




**Lambda-Cyhalothrin and Gamma-Cyhalothrin
Proposed Interim Registration Review Decision
Case Numbers 7408 and 7437**

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for lambda-cyhalothrin (PC Code 128897, case 7408) and gamma-cyhalothrin (PC Code 128807 / 128867, case 7437), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on lambda-cyhalothrin and gamma-cyhalothrin, can be found in EPA's public docket (EPA-HQ-OPP-2010-0480 and EPA-HQ-OPP-2010-0479, respectively) at www.regulations.gov.

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

EPA is issuing a PID for lambda-cyhalothrin and gamma-cyhalothrin 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 national 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 lambda-cyhalothrin and gamma-cyhalothrin prior to completing the lambda-cyhalothrin and gamma-cyhalothrin registration review. Likewise, the Agency will complete endocrine screening for lambda-cyhalothrin and gamma-cyhalothrin, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the lambda-cyhalothrin and gamma-cyhalothrin registration review.

Lambda- and gamma-cyhalothrin (“cyhalothrins”) are non-systemic, Type II pyrethroid insecticides. Type II synthetic pyrethroids contain an alpha-cyano group which renders them more neurotoxic than their non-cyano type I counterparts. The relative toxicities of lambda- and gamma-cyhalothrins are comparable, making it possible for the Agency to combine the toxicity databases for purpose of risk assessment. For that reason, the two active ingredients have been grouped together for registration review. Like other pyrethroids, the cyhalothrins cause neurotoxicity by interacting with sodium channels. Products containing lambda- and gamma-cyhalothrin are formulated as ready-to-use sprays, liquids and granules. They are registered for use on a wide variety of sites, including: agricultural crops, cattle ear tags, food handling establishments, ornamental gardens, lawns, landscapes, turf, golf courses, and general insect control (spot treatments and crack and crevice treatments) in and around buildings, structures, and immediate surroundings. Both lambda- and gamma-cyhalothrin have products labeled for residential uses.

Products containing lambda-cyhalothrin were first registered in the United States in 1989. Formulations for lambda-cyhalothrin include microencapsulated, pelleted/tableted, emulsifiable concentrate, wettable powder, granular and ready-to-use material. Agricultural application methods include sprays made with ground and aerial application equipment, chemigation via irrigation equipment, foliar treatment, and soil treatments (e.g., in-furrow, T-banding). Alfalfa, corn, onions and sweet corn are the major agricultural uses for lambda-cyhalothrin.

Products containing gamma-cyhalothrin were first registered in the United States in 2004. Formulations include microencapsulated, liquid, emulsifiable concentrate, ready-to-use, impregnated collar-tag, pressurized liquid, and granular. Gamma-cyhalothrin products are applied to the following treatment sites: crack and crevice and/or spot, indoor general surface, indoor premise, void, contact and/or surface, spray, directed spray, perimeter, broadcast, chemigation, high volume spray (dilute), low volume spray (concentrate), outdoor premise, on animal (pour-on), ear tag, mound drench, soil treatment (T-banding and in-furrow), mound treatment, band treatment, dip treatment, and bark treatment. Soybeans and rice are the major agricultural uses for gamma-cyhalothrin.

Cyhalothrin are members of the pyrethroids and pyrethrins class of insecticides, which share the same mode of action. The pyrethroids and pyrethrins work by altering nerve function, causing paralysis in target insect pests, eventually resulting in death. The Agency has determined that the pyrethroids and pyrethrins belong to a common mechanism group (<http://www.regulations.gov>; EPA-HQ-OPP-2008-0489-0006). A screening-level cumulative risk assessment to assess human health risks was completed in 2011. This analysis did not identify cumulative risks of concern for children and adults. For further information, please see 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).

EPA previously published and opened 60-day public comment periods on the following documents: *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 the lambda- and gamma-cyhalothrin. Those documents, as well as additional supporting documents, are located in the lambda- and gamma-cyhalothrin dockets and in the Special Docket for Pyrethroids, Pyrethrins, and Synergists located at <http://www.regulations.gov> (EPA-HQ-OPP-2010-0480, EPA-HQ-OPP-2010-0479, and EPA-HQ-OPP-2008-0331, respectively).

The Agency finalized the revised ecological risk mitigation and the response to comments received on the ecological risk mitigation proposal in the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals, September 2020*. This PID is not opening for public comment the ecological risk mitigation proposal for the 23 pyrethroids and pyrethrins. The required ecological risk mitigation measures applicable to lambda- and gamma-cyhalothrin are presented in Appendix B.3 of this PID. The Agency will incorporate the required human health risk mitigation (after consideration of public comments; the proposed human health risk mitigation measures are presented in Appendices B.1 and B.2 of this document) with the ecological risk mitigation when it issues the Interim Decision for the cyhalothrins.

This document is organized in six sections: *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why lambda- and gamma-cyhalothrin are used and summarizes data on usage; *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; *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for EPA's PID; *Next Steps and Timeline* for completion of this registration review; and, lastly, *References* which lists the references used in this PID.

A. Summary of Lambda-Cyhalothrin and Gamma-Cyhalothrin Registration Review

Pursuant to 40 CFR § 155.50, EPA formally initiated registration review for lambda-cyhalothrin and gamma-cyhalothrin with the opening of the registration review dockets for the cases. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of lambda-cyhalothrin and gamma-cyhalothrin.

- December 2010 – The *Lambda-Cyhalothrin and Gamma-Cyhalothrin Summary Document Registration Review: Initial Docket*, dated December 14, 2010 (which contains the Preliminary Work Plan (PWP)), *Lambda-Cyhalothrin and Gamma-Cyhalothrin Human Health Assessment Scoping Document in Support of Registration Review*, dated September 28, 2010, and *EFED Registration Review Problem Formulation for Lambda-cyhalothrin and Gamma-cyhalothrin*, dated November 22, 2010, were posted to the docket for a 60-day public comment period.
- June 2011 – The *Lambda-Cyhalothrin and Gamma-Cyhalothrin Final Work Plan (FWP) for Registration Review*, dated June 14, 2011, was issued. EPA received comments on the

PWP during the 60-day public comment period. The Agency considered the comments and adjusted the data requirements as appropriate. The Agency determined that guideline number 830.7050 UV/Visible Light Absorption study and the non-guideline whole sediment chronic invertebrates freshwater and marine studies for gamma-cyhalothrin would not be requested because sufficient information was available to conduct a risk assessment to support a proposed registration review decision, pursuant to 40 CFR § 155.53(b). These changes also did not affect the projected registration review timeline as described in the PWP.

- December 2012 – Generic Data Call-Ins (GDCIs) for lambda-cyhalothrin (GDCI-128897-1249) and gamma-cyhalothrin (GDCI-128807-1152) were issued for data needed to conduct the registration review risk assessments. All data requirements of the GDCIs have 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 lambda- and gamma-cyhalothrin dockets for a 60-day public comment period. The same FR Notice (81 FR 85952) also announced the availability of the risk assessments for several other pyrethroids, the Ecological Risk Assessment, and the Rationale Document in the individual pyrethroid dockets. The comment period was extended from January until July 2017.
 - During the public comment period, EPA received over 1,400 public comments across all the dockets of the pyrethroids.
 - Almost 300 comments were received in the lambda-cyhalothrin docket. Of these comments, eight were specific to lambda-cyhalothrin. Fifty comments were received in the gamma-cyhalothrin docket. Of these comments, five were specific to gamma-cyhalothrin. The eight lambda-cyhalothrin-specific comments, the five gamma-cyhalothrin-specific comments, and the Agency’s responses are summarized in section I.B. below. The generic pyrethroid comments and the Agency’s responses can be found in the *Joint Response from OPP’s Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for the Pyrethroids and Pyrethrins Insecticides*, which can be found at <http://www.regulations.gov> (Docket # EPA-HQ-OPP-2008-0331). The comments did not change the ecological risk assessment or registration review timeline for lambda- or gamma-cyhalothrins.
- September 2017 - The Agency announced the availability of *Lambda- & Gamma-Cyhalothrin: Human Health Draft Risk Assessment Registration Review* for a 60-day public comment period. The public comment period was extended by another 30 days for gamma-cyhalothrin for a total of 90 days. The Agency received comments from twelve respondents addressing lambda-cyhalothrin, gamma-cyhalothrin, both and pyrethroids in

general. These comments and the Agency's responses are discussed below. The comments resulted in changes to the human health risk assessment for lambda- and gamma-cyhalothrin.

- August 2019 – The Agency published *USEPA Office of Pesticide Programs' Re-Evaluation of the FQPA Safety Factor for Pyrethroids: Updated Literature and CAPHRA Program Data Review* on the webpage <https://www.epa.gov/sites/production/files/2019-08/documents/2019-pyrethroid-fqpa-caphra.pdf>, which discusses the data and rationale underlying the Agency's decision to remove the 10X FQPA safety factor for the pyrethroids, including lambda- and gamma-cyhalothrin.
- 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 <http://www.regulations.gov> (EPA-HQ-OPP-2008-0331).

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

- *Pyrethroids: Documentation of Systematic Literature Review Conducted in Support of Registration Review*
- *cis-Permethrin: Statistical Analysis of PBPK Simulated Data for DDEF*
- *Pyrethroids: Tier II Epidemiology Report*
- November 2019 – The Agency opened a 60-day public comment period for the *Pyrethroids and Pyrethrins Ecological Risk Mitigation Proposal for 23 Chemicals*. This document is 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.

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

- *Joint Response from OPP's Environmental Fate and Effects Division and Pesticide Re-evaluation Division to Comments on the Preliminary Risk Assessments for Pyrethroids and Pyrethrins Insecticides*
- *Updated Ecological Incidents Search for the Pyrethroids and Pyrethrins*
- *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroids Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks*
- *Review of USDA's Assessment of the Benefits of Pyrethroids*

- *Review of Estimated Benefits of Pyrethroids in U.S. Agriculture from “The Value of Pyrethroids in U.S. Agriculture and Urban Settings” Prepared by AgInfomatics, LLC for the Pyrethroid Working Group*
 - *Biological and Economic Analysis Division (BEAD) Summary of Public Comments Related to Benefits of Pyrethroids Submitted in Response to the Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins*
 - *Review of “Economic Benefits of Pyrethroids Insecticides for Select California Crops,” Report Prepared by ERA Economics for the Pyrethroids Working Group*
 - *Alternatives Assessment for Synthetic Pyrethroid/Pyrethrin Insecticides as Wide Area Mosquito Adulticides in Support of Registration Review*
 - *Readers Guide – Instructions for Commenting on the Registration Review Documents in the Pyrethroids Group*
- September 2020 – The Agency has completed the PID for lambda- and gamma-cyhalothrin. The PID is posted to the docket for a 60-day public comment period. The Agency has also finalized the ecological risk mitigation proposed for 23 pyrethroids, which include lambda- and gamma-cyhalothrin.

Along with the PID, the following documents are also posted to the lambda- and gamma-cyhalothrin dockets.

- *Lambda- & Gamma-Cyhalothrin: Updated Human Health Draft Risk Assessment in Support of Registration Review, March 20, 2020*
- *Response to Public Comments on the Lambda-Cyhalothrin and Gamma-Cyhalothrin Draft Risk Assessment for Registration Review, March 20, 2020*
- *Lambda-Cyhalothrin and Gamma-Cyhalothrin. Occupational Handler Exposure and Risk Assessment Addendum to the Registration Review Human Health Risk Assessment to Support the Proposed Interim Decision, August 12, 2020*
- *Pyrethroids: Health Effects Division Response to Public Comments Submitted to the Special Docket for Pyrethroids, Pyrethrins, and Synergists [EPA-HQ-OPP-2008-0331], September 2020*
- *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals, September 2020*

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the public comment period for the cyhalothrins human health draft risk assessment (HHDRA) (September 13, 2017 to November 13, 2017 for lambda-cyhalothrin; September 13, 2017 to December 13, 2017 for gamma-cyhalothrin), the Agency received public comments from twelve sources addressing lambda-cyhalothrin, gamma-cyhalothrin, both, and/or pyrethroids in general. Comments were submitted by the following entities: (1) Almond Alliance of California, (2) Arizona Farm Bureau Federation, (3) Arizona Pest Management Center, (4) California Specialty Crops Council, (5) CropLife America, (6) FMC Corporation (technical registrant for

gamma-cyhalothrin), (7) National Pest Management Association (NPMA), (8) Responsible Industry for a Sound Environment (RISE), (9) San Joaquin County Mosquito & Vector Control District, (10) Syngenta Crop Protection LLC (technical registrant for lambda-cyhalothrin), (11) United States Department of Agriculture (USDA), and (12) Washington State Potato Commission.

The Agency received comments from a variety of stakeholder groups such as the technical registrants, colleges/universities, agriculture associations and local government authorities. Many of the comments received spoke to the benefits of lambda-cyhalothrin and gamma-cyhalothrin products. The lead technical registrants, FMC Corporation (gamma-cyhalothrin) and Syngenta (lambda-cyhalothrin) commented on inconsistencies in the application rates for residential and commercial products used in the human health draft risk assessment. The Agency considered the comments received and revised the human health draft risk assessment accordingly.

A detailed discussion of the comments on the human health draft risk assessment and the Agency's responses is in the *Response to Public Comments on the Lambda-Cyhalothrin and Gamma-Cyhalothrin Draft Risk Assessment for Registration Review*, which is available in both the lambda- and gamma-cyhalothrin dockets (EPA-HQ-OPP-2010-0480 and EPA-HQ-OPP-2010-0479, respectively).

Public comments pertaining to overarching pyrethroid ecological concerns and the Agency's responses are addressed in the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals*. Public comments pertaining to overarching pyrethroid human health issues and 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*. Both documents are available in the Special Docket for Pyrethroids, Pyrethrins, and Synergists (EPA-HQ-OPP-2008-0331).

The Agency thanks all commenters for their comments and has considered them in developing this PID.

II. USE AND USAGE

Lambda- and gamma-cyhalothrin are synthetic pyrethroid insecticides which affect the peripheral and central nervous systems of insects. The cyhalothrins work by keeping sodium channels in neuronal membranes open, which initially stimulates nerve cells to repeatedly discharge resulting in paralysis (also called knockdown) and eventually death of target pests. The Insecticide Resistance Action Committee categorizes cyhalothrins and other synthetic pyrethroids as Mode of Action (MOA) Group 3A (IRAC, 2020).

Products containing lambda- and gamma-cyhalothrin are formulated as ready-to-use sprays, liquids and granules and are registered for use in a wide variety of settings. These settings include crop and livestock production (e.g., barns, litter, ear tags, pour ons, and capsules) as well as indoor and outdoor uses in residential and commercial areas.

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 2016 (NMRD, 2017a). Approximately 20,000 lbs of cyhalothrins were applied from residential outdoor uses outdoors and an unspecified amount were from indoor uses (NMRD, 2017a). These amounts of cyhalothrins include household insecticides used for both indoor and outdoor pest control (e.g., ant, cockroach, termite, fly control, and lawn and garden pest control insecticides) or as insect repellents. Food handling establishments, including processing facilities, warehouses, restaurants, and other food preparation facilities used around 200,000 lbs a.i. of pyrethroids, including 40,000 lbs of cyhalothrins, in 2013 (Kline and Company, 2014). Professional pest management companies used over 3 million lbs a.i. of pyrethroids, including 80,000 lbs of cyhalothrins, for control of various nuisance and public health pests both in and around residential and commercial buildings (Kline and Company, 2013 and NMRD, 2017b). Industrial vegetation management, including roadways and rangeland, used around 2.5 million lbs of pyrethroids, of which cyhalothrins make up 200,000 lbs applied (NMRD, 2017c).

Gamma-cyhalothrin usage in agriculture averages over 9,100 lbs a.i. applied to over 1 million acres of cropland annually, although usage has been trending downwards recently (Kynetec, 2014-2018). Soybean, corn, and winter wheat growers account for most of the usage of gamma-cyhalothrin in terms of area treated. Sunflower growers had the highest proportion of their field applied with gamma-cyhalothrin, at three percent of the crop acres treated (Kynetec, 2014-2018). On average, crop growers apply gamma-cyhalothrin aerially on 204,000 acres annually (or 20% of all acres treated) (Kynetec, 2014-2018).

Lambda-cyhalothrin usage in agriculture averages over 530,000 lbs a.i. applied to 21 million acres of cropland annually, with usage trending up in the recent years (Kynetec, 2014-2018). Soybeans, corn, wheat (winter and spring varieties combined), and alfalfa account for about 50% of the usage in terms of total acres treated with lambda-cyhalothrin. In terms of the proportion of crop acres treated, lettuce, pears, broccoli, cherries, and cauliflower show the highest percent crop area treated (PCT), ranging from 50-65% (Kynetec, 2014-2018). On average, crop growers apply lambda-cyhalothrin aerially on 5.6 million acres (or 27% of all acres treated) annually (Kynetec, 2014-2018).

National level data on cyhalothrins usage in livestock production are not available.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the Agency's human health risk assessment is presented below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of lambda- and gamma-cyhalothrin. For additional details on the human health assessment for lambda- and gamma-cyhalothrin, see the following documents:

(1) *Lambda- & Gamma-Cyhalothrin: Human Health Draft Risk Assessment for Registration Review*, June 30, 2017 (referred to as the 2017 HH DRA); (2) *Lambda- & Gamma-Cyhalothrin: Updated Human Health Draft Risk Assessment in Support of Registration Review*, March 20, 2020 (referred to as the 2020 HH DRA Update); (3) *Response to Public Comments on the Lambda-Cyhalothrin and Gamma-Cyhalothrin Draft Risk Assessment for Registration Review*, March 20, 2020 (referred to as the 2020 HH DRA RTC); and (4) *Lambda-Cyhalothrin and Gamma-Cyhalothrin. Occupational Handler Exposure and Risk Assessment Addendum to the Registration Review Human Health Risk Assessment to Support the Proposed Interim Decision*, August 12, 2020 (referred to as the 2020 HH DRA Addendum) which are available in the public docket.

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

No dietary risks of concern were identified for products containing lambda- and gamma-cyhalothrin. Dietary exposures from both lambda and gamma-cyhalothrin were assessed together in the same analysis. This is because, lambda-cyhalothrin is an equimolar mixture of four isomers with one being gamma-cyhalothrin. The acute dietary (food and water) exposures were not of concern (food and water; $\leq 69\%$ acute population adjusted dose (aPAD)). A chronic dietary risk assessment was not conducted because there is no apparent increase in hazard from repeated/chronic exposures to the cyhalothrin isomeric mixtures. Lambda- and gamma-cyhalothrin are classified as “Not likely to be Carcinogenic to Humans” based on the absence of treatment related tumors in two adequate rodent carcinogenicity studies.

Residential Handler Risks

Lambda- and gamma-cyhalothrin are currently registered on a wide range of indoor and outdoor residential use sites. Indoor uses include spot, and crack and crevice applications. Outdoor uses include broadcast (i.e., turf, ornamentals, and vegetable gardens), spot, and crack and crevice applications. Cyhalothrin products for residential use sites are formulated as liquid concentrates, microencapsulated formulations, granular formulations, and as ready-to-use (RTU) products in trigger pump sprayers and aerosol cans.

There are registered lambda- and gamma-cyhalothrin product labels with residential use sites (e.g., such as lawns, indoor environments, garden and trees) that do not require specific clothing (e.g., long sleeve shirt/long pants) and/or personal protective equipment (PPE), and these labels have been considered in the residential handler assessment for lambda- and gamma-cyhalothrin.

Lambda-cyhalothrin. For lambda-cyhalothrin, there are no risks of concern for residential handlers (aggregate risk indices (ARIs) ≥ 1.0). All the residential handler exposure and risk estimates indicate that the (dermal and inhalation) ARIs are greater than the level of concern (LOC). Therefore, there are no risk estimates of concern.

Gamma-cyhalothrin. There are no risks of concern for residential handlers from turf, crack and crevice, and spot applications. (ARIs ≥ 1.0). However, spray applications to gardens and trees

are of concern (with ARIs = 0.033 to 0.086) using the following equipment: (1) manually pressurized hand-wand, (2) hose-end sprayer, (3) backpack sprayer, and (4) sprinkler can. These risks are mostly driven by the inhalation exposure.

Residential Post-Application Risks

Adults

For adults, the LOC for the dermal exposure is 100.

Lambda-cyhalothrin. There are no risks of concern for adult residential post application for ornamental, crack and crevice and spot applications (MOEs \geq 100; LOC = 100). However, adult residential post-application risks are of concern for high-contact lawn activities (MOE = 90).

Gamma-cyhalothrin. There are no risks of concern for adult residential post application for turf, crack and crevice, and spot applications, (MOEs \geq 100). However, post application risks are of concern to the Agency for applications to gardens and trees (MOE = 8.3; LOC = 100).

Children

For children, the LOCs for the dermal, incidental oral, and combined dermal and incidental oral exposures are 100.

Lambda-cyhalothrin. For lambda-cyhalothrin, residential post-application exposures for children 1 to 2 years old are of concern for the following scenarios: (1) indoor coarse spot-application to carpet (MOE = 55); (2) indoor pin-stream spot application to carpet (MOE = 95); (3) indoor mattress application (MOE = 78); and (4) lawn/turf applications (MOE = 45 for liquid formulations; MOE = 65 for solid formulations).

Gamma-cyhalothrin. For gamma-cyhalothrin, residential post-application exposures for children 1 to 2 years old are of concern for the following scenarios: (1) indoor coarse spot application to carpet (MOE = 74); (2) indoor pin-stream spot application to carpet (MOE = 74); (3) lawn/turf application (liquid/solid formulations, MOEs = 59 to 160); (4) turf application, episodic granular application (MOE = 13). Residential post-application exposure for children ages 6 to <11 years old is of concern for the application to gardens/trees (MOE = 12).

Bystander Risks

The bystander risk assessment considers risk to children (1 to 2 years old) and adults from off target deposition of sprays on turf and lawns. The deposited residue value and the resulting MOE are determined based on the amount of spray drift that may occur at varying distances from the edge of the treated field. The assessment determines the distances from the edge of the treated field at which the MOEs (i.e., MOE \geq LOC) are not of concern.

Lambda-cyhalothrin. There are combined dermal and incidental oral risks of concern for children 1 to 2 years old extending up to >300 feet from the edge of the treated field, with aerial applications to ornamentals and golf courses resulting in the farthest distance.

Gamma-cyhalothrin. There are dermal risks of concern for adults extending up to >300 feet from the edge of the treated field, with aerial applications to typical high acreage field crops and orchard/vineyards resulting in the farthest distance. For children ages 1-2 years old, there are combined dermal and incidental oral risks of concern extending up to >300 feet, with aerial applications to typical high acreage crops (i.e. corn intended for popcorn use) and orchard/vineyards resulting in the farthest distance.

Aggregate Risks

In doing the aggregate risk assessment, EPA considers and aggregates pesticide exposures and risks from three major sources: food, drinking water, residential exposure.

The acute aggregate risk assessment combines risks from food and drinking water only; the resulting exposure estimates are not of concern to the Agency ($\leq 69\%$ aPAD; combined lambda- and gamma-cyhalothrin). Based on toxicological consideration, the acute assessment is protective of chronic exposure.

The short-term aggregate risks assessments were not of concern to the Agency for indoor crack and crevice (lambda- and gamma-gamma), indoor pin-stream spot-application to hard-flooring (lambda) and ornamentals (lambda) (MOEs ≥ 110 ; ARIs ≥ 1.2). However, the previously discussed residential exposures that were of concern would also result in aggregate exposures that would be of concern. In addition, although the residential exposure to gamma-cyhalothrin from indoor coarse/pin stream spot application to hard flooring was acceptable (MOE = 101), the short-term aggregate is of concern (MOE = 90).

Cumulative Risks

The Agency is required to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. The Agency has determined that the pyrethroids and pyrethrins share a common mechanism of toxicity (<http://www.regulations.gov>; EPA-HQ-OPP-2008-0489-0006). The members of this group share the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. The cumulative risk assessment for the pyrethroids/pyrethrins was published on November 9, 2011 and is available at <http://www.regulations.gov>; EPAHQ-OPP-2011-0746. No cumulative risks of concern were identified, allowing the Agency to consider new uses for pyrethroids. For information regarding EPA's efforts to evaluate the risk of exposure to this class of chemicals, refer to <http://www.epa.gov/oppsrrd1/reevaluation/pyrethroids-pyrethrins.html>

Occupational Handler Risks

In the 2017 and 2020 human health draft risk assessments, the Agency identified several occupational handler scenarios that were risks of concern (i.e., the total aggregated risk index

(ARI) <1; the ARI approach was used since the LOC values for dermal exposure and inhalation exposure are different) for both lambda- and gamma-cyhalothrin. The following discussion gives a summary of the scenarios that were identified as risks of concern. For the full detail of the assessment, including MOE and ARI values, refer to the 2017 HH DRA (EPA-HQ-OPP-2010-0480-0299) and the 2020 HH DRA Addendum (EPA-HQ-OPP-2010-0480-DRAFT-1577).

Lambda-cyhalothrin. There are mixer/loader/applicator (M/L/A) scenarios that are of concern (ARIs <1), with several of them failing even at the highest level of personal protective equipment (PPE)¹ (see **Table 1**). **Table 1** categorizes these scenarios by the level of PPE at which they pass or fail (in the case of the highest level of PPE) (i.e., the ARI value is either ≥ 1 or <1, respectively). Many of these scenarios fail due to both dermal and inhalation exposures.

Table 1. Mixer/Loader/Applicator Scenarios that are Risks of Concern for Lambda-Cyhalothrin

M/L/A Exposure Scenario		ARI		
		SL+G+ PF10R	DL+G	DL+G+ PF10R
Scenario(s) that fail(s) at the highest level of PPE (DL+G+PF10R)				
1	Liquid, backpack, foliar spray on nurseries (ornamentals, vegetables, trees, container stock)			0.8
2	Liquid, backpack, broadcast spray landscaping, turf			0.29
3	Liquid, mechanically pressurized handgun broadcast (foliar) on orchards and vineyards			0.57
4	Liquid, mechanically pressurized handgun, drench/soil/ground direct) on orchards and vineyards			0.57
5	Liquid, mechanically pressurized handgun, broadcast spray in greenhouses (ornamentals, cut flowers, roses, container stock, vegetables)			0.23
6	Liquid, mechanically pressurized handgun, soil/ground direct in greenhouse (ornamentals, cut flowers, roses, container stock, vegetables)			0.23
7	Liquid, mechanically pressurized handgun, broadcast (foliar) on nurseries (ornamentals, vegetables, trees, container stock)			0.13
8	Liquid, mechanically pressurized handgun, drench/soil/ground direct on nurseries (ornamentals, vegetables, trees, container stock)			0.13
9	Liquid, mechanically pressurized handgun, broadcast spray on industrial/commercial (tires, rail, yards, junk yards, etc.)			0.9
10	Liquid, mechanically pressurized handgun, broadcast (foliar) on typical field crop uses			0.15
Scenario(s) that pass(es) with DL+G				
1	Liquid, backpack, spot treatment for landscaping turf (lawns, athletic fields, parks, etc.)		1.2	

¹ SL single layer clothing. DL double layer clothing. G gloves. PF10R PF-10 respirator. EC Engineering control

M/L/A Exposure Scenario		ARI		
		SL+G+PF10R	DL+G	DL+G+PF10R
2	Liquid, mechanically pressurized handgun, foliar spray for landscaping trees and shrubs.		1.2	
Scenario(s) that pass(es) with SL+G+PF10R				
1	Liquid, manually pressurized handwand, broadcast spray in food handling establishments	2.3		
2	Liquid, manually pressurized handwand, crack and crevice in food handling establishments	2.3		
3	Liquid, manually pressurized handwand, broadcast spray in warehouses	2.3		
4	Liquid, manually pressurized handwand, crack and crevice in warehouses	2.3		
5	Liquid, manually pressurized handwand, broadcast spray in residential living spaces (homes, apartments)	2.3		
6	Liquid, manually pressurized handwand, crack and crevice in residential living spaces (homes, apartments)	2.3		
7	Liquid, manually pressurized handwand, broadcast spray passes to structural components (walls, framing voids, slabs, beams, lumber, etc.)	2.3		
8	Liquid, manually pressurized handwand, broadcast spray to childcare centers/schools/institutions	2.3		
9	Liquid, mechanically pressurized handgun, broadcast sprays in warehouses	1.5		
10	Liquid, mechanically pressurized handgun, broadcast spray to structural components (walls, framing voids, slabs, beams, lumber, etc.)	1.5		
11	Liquid, mechanically pressurized handgun, broadcast spray in barn/feedlot	1.5		

Gamma-cyhalothrin. The Agency identified risks of concerns across the different occupational handler types: mixer/loader (M/L), mixer/loader/applicator (M/L/A), applicator, and flaggers. Many of the risk estimates indicated the ARIs are below the Agency’s LOC (i.e., ARIs are < 1). See **Table 2** to **Table 5** of this PID for those scenarios. Similar to what was done for lambda-cyhalothrin, the scenarios are categorized by level of PPE at which they pass or fail (in the case of the highest level of PPE) (i.e., the ARI value is either ≥ 1 or <1, respectively).

Table 2. Mixer/Loader Scenarios that are Risks of Concern for Gamma-Cyhalothrin

M/L Exposure Scenario		ARI SL+G+PF10R	ARI EC
Scenario(s) that fail(s) with the highest level of PPE (Engineering Controls - EC)			
1	Liquid, aerial, broadcast to high-acreage field crops		0.34
Scenario(s) that pass(es) with EC			
1	Liquid, aerial, broadcast to orchard/vineyard		1.2

M/L Exposure Scenario		ARI SL+G+PF10R	ARI EC
2	Liquid, chemigation, broadcast to orchard/vineyard		1.2
3	Liquid, aerial, broadcast to typical field crop		1.2
4	Liquid, chemigation, broadcast to typical field crop		1.2
5	Liquid, chemigation, broadcast to high acreage field crop		1.2
6	Liquid, groundboom, broadcast to high acreage field crop		2
Scenario(s) that pass(es) with SL/G/PF10R			
1	Liquid, aerial, broadcast to forestry	1.1	

Table 3. Mixer/Loader/Applicator Scenarios that are Risks of Concern for Gamma-Cyhalothrin

M/L/A Exposure Scenario		ARI SL+G+PF10R	ARI DL/G/PF10R
Scenario(s) that fail(s) with the highest level of PPE (DL/G/PF10R)			
1	Liquid, backpack, ground/soil-directed to orchard/vineyard		0.15
2	Liquid, mechanically pressurized handgun, broadcast (foliar) to orchard/vineyard		0.017
3	Liquid, mechanically pressurized handgun, drench/soil/ground-directed to orchard/vineyard		0.017
4	Liquid, backpack, broadcast to forestry		0.73
5	Liquid, mechanically pressurized handgun, broadcast (foliar) to nursery (ornamentals, vegetables, trees, container stock)		0.33
6	Liquid, mechanically pressurized handgun, drench/soil/ground directed to nursery (ornamentals, vegetables, trees, container stock)		0.33
7	Liquid, backpack, broadcast (foliar) to landscaping, trees/shrubs/bushes		0.96
8	Liquid, mechanically pressurized handgun, broadcast (foliar) to landscaping, trees/shrubs/bushes		0.48
9	Liquid, backpack, broadcast (foliar) to landscaping, plants/flowers		0.96
Scenario(s) that pass(es) with SL/G/PF10R			
1	Liquid, mechanically pressurized handgun, broadcast to greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	1.3	
2	Liquid mechanically pressurized handgun, drench/soil/ground directed to greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)	1.3	
3	Liquid, backpack, broadcast to landscaping, turf (lawns, athletic fields, parks, etc)	1.1	
4	Liquid, backpack, broadcast (foliar) to nursery (ornamentals, vegetables, trees, container stock)	1.1	
5	Liquid, manually pressurized handwand, broadcast to warehouse	3	
6	Liquid, manually pressurized handwand, crack & crevice to warehouse	3	

M/L/A Exposure Scenario		ARI SL+G+PF10R	ARI DL/G/PF10R
7	Liquid, mechanically pressurized handgun, broadcast to warehouse	1.9	
8	Liquid, manually pressurized handwand, crack & crevice to residential living spaces (homes, apartments)	3	

Table 4. *Applicator Scenarios that are Risks of Concern for Gamma-Cyhalothrin*

Applicator Exposure Scenario		ARI SL+G+PF10R	ARI with EC
Scenario(s) that pass(es) with the highest level of PPE (EC)			
1	Spray (all starting formulations), airblast, broadcast to orchard and vineyard		7.1
Scenario(s) that pass(es) with SL+G+PF10R			
1	Spray (all starting formulations), groundboom, broadcast to high acreage field crop	1.4	

Table 5. *Flagger Scenarios that are Risks of Concern for Gamma-Cyhalothrin*

Flagger Exposure Scenario		ARI SL+G+PF10R
Scenario(s) that passes with SL+G+PF10R		
1	Spray (all starting formulations), aerial, broadcast to orchard/vineyard	1.1
2	Spray (all starting formulations), aerial, broadcast to typical field crop	1.1
3	Spray (all starting formulations), aerial, broadcast to high acreage field crop	1.1

Occupational Post-Application Risks

EPA identified dermal risks to individuals performing post-application activities in fields previously treated with lambda- and gamma-cyhalothrin. EPA calculates the exposure and the associated risk estimate (i.e., MOE) as a function of the days after pesticide treatment. **Table 6** and **Table 7** shows the number of days after treatment (DAT) when the MOE for a particular scenario/use site equals or surpasses the LOC =100, i.e., DAT where MOE ≥ LOC. Both tables only show the maximum DAT across all activities assessed for each crop. For lambda-cyhalothrin, the maximum DAT values range from 2 to 9 days, while for gamma-cyhalothrin, the maximum DAT values range from 15 to more than 30 days. For a detailed discussion of the post-application risks, see the 2017 HH DRA.

Table 6. Lambda-cyhalothrin Occupational Post-Application Risks of Concern

Crop	DAT where MOE ≥ LOC (max value across all activities assessed for each crop in the 2017 HH DRA)
Apple	2 (Thinning fruit)
Corn, sweet grain	5 (Hand detasseling)
Nectarine	7 (Thinning fruit)
Pear	8 (Thinning fruit)
Plum, prune	9 (Thinning fruit)

DAT=days after treatment; **LOC**=level of concern; **MOE**=margin of exposure

Table 7. Gamma-Cyhalothrin Occupational Post-Application Risks of Concern

Crop	DAT where MOE ≥ LOC (max value across all activities assessed for each crop in the 2020 HH DRA)
Almond	15 (Scouting)
Apple	>30 (Thinning fruit)
Apricot	>30 (Thinning fruit)
Bean, snap	30 (Hand set irrigation)
Blackberry	30 (Hand set irrigation)
Broccoli	>30 (Scouting, hand harvesting, hand weeding)
Brussels Sprouts	>30 (Scouting, hand harvesting, hand weeding, topping)
Chinese cabbage, bok choy	>30 (Hand weeding)
Chinese cabbage, napa	>30 (Hand weeding)
Cauliflower	>30 (Scouting, hand harvesting, hand weeding, tying/training)
Cherry	>30(Thinning fruit)
Corn, pop	30 (Hand set irrigation)
Corn, sweet grain	>30 (Hand detasseling, hand harvesting)
Corn, processing	30 (Hand set irrigation)
Eggplant	30 (Hand set irrigation)
Fig	26 (Pollination, hand harvesting)
Hazelnut	15 (Scouting)
Macadamia nut	15 (Scouting, hand pruning)
Onion, bulb	>30 (Hand weeding)
Onion, green	>30 (Hand weeding)
Pepper, bell	30 (Hand set irrigation)
Tomato	30 (Hand set irrigation)
Tomato, processing	30 (Hand set irrigation)
English walnut	15 (Scouting)

DAT=days after treatment; **LOC**=level of concern; **MOE**=margin of exposure

2. Human Incidents and Epidemiology

Although there are a relatively large number of lambda- and gamma-cyhalothrin incidents

reported to the Incident Data System (IDS) and the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides, a substantial majority of these incidents were classified as minor severity (96% in IDS and 89% in SENSOR-Pesticides for lambda-cyhalothrin), less than 1% of cases were major, and no deaths were reported. Minor severity means that a person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved rapidly and usually involved skin, eye or respiratory irritation. The Agency will continue to monitor the incident information and if a concern is triggered, additional analysis will be conducted.

3. Tolerances

Tolerances have been established in 40 CFR §180.438(a)(1) for lambda-cyhalothrin and in 40 CFR §180.438(a)(2) for gamma-cyhalothrin. In the U.S., for lambda-cyhalothrin, tolerances are established in terms of four isomers of the parent compound. For gamma-cyhalothrin, tolerances are established in terms of the two of these four isomers. For most commodities, gamma tolerances are based on lambda tolerances since application rates for gamma are generally half that of lambda, and residues will be covered by lambda tolerances.

The tolerance expressions will be revised so that they address both coverage and measurement. The tolerance expression for lambda-cyhalothrin will be revised as follows:

“Tolerances are established for residues of lambda-cyhalothrin, 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 the combined residues of the pyrethroid lambda-cyhalothrin, 1:1 mixture of (*S*)- α -cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)- α -cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and its epimer expressed as epimer of lambda-cyhalothrin, a 1:1 mixture of (*S*)- α -cyano-3-phenoxybenzyl-(*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*R*)- α -cyano-3-phenoxybenzyl-(*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate.”

The tolerance expression for gamma-cyhalothrin will be revised as follows:

“Tolerances are established for residues of gamma-cyhalothrin, including its metabolites and degradates, in or on the commodities. Compliance with the tolerance levels specified below is to be determined by measuring the combined residues of the pyrethroid [gamma-cyhalothrin (the isolated active isomer of lambda-cyhalothrin) (*S*)- α -cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate) and its epimer (*R*)- α -cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate.”

The Agency anticipates the following changes to the tolerances for lambda- and gamma-cyhalothrin (see **Table 8**). In 40 CFR §180.438(a)(1), the lambda-cyhalothrin tolerances for residues in hog tissues are less than the gamma-cyhalothrin tolerances in §180.438(a)(2). The

tolerances for residues of lambda-cyhalothrin in hog tissues need to be increased to match the gamma-cyhalothrin tolerances. Additionally, the gamma-cyhalothrin tolerances for residues in wheat bran and canola seed appear to be incorrect in 40 CFR §180.438(a)(2) and need to be corrected. A permanent tolerance for residues in canola oil under gamma-cyhalothrin also needs to be established.

The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

Table 8. Summary of Recommended Tolerance Actions for Lambda- and Gamma-Cyhalothrin

Commodity	Established Tolerance (ppm)	Proposed Tolerance (ppm)	Comments
40CFR §180.438(a)(1) – Lambda-cyhalothrin			
Hog, fat	0.2	3	Correction of error in 40CFR §180.438(a)(1)
Hog, meat	0.01	0.2	Correction of error in 40CFR §180.438(a)(1)
Hog, meat byproduct	0.02	0.2	Correction of error in 40CFR §180.438(a)(1)
40CFR §180.438(a)(2) – Gamma-cyhalothrin			
Wheat, bran	2.0	0.2	Correction of error in 40CFR §180.438(a)(2)
Canola, seed	0.15	1	Correction of error in 40CFR §180.438(a)(2)
Canola, refined oil	None	2	Correction of error in 40CFR §180.438(a)(2)

Harmonization of US tolerances with MRLs of Codex or Canada is not considered at this time since there are no human health safety findings for cyhalothrins. Codex MRLs are for cyhalothrin which “includes lambda cyhalothrin”; gamma cyhalothrin are not specified. Canada has established MRLs for lambda-cyhalothrin only. It has not established MRLs for gamma-cyhalothrin. While in general the majority of US tolerances for lambda-cyhalothrin agree with Codex and specifically with Canadian MRLs, there is no general trend in the US tolerances in terms of being lower or higher than Codex or Canadian MRLs for the same commodities. The disagreement between US tolerances and Canadian MRLs are mainly in livestock tissues.

4. Human Health Data Needs

The human health database is complete for lambda- and gamma-cyhalothrin. No additional human health data are required to support this registration review decision.

B. Ecological Risks

1. Risk Summary and Characterization

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 pyrethroids cases: bifenthrin, cyfluthrin (beta-cyfluthrin), cyhalothrins (lambda-cyhalothrin and gamma-cyhalothrin), cypermethrin (alpha-cypermethrin and zeta-cypermethrin), deltamethrin, esfenvalerate, fenpropathrin, permethrin, and pyrethrins

The 2016 risk assessment was divided into five sections: risks from indoor “down the drain” uses;² 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. Of these five categories, cyhalothrins are likely to pose risks from outdoor residential, commercial, turf and nursery uses. 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 the nine pesticides, for which the Agency had a relatively large amount of data.

A companion piece, titled the *Ecological Risk Management Rationale for Pyrethroids in Registration Review* or the Rationale Document, summarized potential risk concerns for the remaining pyrethroids and was published at the same time. The pesticides covered in the Rationale Document are: cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, esfenvalerate, and tetramethrin. The Rationale Document describes EPA’s approach in using the quantitative assessment of the nine pyrethroid cases to serve as a basis for making risk management and regulatory decisions for all of the 23 affected pesticides currently undergoing registration review. Potential risks that were identified for the nine pyrethroids and pyrethrins assessed in 2016 were determined to be representative of the risks for the other pyrethroids also undergoing registration review.

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

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

For lambda-cyhalothrin, risks of concern were identified for aquatic invertebrates, and freshwater and estuarine/marine fish from indoor down-the-drain, residential, commercial, turf, nursery (ornamental) and agricultural uses. For gamma-cyhalothrin, risks of concern were identified for aquatic invertebrates from residential, commercial, turf, and nursery (ornamental

² “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.

and agricultural) uses. Risks to bees were identified for both chemicals. Additional details on the bee risk assessment and additional data needs are discussed below.

The Agency finalized the revised ecological risk mitigation and the response to comments received on the ecological risk mitigation proposal in the *Pyrethroids and Pyrethrins Revised Ecological Risk Mitigation and Response to Comments on the Ecological Risk Mitigation Proposal For 23 Chemicals, September 2020*. This PID is not opening up for public comment the ecological risk mitigation proposal for the 23 pyrethroids and pyrethrins. The required ecological risk mitigation measures applicable to lambda- and gamma-cyhalothrin are presented in Appendix B.3 of this PID. As stated previously, these mitigation measures are not open for public comment. The Agency will incorporate the required human health risk mitigation (after consideration of public comments) with the ecological risk mitigation when it issues the Interim Decision for the cyhalothrins.

Terrestrial Invertebrates (Bees)

Risks to bees were assessed for the agricultural uses of certain pesticides in the Agency's *Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins*: bifenthrin, cyfluthrin, cyhalothrins, cypermethrin, 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. Both lambda- and gamma-cyhalothrin are registered for use on several bee-attractive crops, including those requiring managed pollinators. Since the cyhalothrins are not systemic, there is potential for exposure to bees foraging on crops when applications are made (via foliar spray while the crop is in bloom) or in adjacent areas that receive spray drift.

For lambda-cyhalothrin the full suite of Tier 1 honeybee toxicity data are now available (see **Table 9**) for lambda-cyhalothrin. A 2020 risk assessment³ concluded that there are acute risk concerns for adult bees (max contact RQ = 2.8; oral RQ = 1.4) and for larvae (max RQ = 17). There are also chronic risk concerns for adult bees (max RQ = 37) and larvae (max RQ = 110). From 2011-2016 there were 9 separate incidents involving bee kills or losses of entire colonies following applications of lambda-cyhalothrin (including registered uses or those with unknown legality). The certainty that these incidents were associated with lambda cyhalothrin applications were either probable or possible. Incident reports involved tens to thousands of affected hives. Given the risk concerns identified at the Tier 1 level for honey bees exposed to lambda-cyhalothrin, and the incident reports, additional higher-tier honey bee data (e.g., nectar and pollen residue data and/or semi-field studies at environmentally relevant concentrations; see

³ **Lambda-Cyhalothrin: Transmittal of Four Data Evaluation Records for Bee Toxicity Studies and Updated Tier I Bee Risk Assessment** can be found in EPA-HQ-OPP-2010-0480.

Table 9) would help to refine the understanding of potential exposure of bees to lambda-cyhalothrin and colony-level risk.

For gamma-cyhalothrin the full suite of Tier 1 honeybee toxicity data are not available. The 2016 risk assessment concluded that there is risk of acute exposures to adult bees (contact risk quotient (RQ) = 18; dietary RQ = 1.0). Chronic bee data are not available. There are no reported bee incidents for gamma-cyhalothrin. To better understand the risks of gamma-cyhalothrin to individual bees, it would be useful if the remainder of the full suite of Tier 1 toxicity data (i.e., acute larval (OECD TG 237), chronic larval (OECD GD 239) and chronic adult (OECD TG 245)) were submitted. Given that there are already Tier 1 risks identified for adult bees, higher tier toxicity data may also be needed for future risk assessments.

Table 9. Pollinator Data Requirements

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

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

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

2. Ecological Incidents

The Agency conducted a targeted search for pollinator and aquatic ecological incidents (covering fish and aquatic invertebrates) in 2016 and an updated search in November 2018 for the following chemicals: bifenthrin, permethrin, cypermethrin/zeta-cypermethrin, lambda/gamma-cyhalothrin, esfenvalerate, deltamethrin, fenpropathrin, pyrethrins, and cyfluthrin/beta-cyfluthrin. A subsequent search for additional pollinator and aquatic incidents was conducted in August 2019 for the chemicals above for new incidents since November 2018. The August 2019 search was also expanded to cover all pollinator/aquatic incidents reported for the following chemicals which were not covered under previous searches: alpha-cypermethrin, cyphenothrin, d-phenothrin, etofenprox, flumethrin, imiprothrin, momfluorothrin, prallethrin, tau-fluvalinate, tefluthrin, and tetramethrin. The results of the 2016 incidents search are summarized in 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”). **Table 10** summarizes the incidents from 1994 to August 2019 for lambda- and gamma-cyhalothrin.

Table 10. Summary of Pollinator, Fish, and Aquatic Invertebrate Incidents from 1994 to August 2019

Chemical Name	Total Number of Pollinator Incidents	Total Number of Aquatic Animal Incidents	Comments
Lambda-cyhalothrin	17	8	<ul style="list-style-type: none"> • 15 pollinator incidents resulted from exposure to chemical residue during foraging or from spray drift from nearby agricultural and residential use sites. • 2 pollinator incidents are from direct exposure to chemicals from applications in orchards and agricultural fields. • 8 aquatic incidents were caused by treated agricultural fields in close proximity.
Gamma-cyhalothrin	None	1	<ul style="list-style-type: none"> • 1 aquatic incident reported from suspected drift from an agricultural use site near an airport where a crop duster incident occurred. • No pollinator incidents were reported.

The Agency will continue to monitor ecological incident information as it is reported to the Agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

Given, that the Agency did not have sufficient information to fully assess the risk to bees or effects on honeybee colonies, EPA concludes that additional pollinator data are necessary to fully evaluate risks to bees from use of the pyrethroids/pyrethrins. The Agency has determined the full suite of pollinator studies for the pyrethroids/pyrethrins that may impact pollinators is necessary, where such data are not currently available. EPA will issue a Data Call-In (DCI) for the pollinator studies listed in **Table 9**. Given the large number of pyrethroid insecticides and expected similarity in their effects on bees, the Agency would consider a scientifically justified strategy for bridging effects and exposure data among pyrethroids.

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

Other than pollinator data, no additional ecological fate or effects data are anticipated to be needed to be called-in for the registration review of lambda- and gamma-cyhalothrin.

C. Benefits Assessment

Pyrethroids, including lambda- and gamma-cyhalothrin are widely used in agriculture to control a variety of pests that disrupt crop production as well as in urban pest control programs for several public-health and nuisance pests. In terms of the total acres treated and particularly in the variety of crops that depend on them, pyrethroids have now largely surpassed the organophosphate and carbamate classes as the options preferred by growers for cost-effective and broad-spectrum insect control. The rapid knockdown effect provided by cyhalothrins and other pyrethroids is a primary benefit for applicators because it prevents affected insect pests from feeding even before death occurs.

Both lambda- and gamma-cyhalothrin are recommended by university extension specialists to control numerous pests in a variety of settings that includes agricultural crops; barns, stables, housing, and other animal quarters, direct livestock applications; turfgrass and ornamentals; and structures (Townsend, 2012; North Dakota State University Extension, 2019; University of Arkansas Extension, 2020). Of the two cyhalothrins, gamma-cyhalothrin is generally recommended for a smaller subset of target pests in a smaller range of crops, as compared to lambda-cyhalothrin. Agricultural applicators may find lambda- and gamma-cyhalothrin to be useful tools as they provide broad-spectrum pest control (i.e., it affects pests in diverse taxa, from plant bugs, beetles, caterpillars, flies, and grasshoppers) that are often economically important and/or yield limiting (Grant et al., 2017; Haviland et al., 2019; North Dakota State University Extension, 2019; University of Arkansas Extension, 2020). For example, both lambda- and gamma-cyhalothrin are recommended for use in sunflower production and are among the market-leading insecticides used by growers targeting pests such as sunflower moth, sunflower stem and seed weevils, and grasshoppers (Cook et al., 2019; North Dakota State University Extension, 2019; University of Arkansas Extension, 2020).

Lambda-cyhalothrin is commonly recommended by university extension specialists for pest control in soybeans, corn and sweet corn, wheat, alfalfa, cotton, rice, tree nuts (e.g., walnut, pistachio), cucurbits (e.g., squash, cucumber), fruiting vegetables (e.g., tomatoes, peppers), brassica (e.g., cabbage, broccoli), celery, and lettuce and other leafy greens (Grant et al., 2017; Haviland et al., 2019; North Dakota State University Extension, 2019; University of Arkansas Extension, 2020). Within these crops, lambda-cyhalothrin is used to target a variety of economically important and/or disease vectoring pests and pest complexes including aphids, stink bugs, lygus and plant bugs, leafhoppers, caterpillars and borers, and weevils (Cook et al., 2019).

Generally, alternatives to either lambda- or gamma-cyhalothrin include other pyrethroids, carbamates, neonicotinoids, organophosphates spinosyns, diamides, in addition to insect growth regulators and various other chemistries. See *Usage Characterization and Qualitative Overview of Agricultural Importance for Pyrethroid Insecticides for Selected Crops and Impacts of Potential Mitigation for Ecological Risks* (Cook et al., 2019) for more detail.

Several products containing lambda- and gamma-cyhalothrin are recommended for use within animal quarters (e.g., poultry houses, stables, barns, dairy barns, kennels, bedding) in addition to direct applications to livestock (e.g., ear tags, pour-ons, capsules). Generally, for pest control within animal production, gamma-cyhalothrin is more commonly recommended to be used whereas lambda-cyhalothrin is more commonly recommended for direct livestock treatment (University of Arkansas Extension, 2020; Townsend). Both cyhalothrins are used for the control of several nuisance and/or mechanical vectors (e.g., face flies, stable flies, bed bugs, darkling beetles, lice) as well as disease-vectoring pests (e.g., fleas, ticks) (Townsend, 2012; University of Arkansas Extension, 2020). The suitability of specific alternatives to the cyhalothrins depend on the target pest and application method which may be used. These alternatives include other pyrethroids and pyrethrins, carbamates (e.g., methomyl), diflubenzuron, methoprene, neonicotinoids (e.g., dinotefuran, imidacloprid), organophosphates (e.g., coumaphos, DDVP, tetrachlorvinphos, trichlorfon), and spinosad. Additionally, fly traps and sanitation or exclusion practices may reduce or control pest populations.

The cyhalothrins are also used within structures such as mills, granaries, processing facilities, and warehouses or as perimeter treatments to protect stored and processed goods from damage against insects such as beetles, cockroaches, and moth larvae. The cyhalothrins are one of several insecticides registered for such uses. Other examples include fumigants such as sulfuryl fluoride and phosphine, other pyrethroids such as cyfluthrin, insect growth regulators (methoprene), and organophosphates (malathion).

Additionally, the cyhalothrins are used in indoor and outdoor settings that include residential and commercial buildings as well as lawns and gardens to control various nuisance and public health pests. For all these uses, while the cyhalothrins 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 such as organophosphates (e.g., malathion), carbamates (e.g., carbaryl), and neonicotinoids (e.g., imidacloprid) are available for outdoor uses. For indoor uses, hydramethylnon, indoxacarb, and boric acid can control many of the pests targeted by the cyhalothrins.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed Human Health Risk Mitigation and Regulatory Rationale

As discussed in Section III.B, the proposed mitigation outlined in this PID will only address the human health risks. The required ecological risk mitigation measures are discussed in Section IV.B and Appendix B.3. of this PID. As stated earlier, these measures are not open for public comment.

The Agency identified potential human health risks from residential and occupational exposures from the use of products containing lambda- and gamma-cyhalothrin. Proposed mitigation measures to address the residential risks include: removal of uses, removal of certain application methods, and addition of mandatory and advisory spray drift management measures. Proposed

mitigation measures to address the occupational risks include: removal of certain application methods (mostly the use of handheld equipment), addition of PPE (gloves, double layer clothing, a PF10 respirator, and engineering controls). The Agency considered the usage of and benefits from the use of products containing lambda- and gamma-cyhalothrin in developing the mitigation measures to address the risks to occupational handlers.

The Agency discussed the proposed human health mitigation with the technical registrants of lambda- and gamma-cyhalothrin. The technical registrants for lambda- and gamma-cyhalothrin did not completely agree with the proposed mitigation measures for the chemicals and raised questions regarding the parameters the Agency used in the risk assessment. They plan to submit comments on the PID during the comment period.

1. Removal of Uses⁴

Lambda-cyhalothrin

EPA identified risks to adults and children resulting from post application of products containing lambda-cyhalothrin on mattresses and on residential lawns and turfs. To mitigate these risks, EPA is proposing to cancel the use of lambda-cyhalothrin on mattresses and residential lawns and turfs.

Gamma-cyhalothrin

EPA identified risks to residential handlers and to adults and children during and post-application of products containing gamma-cyhalothrin to gardens and trees, and lawn and turf. To mitigate the risk, EPA is proposing to cancel the use of gamma-cyhalothrin in/on outdoor residential areas.

The Agency has not conducted an analysis for either cyhalothrin on the impacts of these proposed mitigation measures. Therefore, the Agency encourages comments on likely impacts on pest management, the efficacy of available alternatives, etc. to help the Agency better understand the effect of these use site removals.

2. Prohibiting Application Methods

Lambda-cyhalothrin

To mitigate the risks to children from post application of products containing lambda-cyhalothrin to carpets by pin-stream or coarse spot application, EPA is proposing to prohibit these application methods to carpets.

EPA is also proposing to prohibit the following application methods to mitigate the risks to occupational handlers (mixers/loaders/applicators) (see *Table 11*). These scenarios continued to

⁴ If finalized, this action will require registrants submit a request to cancel their affected registrations in accordance with Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)).

be risks of concern even with the addition of doubler layer clothing, gloves, and a PF-10 respirator, the highest level of PPE applicable to them (see **Table 1**).

Table 11. Lambda-Cyhalothrin Proposed Mitigation M/L/A - Prohibit Application Method on Use Site

M/L/A Exposure Scenario – Proposed Mitigation: Prohibit Application Method on Use Site	
1	Liquid, backpack, foliar spray on nurseries (ornamentals, vegetables, trees, container stock)
2	Liquid, backpack, broadcast spray landscaping, turf
3	Liquid, mechanically pressurized handgun, broadcast (foliar) on orchards and vineyards
4	Liquid, mechanically pressurized handgun, drench/soil/ground direct on orchard and vineyard
5	Liquid, mechanically pressurized handgun, broadcast spray in greenhouses (ornamentals, cut flowers, roses, container stock, vegetables)
6	Liquid, mechanically pressurized handgun, soil/ground direct in greenhouse (ornamentals, cut flowers, roses, container stock, vegetables)
7	Liquid, mechanically pressurized handgun, broadcast (foliar) on nurseries (ornamentals, vegetables, trees, container stock)
8	Liquid, mechanically pressurized handgun, drench/soil/ground direct on nurseries (ornamentals, vegetables, trees, container stock)
9	Liquid, mechanically pressurized handgun, broadcast spray on industrial/commercial (tires, rail, yards, junk yards, etc.)
10	Liquid, mechanically pressurized handgun, broadcast (foliar) on typical field crop uses

Gamma-cyhalothrin

To mitigate the risks to children from post application of products containing gamma-cyhalothrin to carpets by pin-stream or coarse spot application, EPA is proposing to prohibit these application methods to carpets. EPA is also proposing to prohibit the pin stream or coarse spot application to hard flooring to mitigate the short-term aggregate risk of concern.

EPA is also proposing to prohibit certain application methods (see **Table 12** and **Table 13**) to mitigate the risks to occupational handlers (mixer/loader and mixer/loader/applicator). These scenarios continued to be risks of concern even with the addition of highest level of PPE applicable to them (for mixer/loader, engineering control; for mixer/loader/applicator, double layer clothing, gloves, and respirator) (see **Table 2** and **Table 3**).

Table 12. Gamma-Cyhalothrin Proposed Mitigation M/L - Prohibit Application Method on Use Site

M/L Risk of Concern – Proposed Mitigation: Prohibit of Application Method on Use Site	
1	Liquid, aerial, broadcast to high-acreage field crops

Table 13. Gamma-Cyhalothrin Proposed Mitigation M/L/A - Removal of Application Method on Use Site

M/L/A Risks of Concern – Proposed Mitigation: Removal of Application Method on Use Site	
1	Liquid, backpack, ground/soil-directed to orchard/vineyard
2	Liquid, mechanically pressurized handgun, broadcast (foliar) to orchard/vineyard
3	Liquid, mechanically pressurized handgun, drench/soil/ground-directed to orchard/vineyard
4	Liquid, backpack, broadcast to forestry
5	Liquid, mechanically pressurized handgun, broadcast (foliar) to nursery (ornamentals, vegetables, trees, container stock)
6	Liquid, mechanically pressurized handgun, drench/soil/ground directed to nursery (ornamentals, vegetables, trees, container stock)
7	Liquid, backpack, broadcast (foliar) to landscaping, trees/shrubs/bushes
8	Liquid, mechanically pressurized handgun, broadcast (foliar) to landscaping, trees/shrubs/bushes
9	Liquid, backpack, broadcast (foliar) to landscaping, plants/flowers

The Agency has not conducted an analysis for either cyhalothrin on the impacts of these proposed mitigation measures. Therefore, the Agency encourages comments on likely impacts on pest management, the efficacy of available alternatives, etc. to help the Agency better understand the effect of the removal of these application methods.

3. PPE for Occupational Handlers

Lambda-cyhalothrin

EPA is proposing to require additional PPE to mitigate the risks to occupational handlers performing activities specified in **Table 14** (see also **Table 1**). EPA identified two risks of concern that can be mitigated with the addition of double layer clothing and gloves, and eight with the addition of gloves and a PF10 respirator.

Table 14. Lambda-Cyhalothrin Proposed Mitigation M/L/A - Additional PPE

M/L/A Risks of Concern – Proposed Mitigation: Additional PPE	
<i>Addition of Double Layers + Gloves (DL+G)</i>	
1	Liquid, backpack, spot treatment for landscaping turf (lawns, athletic fields, parks, etc.)
2	Liquid, mechanically pressurized handgun, foliar for landscaping trees and shrubs
<i>Addition of Gloves + PF10 Respirator (G+PF10R)</i>	
1	Liquid, manually pressurized handwand, broadcast spray in food handling establishments
2	Liquid, manually pressurized handwand, crack and crevice in food handling establishments
3	Liquid, manually pressurized handwand, broadcast spray in warehouses
4	Liquid, manually pressurized handwand, crack and crevice in warehouses
5	Liquid, manually pressurized handwand, broadcast spray in residential living spaces (homes, apartments)
6	Liquid, manually pressurized handwand, crack and crevice in residential living spaces (homes, apartments)

M/L/A Risks of Concern – Proposed Mitigation: Additional PPE	
7	Liquid, manually pressurized handwand, broadcast spray passes to structural components (walls, framing voids, slabs, beams, lumber, etc.)
8	Liquid, manually pressurized handwand, broadcast spray to childcare centers/schools/institutions
9	Liquid, mechanically pressurized handgun, broadcast sprays in warehouses
10	Liquid, mechanically pressurized handgun, broadcast spray to structural components (walls, framing voids, slabs, beams, lumber, etc.)
11	Liquid, mechanically pressurized handgun, broadcast spray in barn/feedlot

Gamma-cyhalothrin

EPA is proposing to require additional PPE to mitigate the risks to occupational handlers performing activities specified in **Table 15**, **Table 16**, and **Table 17** (see also **Table 2**, **Table 3**, and **Table 4**). EPA identified seven risks of concern that can be mitigated with the addition of engineering control, and ten with the addition of gloves and a PF10 respirator.

Table 15. Gamma-Cyhalothrin Proposed Mitigation M/L - Additional PPE

M/L Risks of Concern: Proposed Mitigation – Additional PPE	
<i>Addition of Engineering Controls (EC)</i>	
1	Liquid, aerial, broadcast to orchard/vineyard
2	Liquid, chemigation, broadcast to orchard/vineyard
3	Liquid, aerial, broadcast to typical field crop
4	Liquid, chemigation, broadcast to typical field crop
5	Liquid, chemigation, broadcast to high acreage field crop
6	Liquid, groundboom, broadcast to high acreage field crop
<i>Addition of Gloves + PF10 Respirators (G+PF10R)</i>	
1	Liquid, aerial, broadcast to forestry

Table 16. Gamma-Cyhalothrin Proposed Mitigation, M/L/A - Additional PPE

M/L/A Risks of Concern: Proposed Mitigation – Additional PPE	
<i>Addition of Gloves + PF10 Respirators (G+PF10R)</i>	
1	Liquid, mechanically pressurized handgun, broadcast to greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)
2	Liquid mechanically pressurized handgun, drench/soil/ground directed to greenhouse (ornamentals, roses, cut flowers, container stock, vegetables)
3	Liquid, backpack, broadcast to landscaping, turf (lawns, athletic fields, parks, etc)

M/L/A Risks of Concern: Proposed Mitigation – Additional PPE	
4	Liquid, backpack, broadcast (foliar) to nursery (ornamentals, vegetables, trees, container stock)
5	Liquid, manually pressurized handwand, broadcast to warehouse
6	Liquid, manually pressurized handwand, crack & crevice to warehouse
7	Liquid, manually pressurized handwand, crack & crevice to residential living spaces (homes, apartments)
8	Liquid, mechanically pressurized handgun, broadcast to warehouse
9	Liquid, backpack, broadcast spray to nursery

Table 17. Gamma-Cyhalothrin Proposed Mitigation, Applicator – Additional PPE

Applicator Risks of Concern: Proposed Mitigation – Additional PPE	
<i>Addition of Engineering Controls (EC)</i>	
1	Spray (all starting formulations), airblast, broadcast to orchard and vineyard
<i>Addition of Gloves + PF10 Respirator (G+PF10R)</i>	
1	Spray (all starting formulations), groundboom, broadcast to high acreage field crop

Impacts – Addition of respirator

EPA requires fit testing, training, and medical evaluations⁵ for all handlers who are required to wear respirators and whose work falls within the scope of the WPS.⁶ If a lambda- or gamma-cyhalothrin handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler’s employer, which includes the cost of the respirator plus, for WPS-covered products, the cost for a respirator fit test, training, and medical exam.

Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Based on available information that EPA has, the cost of the respirators (whether disposable or reusable) is relatively minor in comparison to the fit-test requirement under the Worker Protection Standard. The Agency expects that the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. The cost of a respirator fit test, training and medical exam was estimated to about \$180 annually in 2015 (US EPA, 2015). Alternatively, users could hire a commercial firm to make applications or use other products. However, if a lambda-cyhalothrin handler typically uses other chemicals requiring a respirator in the production system or as part of the business, additional fit testing is not needed. The handler or employer may only incur the cost of purchasing filters for the respirator on a more frequent

⁵ Fit testing, training, and medical evaluations must be conducted according to OSHA regulations 29 CFR § 1910.134, 29 CFR § 1910.134(k)(1)(i) through(vi), and 29 CFR § 1910.134, respectively.

⁶ 40 CFR 170 (see also Appendix A of Chapter 10 of the Label Review Manual, available at <https://www.epa.gov/pesticide-registration/label-review-manual>)⁷ 29 CFR § 1910.134

basis. Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection.⁷

EPA acknowledges that requiring a respirator and the associated fit testing, training, and medical evaluation places a burden on handlers or employers. However, the proper fit and use of respirators is essential to accomplish the protections respirators are intended to provide. In estimating the inhalation risks, and the risk reduction associated with different respirators, EPA's human health risk assessments assume National Institute for Occupational Safety and Health (NIOSH) protection factors (*i.e.*, respirators are used according to OSHA's standards). If the respirator does not fit properly, use of lambda- and gamma-cyhalothrin may cause unreasonable adverse effects on the pesticide handler.

4. Update of Gloves and Respirator Language

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

For labels that currently have respirator statement, the Agency is proposing to update the respirator statement. The proposed new respirator language does not fundamentally change the personal protective equipment that workers needs to use, and therefore should impose no impacts on users if a respirator is already required on the label.

5. Use of Human Flaggers in Aerial Application

EPA identified risks to flaggers in aerial applications of products containing gamma-cyhalothrin to orchards, vineyards, and field crops. To mitigate this risk, EPA is prohibiting the use of human flaggers when making aerial applications of products containing gamma-cyhalothrin. EPA has heard from industry groups previously that the use of human flaggers in aerial applications is not a common practice anymore. Therefore, the Agency expects minimal impacts from this prohibition.

6. Re-Entry Intervals (REI)

EPA is proposing re-entry intervals (REIs) for both lambda- and gamma-cyhalothrin based on the post-application risks identified for several crops as specified in *Table 18* and *Table 19* (see also *Table 6* and *Table 7*). EPA is proposing REI restrictions on more crops and for longer durations for gamma-cyhalothrin than for lambda-cyhalothrin. As discussed in Section III.C,

⁷ 29 CFR § 1910.134

gamma-cyhalothrin is generally recommended for a smaller subset of target pests in a smaller range of crops, as compared to lambda-cyhalothrin.

The Agency has not assessed the impact to growers from an increased REI for these crops. For an REI of 48 hours or more, there may be impacts due to posting requirements of the Worker Protection Standard (US EPA, 2015). The requirement to post and remove signage around the perimeter of the treated field will result in direct increases in time and labor costs and will likely decrease the ease of use of lambda- and gamma-cyhalothrin. Longer REIs also limit grower access to the crop for other crop maintenance activities and may result in the use of lambda- and gamma-cyhalothrin becoming infeasible for a grower of certain crops. However, given the current low usage of gamma-cyhalothrin and grower access to effective alternatives, the impacts may be limited or low to the majority of growers. Due to the uncertainties, the Agency encourages comments on any impacts to growers from the implementation of the proposed REIs.

Table 18. Proposed REI for Lambda-Cyhalothrin

Crop	Proposed REI (days)
Apple	2
Corn, sweet grain	5
Nectarine	7
Pear	8
Plum, prune	9

Table 19. Proposed REI for Gamma-Cyhalothrin

Crop	Proposed REI (days)
Almond	15
Apple	30
Apricot	30
Bean, snap	30
Blackberry	30
Broccoli	30
Brussels Sprouts	30
Chinese cabbage, bok choy	30
Chinese cabbage, napa	30
Cauliflower	30
Cherry	30
Corn, pop	30
Corn, sweet grain	30
Corn, processing	30
Eggplant	30
Fig	26
Hazelnut	15
Macadamia nut	15

Crop	Proposed REI (days)
Onion, bulb	30
Onion, green	30
Pepper, bell	30
Tomato	30
Tomato, processing	30
English walnut	15

7. Spray Drift Management

The Agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all lambda- and gamma-cyhalothrin products. Reducing spray drift will reduce the extent of environmental exposure and risk to non-target plants and animals. Although the Agency is not making a complete 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 of lambda- and gamma-cyhalothrin.

The Agency is proposing the following spray drift mitigation language to be included on all lambda- and gamma-cyhalothrin product labels for products applied by liquid spray. The proposed spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The Agency is also providing recommendations which allow lambda- and gamma-cyhalothrin registrants to standardize all spray drift advisory language on lambda- and gamma-cyhalothrin product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements proposed in this PID, once they are in effect.

- Applicators must not spray during temperature inversions.
- For aerial applications, do not apply when wind speeds exceed 10 miles per hour at the application site. The boom length must not exceed 75% of the wingspan for airplanes or 90% of the rotor blade diameter for helicopters.
- For aerial applicators, applicators must use ½ swath displacement upwind at the downwind edge of the field.
- For aerial applications, the release height must be no higher than 10 feet from the top of the crop canopy or ground, unless a greater application height is required for pilot safety.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- For ground and aerial applications, select nozzle and pressure that deliver Medium or coarser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572 (ASABE S572).
- For air blast applications, nozzles directed out of the orchard must be turned off in the outer row.

- For air blast applications, applications must be directed into the canopy foliage.

In addition to including the spray drift restrictions on lambda- and gamma-cyhalothrin labels, all references to volumetric mean diameter (VMD) information for spray droplets are proposed to be removed from all lambda- and gamma-cyhalothrin labels where such information currently appears. The proposed new language above, which cites ASABE S572, eliminates the need for VMD information.

The Agency acknowledges that there will be impacts to growers from spray drift restrictions. Potential impacts are discussed below.

Release height. EPA does not expect the requirements for release height to impact users since they largely correspond to current practice and crop expert recommendations.

Droplet size. 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. Aspects of insecticide applications that can affect efficacy (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 application rates, mix the cyhalothrins 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 get with finer droplet sizes.

Wind speed. The application wind speed restriction of no greater than 10 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 requirements 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.

8. Water Soluble Packaging

The Agency is also proposing to include instructions for products with water soluble packaging (WSP). The EPA sent these instructions to registrants of products with WSP in April 2017; therefore, the inclusion of these instructions in this PID does not impose additional requirements.

These instructions are intended to make sure that products with WSP are handled properly to protect handlers from exposure, as was the original intent of the technology.

B. Required Ecological Risk Mitigation and Regulatory Rationale

As discussed previously, the ecological risk mitigation is not open for public comment.

The Agency identified potential risks for various taxa (freshwater and terrestrial invertebrates, and fish). For lambda-cyhalothrin, risks of concern were identified for aquatic invertebrates, and freshwater and estuarine/marine fish from indoor down-the-drain, residential, commercial, turf, nursery (ornamental) and agricultural uses. For gamma-cyhalothrin, risks of concern were identified for aquatic invertebrates from residential, commercial, turf, and nursery (ornamental and 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 this use pattern, the wastewater that goes down-the-drain contains pyrethroid residues and is treated in wastewater treatment plants (WWTPs) or publicly owned treatment works (POTWs) and then discharged to waterbodies. A portion of the pyrethroid residues remains in the water discharged to the outdoor waterbodies and results in potential risks to aquatic invertebrates and fish. Mitigation to address risks from the indoor use of products containing these chemicals focuses on reducing the amount of residues being poured down the drain. The potential ecological risks, which are expected to be reduced with the mitigation, are outweighed by the high benefits associated with the use of pyrethroids for the control of pests with public health significance.

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

Agricultural uses of the pyrethroids are expected to result in potential risks of concern to aquatic invertebrates and fish, primarily from runoff and spray drift. However, the benefits of pyrethroids in agricultural crop production outweigh the risks, and the necessary mitigation is expected to allow continued use of pyrethroids in agricultural settings while putting reasonable measures in place to reduce risk to non-target organisms from runoff and spray drift. The VFS requirement has been expanded in some cases but the Agency has added flexibility for Western irrigated agriculture and areas where soil conservation practices are being used. The Agency has

also identified potential risks of concern to terrestrial invertebrates from the foliar applications of pyrethroids in agricultural areas. The Agency has determined that mitigation to address potential terrestrial invertebrate risks is necessary and has revised the terrestrial invertebrate Environmental Hazard Statement, adding information on stewardship and best management practices, promoting State Managed Pollinator Protection Plans (MP3s), and adding information on Pollinator Incident Reporting.

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 lambda- and gamma-cyhalothrin labels is necessary, where applicable.

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

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

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

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

a) Indoor and Outdoor Use Site Clarification

Label language must explicitly state whether the product is allowed to be applied indoors only, outdoors only, or both indoors and outdoors. For example, label text for a product that is only used indoors could state, "For indoor use only."

For applications to pets, the label must have the following statement to ensure products are applied indoors.

- "Application of product on pets must only be done indoors."

b) Disposal/Stewardship Statement and Pictogram

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

- “Do not pour or dispose down the drain or sewer. Call your local solid waste agency for local disposal options.”

Include a pictogram of an image of a diagonal strikethrough over a drain on all end-use consumer product containers. Place pictogram in a prominent location. The pictogram must be legible (i.e. no smaller than 1.5 square centimeters or .25 square inch unless this size is greater than 10% of the size of the label). Below is an example graphic of an indoor drain image:



c) Advisory Statements

Labels must include the following statements on all end-use consumer product containers in a prominent location. The only exception is for pet products, as residues from these products may be expected to be released down indoor or outdoor drains as a result of standard pet care:

- “Do not allow to enter indoor or outdoor drains.” and also include the Spanish translation, “No permita la entrada a desagües internos o externos.” For products with down-the-drain uses, use the following variation - “Do not allow to enter indoor or outdoor drains unless labeled for drain treatments.” and the Spanish translation, “No permita la entrada a desagües internos o externos a menos que el etiquetado indique que está permitido el uso del producto para tratamiento de desagües.”
- “Follow proper disposal procedures on this label.” and also include the Spanish translation, “Siga las indicaciones del etiquetado para el desecho apropiado del producto.”

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

2. Mitigation Measures for Outdoor Urban Uses

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

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

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

a) Statements for Outdoor Label Consistency and Clean-up

The Agency has determined that several label changes for consistency with other products and current policy (e.g., EPA's January 10, 2013 letter *Revisions to Environmental Hazard and General Labeling for Pyrethroid Non-Agricultural Outdoor Products*) is necessary. Labels must explicitly say whether particular products are to be applied indoors only, outdoors only, or both indoors and outdoors (as described in the previous section).

b) Revised General Outdoor Application Statement

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

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

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

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

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

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

c) Spot Treatment Guidance Statement

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

d) Buffer from Water Statement

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

e) Water Protection Statements

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

f) Rain-Related Statements

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

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

g) Statements for Ornamental/Recreational Turf

- “Do not apply when the wind speed is greater than 10 mph.”

h) Statements for Outdoor Applications at Commercial Nurseries

- “Do not apply when the wind speed is greater than 10 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 10 mph for these industry sectors; however, it is likely to decrease the number of days available for applications. However, high wind speeds interfere with proper dispersion of the pesticide, so relatively few applications may be affected by the prohibition.

The Agency does not know how efficacy may be impacted when droplet sizes are determined to be necessary for various insecticides in commercial nurseries. Pyrethroids are contact insecticides which require thorough coverage of the treated surface for effective pest control. University extension recommendations for contact insecticides such as pyrethroids are for ASABE droplet sizes of fine to medium (Wolf and Bretthauer, 2009⁸). For foliar applications, insect control would likely be negatively impacted given the requirement for a medium or larger droplet size. Growers may be driven to use higher rates, mix with another insecticide, make additional applications per season, or increase application volume with larger droplet sizes to achieve the same efficacy they were able to with finer droplet sizes. However, many pyrethroid products are already subject to droplet size restrictions and buffers to water bodies, so impacts may be limited.

i) Statements for Crack and Crevice Treatments

- “Treat surfaces to ensure thorough coverage but avoid runoff.”
- “To treat insects harbored in voids and cracks-and-crevices, applications must be made in such a manner to limit dripping and avoid runoff onto untreated structural surfaces and plants.”

3. Mitigation Measures for 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 necessary. EPA is concerned that sediment from agricultural land, with which pyrethroids bind, erodes into aquatic habitats exposing aquatic organisms susceptible to these pesticides. Pyrethroid monitoring data have been collected in water and sediment across the United States, with pyrethroid detections widespread that are directly related to agricultural uses. Data supported by the PWG and USDA have shown that VFS can be an effective method of reducing sediment transport into aquatic systems when designed with field specific factors and are well maintained. EPA concludes that the expansion of the VFS size along 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

⁸ Wolf, R., and S. Bretthauer. 2009. Droplet Size Calibration: A New Approach to Effective Spraying. Kansas State University Agricultural Experiment Station and Cooperative Extension Service. MF 2869.
<https://www.bae.ksu.edu/faculty/wolf/PDF/MF2869%20Droplet%20Calibration.pdf>

flexibility will still reduce risk to aquatic organisms while better preserving the agriculture benefits pyrethroids provide.

Currently, all pyrethroid products, except etofenprox and pyrethrins, already have a 10-foot VFS requirement on the labels. VFSs are somewhat expensive to implement and maintain, and they must be maintained or they will lose efficacy and cause channelized flow across the VFS after a few years. VFS are most effective at removing non-source point pollutants (e.g., pesticides) from runoff water sources. However, the effectiveness of a VFS is influenced by various land management practices (e.g., flood and furrow irrigated fields) which may impact their utility.⁹ 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-foot VFS are: areas considered prime farmland, areas where conservation tillage is implemented, areas with a functional terrace system, areas where water and sediment control basins are present and maintained, and areas that are less than or equal to 10 acres. Prime farmland, as defined in 7 CFR § 657.5, is not excessively erodible and pyrethroids binding to soil particles are less likely to enter adjacent waterways. Conservation tillage also works to reduce soil erosion, because remaining crop residues remain on the field. Terrace farming and the presence of water and sediment control basins also reduce soil erosion. Additionally, based on public comments on the Ecological Risk Mitigation Proposal, the VFS requirement is reduced to 15 feet, if the area of application is less than or equal to 10 acres—this reduces the impact on small-scale operations that are not primary contributors to runoff. These added criteria for a reduced VFS are intended to allow more flexibility for stakeholders.

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

Since sediment control basins may be installed in Western irrigated agriculture to collect runoff and improve drainage, and may fulfill similar functions as a VFS, the Agency revised the VFS requirement for Western irrigated agriculture: if a functioning sediment control basin is already present, the Agency has determined that creating or maintaining a 10 foot VFS will no longer be

⁹ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0331-0175>

necessary. In many situations a sediment control basin is as effective at controlling runoff and erosion for this type of agriculture. EPA decided to promote the use of sediment control basins for Western irrigated agriculture by allowing growers in these areas to use sediment control basins in lieu of creating and maintaining a VFS when pyrethroids are used. This exception will also reduce the amount of water Western growers will be required to use to maintain a VFS.

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

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

Only apply products containing (name of pyrethroid) onto fields where a maintained vegetative filter strip of at least 25 feet exists between the field edge and where a down gradient aquatic habitat exists. This minimum required width of 25 feet may be reduced or removed under the following conditions:

For Western irrigated agriculture, a maintained vegetative filter strip of at least 10 feet wide is required. Western irrigated agriculture is defined as irrigated farmland in the following states: WA, OR, CA, ID, NV, UT, AZ, MT, WY, CO, NM, and TX (west of I-35).

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

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

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

Rice fields are not required to have a vegetative filter strip.

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 disproportionately 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.¹⁰

These additional costs could lead growers to substitute an alternative insecticide to replace pyrethroids. If the necessary mitigation prevent growers from using pyrethroids, they will most likely replace pyrethroid applications with other insecticides, such as organophosphates and

¹⁰ Lynch and Tjaden, 2003 and Solano and Yolo Co. Resource Conservation. Dist., 2006

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

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).

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

4. 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 necessary:

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

a) Pollinator Environmental Hazard

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

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

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

b) Pollinator Stewardship – Promoting Pollinator Best Management Practices

In addition to establishing both advisory and compulsory language for product labels, EPA's registration review process provides an opportunity to inform stakeholders and the general public about opportunities to minimize potential ecological risks and promote pollinator health more generally. Beyond the necessary mitigation measures above, voluntary stewardship activities and use of best management practices (BMPs)¹¹ 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;

¹¹ <https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-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 webpage¹².

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

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

Other things the public can do to minimize potential exposure of pollinators are listed on EPA's *What You Can Do to Protect Honey Bees and Other Pollinators* webpage.¹³

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.

¹² <https://www.epa.gov/pollinator-protection>

¹³ <https://www.epa.gov/pollinator-protection/what-you-can-do-protect-honey-bees-and-other-pollinators>

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

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

c) Promoting State Managed Pollinator Protection Plans (MP3s)

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

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

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

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

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

d) Pollinator Incident Reporting

EPA considers incident reporting data as a line of evidence to inform pesticide regulatory decisions. Information from these reports can help the Agency identify patterns of bee kills associated with specific uses and specific pesticides or classes of pesticides. EPA has determined that adding incident reporting information to pyrethroid/pyrethrin labels to encourage users to report bee kill incidents to the Agency is necessary. This language is only required for pyrethroid

and pyrethrins labels with foliar agricultural uses and excludes products formulated for residential use and Ultra Low Volume (ULV) wide area mosquito control applications, which will be indicated in the label clarifications column of the label table.

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

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

5. Insecticide Resistance Management

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

EPA has determined that resistance-management labeling, as listed in Appendix B, for products containing esfenvalerate is necessary in order to provide pesticide users with easy access to important information to help end users delay or even avoid the development of resistance and maintain the effectiveness of useful pesticides. Additional information on EPA’s guidance for resistance management can be found at the following website: <https://www.epa.gov/pesticide-registration/prn-2017-1-guidance-pesticide-registrants-pesticide-resistance-management>.

C. Tolerance Actions

Tolerances for residues of lambda- and gamma-cyhalothrin are currently established under 40 CFR §180.438. Section III.A.3 discusses the recommended revisions to the tolerance levels and expressions for both chemicals. The Agency will use its FFDCA rulemaking authority to make the needed changes to the tolerances.

D. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the Agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the Agency has made the following proposed interim decision: (1) pollinator data is required; 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.

In this PID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of lambda- and gamma-cyhalothrin, nor is it making a complete endangered species finding. Although the Agency is not making a complete endangered species finding at this time, the proposed 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 lambda- and gamma-cyhalothrin. The Agency's final registration review decision for lambda- and gamma-cyhalothrin 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.

E. Data Requirements

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

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for lambda- and gamma-cyhalothrin and will allow a 60-day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the Agency to change its proposed interim decision, EPA may issue an interim registration review decision for lambda- and gamma-cyhalothrin. However, a final decision for lambda- and gamma-cyhalothrin may be issued without the Agency having previously issued an interim decision. A final decision on the lambda- and gamma-cyhalothrin 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 lambda- and gamma-cyhalothrin 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 60 days following issuance of the Interim Registration Review Decision in the docket.

VI. References

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Appendix A.1. Summary of Proposed Actions for Lambda-Cyhalothrin to Address the Human Health Risks

Registration Review Case#: 7408 (Lambda-Cyhalothrin) PC Code: 128897 Chemical Type: Insecticide Chemical Family: Pyrethroid Mode of Action: axonic excitotoxins (alter nerve function)						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment
Children 1-2 years old	Residential post application Residue	Ingestion Dermal	Chronic	- Neurotoxicity - Decreased body weight	Remove certain indoor and outdoor uses Prohibit certain application methods	
Adults	Residential post application Air – high contact lawn activity	Dermal	Chronic	- Neurotoxicity - Decreased body weight	Remove certain outdoor uses	
Bystander - Children 1-2 years old	Air Residues	Dermal Incidental Oral Inhalation	Acute toxicity	- Neurotoxicity - Decreased body weight	Require mandatory spray drift mitigation measures	
Bystander - Adults	Air Residues	Dermal Inhalation	Acute toxicity	- Neurotoxicity - Decreased body weight	Require mandatory spray drift mitigation measures	
Occupational Handler	Air Soil Residues	Inhalation Dermal	Acute Chronic	- Neurotoxicity - Decreased body weight	Prohibit certain application methods Require additional PPE	
Occupational Handler Post-application	Residue	Dermal Inhalation	Acute Chronic	- Neurotoxicity - Decreased body weight	Adjust REI for certain crops.	

Appendix A.2. Summary of Proposed Actions for Gamma-Cyhalothrin to Address the Human Health Risks

Registration Review Case#: 7437 (Gamma-Cyhalothrin) PC Code: 128807 Chemical Type: Insecticide Chemical Family: Pyrethroid Mode of Action: axonic excitotoxins (alter nerve function)						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment
Residential Handler	- Air - Residue	- Inhalation - Dermal	- Chronic	- Neurotoxicity - Decreased body weight	- Remove certain outdoor uses	
Children 1-2 years old	- Residential post-application - Residue	- Dermal - Ingestion	- Chronic	- Neurotoxicity - Decreased body weight	- Remove certain indoor and outdoor uses - Prohibit certain application methods	
Children 6-11 years old	- Residential post-application - Residue	- Dermal	- Chronic	- Neurotoxicity - Decreased body weight	- Remove certain outdoor uses	
Adults	- Residential post-application - Residue	- Dermal	- Chronic	- Neurotoxicity - Decreased body weight	- Remove certain outdoor uses	
Bystander - Children 1 to 2 years old	- Air - Residues	- Dermal - Incidental oral	- Chronic	- Neurotoxicity - Decreased body weight	- Require mandatory spray drift mitigation measures	
Bystander - Adult	- Air - Residues	- Dermal	- Chronic	- Neurotoxicity - Decreased body weight	- Require mandatory spray mitigation measures	
Occupational Handler	- Air - Liquid	- Dermal - Inhalation	- Acute - Chronic	- Neurotoxicity - Decreased body weight	- Prohibit certain handheld application methods - Require additional PPE - Prohibit use of human flaggers	

Registration Review Case#: 7437 (Gamma-Cyhalothrin) PC Code: 128807 Chemical Type: Insecticide Chemical Family: Pyrethroid Mode of Action: axonic excitotoxins (alter nerve function)						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment
Occupational Handler Post-application	- Residue	- Dermal - Inhalation	- Acute - Chronic	- Neurotoxicity - Decreased body weight	- Adjust REI for certain crops.	

Appendix A.3. Summary of Required Actions for Lambda- and Gamma- Cyhalothrin to Address the Ecological Risks

Appendix A.3 is not open for public comment.

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions
Aquatic invertebrates	<ul style="list-style-type: none"> • Water (non-dietary) • Residues (at/on site of treatment) 	<ul style="list-style-type: none"> • Contact • Ingestion 	<ul style="list-style-type: none"> • Acute • Sub-chronic • Chronic 	<ul style="list-style-type: none"> • Growth survival • Mortality 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Water (non-dietary) Residues (at/on site of treatment) 	<ul style="list-style-type: none"> • Contact • Ingestion 	<ul style="list-style-type: none"> • Acute • Sub-chronic • Chronic 	<ul style="list-style-type: none"> • Growth survival • Mortality 	<ul style="list-style-type: none"> • 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

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions
Pollinators	<ul style="list-style-type: none"> • Residues (at/on site of treatment) 	<ul style="list-style-type: none"> • Contact • Ingestion 	<ul style="list-style-type: none"> • Acute 	<ul style="list-style-type: none"> • Mortality 	<ul style="list-style-type: none"> • Stewardship information • Incident reporting information • Pollinator data requirements

Appendix B.1. Proposed Labeling Changes for Lambda-Cyhalothrin Products

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	Technical Products	
Removal of Uses	Delete the following use sites from the labels: <ul style="list-style-type: none"> • Outdoor uses on residential lawns and turf • Indoor uses on mattresses 	
	End-Use Products	
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Updated Respirator Language	<p>For labels that currently have respirator language, update the language to the following:</p> <p>For respiratory protection from particulates only (low volatility), use the following language:</p> <p>“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.”</p> <p>*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.</p> <p>For respiratory protection from organic vapor and particulates (or aerosols), use the following language:</p> <p>“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</p>	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p>NIOSH-approved gas mask with OV canisters; <u>OR</u> a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters.”</p> <p>For respiratory protection from organic vapor only, use the following language:</p> <p>“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.”</p> <p>*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.</p>	
<p>Addition of PPE for Products with the Following Use Sites:</p> <ul style="list-style-type: none"> • Landscaping turf • Landscaping trees and shrubs • Food handling establishments • Warehouses • Residential living spaces • Childcare centers/schools/institutions • Structural components • Barn/feedlot 	<p>Note to registrant - If your label has any of the use sites specified below, include the corresponding bolded PPE listed below the site(s).</p> <p>For the correct glove type, refer to Chapter 10 of the Label Review Manual.</p> <p><i>Landscaping</i></p> <ul style="list-style-type: none"> • Spot treatment using a backpack sprayer on landscaping turf (e.g., lawns, athletic fields, parks) • Foliar spray treatment using a mechanically pressurized handgun on landscaping trees and shrubs <p>“Mixers, loaders, and applicators must wear long-sleeved shirt, long pants, shoes and socks, coveralls, and gloves.”</p> <p><i>Food handling establishments</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a manually pressurized handwand in food handling establishments • Crack and crevice treatment using a manually pressurized handwand in food handling establishments 	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</p>

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p><i>Warehouses</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a manually pressurized handwand in warehouses • Crack and crevice treatment using a manually pressurized handwand in warehouses • Broadcast spray treatment using a mechanically pressurized handgun in warehouses <p><i>Residential living spaces</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a manually pressurized handwand in residential living spaces • Crack and crevice treatment using a manually pressurized handwand in residential living spaces <p><i>Childcare centers/schools/institutions</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a manually pressurized handwand to childcare centers/schools/institutions <p><i>Structural components</i></p> <ul style="list-style-type: none"> • Broadcast spray pass treatment using a manually pressurized handwand to structural components (e.g., walls, framing voids, slabs, beams, lumber) • Broadcast spray treatment using a mechanically pressurized handwand to structural components ((e.g., walls, framing voids, slabs, beams, lumber) <p><i>Barn/feedlot</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a mechanically pressurized handgun in barns/feedlots <p>“Mixers, loaders, and applicators must wear long-sleeved shirt, long pants, shoes and socks, gloves, and respirator.”</p>	

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p>For respiratory protection from particulates only (low volatility), use the following language:</p> <p>“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.”</p> <p>*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.</p> <p>For respiratory protection from organic vapor and particulates (or aerosols), use the following language:</p> <p>“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.”</p> <p>For respiratory protection from organic vapor only, use the following language:</p> <p>“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.”</p> <p>*Drop the “N” option if there is oil in the product’s formulation and/or the</p> <ul style="list-style-type: none"> • product is labeled for mixing with oil-containing products. 	
<p>Removal of Uses – For Products Used on Residential Sites</p>	<p>Delete the following use sites from the labels:</p> <ul style="list-style-type: none"> • Outdoor uses on residential lawns and turf • Indoor uses on mattresses 	<p>Directions for Use</p>

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
<p>Prohibit Application Methods on Certain Use Sites – For Products with the Following Use Sites:</p> <ul style="list-style-type: none"> • Indoor residential sites • Nurseries (ornamentals, vegetables, trees, container stock) • Landscaping and turf • Orchards and vineyards • Greenhouses (ornamentals, cut flowers, roses, container stock, vegetables) • Industrial and commercial areas • Field crops (typical) 	<p>Note to registrant - If your label has any of the use sites specified below, include the following statement(s) as applicable to your label.</p> <p><i>Indoor residential sites</i></p> <ul style="list-style-type: none"> • “Do not apply to carpets as a pin stream or coarse spot treatment.” <p><i>Nurseries</i></p> <ul style="list-style-type: none"> • “Do not apply as a foliar spray using a backpack sprayer in nurseries (such as for ornamentals, vegetables, trees, container stock).” • “Do not apply as a foliar broadcast application using mechanically pressurized handgun in nurseries (such as for ornamentals, vegetables, trees, container stock).” • “Do not apply as a drench, soil, or ground directed application using a mechanically pressurized handgun in nurseries (such as for ornamentals, vegetables, trees, container stock).” <p><i>Landscaping and turf</i></p> <ul style="list-style-type: none"> • “Do not apply as a broadcast application using a backpack sprayer on landscaping and turf.” <p><i>Orchards and vineyards</i></p> <ul style="list-style-type: none"> • “Do not apply as a foliar broadcast application using a mechanically pressurized handgun on orchards and vineyards.” • “Do not apply as a soil, drench, or ground directed application using a mechanically pressurized handgun on orchards and vineyards.” <p><i>Greenhouses</i></p> <ul style="list-style-type: none"> • “Do not apply as broadcast spray using a mechanically pressurized handgun in greenhouses (such as for ornamentals, cut flowers, roses, container stock, vegetables)” • “Do not apply as a soil or ground directed application using mechanically pressurized handgun in greenhouses (such as for ornamentals, cut flowers, roses, container stock, vegetables).” 	<p>Directions for Use</p>

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p><i>Industrial and Commercial Areas</i></p> <ul style="list-style-type: none"> “Do not apply as a broadcast spray application using a mechanically pressurized handgun in industrial/commercial areas (e.g., tires, rail, yards, junk yards).” <p><i>Field Crops, typical</i></p> <ul style="list-style-type: none"> “Do not apply as foliar broadcast application using a mechanically pressurized handgun on [INCLUDE CROPS APPLICABLE TO YOUR LABEL: (Brassica (head and stem), Cucurbit Vegetables, Fruiting Vegetables, Garlic, Legume Vegetables, Lettuce (head and leaf), Onion (dry bulb), Tobacco, Tuberous and Corm Vegetables)].” 	
Re-entry Intervals	<p>Specify the re-entry intervals for the following crops, as follows:</p> <ul style="list-style-type: none"> Apple – 2 days Corn, sweet grain – 5 days Nectarine – 7 days Pear – 8 days Plum, prune – 9 days 	Directions for Use
Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	<p>“MANDATORY SPRAY DRIFT MANAGEMENT <u>Aerial Applications:</u></p> <ul style="list-style-type: none"> Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. Applicators are required to use nozzle and pressure that deliver a Medium or coarser droplet size (ASABE S641). Applicators must use ½ swath displacement upwind at the downwind edge of the field. Do not apply when wind speeds exceed 10 miles per hour at the application site. The boom length must not exceed 75% of the wingspan for airplanes or 90% of the rotor diameter for helicopters. Do not apply during temperature inversions.” 	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Aerial Applications”</p> <p>Placement for these statements should be in general directions for use, before and use-specific directions for use.</p>

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
<p>Spray Drift Management Application Restrictions for products that allow airblast applications</p>	<p>“MANDATORY SPRAY DRIFT MANAGEMENT</p> <p>Airblast applications:</p> <ul style="list-style-type: none"> • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 10 miles per hour 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.” 	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Airblast Applications”</p>
<p>Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications</p>	<p>“MANDATORY SPRAY DRIFT MANAGEMENT</p> <p>Ground Boom Applications:</p> <ul style="list-style-type: none"> • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a Medium or coarser droplet size (ASABE S572). • Do not apply when wind speeds exceed 10 mph at the application site. • Do not apply during temperature inversions.” 	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Ground Boom Applications”</p>
<p>Spray Drift Management Application Restrictions for products that are applied as liquids and allow boomless ground sprayer applications</p>	<p>“MANDATORY SPRAY DRIFTMANAGEMENT</p> <p>Boomless Ground Applications:</p> <ul style="list-style-type: none"> • Applicators are required to select nozzle and pressure that deliver a Medium or coarser droplet size (ASABE S572) for all applications. • Do not apply when wind speeds exceed 10 miles per hour at the application site. • Do not apply during temperature inversions.” 	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Boomless Applications”</p>
<p>Advisory Spray Drift Management Language for all products that allow aerial and/or ground boom applications</p>	<p>“SPRAY DRIFT ADVISORIES</p> <p>THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT.</p> <p>BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.</p> <p>IMPORTANCE OF DROPLET SIZE</p>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p>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.</p> <p>Controlling Droplet Size – Ground Boom <i>(note to registrants: remove if ground boom is prohibited on product labels)</i></p> <ul style="list-style-type: none"> • 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. <p>Controlling Droplet Size – Aircraft <i>(note to registrants: remove if aerial application is prohibited on product labels)</i></p> <ul style="list-style-type: none"> • 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. <p>BOOM HEIGHT – Ground Boom <i>(note to registrants: remove if ground boom is prohibited on product labels)</i> For ground equipment, the boom should remain level with the crop and have minimal bounce.</p> <p>RELEASE HEIGHT - Aircraft <i>(note to registrants: remove if aerial application is prohibited on product labels)</i> Higher release heights increase the potential for spray drift.</p> <p>SHIELDED SPRAYERS</p>	

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p>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.</p> <p>TEMPERATURE AND HUMIDITY When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.</p> <p>TEMPERATURE INVERSIONS Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions.</p> <p>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.</p> <p>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.”</p>	
<p>Advisory Spray Drift Management Language for all products that allow liquid</p>	<p>“SPRAY DRIFT ADVISORIES <u>Handheld Technology Applications:</u></p> <ul style="list-style-type: none"> • Take precautions to minimize spray drift.” 	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
applications with handheld technologies		
Directions for Mixing/Loading Products Packaged in Water Soluble Packages	<p>Instructions for Introducing Water Soluble Packages Directly into Spray tanks:</p> <p>"Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 CFR 170.607(d)].</p> <p>Handling Instructions Follow these steps when handling pesticide products in WSPs.</p> <ol style="list-style-type: none"> 1. Mix in spray tank only. 2. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 3. Keep the WSP in outer packaging until just before use. 4. Keep the WSP dry prior to adding to the spray tank. 5. Handle with dry gloves and according to the label instructions for PPE. 6. Keep the WSP intact. Do not cut or puncture the WSP. 7. Reseal the WSP outer packaging to protect any unused WSP(s). <p>Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions.</p>	Directions for Use

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<ol style="list-style-type: none"> 1. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 2. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 3. Stop adding water and stop any agitation. 4. Place intact/unopened WSP into the tank. 5. Do not spray water from a hose or fill pipe to break or dissolve the WSP. 6. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation. 7. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation. 8. Stop agitation before tank lid is opened. 9. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution. 10. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed. 11. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation. 12. Use the spray solution when mixing is complete. 13. Maintain agitation of the diluted pesticide mix during transport and application. 14. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label. <p>For Toxicity Category I and II products:</p> <p>“ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers</p>	

Description	Proposed Label Language for Lambda-Cyhalothrin Products	Placement on Label
	<p>and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p> <p>For Toxicity Category III and IV products:</p> <p>“ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p>	

Appendix B.2. Proposed Labeling Changes for Gamma-Cyhalothrin Products

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	Technical Products	
Removal of Uses	Delete the following use site from the labels: <ul style="list-style-type: none"> • Outdoor residential uses on lawns and turf • Outdoor residential uses on gardens and trees 	
	End-Use Products	
Updated Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA’s chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Updated Respirator Language	<p>For labels that currently have respirator language, update the language to the following:</p> <p>For respiratory protection from particulates only (low volatility), use the following language:</p> <p>“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.”</p> <p>*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.</p> <p>For respiratory protection from organic vapor and particulates (or aerosols), use the following language:</p> <p>“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-</p>	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<p>approved gas mask with OV canisters; <u>OR</u> a NIOSH-approved powered air purifying respirator with OV cartridges and combination HE filters.”</p> <p>For respiratory protection from organic vapor only, use the following language:</p> <p>“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.”</p> <p>*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.</p>	
<p>Addition of PPE for Certain Occupational Handlers – For Products with the Following Use Sites:</p> <ul style="list-style-type: none"> • Orchards and vineyards • Field crops • Forestry • Greenhouses • Landscaping turf • Nurseries • Warehouses • Residential living spaces 	<p>Note to registrant - If your label has any of the use sites specified below, include the corresponding bolded PPE listed below the site(s).</p> <p>For the correct glove type, refer to Chapter 10 of the Label Review Manual.</p> <p><i>Orchards and vineyards</i></p> <ul style="list-style-type: none"> • Aerial broadcast application of liquid product to orchards and vineyards • Chemigation broadcast application of liquid product to orchards and vineyards <p><i>Field crops</i></p> <ul style="list-style-type: none"> • Aerial broadcast application of liquid product to typical field crops which include Beans (snap), Broccoli, Brussels Sprouts, Cabbage, Chinese Cabbage, Cauliflower, Eggplant, Garlic, Groundcherry, Lettuce (Head), Lettuce (Leaf), Mustard Cabbage, Onion, Pepino, Pepper, Succulent Pea, Sweet Corn, Tomato) • Chemigation broadcast application of liquid product to typical field crops which include Beans (snap), Broccoli, Brussels Sprouts, Cabbage, Chinese Cabbage, Cauliflower, Eggplant, Garlic, Groundcherry, Lettuce (Head), Lettuce (Leaf), Mustard Cabbage, Onion, Pepino, Pepper, Succulent Pea, Sweet Corn, Tomato) • Chemigation broadcast application of liquid product to high acreage field crops which include corn intended for popcorn 	<p>In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable</p>

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<ul style="list-style-type: none"> • Groundboom broadcast application of liquid product to high acreage field crops which include corn intended for popcorn <p>“Mixers and loaders must use engineering control (i.e., enclosed transfer system).”</p> <p><i>Forestry</i></p> <ul style="list-style-type: none"> • Aerial broadcast application of liquid product to forestry <p>“Mixers and loaders must wear long-sleeved shirt, long pants, shoes and socks, gloves, and a respirator.”</p> <p><i>Greenhouses</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a mechanically pressurized handgun in greenhouses (ornamentals, roses, cut flowers, container stock, vegetables) • Drench, soil, or ground directed treatment using mechanically pressurized handgun in greenhouses (ornamentals, roses, cut flowers, container stock, vegetables) <p><i>Landscaping, turf</i></p> <ul style="list-style-type: none"> • Broadcast spray treatment using a backpack sprayer to landscaping turf (e.g., lawns, athletic fields, parks) <p><i>Nurseries</i></p> <ul style="list-style-type: none"> • Foliar broadcast treatment using a backpack sprayer in nurseries (ornamentals, vegetables, trees, container stock) <p><i>Warehouses</i></p> <ul style="list-style-type: none"> • Broadcast spray application using a manually pressurized handwand in warehouses • Crack and crevice treatment using a manually pressurized handwand in warehouses 	

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<ul style="list-style-type: none"> • Broadcast spray treatment using a mechanically pressurized handgun in warehouses <p><i>Residential living spaces</i></p> <ul style="list-style-type: none"> • Crack and crevice treatment using a manually pressurized handwand to residential living spaces (e.g., homes, apartments) <p>“Mixers, loaders, and applicators must wear long-sleeved shirt, long pants, shoes and socks, gloves, and a respirator.”</p> <p><i>Orchards and vineyards</i></p> <ul style="list-style-type: none"> • Airblast broadcast spray treatment to orchards and vineyards <p>“Applicators must use engineering control (i.e., enclosed cab).”</p> <p><i>Field crops</i></p> <ul style="list-style-type: none"> • Groundboom broadcast spray treatment to high acreage field crops which include corn intended for popcorn. <p>“Applicators must wear long-sleeved shirt, long pants, shoes and socks, gloves, and a respirator.”</p> <p>For respiratory protection from particulates only (low volatility), use the following language:</p> <p>“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.”</p> <p>*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.</p>	

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<p>For respiratory protection from organic vapor and particulates (or aerosols), use the following language:</p> <p>“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.”</p> <p>For respiratory protection from organic vapor only, use the following language:</p> <p>“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.”</p> <p>*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.</p>	
<p>Removal of Uses – For Products Used on Residential Sites</p>	<p>Delete the following use site from the labels:</p> <ul style="list-style-type: none"> • Outdoor residential uses on lawns and turf • Outdoor residential uses on gardens and trees 	<p>Directions for Use</p>
<p>Prohibition of Application Methods on Certain Use Sites – For Products with the Following Use Sites:</p> <ul style="list-style-type: none"> • Indoor residential sites • High acreage field crops • Orchards and vineyards 	<p>Note to registrant - If your label has any of the use sites specified below, include the following statement(s) as applicable to your label.</p> <p><i>Indoor residential site</i></p> <ul style="list-style-type: none"> • “Do not apply to carpet or hard flooring as a pin stream or coarse spot treatment.” <p><i>High acreage field crops</i></p> <ul style="list-style-type: none"> • “Do not apply as an aerial broadcast on high acreage field crops (such as corn intended for popcorn).” 	<p>Directions for Use</p>

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
<ul style="list-style-type: none"> • Forestry • Nurseries • Landscaping (trees/shrubs/bushes) • Landscaping (plants/flowers) 	<p><i>Orchards and vineyards</i></p> <ul style="list-style-type: none"> • “Do not apply a ground or soil-directed application to orchards and vineyards.” • “Do not apply as a foliar broadcast spray using a mechanically pressurized handgun to orchards and vineyards.” • “Do not apply as a drench, soil, or ground directed application using a mechanically pressurized handgun to orchards and vineyards.” <p><i>Forestry</i></p> <ul style="list-style-type: none"> • “Do not apply as broadcast spray using a backpack sprayer to forestry.” <p><i>Nurseries</i></p> <ul style="list-style-type: none"> • “Do not apply as a foliar broadcast spray using a liquid mechanically pressurized handgun to nurseries.” • “Do not apply as a drench, soil, or ground directed application using a mechanically pressurized handgun to nurseries.” <p><i>Landscaping (trees, shrubs, bushes)</i></p> <ul style="list-style-type: none"> • “Do not apply as foliar broadcast spray using a backpack sprayer to landscaping of trees, shrubs, and bushes.” • “Do not apply as a foliar broadcast spray using a mechanically pressurized handgun to landscaping of trees, shrubs, and bushes.” <p><i>Landscaping (plants, flowers)</i></p> <ul style="list-style-type: none"> • “Do not apply as foliar broadcast spray using a backpack sprayer to landscaping of plants and flowers.” 	
Re-entry Intervals	<p>Specify the re-entry intervals for the following crops, as follows:</p> <ul style="list-style-type: none"> • Almond – 15 days • Apple – 30 days • Apricot – 30 days • Bean, snap – 30 days • Blackberry – 30 days 	Directions for Use

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<ul style="list-style-type: none"> • Broccoli – 30 days • Brussels sprouts – 30 days • Chinese cabbage, bok choy – 30 days • Chinese cabbage, napa – 30 days • Cauliflower – 30 days • Cherry – 30 days • Corn, pop – 30 days • Corn, sweet grain – 30 days • Corn, processing – 30 days • Eggplant – 30 days • Fig – 26 days • Hazelnut – 15 days • Macadamia nut – 15 days • Onion, bulb – 30 days • Onion, green – 30 days • Pepper, bell – 30 days • Tomato – 30 days • Tomato, processing – 30 days 	
<p>Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application</p>	<p>“MANDATORY SPRAY DRIFT MANAGEMENT <u>Aerial Applications:</u></p> <ul style="list-style-type: none"> • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary 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 10 miles per hour at the application site. • The boom length must not exceed 75% of the wingspan for airplanes or 90% of the rotor diameter for helicopters. • Applicators must use ½ swath displacement upwind at the downwind edge of the field. • Do not apply during temperature inversions.” 	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Aerial Applications”</p> <p>Placement for these statements should be in general directions for use, before and use-specific directions for use.</p>

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
Spray Drift Management Application Restrictions for products that allow airblast applications	<p>“MANDATORY SPRAY DRIFT MANAGEMENT</p> <p>Airblast applications:</p> <ul style="list-style-type: none"> • Sprays must be directed into the canopy. • Do not apply when wind speeds exceed 10 miles per hour 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”
Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications	<p>“MANDATORY SPRAY DRIFT MANAGEMENT</p> <p>Ground Boom Applications:</p> <ul style="list-style-type: none"> • User must only apply with the release 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 droplet size (ASABE S572). • Do not apply when wind speeds exceed 10 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”
Spray Drift Management Application Restrictions for products that are applied as liquids and allow boomless ground sprayer applications	<p>“MANDATORY SPRAY DRIFTMANAGEMENT</p> <p>Boomless Ground Applications:</p> <ul style="list-style-type: none"> • Applicators are required to select nozzle and pressure that deliver a Medium or coarser droplet size (ASABE S572) for all applications. • Do not apply when wind speeds exceed 10 miles per hour at the application site. • Do not apply during temperature inversions.” 	Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Boomless Applications”
Advisory Spray Drift Management Language for all products that allow aerial and/or ground boom applications	<p>“SPRAY DRIFT ADVISORIES</p> <p>THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT.</p> <p>BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.</p> <p>IMPORTANCE OF DROPLET SIZE</p>	Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<p>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.</p> <p>Controlling Droplet Size – Ground Boom <i>(note to registrants: remove if ground boom is prohibited on product labels)</i></p> <ul style="list-style-type: none"> • 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. <p>Controlling Droplet Size – Aircraft <i>(note to registrants: remove if aerial application is prohibited on product labels)</i></p> <ul style="list-style-type: none"> • 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. <p>BOOM HEIGHT – Ground Boom <i>(note to registrants: remove if ground boom is prohibited on product labels)</i> For ground equipment, the boom should remain level with the crop and have minimal bounce.</p> <p>RELEASE HEIGHT - Aircraft <i>(note to registrants: remove if aerial application is prohibited on product labels)</i> Higher release heights increase the potential for spray drift.</p> <p>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.</p>	

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<p>TEMPERATURE AND HUMIDITY When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.</p> <p>TEMPERATURE INVERSIONS Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions.</p> <p>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.</p> <p>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.”</p>	
<p>Advisory Spray Drift Management Language for all products that allow liquid applications with handheld technologies</p>	<p>“SPRAY DRIFT ADVISORIES <u>Handheld Technology Applications:</u></p> <ul style="list-style-type: none"> • Take precautions to minimize spray drift.” 	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>
<p>Directions for Mixing/Loading</p>	<p>Instructions for Introducing Water Soluble Packages Directly into Spray tanks:</p>	<p>Directions for Use</p>

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
<p>Products Packaged in Water Soluble Packages</p>	<p>"Soluble Packages (WSPs) are designed to dissolve in water. Agitation may be used, if necessary, to help dissolve the WSP. Failure to follow handling and mixing instructions can increase your exposure to the pesticide products in WSPs. WSPs, when used properly, qualify as a closed mixing/loading system under the Agricultural Worker Protection Standard [40 CFR 170.607(d)].</p> <p>Handling Instructions Follow these steps when handling pesticide products in WSPs.</p> <ol style="list-style-type: none"> 8. Mix in spray tank only. 9. Handle the WSP in a manner that protects package from breakage and/or unintended release of contents. If package is broken, put on PPE required for clean-up and then continue with mixing instructions. 10. Keep the WSP in outer packaging until just before use. 11. Keep the WSP dry prior to adding to the spray tank. 12. Handle with dry gloves and according to the label instructions for PPE. 13. Keep the WSP intact. Do not cut or puncture the WSP. 14. Reseal the WSP outer packaging to protect any unused WSP(s). <p>Mixing Instructions Follow the steps below when mixing this product, including if it is tank-mixed with other pesticide products. If being tank-mixed, the mixing directions 1 through 9 below take precedence over the mixing directions of the other tank mix products. WSPs may, in some cases, be mixed with other pesticide products so long as the directions for use of all the pesticide product components do not conflict. Do not tank-mix this product with products that prohibit tank-mixing or have conflicting mixing directions.</p> <ol style="list-style-type: none"> 15. If a basket or strainer is present in the tank hatch, remove prior to adding the WSP to the tank. 16. Fill tank with water to approximately one-third to one-half of the desired final volume of spray. 17. Stop adding water and stop any agitation. 18. Place intact/unopened WSP into the tank. 	

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<p>19. Do not spray water from a hose or fill pipe to break or dissolve the WSP.</p> <p>20. Start mechanical and recirculation agitation from the bottom of tank without using any overhead recirculation, if possible. If overhead recirculation cannot be turned off, close the hatch before starting agitation.</p> <p>21. Dissolving the WSP may take up to 5 minutes or longer, depending on water temperature, water hardness and intensity of agitation.</p> <p>22. Stop agitation before tank lid is opened.</p> <p>23. Open the lid to the tank, exercising caution to avoid contact with dusts or spray mix, to verify that the WSP has fully dissolved and the contents have been thoroughly mixed into the solution.</p> <p>24. Do not add other allowed products or complete filling the tank until the bags have fully dissolved and pesticide is thoroughly mixed.</p> <p>25. Once the WSP has fully dissolved and any other products have been added to the tank, resume filling the tank with water to the desired level, close the tank lid, and resume agitation.</p> <p>26. Use the spray solution when mixing is complete.</p> <p>27. Maintain agitation of the diluted pesticide mix during transport and application.</p> <p>28. It is unlawful to use any registered pesticide, including WSPs, in a manner inconsistent with its label.</p> <p>For Toxicity Category I and II products:</p> <p>“ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks, a chemical-resistant apron, and chemical-resistant gloves. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p>	

Description	Proposed Label Language for Gamma-Cyhalothrin Products	Placement on Label
	<p>For Toxicity Category III and IV products:</p> <p>“ENGINEERING CONTROLS STATEMENT Water soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard [40 CFR 170.607(d)]. Mixers and loaders handling this product while it is enclosed in intact water soluble packets may elect to wear reduced PPE of long-sleeved shirt, long pants, shoes, socks. When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for “applicators and other handlers” and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.”</p>	


Appendix B.3. Required Labeling Language for Lambda- and Gamma-Cyhalothrin Products

Appendix B.3 is not open for public comment.

Description	Required Label Language for Lambda-and Gamma-Cyhalothrin End Use Products	Placement on Label				
All End Use Products (unless specified otherwise)						
<p>Mode of Action Group Number</p> <p><i>Applies only to products with agricultural and/or wide-area mosquito uses</i></p>	<p>Note to registrant:</p> <ul style="list-style-type: none"> • Include the name of the ACTIVE INGREDIENT in the first column. • Include the word “GROUP” in the second column. • Include the MODE/MECHANISM/SITE OF ACTION CODE in the third column (for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action; for Herbicides this is SITE OF ACTION). • Include the type of pesticide (i.e., INSECTICIDE) in the fourth column. <table border="1" data-bbox="506 769 1530 980" style="margin-left: auto; margin-right: auto;"> <tr> <td style="text-align: center; padding: 5px;">Pyrethroid Name</td> <td style="text-align: center; padding: 5px;">GROUP</td> <td style="text-align: center; padding: 5px;">3A</td> <td style="text-align: center; padding: 5px;">INSECTICIDE</td> </tr> </table>	Pyrethroid Name	GROUP	3A	INSECTICIDE	<p>Front Panel, upper right quadrant.</p> <p>All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.</p>
Pyrethroid Name	GROUP	3A	INSECTICIDE			
<p>Resistance-management labeling statements for insecticides</p> <p><i>Applies only to products with agricultural and/or wide-area mosquito uses</i></p>	<p>Include resistance management label language for insecticides/acaricides from PRN 2017-1 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)</p>	<p>Directions for Use, prior to directions for specific crops</p>				

Description	Required Label Language for Lambda-and Gamma-Cyhalothrin End Use Products	Placement on Label
All End Use Products (unless specified otherwise)		
Additional Required Labeling Action <i>Applies to all products delivered via liquid spray applications (except those with mosquito adulticide use)</i>	Remove information about volumetric mean diameter from all labels delivered via liquid spray application, except from products with mosquito adulticide use, where such information currently appears.	Directions for Use

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
End-use products with indoor residential uses		
For all products that have indoor uses only	Add the following language: “For indoor use only.”	Front Label Panel and/or Directions for Use
For all products that have both indoor and outdoor uses	Add the following language: “For both indoor and outdoor use.”	Front Label Panel and/or Directions for Use
For all products used on pets	Add the following language: “Application of product on pets must only be done indoors.”	Directions for Use
Required disposal statement for products not labeled for use	“Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options.”	Storage and Disposal

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
	End-use products with indoor residential uses	
directly into drains and sewers.		
<p>Stewardship statement that includes a Spanish translation</p> <p><i>Stewardship statement not required for products applied to pets</i></p>	<p>Note to registrants: If adding stewardship statements on end-use consumer products, the followings language is required and must be placed in a prominent location.</p> <p>For products without drain treatment uses: “Do not allow to enter indoor or outdoor drains” <i>“No permita la entrada a desagües internos o externos.”</i></p> <p>For products with drain treatment uses: “Do not allow to enter indoor or outdoor drains unless labeled for drain treatments.” <i>“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.”</i></p> <p>For products with and without drain treatment uses: “Follow proper disposal procedures on this label” <i>“Siga las indicaciones del etiquetado para el desecho apropiado del producto.”</i></p> <p>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).</p> <p>Use the following pictogram on product labels:</p> <div style="text-align: center;">  </div>	<p>Directions for Use</p>

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
End-use products with outdoor, urban, non-agricultural uses		
For all products that have outdoor uses only	Add the following language: “For outdoor use only.”	Front Label Panel and/or Directions for Use
For all products that have both indoor and outdoor uses	Add the following language: “For both indoor and outdoor use.”	Front Label Panel and/or Directions for Use
<p>General Outdoor Application Statement to replace existing general outdoor statement</p> <p><i>Registrants may not add new uses from items 1-6 which are not currently on the existing label. Registrants are required to choose only the uses from items 1-6 which apply to their product.</i></p>	<p>“All outdoor spray applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:</p> <ol style="list-style-type: none"> 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 (<i>e.g.</i>, 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 (<i>e.g.</i>, driveways, sidewalks, etc.), up to 2 feet above ground level; 	Directions for Use

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
	End-use products with outdoor, urban, non-agricultural uses	
	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	<p>“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.”</p> <p>“Do not allow the product to enter any drain during or after application.”</p> <p>“Do not apply directly to impervious horizontal surfaces such as sidewalks, driveways, and patios except as a spot or crack-and-crevice treatment.”</p> <p>“Do not apply or irrigate to the point of runoff.”</p>	Directions for Use
Rain-Related Statements (except for products that require watering-in)	<p>"Do not make applications during rain. Avoid making applications when rainfall is expected before the product has sufficient time to dry (minimum 4 hours)."</p> <p>“Rainfall within 24 hours after application may cause unintended runoff of pesticide application.”</p>	Directions for Use
Wind speed requirement for ornamental/	“Do not apply when the wind speed is greater than 10 mph.”	Directions for Use

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
	End-use products with outdoor, urban, non-agricultural uses	
recreational turf applications		
Spray drift management for commercial nurseries	<p>For outdoor applications to commercial nurseries:</p> <ul style="list-style-type: none"> • “Do not apply when the wind speed is greater than 10 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	<ul style="list-style-type: none"> • “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

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
	End-use products with agricultural uses	
Vegetative Filter Strips	<p>“VEGETATIVE FILTER STRIPS</p> <p>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).</p> <p>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:</p>	Directions for Use
Note: This requirement is separate and in addition to buffer zones to aquatic areas, which are still required if a		

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
End-use products with agricultural uses		
<p>vegetated filter strip is present.</p>	<ul style="list-style-type: none"> – 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). <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ 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. ○ The area of application is less than or equal to 10 acres. <p>Rice fields are not required to have a vegetative filter strip.</p> <p>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”</p>	
<p>Buffer Zones to Water Bodies</p>	<p>Ground Application</p> <ul style="list-style-type: none"> • “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).” <p>Ultra Low Volume (ULV) Aerial Application</p>	<p>Directions for Use</p>

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
End-use products with agricultural uses		
	<ul style="list-style-type: none"> • “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.” <p>Non-ULV Aerial Application</p> <ul style="list-style-type: none"> • “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).” 	
<p>New text to include under Environmental Hazard statements: (For liquid products formulated for outdoor foliar applications to agricultural row crops.)</p> <p><i>Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area mosquito control applications</i></p>	<p>Update the Environmental Hazard with the bolded statement:</p> <p>“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.”</p>	<p>Environmental Hazard</p>
<p>Link to pollinator best management practices (For liquid products formulated for outdoor foliar applications to agricultural row crops.)</p> <p><i>Excludes products formulated for residential and/or</i></p>	<p>“Following best management practices can help reduce risk to terrestrial pollinators. Examples of best management practices include applying pesticides in the evening and at night when pollinators are not foraging and checking to confirm hive locations before spraying. For additional resources on pollinator best management practices, visit https://www.epa.gov/pollinator-protection/find-best-management-practices-protect-pollinators.”</p>	<p>Directions for Use, prior to crop specific directions</p>

Description	Required Label Language for Lambda- and Gamma-Cyhalothrin End Use Products	Placement on Label
End-use products with agricultural uses		
<p><i>Ultra Low Volume (ULV) wide area mosquito control applications</i></p>		
<p>Information on state managed pollinator protection plans (For liquid products formulated for outdoor foliar applications to agricultural row crops.)</p> <p><i>Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area mosquito control applications</i></p>	<p>“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.”</p>	<p>Directions for Use, prior to crop specific directions</p>
<p>Information on how to report bee incidents (For liquid products formulated for outdoor foliar applications to agricultural row crops.)</p> <p><i>Excludes products formulated for residential and/or Ultra Low Volume (ULV) wide area mosquito control applications</i></p>	<p>“How to Report Bee Kills</p> <p>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.”</p>	<p>Directions for Use, prior to crop specific directions</p>

Appendix C. Endangered Species Assessment

In 2013, EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, after receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* (i.e., Revised Method) in March 2020.¹⁴ During the same timeframe, EPA also released draft BEs for carbaryl and methomyl, which were the first to be conducted using the Revised Method.

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group (IWG) to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role in this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019. The recommendations from the IWG and progress on implementing those recommendations are outlined in reports to Congress.¹⁵

Given that the agencies are continuing to work toward implementation of the Revised Method to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for lambda- and gamma-cyhalothrin does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this PID, EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of lambda- and gamma-cyhalothrin. This will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the Revised

¹⁴ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0185-0084>

¹⁵ <https://www.epa.gov/endangered-species/reports-congress-improving-consultation-process-under-endangered-species-act>

Docket Numbers EPA-HQ-OPP-2010-0480 and EPA-HQ-OPP-2010-0479
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Method has been fully implemented. Once that occurs, the Revised Method will be applied to subsequent analyses for lambda- and gamma-cyhalothrin as part of completing this registration review.

Appendix D. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for lambda- and gamma-cyhalothrin, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), lambda- and gamma-cyhalothrin are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,¹⁶ and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Lambda- and gamma-cyhalothrin are not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, visit EPA website.¹⁷

In this PID, EPA is making no human health or environmental safety findings associated with the EDSP screening of lambda- and gamma-cyhalothrin. Before completing this registration review, the Agency will make an EDSP FFDCA § 408(p) determination.”

¹⁶ See <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

¹⁷ <https://www.epa.gov/endocrine-disruption>