency primarily focused on potential effects to aquatic organisms (for all uses) as well as terrestrial invertebrates (for agricultural uses). A quantitative assessment was conducted for these nine pesticides, for which the Agency had a relatively large amount of data. A companion piece, titled the Ecological Risk Management Rationale for Pvrethroids in Registration Review or the Rationale Document, summarized potential risk concerns for the remaining pyrethroids and was published at the same time. The pesticides covered in the Rationale Document are: cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, esfenvalerate, and tetramethrin. The Rationale Document describes EPA's approach in using the quantitative assessment of the nine cases to serve as a basis for making risk management and regulatory decisions for all 23 affected pesticides currently undergoing registration review. Potential risks that were identified for the eight pyrethroids and pyrethrins assessed in 2016 were determined to be representative of the risks for the other pyrethroids also undergoing registration review.

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

For registration review, the Agency issued a single ecological risk mitigation proposal to address the potential ecological risks of concern for the 23 pyrethroids and pyrethrins, based on their

⁷ "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.

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 cyfluthrins, risks of concern were identified for aquatic invertebrates (marine and freshwater) and freshwater fish from indoor, outdoor non-agricultural (turf, residential, commercial, and nursery) and agricultural uses. In addition, there were pollinator risks of concern from agricultural and outdoor non-agricultural uses.

Terrestrial Invertebrates (honeybees)

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

The Agency did not have sufficient information to assess chronic risk to bees or effects on honeybee colonies. EPA concludes that additional pollinator data are appropriate 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 appropriate, where such data are not currently available. EPA will issue a Data Call-In (DCI) for the pollinator studies listed in Table 1.

Guideline #	Study				
Tier 1					
850.3020	Acute contact toxicity study with adult				
	honeybees				
850.3030	Honeybee toxicity of residues on foliage				
Non-Guideline (OECD	Honeybee adult acute oral toxicity				
213)					
Non-Guideline (OECD	Honeybee larvae acute oral toxicity				
237)					
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				

Table 2: Pollinator Data Requirements

Guideline #	Study		
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 cyfluthrins.

1. Ecological and Environmental Fate Data Needs

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

C. Benefits Assessment

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

Cyfluthrin provides agricultural benefits to growers of a wide range of crops including alfalfa, citrus, cotton, corn, grapes, soybeans, sunflowers, vegetables (e.g., Brassica, cucurbits, pepper, tomato), tree nuts (e.g., walnut, pecan), and wheat⁸. Beta-cyfluthrin is reported to provide benefits to growers of brassica, citrus, and sunflowers.¹⁶ In these crops, pyrethroids, including cyfluthrin, were among the top market-leading insecticides providing efficacious control of specific economically important target pests such as corn rootworm, cotton bollworm, potato leafhopper, sunflower moth and sunflower seed weevil, and lygus bug in addition to providing broad-spectrum control of crop-pest complexes like aphids, stink bugs, and caterpillars. Cyfluthrin is also beneficial in cattle and poultry production for the control of litter beetles, horn and face flies, lice, and ticks⁹. Additionally, cyfluthrin and other pyrethroids are important chemicals to growers who export their products, as there are internationally accepted residue levels ("maximum residue levels") for this class of insecticides on many food commodities.

⁸ Cook, C., L.R. English, C. Hawkins, N. Mallampalli, J. Alsadek, and S. Smearman. 2019. Usage characterization and qualitative overview of agricultural importance for pyrethroid insecticides for selected crops and impacts of potential mitigation. Biological and Economic Analysis Division, U.S. EPA.

⁹ University of Arkansas Extension. 2019. Animal Insect Control. In Insecticide recommendations for Arkansas. University of Arkansas Division of Agriculture Research and Extension MP 144. https://www.uaex.edu/publications/MP144.pdf. Accessed August 2019.

Cyfluthrin and *beta*-cyfluthrin are among several pyrethroids, including bifenthrin, cyphenothrin and tetramethrin, that can be used indoors to control insects that attack fabrics. Such pests include carpet beetles and clothes moths. While over-the-counter pyrethroids are commonly available as "do-it-yourself" insecticidal treatments, additional options are available to licensed pest control operators, such forced-heat treatments. Such treatment tactics are likely to be effective against fabric-damaging insects as well as the other pests described below. In addition, homeowners can use sanitation tactics such as intensive laundering, dry cleaning, or vacuuming to eliminate infestations.

In outdoor residential settings, the cyfluthrins may be used in products intended as perimeter treatments to stop arthropods from entering structures, or as lawn treatments for various insects that are nuisance pests or that damage turf. Some of the target pests can be of public health concern (such as ants, ticks, etc.). For all these uses, while the cyfluthrins generally offer effective pest control, various alternatives with efficacy also exist in the marketplace. Many are other pyrethroids. Depending on the use setting, other chemistries are also available. For example, some organophosphates (e.g., malathion), carbamates (e.g., carbaryl), and neonicotinoids (e.g., imidacloprid) are available for outdoor residential uses.

For more information on the usage of cyfluthrins, refer to the Usage Characterization and Alternatives Summary for Synthetic Pyrethroids Used in Residential Lawns and Outdoor Vegetative Spot Treatments, Crop Selection for BEAD's Usage Characterization and EFED's Ecological Risk Assessment for Pyrethroid Insecticides, 9/28/09. CYFLUTHRIN (128831) Screening Level Usage Analysis (SLUA), and 1/26/10. Usage/Use Report Package in Support of Registration Review for Cyfluthrin (128831), which are available in the public docket (EPA-HQ-OPP-2010-0684). For additional information on the benefits of pyrethroids in general, refer to the Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals, also available in the public docket (EPA-HQ-OPP-2008-0331).

IV. INTERIM REGISTRATION REVIEW DECISION

A. Required Risk Mitigation and Regulatory Rationale

The Agency has determined that there are occupational risks of concern from registered cyfluthrins uses. The Agency is requiring restrictions on application methods to address risks to occupational handlers from applications of granular formulations to insect mounds. The Agency also identified risks of concern to occupational handlers from liquid applications by manually pressurized handwands to residential living spaces; however, risks were identified for 40 gallons at maximum application rates, which is not feasible. The Agency also assessed this scenario assuming 10 and 5 gallons handled, which more accurately reflects use in residential living spaces. There are no risks of concern using these assumptions; therefore, the Agency is not requiring mitigation for this use. Additionally, the registrant has indicated that it intends to voluntarily cancel this product. See the *Cyfluthrin. Response to Comments on the Revised Human Health Draft Risk Assessment, the Proposed Interim Decision, and HED's Previous Response to Comments on the Human Health Draft Risk Assessment, available in the cyfluthrins public docket, for more details. The Agency identified potential risks for various taxa with the major potential risks of concern focusing on aquatic invertebrates from indoor, outdoor, and agricultural uses, and on terrestrial invertebrates from agricultural uses. Mitigation to address*

risks to aquatic and terrestrial invertebrates will benefit the other taxa to the extent that there is any risk.

The residential indoor products containing pyrethroids are expected to result in 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 downthe-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 appropriate 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 required mitigation measures are 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 appropriate and has revised the terrestrial invertebrate Environmental Hazard Statement, adding information on stewardship and best management practices, promoting State Managed Pollinator Protection Plans (MP3s), and adding information on Pollinator Incident Reporting.

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

language to cyfluthrins labels and updates to respirator language are appropriate, where applicable.

1. Prohibit Application Methods for Outdoor Uses on Insect Mounds of Granular Formulations

To address risks to occupational handlers, the Agency has determined that labels must include the statement "Do not apply by using your hand or using a spoon to scatter granules." As a result, all label language suggesting application by these methods (i.e., application instructions or other label statements) must be removed.

This change is in lieu of the respirator requirements previously proposed in the PID.

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

To address concerns for residues in wastewater discharges, the Agency has determined that advisory label language and graphics on indoor pyrethroid products that have uses that could end up down-the-drain are appropriate 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 appropriate, 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 appropriate amendments are those with any indoor or outdoor use in a residential or commercial setting. Note that all products registered for indoor residential and commercial uses are included, not just the those with indoor down-the-drain uses, because the potential for improper use or disposal is present for any household pyrethroid product. The specific measures are appropriate to reduce the potential for runoff and drain disposal, and subsequent potential aquatic risk, and are outlined below.

a. Indoor and Outdoor Use Site Clarification

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

b. Disposal/Stewardship Statement and Pictogram

- Labels must include the following statement on the product label unless labeled for use directly inside pipes/sinks.
 - "Do not pour or dispose down the drain or sewer. Call your local solid waste Agency for local disposal options."
- Include a pictogram of 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 a .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.

3. 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 appropriate. 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 appropriate 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 overspraying. Although potential risks to aquatic organisms are expected to remain after the implementation of the measures, these necessary label changes are directionally correct with respect to reducing the amount of environmental exposure to pyrethroids in urban areas.

A. Statements for Outdoor Label Consistency and Clean-up

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

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

B. Revised General Outdoor Application Statement

The Agency is revising the general outdoor statement for all outdoor spray applications, which includes a maximum horizontal perimeter treatment of 7 feet from the base of a structure and a reduction from 3 feet to 2 feet for vertical applications to man-made structures. Current pyrethroid product labels specify the vertical and horizontal distance that may be treated with a pyrethroid; the vertical distance is measured from the ground upward and the horizontal distance is measured outward, away from the side of a man-made structure. Due to varying use sites and target pests, it is difficult to determine a single effective vertical and horizontal specification

across all products. Insects need to come into contact or ingest a lethal dose of insecticide to be effectively controlled. However, reduction of the area that can be treated at the same application rate represents a load reduction for each pyrethroid treatment, which represents a clear reduction in the amount of pyrethroid material that can be transported from a treated area to nearby waterbodies. The Agency has determined that the vertical application distance may extend up to 2 feet above ground level, rather than "3 feet above grade" as previously stated on labels. The horizontal application distance is restricted to 7 feet or less from the base of a man-made structure to pervious surfaces (e.g., grass, mulched groundcover, planted areas).

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

"All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:

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

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

C. Spot Treatment Guidance Statement

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

D. Buffer from Water Statement

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

E. Water Protection Statements

- "Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur."
- "Do not allow the product to enter any drain during or after application."
- "Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment."
- "Do not apply or irrigate to the point of runoff."

F. Rain-Related Statements

- "Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours)."
- "Rainfall within 24 hours after application may cause unintended runoff of pesticide application."

The Agency has determined that mitigation measures for specific industry sectors to reduce offsite drift to waterbodies, increase distances between the area treated and waterbodies, as well as to reduce the potential for overspraying are appropriate. These include:

G. Statements for Ornamental/Recreational Turf

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

H. Statements for Outdoor Applications at Commercial Nurseries

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

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

The Agency does not know how efficacy may be impacted when droplet sizes are determined to be appropriate 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, 2009¹⁰). For foliar applications, insect control would likely be negatively impacted given the requirement for a medium or larger

¹⁰ 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. <u>https://www.bae.ksu.edu/faculty/wolf/PDF/MF2869%20Droplet%20Calibration.pdf</u>

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."

4. Mitigation Measures for Agricultural Use Products

Vegetative Filter Strip (VFS) Language

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

Currently, all pyrethroid products, except etofenprox and pyrethrins, already have a 10-foot VFS requirement on the label. 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, etc.) which may impact their utility. ¹¹ 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

¹¹ https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175

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

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

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

The following mitigation measures apply to all pyrethroids with agricultural uses (except pyrethrins). They are determined to be appropriate 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, EPA has determined that 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.¹²

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

Spray Drift Reduction Measures

Most pyrethroids and pyrethrins labels currently have spray drift language to reduce the potential for the pesticides to drift off-target. EPA has determined that label clarifications to bring all labels up to date with the latest existing spray drift language, to reduce off-target spray drift and establish a baseline level of protection that is consistent across all affected products for this interim decision are appropriate. 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 appropriate. 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).

¹² Lynch and Tjaden, 2003 and Solano and Yolo Co. Resource Conservation. Dist., 2006

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

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).
- Applicators are required to select nozzle and pressure that deliver a medium or coarser droplet size.
- Do not apply when wind speeds are sustained above 15 miles per hour at the application site.
- Do not apply during temperature inversions."

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

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

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

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

Required Updates to Spray Drift Buffers

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

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

5. Pollinator Risk Mitigation

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

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

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

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

- 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 appropriate. 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 appropriate mitigation measures above, voluntary stewardship activities and use of best management practices (BMPs)¹³ 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 webpage¹⁴.

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

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

¹³ <u>https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators</u>

¹⁴ <u>https://www.epa.gov/pollinator-protection</u>

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.¹⁵

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 appropriate:

"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 <u>https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators</u>."

c. Promoting State Managed Pollinator Protection Plans (MP3s)

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

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

In order to promote awareness of MP3s, EPA has determined that adding a statement to pyrethroid/pyrethrin labels to educate pesticide users on the existence of MP3s and to encourage users to follow their state plans is appropriate. This language is only required for pyrethroid and pyrethrins labels with foliar agricultural uses and excludes products formulated for residential

¹⁵ <u>https://www.epa.gov/pollinator-protection/what-you-can-do-protect-honey-bees-and-other-pollinators</u>

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 appropriate:

"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 appropriate. 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 appropriate:

"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."

6. Insecticide Resistance Management

Pesticide resistance occurs when genetic or behavioral changes enable a portion of a pest population to tolerate or survive what would otherwise be lethal doses of a given pesticide. The development of such resistance is influenced by several factors. One important factor is the repeated use of pesticides with the same mode (or mechanism) of action. This practice kills sensitive pest individuals but allows less susceptible ones in the targeted population to survive and reproduce, thus increasing in numbers. These individuals will eventually be unaffected by the repeated pesticide applications and may become a substantial portion of the pest population. An alternative approach, recommended by resistance management experts as part of integrated pest management (IPM) programs, is to use pesticides with different chemical modes (or mechanisms) of action against the same target pest population. This approach may delay and/or prevent the development of resistance to a particular mode (or mechanism) of action without resorting to increased rates and frequency of application, possibly prolonging the useful life of pesticides.

EPA has determined that resistance-management labeling, as listed in Appendix B, for products containing cyfluthrins, 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: <u>https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management</u>.

7. Update Respirator Language

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 anticipated at this time. The tolerance expression for cyfluthrin in 40CFR \$180.436(a)(1), \$180.436(a)(2)((i), (ii), and (iii)), \$180.436(a)(3), and \$180.436(a)(4), needs to be revised. Updates are required 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 as the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response toComments 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 cyfluthrins, nor is it making a complete endangered species finding. Although the Agency is not making a complete endangered species finding at this time, the required 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 cyfluthrins. The Agency's final registration review decision for cyfluthrins will be dependent upon the result of the Agency's ESA assessment and any needed § 7 consultation with the Services and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

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

The GDCI-128831-1105 (cyfluthrin) and GDCI-118831-1119 (*beta*-cyfluthrin) (for guideline 875.1700 product use information) was issued to registrants who formed the Residential

Exposure Joint Venture (REJV) and is satisfied. EPA has received and accepted data from companies who represent the REJV.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

A Federal Register Notice will announce the availability of this interim decision for cyfluthrins. A final decision on the cyfluthrins 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 cyfluthrins 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 Cyfluthrins 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 Cyfluthrins 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 Reevaluation 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 fasttrack, Agency-initiated non-PRIA label amendment to Michelle Nolan at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

VIA US Mail

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

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

APPENDICES

Appendix A: Summary of Required Actions for Cyfluthrin and *beta*-Cyfluthrin

Chemical Type: Ins Chemical Family: P Mode of Action: So	cyfluthrin], 118831 [<i>beta-</i> ecticide yrethroids <u>dium channel modulator</u>				
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions
Occupational handler	• Spray and granular application	• Inhalation	• Short, intermedia te	 Developmental effects 	For granular applications to insect mounds by hand or spoon, remove application method.
Aquatic invertebrates	 Water (non-dietary) Residues (at/on site of treatment) 	ContactIngestion	 Acute Sub- chronic Chronic 	GrowthSurvivalMortality	 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)	ContactIngestion	 Acute Sub- chronic 	GrowthSurvivalMortality	 Label clarity and consistency Advisory storage and disposal statements

	• Residues (at/on site of treatment)		• Chronic		 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	ContactIngestion	• Acute	• Mortality	 Stewardship information Incident reporting information Pollinator data requirements

Appendix B: Required Human Health Labeling Changes for Cyfluthrin and *Beta*-cyfluthrin Products

Description	Requir	ed Label Lan	guage for Cyfluthrin and <i>Beta</i> -cy	fluthrin Products	Placement on Label
			End Use Products		
Mode of Action	 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., [pick one: HERBICIDE or FUNGICIDE or INSECTICIDE]) in the fourth column. 			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	
Group Number Applies only to products with agricultural use	Cyfluthrin	GROUP	3 A	INSECTICIDE	and columns should be surrounded by a black rectangle.
			OR		
	<i>Beta-</i> cyfluthrin	GROUP	3A	INSECTICIDE	
Resistance- management labeling statements for insecticides		•	bel language for insecticides/acarici gistration/pesticide-registration-not		Directions for Use, prior to directions for specific crops

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
Applies only to		
products with		
agricultural use Additional Required Labeling Action Applies to all products delivered via liquid spray applications (except those with mosquito	Remove information about volumetric mean diameter from all labels <u>delivered via liquid spray</u> <u>application, except from products with mosquito adulticide use</u> , where such information currently appears.	Directions for Use, prior to directions for specific crops
adulticide use)		
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; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; <u>OR</u> 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; <u>OR</u> a NIOSH-approved gas mask with OV canisters; <u>OR</u> a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters." 	In the Personal Protective Equipment (PPE) within the Precautionary Statements

Description	Required Label Language for Cyfluthrin and Beta-cyfluthrin Products	Placement on Label
	[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; <u>OR</u> a NIOSH-approved full face respirator with OV cartridges; <u>OR</u> a gas mask with OV canisters; <u>OR</u> 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.	
Prohibit Application Methods for Outdoor Uses on Insect Mounds of Granular Formulations	"Do not apply by using your hand or using a spoon to scatter granules."	Directions for Use
	End-use products formulated for indoor residential uses	
For all product 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	Add the following language:	Front Label Panel and/or Directions for Use
indoor and outdoor uses	"For both indoor and outdoor use."	
For all products used on pets	Add the following language:	Directions for Use
	"Application of product on pets must only be done indoors."	

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
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 followings language is required and placed in a prominent location: For products without drain treatment uses: "Do not allow to enter indoor or outdoor drains" "No permita la entrada a desagües internos o externos." For products with drain treatment uses: "Do not allow to enter indoor or outdoor drains unless labeled for drain treatments." "No permita la entrada a desagües internos o externos a menos que el etiquetado indique que está permitido el uso del producto para tratamiento de desagües." For products with and without drain treatment uses: "Follow proper disposal procedures on this label" "Siga las indicaciones del etiquetado para el desecho apropiado del producto." Graphic on the product package showing an image of a diagonal strikethrough over a drain. The pictogram must be legible (i.e. no smaller than 1.5 square centimeters or 0.25 square inches unless this size is greater than 10% of the size of the label). Use the following pictogram on product labels: 	Directions for Use

Description	Required Label Language for Cyfluthrin and Beta-cyfluthrin Products	Placement on Label
	End-use products with outdoor, urban, non-agricultural uses	
For all products	Add the following language:	Front Label Panel and/or
that have		Directions for Use
outdoor	"For outdoor use only."	
uses only		Front Label Panel and/or
For all products that have both	Add the following language:	Directions for Use
indoor and outdoor uses	"For both indoor and outdoor use."	
General Outdoor	"All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:	Directions for Use
Application Statement to replace existing	1. Application to pervious surfaces such as soil, lawn, turf, and other vegetation;	
general outdoor statement	2. Perimeter band treatments of 7 feet wide or less from the base of a man-made structure to pervious surfaces (<i>e.g.</i> , soil, mulch, or lawn);	
[Registrants may not add new uses from	3. Applications to underside of eaves, soffits, doors, or windows permanently protected from rainfall by a covering, overhang, awning, or other structure;	
items 1-6 which are not currently on the	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;	
existing label. Registrants are required to	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;	

Description	Required Label Language for Cyfluthrin and Beta-cyfluthrin Products	Placement on Label
choose only the uses from items 1-6 which apply to their product.]	6. Applications to vertical surfaces directly above pervious surfaces, such as soil, lawn, turf, mulch or other vegetation) only if the pervious surface does not drain into ditches, storm drains, gutters, or surface waters."	
Spot Treatment Guidance Statement	"Spot treatments must not exceed two square feet in size (for example, 2 ft. by 1 ft. or 4 ft. by 0.5 ft.)."."	Directions for Use
Buffer from Water Statement	"For soil or foliar applications, do not apply by ground within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds."	Directions for Use
Water Protection Statements	 "Do not spray the product into fish pools, ponds, streams, or lakes. Do not apply directly to sewers or storm drains, or to any area like a drain or gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur." "Do not allow the product to enter any drain during or after application." "Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment." "Do not apply or irrigate 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/	"Do not apply when the wind speed is greater than 15 mph."	Directions for Use

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
recreational turf applications		
Spray drift management for commercial nurseries	 For outdoor applications to commercial nurseries: "Do not apply when the wind speed is greater than 15 mph." "Applicators are required to select the nozzle and pressure that deliver a medium or coarser droplet size (ASABE S572)." "For soil or foliar applications, do not apply by ground equipment within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries and commercial fish farm ponds." 	Directions for Use
Crack and crevice treatments	 "Treat surfaces to ensure thorough coverage but avoid runoff." "To treat insects harbored in voids and cracks-and-crevices, applications must be made in such a manner to limit dripping and avoid runoff onto untreated structural surfaces and plants." 	Directions for Use
	End-use products with 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 appropriate 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. 	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.

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
	 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. 	
Enforceable Spray Drift Management Language	 Airblast Applications: Sprays must be directed into the canopy. Do not apply when wind speeds exceed 15 mph at the application site. User must turn off outward pointing nozzles at row ends and when spraying outer row. Do not apply during temperature inversions. 	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Airblast Applications".
Enforceable Spray Drift Management Language for products that allow ground boom applications	 Ground Boom Applications: User must only apply with the nozzle height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. Applicators are required to select nozzle and pressure that deliver medium or coarser droplets (ASABE S572). Do not apply when wind speeds exceed 15 mph at the application site. Do not apply during temperature inversions. 	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications".
Advisory Spray Drift Management Language for all products that allow aerial and ground boom uses	 THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. IMPORTANCE OF DROPLET SIZE An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. Controlling Droplet Size – Ground Boom 	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories".

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
	• 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 - AircraftHigher release heights increase the potential for spray drift.	
	 SHIELDED SPRAYERS Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. 	
	 TEMPERATURE AND HUMIDITY When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. 	
	 TEMPERATURE INVERSIONS Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with 	

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
	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	"SPRAY DRIFT ADVISORIES Handheld Technology Applications:	Directions for Use, just below the Spray Drift box,
Management Language for all products that allow liquid applications with handheld technologies	Take precautions to minimize spray drift."	under the heading "Spray Drift Advisories".
Vegetative Filter Strips Note: This requirement is separate and in addition to buffer	"VEGETATIVE FILTER STRIPS Construct and maintain a vegetative filter strip, according to the width specified below, of grass or other permanent vegetation between the field edge and nearby down gradient aquatic habitat (such as, but not limited to, lakes; reservoirs; rivers; streams; marshes or natural ponds; estuaries; and commercial fish farm ponds).	Directions for Use

Description	Required Label Language for Cyfluthrin and Beta-cyfluthrin Products	Placement on Label
zones to aquatic	Only apply products containing (name of pyrethroid) onto fields where a maintained vegetative	
areas, which are	filter strip of at least 25 feet exists between the field edge and where a down gradient aquatic	
still required if a	habitat exists. This minimum required width of 25 feet may be reduced or removed under the	
vegetated filter	following conditions:	
strip is present.	• 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 vegetative filter strip requirement 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 functional and	
	maintained.	
	\circ 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. <u>https://www.regulations.gov/document?D=EPA-HQ-</u>	
	<u>OPP-2008-0331-0175</u> "	
Buffer Zones to	Ground Application	Directions for Use
Water Bodies	• "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)."	
	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)."	

Description	Required Label Language for Cyfluthrin and <i>Beta</i> -cyfluthrin Products	Placement on Label
New text to include under Environmental Hazard statements: (For liquid products formulated for outdoor foliar applications to agricultural row crops.) Excludes products formulated for residential use	Update the Environmental Hazard with the bolded statement: "This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. Protect pollinating insects by following label directions intended to minimize drift and to reduce risk to these organisms. "	Environmental Hazard
Link to pollinator best management practices (For liquid products formulated for outdoor foliar applications to agricultural row crops.) Excludes products formulated for residential use	"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 <u>https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators</u> ."	Directions for Use, prior to crop specific directions

Description	Required Label Language for Cyfluthrin and Beta-cyfluthrin Products	Placement on Label
Information on	"Managed pollinator protection plans are developed by states/tribes to promote communication	Directions for Use, prior to
state managed	between growers, landowners, farmers, beekeepers, pesticide users, and other pest management	crop specific directions
pollinator	professionals to reduce exposure of bees to pesticides. If available, visit state plans for additional	
protection plans	information on how to protect pollinators."	
(For liquid		
products formulated for		
outdoor foliar		
applications to		
agricultural row		
crops.)		
Excludes		
products		
formulated for		
residential use		
Information on	"How to Report Bee Kills	Directions for Use, prior to
how to report	It is recommended that users contact both the state lead agency and the U.S. Environmental	crop specific directions
bee incidents	Protection Agency to report bee kills due to pesticide application. Bee kills can be reported to EPA	
(For liquid products	at <u>beekill@epa.gov</u> . To contact your state lead agency, see the current listing of state pesticide regulatory agencies at the National Pesticide Information Center's website:	
formulated for	http://npic.orst.edu/reg/state_agencies.html "	
outdoor foliar	<u>nttp://npic.orst.edu/reg/state_agencies.num</u>	
applications to		
agricultural row		
crops.)		
1 /		
Excludes		
products		
formulated for		
residential use		