Re-evaluation Decision RVD2021-04

Lambda-cyhalothrin and its associated end-use products

Final Decision

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Re-evaluation decision for lambda-cyhalothrin and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Lambda-cyhalothrin is a synthetic pyrethroid insecticide used to control a broad range of insect pests on a wide variety of sites such as greenhouse food crops, terrestrial food and feed crops, shelterbelts, turf, livestock, structural sites and ornamentals. Currently registered products containing lambda-cyhalothrin can be found in the Pesticide Label Search and in Appendix I. The Proposed Re-evaluation Decision PRVD2017-03, *Lambda-cyhalothrin*[1] containing the evaluation of lambda-cyhalothrin and proposed decision, underwent a 90-day consultation period ending on 21 September 2017. PRVD2017-03 proposed cancellation of the use on all food and feed commodities, all indoor structural uses in residential areas, turf application in residential areas, as well as mitigation measures for the remaining uses.

Health Canada received comments (and information) relating to the health, environmental and value assessments. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. These comments and new data/information resulted in revisions to the toxicology, dietary, occupational, and environmental risk assessments (see Science evaluation update), and resulted in changes to the proposed re-evaluation decision as described in PRVD2017-03.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2017-03, and further information used in the re-evaluation decision is listed in Appendix XI of this RVD. Therefore, the complete reference list of all information used in this final re-evaluation decision includes both the information set out in PRVD2017-03 and the information set out in Appendix XI herein.

This document presents the final re-evaluation decision[2] for the re-evaluation of lambda-cyhalothrin, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing lambda-cyhalothrin that are registered in Canada are subject to this re-evaluation decision.

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Re-evaluation decision for lambda-cyhalothrin

Health Canada has completed the re-evaluation of lambda-cyhalothrin. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing lambda-cyhalothrin is acceptable with additional risk mitigation measures. An evaluation of available scientific information found that most uses of lambda-cyhalothrin products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes new mitigation measures. Risks were shown to be acceptable when mitigation measures were considered for the following uses:

- Crop Group 5-13: *Brassica* Head and Stem Vegetable Group;
- Crop Group 6: Legume Vegetables (Succulent or Dried);
- Crop Group 8-09: Fruiting Vegetables;
- Crop Group 9: Cucurbit Vegetables;
- Crop Group 14-11: Tree Nuts;
- Crop Group 15: Cereal Grains;
- alfalfa; apple; arrowroot; asparagus; beef and non-lactating dairy cattle; carrot; cassava; celery; cherry; Chinese broccoli; cover crops; dasheen; flax seed; garden beet; ginger; Jerusalem artichoke; kohlrabi; mustard seeds (oilseed type); nectarine; peach; pear; plum; potato; rapeseed (including canola); Saskatoon berry; strawberry; sweet potato; tanier corms; timothy; turmeric; yam bean; and yam.
- turf
- greenhouse tobacco seedlings
- tobacco
- shelterbelts
- poplar and willow
- conifer seed orchards
- structural sites (indoors and outdoors) and surrounding soil,
- outdoor nests (wasp, hornet, ant and termites)
- outdoor ornamentals

The following uses of lambda-cyhalothrin are cancelled since health risks were not shown to be acceptable when used according to the current conditions of registration, or when additional mitigation is considered: lettuce, mustard seed (condiment type), all feed uses, all registered commodities from Crop Group 3-07: Bulb Vegetables, and all registered commodities from Crop Group 20: Oilseeds (Revised), **except for** flax seed, mustard seed (oilseed type), and rapeseed (including canola).

Label amendments, as summarized below and listed in Appendix X, are required.

Risk mitigation measures

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and mitigation measures, as a result of the re-evaluation of lambda-cyhalothrin, are summarized below. Refer to Appendix X for details.

Cancelled uses to be removed from all product labels:

- lettuce,
- mustard seed (condiment type),
- all feed uses,
- all registered commodities from Crop Group 3-07: Bulb Vegetables, and
- all registered commodities from Crop Group 20: Oilseeds (Revised), **except for** flax seed, mustard seed (oilseed type), and rapeseed (including canola).

Human health

Risk mitigation:

To protect workers, consumers, and those entering treated areas from potential dietary, residential, and occupational exposure, the following risk-reduction measures are required for the uses with continued registration of lambda-cyhalothrin in Canada:

- Due to dietary risks of concern, changes to the MRLs for some commodities will be published as a Proposed Maximum Residue Limit (PMRL) document for consultation.
- Label amendments to minimize the likelihood of residues in milk and livestock (other than beef cattle).
- Additional personal protective equipment (PPE) and engineering controls when mixing/loading and applying to various crops/sites.
- Restrictions on amount of active ingredient handled per day for some application equipment.
- Extension of the retreatment interval (RTI) for turf applications from 7 days to 14 days.
- Revision or establishment of restricted-entry intervals (REIs) for some postapplication activities.
- Label modifications to include structural definitions and precautionary statements from the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* for structural products.
- Registrant-implemented national product stewardship program is required with the aim to encourage and promote the proper handling and use of commercial class lambda-cyhalothrin product in indoor residential areas by communicating the revised label statements and risk mitigation and educating users.

Environment

Label improvements to meet current standards:

- Updated storage and disposal statements.

Risk mitigation:

To protect the environment, the following risk-reduction measures are required:

- Environmental hazard statements for bees, beneficial arthropods (parasitic insects and predatory mites), small wild mammals, and aquatic organisms.
- To reduce risk to pollinators, users are to avoid application during the crop blooming period. If application is required during this period, applications are restricted to the evening when most bees are not foraging.
- For greenhouses, the product must not be applied when bees or beneficial insects are present and effluent containing lambda-cyhalothrin must not be released into aquatic environments.
- To reduce the potential for runoff of lambda-cyhalothrin to adjacent aquatic habitats, precautionary statement for sites with characteristics that may be conducive to runoff and when heavy rains are forecasted.
- Addition of a mandatory vegetative filter strip between the treatment area and the edge of a down-gradient water body to reduce runoff of lambda-cyhalothrin to aquatic environments.
- Spray buffer zones to protect non-target aquatic habitats.

Next steps

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

Other information

Any person may file a notice of objection[3] regarding this decision on lambda-cyhalothrin and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (hc.pmra-info-arla.sc@canada.ca).

The relevant confidential test data on which the decision is based (as referenced in PRVD2017-03 and in Appendix XI of this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*

Science evaluation update

Based on the comments and additional information received during consultation, Health Canada revised the human health and environmental assessments.

1.0 Revised health risk assessment

1.1 Toxicology assessment for lambda-cyhalothrin

Health Canada received detailed toxicology-related comments from Syngenta and ADAMA Agricultural Solutions Canada Ltd. in addition to general comments from provincial authorities, growers, and grower associations during the consultation period in response to PRVD2017-03. The extensive toxicology comments received from the registrant covered a range of issues pertaining to the toxicology assessment including the weight of evidence for genotoxicity, carcinogenicity and male reproductive toxicity, the choice of study and benchmark dose analysis supporting the acute reference dose (ARfD) and non-dietary incidental oral reference values, and the magnitude of the applied uncertainty factors. The registrants' comments included scientific rationales addressing the issues noted above, and new historical control data for mammary gland and uterine tumours in rodents. An updated literature search of toxicology-related data was conducted by Health Canada, and identified new studies that were relevant to the risk assessment. Based on the information received and retrieved, the toxicology reference values outlined in PRVD2017-03 and the cancer risk assessment approach for lambda-cyhalothrin were updated. Detailed responses to comments and updated toxicology reference values are presented in Appendix III and IV, respectively.

1.2 Dietary exposure and risk assessment

In PRVD2017-03, dietary risks for lambda-cyhalothrin were not shown to be acceptable; therefore, cancellation of all food and feed uses and revocation of the existing MRLs were proposed.

Comments were received regarding the value of food uses, including a priority list of food commodities from Syngenta Canada Inc. This registrant also proposed refinements to certain commodities via extending monitoring data, removing certain commodities, and using monitoring data without detections to set certain residues to zero. A comment from the registrant Intervet Canada Corp. regarding beef commodities was also proposed for the mitigated risk assessment. These refinements have been reviewed and some have been considered adequate to refine the assessment. Health Canada's responses to specific comments for the dietary assessment are provided in Appendix III.

The dietary risk assessment was updated with the revised ARfD, the removal of the cancer potency estimate (q_1*), which was replaced using a threshold approach, revised estimated environmental concentrations (EEC) in drinking water, removal of certain commodities that are grown in Canada that had previously been estimated using a Codex MRL, additional monitoring data translations, refinements based on Canadian Grain Commission data, and refinements to beef residue inputs when feed commodities are no longer included in the risk assessment. Results of the updated dietary risk assessment are presented in Appendix V.

Based on the existing use pattern, the updated acute dietary (food and drinking water) exposure estimates at the 99.9th percentile for the general population and all subpopulations (including females 13–49 years of age) range from 103–550% of the ARfD, and therefore risks were not shown to be acceptable. The highest exposed subpopulation was adults 20–49 years of age. When a revised use pattern based on the registrant priority list was considered, the acute dietary exposure estimates range from 30–99% of the ARfD, and risks were shown to be acceptable with this mitigation.

Based on the existing current use pattern, the updated chronic (cancer and non-cancer) exposure estimates for the general population and all subpopulations range from 32–93% of the acceptable daily intake (ADI), and therefore risks were shown to be acceptable. When the use pattern that resulted in an acceptable acute risk assessment was applied, the chronic exposure estimates range from 6–31% of the ADI.

The subset of food commodities that resulted in acceptable acute and chronic (cancer and non-cancer) risk assessments and therefore will be retained are: Crop Group 5-13: *Brassica* Head and Stem Vegetable Group; Crop Group 6: Legume Vegetables (Succulent or Dried); Crop Group 8-09: Fruiting Vegetables; Crop Group 9: Cucurbit Vegetables; Crop Group 14-11: Tree Nuts; Crop Group 15: Cereal Grains; alfalfa; apple; arrowroot; asparagus; beef cattle commodities; carrot; cassava; celery; cherry; Chinese broccoli; cover crops; dasheen; flax seed; garden beet; ginger; Jerusalem artichoke; kohlrabi; mustard seeds (oilseed type); nectarine; peach; pear; plum; potato; rapeseed (including canola); Saskatoon berry; strawberry; sweet potato; tanier corms; timothy; turmeric; yam bean; and yam. These commodities, when treated with lambda-cyhalothrin, are not permitted to be used as livestock feed (see Appendix X; Section 2.2.1).

However, cancellation of use on lettuce, mustard seed (condiment type), all feed uses, all registered commodities from Crop Group 3-07: Bulb Vegetables, and all registered commodities from Crop Group 20: Oilseeds (Revised), **except for** flax seed, mustard seed (oilseed type), and rapeseed (including canola) is required.

Label changes resulting from the dietary assessment are included in Appendix X. MRLs for the following commodities will be proposed to be set at 0.01 ppm: Crop Group 3: Bulb Vegetables, animal commodities (except beef commodities), apricots, avocados, cardoon, chokecherries, fresh Florence fennel leaves and stalks, grapes, head lettuce, leaf lettuce, olives, oranges, peanuts, rhubarb, satsuma mandarins, sugarcane cane, sunflower oil, sunflower seeds, Swiss chard, tea (dried leaves), and undelinted cotton seeds. Changes to MRLs will be published in a Proposed Maximum Residue Limit (PMRL) document for consultation. Recommendations for changes to MRLs are included in Appendix V.

1.3 Occupational and non-occupational exposure and risk assessment

In PRVD2017-03, risks were not shown to be acceptable for residential turf (except golf courses) and indoor residential sites, and these uses were proposed for cancelation. Risks were shown to be acceptable for all other uses with mitigation measures such as increased personal protective equipment (PPE), restrictions on amount of active ingredient handled per day and longer restricted-entry intervals.

During the PRVD consultation period, additional information was received from registrants, user/grower groups, and other stakeholders. Chemical-specific studies, such as dislodgeable foliar residue (DFR) and hand press studies were also available. This information was incorporated into the revised assessment to the extent possible. A turf transferrable residue (TTR) study was also revisited based on comments received from registrants.

As a result of the comments and chemical-specific data, the outcome of the occupational and residential risk assessments and proposed mitigation in PRVD2017-03 have changed. All currently registered uses, including those on residential turf and indoor residential sites, are now acceptable for continued registration, provided that the use pattern changes and mitigation measures outlined in Appendix X are followed.

Health Canada responses to specific comments are located in Appendix III. Details of the revised occupational, residential and aggregate risk assessments are presented in Appendices VI and VII.

1.4 Aggregate exposure and risk assessment

In PRVD2017-03, the aggregate assessment was conducted for uses for which risks were shown to be acceptable. The assessment did not include food uses, as these were proposed for cancellation based on risks identified in the dietary risk assessment.

The aggregate exposure and risk assessment was updated to include those uses and scenarios for which risks are now shown to be acceptable, as well as to include the updated toxicology reference value for short- to intermediate-term durations. Exposure from use of lambda-cyhalothrin in residential gardens and trees, lawns and turf, animal housing and indoor environments was aggregated with dietary exposure from food and drinking water.

Results are summarized in Appendix VII. Aggregate risks were shown to be acceptable for all currently registered uses, including those on residential turf and indoor residential environments, provided the use pattern changes and mitigation measures outlined in Appendix X are followed. These mitigation measures include an increase in the retreatment interval for turf from 7 days to 14 days to address aggregate risks for children (1<2 years).

1.4.1 Human biological monitoring data

In PRVD2017-03, potential aggregate risk was also assessed using human biological monitoring data in a reverse dosimetry approach. Calculated aggregate MOEs were below the target MOE and supported the conclusion of the standard evaluation approach and assumptions. As no comments on this part of the assessment were received during the PRVD consultation, the

assessment using human biological monitoring data was not updated. However, the results continue to support the conclusions of the risk assessment in that risk mitigation is required based on the currently registered uses of lambda-cyhalothrin.

1.5 Health incident reports

Since the publication of PRVD2017-03, Health Canada received 40 human and 18 domestic animal incidents involving lambda-cyhalothrin (in other words, from 28 February 2017 to 30 November 2020).

Lambda-cyhalothrin pesticide incidents in people mainly occurred following exposure to agricultural class products or to liquid formulations of commercial class products registered for use in indoor residential areas. Exposures frequently related to mixing, loading and applying agriculture class products as well as people living or working in indoor areas treated with liquid formulations of commercial class products. In general, the symptoms reported in people following exposure were mainly minor in severity and included skin and respiratory effects such as tingling skin, coughing and respiratory irritation.

Domestic animal incidents frequently involved commercial class lambda-cyhalothrin products used in residential areas or pour-on type products for use on livestock. Oral exposure to lambda-cyhalothrin was reported mainly in pets (cats and dogs) as result of either licking accidental pesticide spills or following contact with product residues in treated areas. The signs reported in animals included effects such as vomiting and lethargy. The more serious signs of ataxia, muscle tremors as well as death were noted in cats.

Overall, the patterns observed in incidents are similar to the incident trends outlined in PRVD2017-03. There is potential for related dermal and/or inhalation exposure in applicators when mixing, loading or applying lambda-cyhalothrin products as well as in homeowners, children and pets following use of commercial class lambda-cyhalothrin products in residential areas. In addition, there were a few incidents relating to excessive product application (in other words, potential product misuse) by Pest Control Officers (PCOs) when using commercial class lambda-cyhalothrin products in residential areas. Notices of violations have been issued to PCOs by Health Canada under the *Administrative Monetary Penalties Act* for using commercial class lambda-cyhalothrin products in indoor areas contrary to label directions.

In general, the product labels of agricultural class lambda-cyhalothrin products do contain appropriate hazard signal words, precautionary statements, personal protective equipment and use directions aimed at reducing the exposure of mixers, loaders and applicators. Hence, no additional mitigation measures are required for agricultural class lambda-cyhalothrin products based on the current incident report review.

For commercial class lambda-cyhalothrin products registered for use in indoor sites, the product labels must be updated, as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* (2020), in order to reduce the likelihood of product misuse by PCOs and minimize unnecessary exposure in occupants living in treated areas. This requirement includes clearly defining the type of applications permitted in indoor areas; prohibiting the use of other application types (for example, general surface spray) as well as outlining ventilation and

other best practice statements aimed at reducing postapplication exposure. In addition, given the ongoing concern for product misuse by PCOs, a registrant-implemented national product stewardship program is required with the aim to encourage and promote the proper handling and use of commercial class lambda-cyhalothrin product in indoor residential sites.

2.0 Revised environmental risk assessment

2.1 Fate and behaviour in the environment

The fate and behaviour of lambda-cyhalothrin were described previously in PRVD2017-03. As a result of comments received during the consultation period for PRVD2017-03, Health Canada reassessed the aerobic biotransformation data for two soils (Lohmingen loam and Gartenacker loam). In the Lohmingen loam soil, there was an apparent lack of microbial activity and resulted in an unrealistic half-life (representative half-life of 9.58×10^3 d) which was inconsistent with other soils that were tested. Due to these concerns, results from the Lohmingen loam soil were removed from the analysis. For the Gartenacker loam soil, mass balance was poor (ranging from 58.2–108.6% AR). Due to these concerns, the results from the Gartenacker loam soil (calculated DT_{50} of 7.2 day) were also removed from the analysis. Health Canada's removal of these two soils is consistent with the European Union's (EU) assessment and results in the 90 percent upper confidence bound on the mean for the representative half-lives in aerobic soil being reduced from 4823 days (n = 8, adjusted to 25°C) to 413 days (n = 6, adjusted to 25°C) in the revised analysis. Modelled concentrations of lambda-cyhalothrin in water, used for both drinking water sources (Appendix VIII, Table 1) and the environmental risk assessment (see Section 3.2.2), were updated using this revised value. Lambda-cyhalothrin is slightly persistent to persistent in aerobic soil (DT_{50} values of 16 to 417 days) based on laboratory studies. Under field conditions, DT_{50} values ranged from 7.9–55 days.

The bioaccumulation criteria for the Toxic Substances Management Policy (TSMP) assessment has been updated, with the bioconcentration factors (BCF; determined in an early life-stage test with fish) being re-assessed. The range of BCF values previously reported (1500–6692) included two BCF values that had observed adverse effects at reported test concentrations. It was determined that these values were not valid for the determination of a BCF as it was possible that the stress of higher treatment exposures could have affected the uptake of the chemical into tissues. As only values from treatments where no effects were seen are considered in the TSMP assessment, the range of BCF values (3275–3995) has been revised. This is consistent with the values assessed and used by the EU. In addition, information for certain transformation products was added to the TSMP assessment.

2.2 Environmental risk characterization

The highest cumulative application rate assessed in PRVD2017-03 was 148 g a.i./ha (4 × 37.0 g a.i./ha, 7-day interval, turf). Rates for conifer seed orchard use are higher, with a maximum cumulative rate of 175 g a.i./ha (airblast to point of runoff, 3 × 58.56 g a.i./ha, minimum 10-day interval). Where applicable, the risk assessment has been revised to include the higher cumulative rate for conifer seed orchards.

2.2.1 Risks to terrestrial organisms

The changes related to the characterisation of aerobic soil biotransformation and the DT_{50} values in soil did not impact the risk assessment for terrestrial organisms at application rates previously reported in PRVD2017-03. The following discussion addresses the potential risks to terrestrial organisms from application of lambda-cyhalothrin to conifer seed orchards.

Lambda-cyhalothrin is not expected to pose a risk to earthworms because the level of concern (LOC) is not exceeded when the higher conifer rate is considered. Given that the mode of action (disruption of action potential in neurons) does not apply to plants, adverse effects to terrestrial vascular plants are not anticipated (see rationale presented in PRVD2017-03).

A quantitative risk assessment was conducted for birds and potential risks were considered to be minimal. The risk quotient (RQ) values (<2.5 on-field and off-field) are similar to values reported in PRVD2017-03 and only marginally exceeded the LOC. Under field conditions, it is unlikely that birds would consume enough food contaminated with residues to reach a level which would be expected to cause adverse effects (Appendix VIII, Table 2). Conifer seed orchards are also expected to be small in area, which reduces the potential for birds to consume a large portion of their diet from within these sites.

For wild mammals, on- and off-field risk quotients (for both acute and reproductive exposure) exceeded the level of concern for various feeding guilds for most mammal size classes under the conifer seed orchard application scenario. RQ values range from 9–12 for maximum residues and 3–4.5 for mean residues in food items. Potential effects on mammals through consumption of contaminated food cannot be discounted; therefore, a label statement to inform users of the toxicity to small mammals is required.

At the application rate for conifer seed orchard uses, which is 18% higher than the highest rate assessed in PRVD2017-03, the LOC for bees (off-field) and other beneficial arthropods (in- and off-field) would be exceeded as was determined previously for lower application rates. Conifer seed orchards (on-site) are not expected to be attractive to pollinating insects, such as honeybees. Label statements to inform users of the potential toxicity to beneficial insects, including bees, are required.

2.2.2 Risks to aquatic organisms

In response to the publication of PRVD2017-03, Health Canada received the following toxicity studies from the registrant:

- An acute freshwater toxicity test with *Hyalella* (PMRA# 2805502)
- Three 10-day sediment toxicity studies with *Hyalella* and *Chironomus* (PMRA# 2805500, 2805501, 2805503)

PMRA# 2805502 was acceptable and the results were included in the calculation of a revised acute HC_5 for freshwater aquatic invertebrates. As the other three studies were done in sediment, their results are considered in the risk assessment but not included in the HC_5 calculation. The data did not provide a more sensitive endpoint and they do not impact the risk characterization for aquatic habitats as risks to aquatic organisms have already been identified.

Other revisions to the aquatic risk assessment included the following:

- Freshwater aquatic invertebrate endpoints were reported as mean measured values instead of nominal values, which is consistent with converted values used by the EU. These were used to re-calculate the HC_5 (from 1.39 ng/L to 0.94 ng/L). This endpoint was also used to update spray buffer zones for freshwater habitats.
- Modelled runoff EECs were re-calculated using the revised aerobic soil half-life of 413 days.
- Spray buffer zones for marine habitats were revised based on current methodologies (single application and an acute marine endpoint).
- Water monitoring data for lambda-cyhalothrin were updated and considered.
- The cumulative application rate for conifer seed orchards was included in the risk assessment.

Spray Drift

The refined risk assessment for spray drift is summarized in Appendix VIII, Tables 2 and 3. Spray buffer zones have been updated (Appendix X).

The initial spray buffer zones calculated based on fine ASAE spray quality were large and did not fully mitigate the risk to aquatic organisms for some agricultural ground applications and all aerial applications. To better mitigate the potential risk to aquatic organisms, spray buffer zones were refined by setting restrictions on various spray application parameters (spray droplet size, wind speed, humidity, temperature, low drift spray nozzle technology, reduced number of applications). Restrictions for aerial applications include adjustments to spray droplet size (medium/coarse), as well as wind speeds (< 10 km/h), temperature (<20°C) and relative humidity (<50%), all applicable at the time of application. For all ground field sprayer use, restrictions include the use of low drift air induction nozzles only and application under low wind speeds (<8 km/h).

With these restrictions, the spray buffer zones required for aerial application of lambda-cyhalothrin for the protection of aquatic habitats remain large in many instances (up to 800 meters). The spray buffer zones for the protection of these habitats are calculated based on acute effects to aquatic invertebrates, which are known to be highly sensitive to pyrethroid insecticides relative to other aquatic organisms. However, the potential for acute risk to aquatic invertebrates is expected to be acceptable because:

1. The aerial buffer zones (up to 800 meters) are expected to mitigate >99% of the acute risk for aquatic invertebrates.

2. Based on laboratory data and some limited field data, lambda-cyhalothrin is expected to partition to sediment rapidly; therefore, detection in surface waters is expected to be short-lived. The adherence to spray buffer zones will further reduce the potential acute exposure risk and aquatic invertebrate populations would be expected to recover via recolonization.
3. Marine/estuarine environments are subject to daily tidal flushing events. As a result, marine invertebrate populations that are potentially at risk from receiving aerial spray drift would also be expected to recover via recolonization.

Therefore, the risk to aquatic organisms from spray drift is considered acceptable when label restrictions are followed.

Runoff

The refined aquatic assessment to determine potential risks to aquatic organisms from runoff used exposure estimates from modeling (Appendix VIII, Table 4) and relevant water monitoring data. An updated analysis of available water monitoring data (Appendix IX) indicated that lambda-cyhalothrin is rarely detected in Canadian surface waters (2923 sample, 12 detections, 0.4% detection frequency, maximum detection of 0.66 µg/L, second highest detection of 0.17 µg/L). Lambda-cyhalothrin was detected more frequently in American water monitoring data (17 909 samples, 169 detections, 0.94% detection frequency). Due to differences in the use pattern and application rates, the American water monitoring data may not be representative of potential concentrations in Canada. For modeled EECs, some RQ values exceed the LOC, with the greatest exceedances being observed for aquatic invertebrates. Acute and chronic risk from lambda-cyhalothrin residues in runoff were identified for aquatic invertebrates.

In conclusion, the LOC for aquatic invertebrates is exceeded based on modelled EECs and peak concentrations in water monitoring data. However, the assessment of risk also considers the following lines of evidence: 1) Lambda-cyhalothrin was rarely detected in Canadian surface water samples, 2) Invertebrates can generally replenish their populations through migration and rapid reproduction, and 3) The LOC was only slightly exceeded for fish and aquatic plants. Given the low solubility of lambda-cyhalothrin and that it readily adsorbs to soil and sediments, a vegetative filter strip of 10 m is expected to be an effective mitigation measure to reduce concentrations entering aquatic habitats due to runoff. Therefore, with the required 10 m vegetative filter strip in place, acute and chronic risks to aquatic organisms resulting from runoff are acceptable.

2.2.3 Environmental incident reports

As of 10 August 2020, three additional environmental incidents reports involving lambda-cyhalothrin were submitted to Health Canada since the publication of the PRVD2017-03. The incidents were assigned the severity classification of Major. In all three incident reports, death was reported to non-target aquatic organisms (water beetles, crayfish or trout) following assumed exposure to lambda-cyhalothrin through spray drift deposition to a waterbody. Two of these reports were for the same incident, which occurred in a lake in central Canada and involved the product Matador 120 EC insecticide (Reg. No. 24984, active ingredient lambda-cyhalothrin).

The third incident occurred in a western province and involved the product Silencer 120 EC insecticide (Reg. No. 29052, active ingredient lambda-cyhalothrin). Both products are registered as agricultural commercial class pesticides.

Health Canada has reviewed these incidents and has concluded that it is possible that the use of Matador 120 EC and Silencer 120 EC contributed to the death of crayfish and water beetles, and the fish, respectively. Revised spray buffer zones are expected to mitigate risks associated with spray drift. When directions on the label are followed, incidents such as these are not expected.

2.3 Revised toxic substances management policy

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, in other words, those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, lambda-cyhalothrin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[4] and evaluated against the Track 1 criteria. Health Canada has reached the conclusion that lambda-cyhalothrin and its transformation products do not meet all of the TSMP Track 1 criteria.

Please refer to Appendix VIII, Table 5 for further information on the TSMP assessment.

3.0 Value assessment

Lambda-cyhalothrin is a broad spectrum synthetic pyrethroid insecticide. It is registered for use on a wide spectrum of arthropod pests on many sites such as greenhouse lettuce and tobacco seedlings, industrial oilseed crops, terrestrial feed crops, terrestrial food crops, shelterbelts, tobacco, turf, poplar and willow (including Short-Rotation-Intensive-Culture), cattle, structural sites (indoors and outdoors) and surrounding soil, outdoor wasp and hornet nests, ant nests, termites and outdoor ornamentals. Lambda-cyhalothrin products are of value since contact or ingestion of the active ingredient results in rapid knockdown of pests, and provides long residual control. Based on these properties, it has one of the broadest registered use patterns of the synthetic pyrethroids and is widely used in Canadian agricultural and structural pest management. It is one of the main alternatives to organophosphates, diamides and neonicotinoids, and it is a valuable tool in resistance management.

Lambda-cyhalothrin has a role in an Integrated Pest Management approach to manage pests in structural sites. It is used by professional pest control applicators in residential settings to treat bedbugs, cockroaches, and ants.

[4] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

Lambda-cyhalothrin is important in the control of face flies and horn flies on beef and non-lactating dairy cattle, and the control of lice and ticks on beef cattle and calves as it is an important tool in an industry with major pesticide resistance concerns.

Lambda-cyhalothrin is the only active ingredient registered for suppression of black vine weevils in strawberries, and for control of a number of labeled pests on poplar and willow grown under short rotation intensive culture.

Following the re-evaluation of lambda-cyhalothrin, cancellation of use on lettuce, mustard seed (condiment type), all feed uses, all registered commodities from bulb vegetables crop group, and all registered commodities from oilseeds crop group, **except for** flax seed, mustard seed (oilseed type), and rapeseed (including canola) is required, as the potential risks to human health risks are not shown to be acceptable. For those uses that are to be cancelled, there are alternatives registered for all site and pest combinations.

List of abbreviations

↑	increased
↓	decreased
°C	degrees Celsius
3-PBA	3-phenoxybenzoic acid
a.i.	active ingredient
abs	absolutes
ADI	acceptable daily intake
AHETF	Agricultural Handlers Exposure Task Force
AR	applied radioactivity
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
BMD	benchmark dose
BMDL	benchmark dose lower confidence limit
BMDS	USEPA benchmark dose software
bw	body weight
CAF	composite assessment factor
CAPHRA	Council for Advancement of Pyrethroid Human Risk Assessment
CFIA	Canadian Food Inspection Agency
CPMA	Canadian Pest Management Agency
CR	chemical-resistant
d	days
DEEM	Dietary Exposure Evaluation Model
DOC	dissolved organic carbon
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DNT	developmental neurotoxicity
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
EEC	estimated environmental concentration
EFSA	European Food Safety Authority
EU	European Union
FQPA	Food Quality Protection Act
FOB	functional observational battery
g	gram
GMRL	general maximum residue limit
ha	hectare
HC_5	hazardous concentration to 5% of the species
IPCS	International Programme on Chemical Safety
IT	intermediate-term
K_{DOC}	dissolved organic carbon partition coefficient
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient
km	kilometre
L	litre(s)

LLE	liquid-liquid extraction
LOAEL	lowest observed adverse effect level
LOC	level of concern
log K_{ow}	octanol-water partition coefficient
m	metre
mg	milligram(s)
mL	millilitre(s)
MOE	margin of exposure
MRL	maximum residue limit
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no observed adverse effect level
PCO	Pest Control Operator
PCPA	*Pest Control Products Act*
PDP	Pesticide Data Program
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PMRL	Proposed Maximum Residue Limit
PPE	personal protective equipment
PRVD	Proposed Re-evaluation Decision
POC	median carbon concentration
POD	point of departure
ppm	parts per million
q_1*	cancer potency factor
RAR	renewal assessment report
Reg #	registration number
REI	restricted entry interval
Resp	respirator
RQ	risk quotient
RTI	retreatment interval
SD	standard deviation
SOP	standard operating procedure
SPME	solid phase microextraction
SPN	Science Policy Note
SSD	species sensitivity distribution
ST	short-term
TSMP	Toxic Substances Management Policy
TTR	turf transferable residue
UK	United Kingdom
USEPA	United States Environmental Protection Agency
µg	microgram
wt	weight

Appendix I Registered products containing lambda-cyhalothrin in Canada

Table 1 Registered products containing lambda-cyhalothrin in Canada requiring label amendments[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24984	Commercial	Syngenta Canada Inc.	MATADOR 120EC	Emulsifiable Concentrate Or Emulsion	Lambda-Cyhalothrin = 120g/L
26646	Commercial	Intervet Canada Corp.	SABER Insecticide Ear Tag	Slow-Release Generator	Lambda-Cyhalothrin = 10%
26837	Commercial	Syngenta Canada Inc.	WARRIOR Insecticide	Microcapsule Suspension	Lambda-Cyhalothrin = 122g/L
27428	Commercial	Syngenta Canada Inc.	DEMAND CS Insecticide	Microcapsule Suspension	Lambda-Cyhalothrin = 100g/L
27829	Commercial	Intervet Canada Corp.	SABER POUR-ON INSECTICIDE	Solution	Lambda-Cyhalothrin = 1.0%
27954	Commercial	Intervet Canada Corp.	SABER ER PREMISE INSECTICIDE	Microcapsule Suspension	Lambda-Cyhalothrin = 100g/L
28485	Commercial	BASF Canada Inc.	Prescription Treatment brand 221L Residual Insecticide Formula 2	Pressurized Product	Lambda-Cyhalothrin = 0.05%
28946	Commercial	Syngenta Canada Inc.	LAMBDA-CYHALOTHRIN CS INSECTICIDE	Microcapsule Suspension	Lambda-Cyhalothrin = 100g/L
29052	Commercial	Adama Agricultural Solutions Canada Ltd.	SILENCER 120 EC Emulsifiable Concentrate Insecticide	Emulsifiable Concentrate Or Emulsion	Lambda-Cyhalothrin = 120g/L
30325	Commercial	Syngenta Canada Inc.	VOLIAM XPRESS Insecticide	Suspension	Chlorantraniliprole = 100g/L; Lambda-Cyhalothrin = 50g/L;
30404	Commercial	Syngenta Canada Inc.	ENDIGO	Suspension	Thiamethoxam = 141g/L; Lambda-Cyhalothrin = 106g/L
32427	Commercial	Adama Agricultural Solutions Canada Ltd.	SILENCER 120 EC LOW VOC	Emulsifiable Concentrate Or Emulsion	Lambda-Cyhalothrin = 120g/L
33576	Commercial	Sharda Cropchem Limited	LABAMBA INSECTICIDE	Emulsifiable Concentrate Or Emulsion	Lambda-Cyhalothrin = 120g/L
24567	Technical	Syngenta Canada Inc.	LAMBDA-CYHALOTHRIN TECHNICAL INSECTICIDE	Liquid	Lambda-Cyhalothrin = 89%

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
29026	Technical	Adama Agricultural Solutions Canada Ltd.	Lambda-Cy Technical Insecticide	Dust Or Powder	Lambda-Cyhalothrin = 98.1%
30818	Technical	Syngenta Canada Inc.	Lambda-Cyhalothrin Technical 2 Insecticide	Solid	Lambda-Cyhalothrin = 98%
31604	Technical	Nufarm Agriculture Inc.	NUFARM LAMBDA-CYHALOTHRIN TECHNICAL	Solid	Lambda-Cyhalothrin = 97.0%
31668	Technical	UPL NA Inc.	UPI Lambda-Cyhalothrin Technical Insecticide	Solid	Lambda-Cyhalothrin = 95.95%
31859	Technical	Sharda CropChem Limited	Sharda Lambda-Cyhalothrin Technical Insecticide	Solid	Lambda-Cyhalothrin = 95.27%

[1]as of 25 November 2020, excluding discontinued products or products with a submission for discontinuation

Table 2 Registered products containing lambda-cyhalothrin in Canada that do not require label amendments[1]

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (%, g/L)
32243	Manufacturing Concentrate	Nufarm Agriculture Inc.	NUP-14001 MUP	Solution	Imidacloprid = 19.19%; Lambda-Cyhalothrin = 3.84%

[1] as of 25 November 2020, excluding discontinued products or products with a submission for discontinuation

Appendix II List of Commenters to PRVD2017-03

List of commenters' affiliations for comments submitted in response to PRVD2017-03

Category	Commenter
Registrant	Adama Agricultural Solutions Canada Ltd.
	Intervet Canada Corp.
	Syngenta
Governmental Organization	British Columbia Ministry of Agriculture
	New Brunswick Department of Agriculture
	Ontario Ministry of Agriculture
	Saskatchewan Ministry of Agriculture
Agricultural association	Agricultural Certification Services
	Alberta Barley, Canola, Pulse and Wheat Commission
	Alberta Canola
	Alberta Oats Growers Association
	Association des producteurs de Fraises et Framboises du Québec
	Canadian Canola Growers Association
	Canadian Horticultural Council
	Canadian Pest Management Association
	Canola Council of Canada
	Cereals Canada
	Consortium PRISME
	Fédération Fruits et Légumes
	Grain Growers of Canada
	Les Producteurs de Pommes du Québec
	Manitoba Canola Growers Association
	Ontario Fruit and Vegetable Growers' Association
	PEI Horticultural Association Inc.
	Pulse Canada
	SaskCanola
Grower/Stakeholder/General Public	Cargill
	Peak of the Market
	Paintearth County
	R&H Rempel Farms
	Association des producteurs maraîchers du Québec
	Promax Agronomy Services
	Pest Control Operators
	Growers

Appendix III Comments and responses

Health Canada received 92 written comments during the public consultation for the lambda-cyhalothrin proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

1.0 Comments related to the health risk assessment

1.1 Comments related to toxicology

1.1.1 Comments related to the weight of evidence for genotoxicty

A) One registrant provided extensive detailed comments on each of the ten genotoxicity studies for which positive results were reported in the PRVD2017-03 (PMRA# 2413376, 1248976, 2413382, 2413378, 2413365, 2413380, 2413381, 2413367, 2413369, 2413372) and assessed each study for reliability with respect to regulatory decision-making using the ToxRTool (PMRA# 2918243) and the Klimisch criteria (PMRA# 2918245). Based on the results of this analysis, the registrant concluded that only two of the ten studies (PMRA# 2413376, 1248976) met the Klimisch criteria for reliability (that is, Klimisch class 1 or 2), while the remaining eight studies did not meet these criteria (that is, Klimisch class 3, "not reliable"). The registrant concluded that lambda-cyhalothrin does not have genotoxic potential based on the low Klimisch reliability scores, "methodological and interpretive deficiencies" in the studies, and negative results in registrant-supplied genotoxicity studies.

Health Canada response

Following the critical review of the registrant's detailed comments and supporting information, Health Canada concludes that, of the eight genotoxicity studies considered by the registrant to be unreliable, two of the studies are supplemental (PMRA# 2413381, 2413382) and six of the studies (PMRA# 2413378, 2413365, 2413380, 2413367, 2413369, 2413372) are of insufficient quality and/or relevance to be used in the weight of evidence for genotoxicity. Based on questionable control data, lack of reporting detail and other factors, the six unacceptable studies noted above will not be considered in the weight of evidence for genotoxicity of lambda-cyhalothrin. Health Canada recognizes that the two supplemental studies have limitations, including the use of non-guideline methodologies and limited reporting of study details (which are not uncommon in literature studies). However, the studies met most of the screening criteria to be eligible for consideration in support of the human health risk assessment based on the USEPA Guidance Document for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment (USEPA, 2012), investigated endpoints which were not assessed in registrant-supplied studies, and showed similarities in lines of evidence. Specifically, the literature studies suggest the potential for lambda-cyhalothrin to damage DNA, and an assessment of DNA damage in vivo was not undertaken in registrant-supplied guideline studies.

In the literature studies considered to be acceptable or supplemental by Health Canada, positive results for the induction of DNA damage by lambda-cyhalothrin in mouse macrophages in a supplemental in vitro study were confirmed in vivo with positive results for DNA damage in rat hepatocytes (acceptable non-guideline study) following gavage administration of lambda-cyhalothrin. Additional positive results were obtained in a supplemental study conducted with lambda-cyhalothrin assessing chromosomal aberrations in rat lymphocytes in vivo. With that being said, negative results were obtained for cyhalothrin or lambda-cyhalothrin in in vitro studies of reverse mutation in bacteria, forward mutation in mouse lymphoma cells, unscheduled DNA synthesis in HeLa cells and rat hepatocytes, as well as chromosomal aberrations in a supplemental human lymphocyte assay. Negative results were also obtained in a dominant lethal mutation assay in mice and a chromosomal aberration study in rat bone marrow cells following gavage administration of cyhalothrin. It is noteworthy that protocols were limited in several registrant-supplied cytogenic assays, including a single exposure and harvest time in the in vitro chromosomal aberration assay in human lymphocytes and the use of intraperitoneal injection, considered an irrelevant route of exposure, in the in vivo mouse bone marrow micronucleus assay.

As a result of the re-consideration of the available genotoxicity data, the six unacceptable studies noted previously will not be considered in the assessment of the weight of evidence for the genotoxicity of lambda-cyhalothrin. For the reasons outlined above, however, the available genotoxicity data indicate that lambda-cyhalothrin may have the potential to damage DNA; however there is some uncertainty in the overall weight of evidence for genotoxicity due to mixed results in clastogenicity assays and negative results in mutation assays. Health Canada maintains that the results of genotoxicity studies are mixed as noted in the PRVD. Moreover, Health Canada is of the opinion that there is now a lower level of concern in the genotoxicity evidence than originally determined in the PRVD, since some literature studies with positive results are now considered to be supplemental or unacceptable.

B) One registrant indicated that treatment-related DNA damage due to an oxidative stress mode of action would be a threshold effect.

Health Canada response

Lambda-cyhalothrin demonstrated the ability to increase oxidative stress and damage DNA in mouse macrophage cells in vitro. Lambda-cyhalothrin technical and tested formulations also increased oxidative stress and decreased antioxidant enzyme activity in various tissues in rats (liver, kidney, brain, testes) and rabbits (testes) in short-term oral toxicity studies. Although there is evidence in both in vitro and in vivo studies that lambda-cyhalothrin increases oxidative stress, which may contribute to the potential for DNA damage, the mode of action for DNA damage remains unclear.

1.1.2 Comments related to the assessment of carcinogenicity

A) One registrant contended that the mammary gland adenocarcinomas in female mice treated with cyhalothrin are not treatment-related, and questioned the relevance of animal models of mammary gland tumours to humans. The registrant provided additional historical control data, suggested the use of alternative statistical analyses, and also supported the USEPA Benchmark Dose Software (BMDS) statistical approach using the cancer multistage model.

Health Canada response

The International Programme on Chemical Safety (IPCS) framework for the assessment of the weight of evidence for relevance of animal carcinogenesis to humans indicates that a substantial amount of information is required to conclude that a given cancer mode of action in animals is not relevant to humans, including chemical-specific mode of action data and kinetic and dynamic information from both experimental animals and humans (Boobis et al., 2006). In the absence of these data, the rodent model of carcinogenesis is considered to be relevant to humans, even where effects are observed in tissues with no direct human equivalent.

Health Canada re-visited the previously available and newly submitted information in the context of the weight of evidence for the mammary gland adenocarcinomas in female mice. Health Canada concurs that the mammary gland adenocarcinomas in treated and control mice were morphologically similar, there was no evidence of tumour multiplicity with increasing dose, and there were no pre-neoplastic lesions in the mammary gland. However, evidence supporting a treatment-related increase in the incidence of mammary gland adenocarcinomas in female mice at 10.6 mg/kg bw/day (7/52 or 13.5%; $p = 0.03$) or 50.7 mg/kg bw/day (6/52 or 11.5%; $p = 0.05$) included positive pair-wise tests, a positive trend test ($p = 0.017$) and evidence of decreased time to tumour onset. The data suggest an early onset of the tumours in treated females based on the occurrence of mammary gland adenocarcinomas and associated subcutaneous masses as early as 91 weeks and 85 weeks at 10.6 mg/kg bw/day and 50.7 mg/kg bw/day, respectively, compared to a single incidence in concurrent controls at termination. Moreover, there is evidence that lambda-cyhalothrin has the potential to interact with the endocrine system, including a treatment-related increase in uterine tumours in mice and evidence of female (and male) reproductive toxicity throughout the database, as well as some evidence that lambda-cyhalothrin can damage DNA in vivo.

Health Canada is of the opinion that historical control data should not be combined with concurrent control data for the statistical analysis of tumour incidence data to determine treatment-related effects, as suggested by the registrant's use of the statistical methods of Elmore and Peddada (2009) and Kitsche et al. (2012). Historical control data can provide important contextual information regarding the concurrent controls, but should not be used in isolation to determine a treatment-related effect. Elmore and Peddada (2009) indicated that the concurrent controls are the most relevant comparison group for statistical analysis of the data in treated groups, while historical control data are considered to provide "a broader perspective to assist in understanding the significance of the current study." That is, treatment-related effects are best discerned in randomized studies using the concurrent control group.

Formal statistical tests of the fit of the data in the USEPA BMDS are increasingly being recognised as problematic (EFSA, 2016). There are many reasons for a low p-value, and it is difficult to discern whether or not a low p-value is primarily due to the absence of a dose-response relationship. To use p-values for the determination of fit in the EPA BMDS, the concerns and limitations of p-values should be considered. Some of these are noted in the 2016 American Statistical Association statement on p-values (Wasserstein and Lazar, 2016). With regards to the claim that the fit of the adenocarcinomas are a "binomial no/yes response", it is not clear to Health Canada what is meant by a binomial no/yes response with regards to the dose response given that there are multiple dose levels in the mouse cancer bioassay.

For cancer risk assessment, Health Canada also uses a model-free approach to low-dose extrapolation (Krewski et al., 1991) as a way to assess the practical importance of any lack of fit. In the case of lambda-cyhalothrin, this analysis resulted in an almost identical slope and q_1* estimate, thereby alleviating concerns regarding model fit.

In conclusion, Health Canada maintains that the available information supports the position that the mammary gland adenocarcinomas in female mice treated with cyhalothrin are treatment-related. However, given the lower level of concern in the genotoxicity evidence, a linear low-dose extrapolation approach for the assessment of cancer risk is considered to be overly conservative, and a q_1* is no longer warranted for lambda-cyhalothrin. A threshold approach was undertaken instead for the carcinogenic risk assessment.

B) One registrant contended that the mammary gland fibroadenomas in female rats are not treatment-related and provided additional historical control data to support the rationale that tumours were within the control range.

Health Canada response

Health Canada re-visited its position regarding the mammary gland fibroadenomas in rats in light of the newly submitted information. In the PRVD, Health Canada concluded that there was equivocal evidence of a treatment-related increase in mammary gland fibroadenomas in the female rat based on increased tumour incidences in treated females, relative to concurrent controls, and a marginally positive test for trend ($p = 0.05$); there was also a lack of historical control data. Based on the assessment of the weight of evidence, including the lack of statistical significance in pair-wise tests and consideration of the new historical control data provided by the registrant which indicates that the incidences of mammary gland fibroadenomas in treated rats are within the historical control range, Health Canada concludes that the mammary gland fibroadenomas in female rats are not treatment-related. Therefore, the carcinogenicity assessment for lambda-cyhalothrin with respect to the mammary gland fibroadenomas in female rats will be revised from equivocal evidence of carcinogenicity in the female rat to no evidence of carcinogenicity in the rat.

C) One registrant contended that the uterine leiomyomas and leiomyosarcomas in mice are not treatment-related, suggesting that these tumours in the uterus be considered as part of the total incidence of smooth muscle tumours, and thus compared to historical control data for the incidence of leiomyosarcomas and leiomyomas for all tissues containing smooth muscle. They also questioned the practice of combining the two tumour types for statistical analysis, suggested alternative statistical analyses, and provided additional historical control data.

Health Canada response

Health Canada re-visited the toxicology information in the context of the weight of evidence for the uterine tumours in mice. There is evidence in the published literature for the potential transformation of some benign uterine leiomyomas to malignant uterine leiomyosarcomas. This includes immunohistochemical and microscopic evidence of an identifiable spectrum of transition from leiomyoma cells to leiomyosarcoma cells, and genetic evidence of identical gene mutations, aberrations and inactivation patterns in both tumour types suggesting a common

origin for these tumours (PMRA# 2918189; PMRA# 2918194). Guidance from the National Toxicology Program recommends combining the incidences of uterine leiomyomas and uterine leiomyosarcomas for statistical analysis, and indicates that smooth muscle tumours in reproductive organs should be considered independently, and should not be combined for all anatomic sites. Based on the re-analysis of the data, Health Canada concludes that there is a treatment-related increase in the combined incidence of uterine leiomyoma and uterine leiomyosarcoma [1/52 (2%), 0/52 (0), 3/52 (6%) and 5/52 (10%) at 0, 2, 10.6 and 50.7 mg/kg bw/day, respectively] in treated female mice. The weight of evidence includes a dose-related increase with positive test for trend ($p < 0.01$) and a high-dose level incidence which is at the top of the historical control range. It was noted that the historical control range for combined uterine smooth muscle tumours was unchanged following submission of the extended historical control data. Additionally, there is evidence that lambda-cyhalothrin has the potential to interact with the endocrine system, and some evidence that lambda-cyhalothrin can damage DNA in vivo.

As discussed previously, Health Canada is of the opinion that historical control data should not be combined with concurrent control data for the statistical analysis of tumour incidence data to determine treatment-related effects, as suggested by the registrant's use of the statistical method of Kitsche et al. (2012). Historical control data can contextually provide important information regarding the concurrent controls, but should not be used to determine a treatment-related effect.

In conclusion, the increased combined incidence of uterine leiomyomas and leiomyosarcomas in female mice exposed to cyhalothrin is considered to be treatment-related.

D) One registrant stated that it is unclear how the cancer potency factor was derived by Health Canada, and contended that the uterine tumours could not be derived from the direct genotoxic action of cyhalothrin since positive evidence of genotoxicity in hepatocytes and lymphocytes in vivo did not translate into liver tumours or hemolysis.

Health Canada response

A description of how Health Canada determines acceptable risk is available in PMRA Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products*. As discussed, Health Canada has conducted a re-analysis of the previously available genotoxicity studies and animal bioassay data, new toxicology data, and historical control incidence values in the context of an overall weight of evidence for cancer risk assessment. Health Canada concludes that the cyhalothrins pose a carcinogenic hazard based on the increased incidences of mammary gland and uterine tumours in the mouse. There is some evidence that lambda-cyhalothrin may have the potential to damage DNA; however, results are mixed for other genotoxicity endpoints and there is a lower level of concern for the genotoxicity weight of evidence than previously determined in the PRVD as a result of the re-consideration of the genotoxicity literature studies. Given the lower level of concern in the genotoxicity evidence, a linear low-dose extrapolation approach for the assessment of cancer risk is considered to be overly conservative, and a q_1^* is no longer warranted for lambda-cyhalothrin. A threshold approach was undertaken instead for the carcinogenic risk assessment. The margin from the ADI to the NOAEL for the treatment-related tumours in female mice (2 mg/kg bw/day) is 6600, and thus is considered to be sufficiently health protective.

1.1.3 Comments - reproductive toxicity

A) One registrant provided extensive detailed comments on each of the five literature studies (PMRA# 2413360, 2413361, 2418364, 2418360, 2418361) which were used for the assessment of the weight of evidence for reproductive toxicity, and scored each study for reliability using the ToxRTool (Schneider et al., 2009) and the Klimisch criteria (Klimisch, 1997). Based on the results of this analysis, the registrant concluded that each of the five studies met the class 2 Klimisch criteria for reliability, that is, reliable with restrictions, but each was inadequate for risk assessment purposes owing to "significant concerns with regards to the accuracy, interpretation, reliability and reproducibility of the studies". The registrant contended that there is no evidence of male reproductive toxicity in the lambda-cyhalothrin database, and that the testicular effects in experimental animals noted by Health Canada reflect general toxicity, differential body weight and body weight gain, normal pathology or normal variability. Comments provided by another registrant supported the treatment-related male reproductive effects, but concluded that the addition of a threefold database uncertainty factor is not warranted for risk assessment purposes.

Health Canada response

Following critical review of the detailed comments and supporting information from the registrant, and re-analysis of the five literature studies used by Health Canada for the assessment of reproductive toxicity, Health Canada concludes that each of the five studies is sufficient to be considered qualitatively in the weight of evidence for the reproductive toxicity of lambda-cyhalothrin. Uncertainties in these studies which were identified by the registrant included the use of formulations, small group sizes, non-guideline methodologies which may have underpowered the studies, and limited reporting of study detail, which is not uncommon in literature studies.

However, the studies met most of the screening criteria to be eligible for consideration in support of the human health risk assessment based on the USEPA Guidance Document for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment (USEPA, 2012).

Health Canada concurs that these studies have numerous limitations, and accordingly, designated them supplemental in the PRVD. The most serious limitation identified by Health Canada is the lack of detail on product characterization in PMRA# 2418360 and 2418361 and the use of a formulated product in PMRA# 2413361, 2413360 and 2418364. With regards to the latter limitations, Health Canada acknowledges that the contribution of the formulants to the observed toxicity cannot be excluded. Nevertheless, the literature studies identified the male reproductive system as a target of toxicity and showed some similarities with lines of evidence in the toxicology database. Specifically, reductions in testicular weights were noted in guideline oral studies in rodents and dogs. Tubular degeneration and calcification of the testes were noted in the chronic rat dietary study with cyhalothrin. In short-term dermal toxicity studies, there were decreased absolute testes weights in rats treated with lambda-cyhalothrin and decreased gonad weights in rabbits treated with cyhalothrin.

The published studies, as a whole, identified potential effects on spermatazoa parameters concurrent with effects on testicular weight. At the time of conduct of the rat multi-generation reproduction study with cyhalothrin, an assessment of spermatazoa was not required and thus was not undertaken. Although no effects on fertility were noted in this study, this parameter is not particularly sensitive to testicular changes. Thus, the lack of assessment of testicular function is considered to be a deficiency in the database for lambda-cyhalothrin.

Given that the published studies on reproductive toxicity are considered in a qualitative manner only, Health Canada re-visited the toxicology reference values to determine the necessity of the extra 3-fold factor applied to reflect the lack of assessment of testicular function. For the ADI, the NOAEL of 0.1 mg/kg bw/day from a one year oral dog study conducted with lambda-cyhalothrin was selected for risk assessment purposes. This NOAEL was based on neurotoxic signs, liquid feces and decreased relative testes weights at the LOAEL of 0.5 mg/kg bw/day. Specifically, relative testes weights were decreased 9% and 13% at 0.5 and 3.5 mg/kg bw/day, compared to controls, respectively. These decreases did not achieve statistical significance. Absolute testes weights were unaffected by treatment. A second one year oral dog study with lambda-cyhalothrin failed to show an effect on absolute or relative testes weights at dose levels of 0.75, 1.5 or 3.0 mg/kg bw/day. The lack of reproducibility of the decreased testes weights at levels up to 3.0 mg/kg bw/day suggests that the finding in the first study at 0.5 mg/kg bw/day may have been spurious. Although the effect at 3.5 mg/kg bw/day cannot be as readily discounted, the use of the NOAEL of 0.1 mg/kg bw/day without the threefold uncertainty factor would provide inherent protection to the observed testicular effects.

For dermal risk assessment, Health Canada selected a NOAEL of 10 mg/kg bw/day from a 21-day dermal toxicity study with lambda-cyhalothrin based on neurotoxic signs, decreased bodyweight, decreased relative ovary weight and atrophy of the seminal vesicles in rats occurring at the LOAEL of 50 mg/kg bw/day. It should be noted that atrophy of the seminal vesicles at this level was seen in two males that died on day four of the study; the study authors speculated that this was possibly an agonal effect. Given the early occurrence of the observation, Health Canada contends that the atrophy is unlikely related to treatment. However, absolute testes weights were also reduced by 20%, though not statistically significant, at the LOAEL; relative testes weights were unaffected by treatment. In light of the reduction in absolute testes weights at the LOAEL, there is no inherent protection to account for the uncertainty related to testicular function and the threefold uncertainty factor outlined in the PRVD is retained.

For inhalation exposure, the NOAEL of 0.08 mg/kg bw/day from the short-term inhalation toxicity study in the rat was selected for risk assessment purposes. No evidence of testicular toxicity was apparent in this study. This NOAEL is well below the lowest level in the acceptable oral studies which resulted in a reduction in testicular weight (3.5 mg/kg bw/day in the one year dog study, see above), and inherently provides extra protection to account for uncertainty related to testicular function.

In conclusion, the threefold database uncertainty factor for uncertainty related to testicular function will be retained for dermal risk assessment, but has been removed for chronic dietary risk assessment and inhalation risk assessment. However, as explained in the PRVD, where concerns were identified for uncertainties relating to both testicular function and potential neurotoxicity in the young, only one threefold factor was applied for risk assessment purposes.

As the concerns relating to potential neurotoxicity remain relevant for the inhalation and chronic dietary risk assessments, the overall target margin of exposure (MOE) or composite assessment factor (CAF) for these scenarios will remain unchanged at 300.

B) One registrant stated that lambda-cyhalothrin was evaluated by the USEPA ToxCast program in a range of assays to evaluate the potential effects on endocrine-related endpoints and the results demonstrated no evidence of endocrine-related activity.

Health Canada response

The USEPA's ToxCast program generates predictive data using high-throughput in vitro screening methods and computational toxicology approaches to rank and prioritize chemicals. The USEPA considers these data to be "iterative and intended for review and comment purposes only. Data presented should not be taken as final decisions regarding potential bioactivity, exposure, hazard or risk of the chemical or substance, or that the USEPA has or will make a determination that any use of the chemicals or substances necessarily will pose a risk. These data do not provide a scientific basis, by themselves, supporting a conclusion that chemicals or substances have potential for endocrine disruption." Accordingly, the USEPA ToxCast results cannot be used in isolation to determine the potential for lambda-cyhalothrin to alter endocrine-related function and cause adverse outcomes in vivo. As noted in the PRVD, there are indications of endocrine-related effects; however, the toxicology reference values used in the risk assessment are considered protective of these effects.

1.1.4 Comments - Acute reference dose (ARfD), Acceptable daily intake (ADI)

A) One registrant suggested that the NOAEL of 2.5 mg/kg bw from the guideline rat acute neurotoxicity study (PMRA# 1124601) previously selected by Health Canada for derivation of the acute reference dose should continue to be used rather than the Wolansky et al. (2006) study of locomotor activity in male rats. The acute neurotoxicity study was conducted under GLP and included multiple neurobehavioral, clinical and pathology assessments in both sexes. The registrant did not consider the Wolansky et al. (2006) assay to be an adequate study for the derivation of the ARfD as there was no indication that it was subject to a GLP audit, and the study examined only one measure of neurotoxicity (locomotor activity) in one sex. Further, locomotor activity is recognized as a non-specific assessment and may be confounded by external factors and adverse or non-adverse effects, including "abnormal sensations" (such as those associated with paresthesia).

Health Canada response

Health Canada considers the Wolanksy et al. (2006) acute locomotor activity assay to be an acceptable non-guideline study, which provides robust dose-response data for a sensitive neurobehavioral endpoint in the rat. The assessment of locomotor activity at low oral dose levels in male rats in this assay is considered to be relevant to acute dietary risk assessment in view of the weight of evidence in both guideline and literature studies which demonstrate effects on gait and mobility as prominent findings in experimental animals exposed to lambda-cyhalothrin, with no significant sex-related differences. Locomotor activity was assessed in the Wolansky study at the time of peak effect (2.5 hours) using nine dose levels, thus minimizing the variability in the

data and increasing confidence in the results. The dose levels tested were lower than those assessed in other oral toxicity studies in the database, including the guideline acute oral neurotoxicity study and the recent acute locomotor activity assay of similar design by Moser et al. (2016). The results of the Wolansky et al. (2006) study are supported by the results of the Moser et al. (2016) assay, in which the effects of lambda-cyhalothrin on locomotor activity were assessed at the time-of-peak effect (1.5 hours post-dosing) in male Long Evans rats using three dose levels in the range-finding study, and six dose levels in the main dose-response study. The Moser study is considered to be an acceptable non-guideline study which provides additional robust data to support the effects on locomotor activity noted in the Wolansky et al. (2006) study. Despite the difference, which is considered small, in the time-of-peak effect in the Wolansky (2.5 hours) and Moser (1.5 hours) studies, there is similarity of the robust dose-response curves in the two studies, and acceptable fit of the combined locomotor activity data according to the current EFSA guidance (EFSA, 2016).

The guideline acute neurotoxicity study was not considered for risk assessment purposes since it did not evaluate neurotoxicity at the time-of-peak effect (motor activity and Functional Observational Batter (FOB) were assessed seven hours post-dosing), and provides a point of departure (POD) which is 10-fold higher than those derived on the basis of the Wolansky and Moser locomotor activity studies. Moreover, a relatively high dosing volume (10 mL/kg) was used in the guideline study, compared to the dosing volume (1 mL/kg) used in the Wolansky (and Moser et al., 2016) locomotor activity study. This higher dosing volume may have significantly affected the severity of neurotoxic effects. Gavage dosing volume can impact the potency of the cyhalothrins with respect to neurotoxic effects by affecting absorption (USEPA, 2017). Thus, the relatively high dosing volume used in the guideline acute neurotoxicity study may have limited the absorption of lambda-cyhalothrin, thus reducing peak concentrations in the brain, and accordingly, the degree of neurotoxicity. The Moser et al. (2016) study demonstrated that the administration of an acute oral dose of lambda-cyhalothrin in rats correlates with brain (and plasma) concentrations, which in turn correlates with effects on locomotor activity.

There is no evidence to suggest that the locomotor activity data in the Wolansky study (or the Moser et al, 2016 study) are confounded by environmental conditions, gross toxicity or “abnormal sensations” in oral or esophageal tissues in treated animals. The dose levels utilized in the main studies, which were selected based on the findings of the pilot study, did not result in mortality or signs of excessive toxicity in rats treated by gavage with lambda-cyhalothrin. Transient signs of paresthesia at the site of contact have been noted in humans (tingling skin) and animals (upward curvature of the spine, repetitive grooming, biting and chewing, dermal wounds) exposed to lambda-cyhalothrin or cyhalothrin as an acute effect distinct from irritation. However, given that site of contact effects were limited by gavage administration of lambda-cyhalothrin in the locomotor activity assays, and abnormal sensations in esophageal tissues have not been documented in human incidents involving accidental ingestion of lambda-cyhalothrin, potential abnormal sensations in oral tissues is not considered to be a confounding factor in experimental species exposed to lambda-cyhalothrin by gavage dosing.

In summary, Health Canada considers the Wolansky et al. (2006) assay to be an acceptable non-guideline study which provides robust dose-response data for a sensitive neurobehavioral endpoint in the adult rat, and is supported by other adequate oral toxicity studies in the database which demonstrate a similar POD and adverse effects on mobility and gait.

B) One registrant expressed the following concerns regarding Health Canada's benchmark dose (BMD) analysis of the Wolansky study data:

The selection of a 20% response level for BMD analysis of the locomotor activity data in the Wolansky study is arbitrary and is not congruent with the USEPA's selection of a response level of one standard deviation from the control mean ($BMDL_{1SD}$) for the same endpoint. The USEPA's selection of a $BMDL_{1SD}$ for locomotor activity is also considered to be arbitrary. It is not possible to demonstrate a statistically significant difference from control at the 20% effect level in the Wolansky et al. (2006) study. Also, a 20% change in locomotor activity is smaller than the variability in the Wolansky data, indicating that this assay is not sensitive enough to reliably detect a 20% change in locomotor activity, relative to controls.

There were errors in the standard deviation data from the Wolansky assay which were used by Health Canada for derivation of the $BMDL_{20}$. Based on the group mean data and corrected standard deviations from the Wolansky study, the Proast model output (Version 38.9) indicates less confidence in the fit (log likelihood of -33.24), compared to Health Canada's estimate (log likelihood = -53.3). Guidance documents on BMD modelling from the USEPA (2012) and EFSA (2016) recommend comparing the fit of the Proast data in both the exponential and Hill models. Visual inspection of modelling with the Proast exponential and Hill model outputs (dose expressed on log scale) demonstrates that "the Hill equation represents the lower dose data better" (Hill log dose $BMDL_{20}$ = 0.28 mg/kg bw).

The variability in the locomotor activity data confounds the determination of an effect level. The use of a "best-fit" approach to define the threshold must be viewed in the context of this variability. Also, it is not appropriate to include the high-dose data in the BMD analysis of the Wolansky study since gross toxicity is evident at the higher doses. Elimination of the high-dose group from the analysis increased the $BMDL_{20}$ to 0.65 mg/kg bw in the Hill model. It is evident that small changes to the data or "fitting parameters" can yield unpredictable changes in the BMD and BMDL. Given this uncertainty, a NOEL/LOEL of 0.5/1.25 mg/kg bw from the Wolansky study "is not a markedly worse description of this data".

Based on the Proast BMD modelling results (Version 38.9) of the combined locomotor activity data from the Wolansky et al. (2006) and Moser et al. (2016) studies, the datasets mostly overlap, but the "variability in the locomotor activity in both studies indicates it is not suitable for a precise determination of an effect level" (log likelihood of fit of the combined data = -71). In a later comment, the registrant indicated that a BMDL derived based on the combined locomotor activity data from the Moser et al. (2016) and Wolansky et al. (2006) studies would be adequate to eliminate the 10-fold uncertainty factor for intraspecies variability used to derive the ARfD.

Health Canada response

The general scientific community has not established the degree of change in locomotor activity that is considered to be adverse, nor has it specified an effect size for BMD modelling, although 5% is often recommended for continuous data. In the case of variable data, the effect size can be increased. Accordingly, Health Canada selected a response level of 20% based on the normal variability of motor activity in control rats (9.6% to 26%) in the literature (PMRA# 2351167).

For BMD analysis of the locomotor activity data in the study by Moser et al. (2016), the USEPA selected a response level of one standard deviation from the control mean, as recommended in the Agency's Benchmark Dose Guidance Document (USEPA, 2012) for continuous endpoints. Limitations of the latter approach are outlined in the EFSA guidance document on the use of the benchmark dose approach in risk assessment (EFSA, 2016). Health Canada concurs with these limitations and thus follows the EFSA approach.

There is no evidence that the maximum tolerated dose (MTD) was exceeded in the high-dose animals in the Wolansky study, and thus there is no rationale for the elimination of the high-dose data from the BMD analysis. Dose levels which produced excessive toxicity in the pilot study, that is, those leading to prolonged clinical signs or mortality, were not included in the main dose-response study. There was no mortality or signs of excessive toxicity before or after the assessment of locomotor activity in rats treated with lambda-cyhalothrin in the main dose-response study. Health Canada considers the Wolansky et al. (2006) study to provide robust dose-response data for a sensitive neurobehavioral endpoint in the adult rat. This is supported by the results of the locomotor activity study of similar design in the same strain of rat by Moser et al. (2016).

Health Canada acknowledges that there was a minor error in the data from the Wolansky study used to derive the acute reference dose in the PRVD. Health Canada has conducted a new BMD analysis of the corrected locomotor activity data in the Wolansky et al. (2006) study, in addition to the recent comparable Moser et al. (2016) study in accordance with the EFSA's current guidance document on the use of the BMD approach in risk assessment (EFSA, 2016). The EFSA guidance document clearly outlines the procedures for statistical analysis, and the corresponding rationales for these procedures.

Health Canada's updated BMD analysis yielded a $BMDL_{20}$ of 0.20 mg/kg bw based on the corrected Wolansky et al. (2006) study data, a $BMDL_{20}$ of 0.12 mg/kg bw based on the Moser et al. (2016) study data, and a $BMDL_{20}$ of 0.28 mg/kg bw based on the combined locomotor activity data from Wolansky et al. (2006) and Moser et al. (2016). In view of the robust combined dataset for this sensitive neurobehavioral endpoint, the similarity of the well-defined dose-response curves in the two studies, and the acceptable fit of the combined data according to the current EFSA guidance, confidence in the combined $BMDL_{20}$ of 0.28 mg/kg bw is considered to be high and this POD is considered to be most appropriate for risk assessment purposes. Therefore, Health Canada has revised the ARfD and the short- and intermediate-term non-dietary incidental oral reference values based on the $BMDL_{20}$ of 0.28 mg/kg bw derived from the combined locomotor activity data in the Wolansky et al. (2006) and Moser et al. (2016) studies. Since there remains some concern that the critical endpoint in adults may not be adequate for assessment of the young, the threefold database uncertainty factor applied for potential sensitivity of the young is retained for risk assessment purposes. Consequently, the PCPA factor is reduced to onefold and standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability are applied, resulting in a CAF or target MOE of 300.

The short- and intermediate-term oral aggregate reference values, which were based on the NOAEL of 0.1 mg/kg bw/day for neurotoxic signs from the 1-year dog oral toxicity study in the PRVD, were also revised to be consistent with the short- and intermediate-term non-dietary incidental oral reference values. Therefore, these oral aggregate reference values are also now based on the $BMDL_{20}$ of 0.28 mg/kg bw derived from the combined locomotor activity data in

the Wolansky et al. (2006) and Moser et al. (2016) studies, with a target MOE of 300. It was considered appropriate to aggregate decreased motor activity (for oral exposure) with the neurotoxic signs (for inhalation and dermal exposures) given that decreased activity and neurotoxic signs are considered to be functional neuromuscular effects associated with the mode of action for the pyrethroids. The long-term oral aggregate reference value was not changed, and will continue to be based on the NOAEL of 0.1 mg/kg bw/day for neurotoxic signs from the 1-year dog oral toxicity study.

In summary, Health Canada has revised the ARfD, as well as the short- and intermediate-term non-dietary incidental oral and short- and intermediate-term oral aggregate reference values to reflect the new $BMDL_{20}$ of 0.28 mg/kg bw based on the combined locomotor activity data from the Wolansky et al. (2006) study (corrected data) and the Moser et al. (2016) study. The PCPA factor was reduced to onefold, standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were used, and a threefold database uncertainty factor was applied, resulting in a CAF or target MOE of 300. The resulting ARfD is 0.0009 mg/kg bw.

C) The registrants, growers, grower associations and provincial authorities requested that Health Canada either remove the threefold database uncertainty factor applied for the derivation of the ARfD and ADI, or wait for the final results of the lambda-cyhalothrin PBPK modelling data and the Council for Advancement of Pyrethroid Human Risk Assessment (CAPHRA) data before making a final decision. The registrant contends that the increased sensitivity of young rats to the lethal effects of some pyrethroids is not applicable to humans, and there is no evidence of increased sensitivity of the young to lambda-cyhalothrin in the database.

Health Canada response

As discussed in the PRVD, the design of the available studies was limited in addressing the relative sensitivity of the young animal to the adult. Despite this, several flags for sensitivity and/or concern for the young were identified in the available studies. Notwithstanding the limitations of the DNT study, serious effects in the young were noted in this study and two range-finding DNT studies conducted in rats exposed orally to lambda-cyhalothrin. In offspring in the main DNT study, reductions were noted in pup survival, body weight and litter weight, as well as impaired learning and memory, decreased brain morphometric measurements and decreased auditory startle response. These findings were noted in the presence of reduced maternal body weight only. In the range-finding DNT studies, decreased pup survival and increased missing or presumed dead pups were observed in the absence of maternal toxicity. There was also some evidence of sensitivity of the young in the multi-generation reproductive toxicity study, with decreased pup body weight during the lactation period observed in the absence of maternal toxicity. Given this evidence, and the absence of robust data to address sensitivity, residual uncertainty remains concerning sensitivity of the young to potential neurotoxic effects of lambda-cyhalothrin. Accordingly, this uncertainty has been reflected in the form of the threefold database uncertainty factor. Since concerns were addressed with the database uncertainty factor, the PCPA factor was reduced to onefold.

The results of the work undertaken by CAPHRA to address the potential sensitivity of the young to the pyrethroids at large were submitted to Health Canada after the closing date for public comment on the PRVD for lambda-cyhalothrin. Since these data are relevant to all pyrethroids, Health Canada is reviewing the studies under separate cover in conjunction with the recent USEPA assessment. Following the review of the CAPHRA data, Health Canada will also review the final report of the lambda-cyhalothrin toxicokinetic study and the report of the assessment of potential childhood sensitivity, both of which were submitted by the registrant after the closing date for public comment. To date there is no indication of increased health risks related to this information, however, should any concerns be identified, Health Canada will take the appropriate regulatory action.

In conclusion, there are no changes to Health Canada's risk assessment at this time with regards to the CAPHRA data.

D) The registrant, growers and grower associations indicated that the risk assessment should be aligned with other regulatory risk assessments, such as the USEPA (2017) evaluation, in which the ARfD for lambda-cyhalothrin was based on a $BMDL_{1SD}$ from the more recent Moser et al. (2016) study and a threefold uncertainty factor for children under six years of age only.

Health Canada response

Health Canada uses contemporary risk assessment methodologies which are based on sound science, agency policies and practices, and are recognized globally by our pesticide regulatory partners. Notwithstanding the similarities in approach, it is not uncommon for regulatory bodies to differ with regards to study selection, requirements to refine assessments, or for them to have unique regulatory policies. As discussed previously, Health Canada's recent BMD analyses of the combined locomotor activity data in the Wolansky and Moser studies of similar design yielded a $BMDL_{20}$ of 0.28 mg/kg bw. Confidence in this estimate is considered to be high. This POD is considered to be most relevant for acute dietary risk assessment since it is based on a sensitive neurobehavioral endpoint with a well-defined dose-response relationship from two robust datasets.

The USEPA retained a threefold FQPA Safety Factor to protect for exposures of children less than six years of age, but had no concerns regarding age-related sensitivity of the unborn children of pregnant women or for children greater than six years of age owing to "the absence of pre-natal sensitivity in 76 guideline studies for 24 pyrethroids and in vitro assays of age-related expression of enzyme activity (plasma/hepatic carboxylesterase, CYP450's) in the scientific literature" (PMRA# 2918248). At this time, Health Canada will retain the threefold database uncertainty factor for all age groups.

E) The registrants contended that the 100-fold standard uncertainty factor used for the derivation of the ARfD is not warranted since the use of a BMDL is inherently protective and accounts for individual variability in the dataset, thus removing or reducing the need for the 10-fold uncertainty factor for intraspecies variability.

Health Canada response

Application of the default 10-fold uncertainty factor for intraspecies variability is generally accepted by the international regulatory community as protective for natural variability within the human population, including age- and sex-related differences and variability in individual health status. In the absence of an appropriate data-derived chemical-specific adjustment factor for lambda-cyhalothrin, the application of a 10-fold uncertainty factor to a BMDL is relevant and consistent with current Health Canada practice, as well as that of other pesticide regulatory jurisdictions. Therefore, Health Canada will retain the standard 10-fold uncertainty factor applied for intraspecies variability as described in PRVD2017-03.

1.2 Comments related to dietary exposure

1.2.1 Use pattern for drinking water residue input

A comment was received from the Saskatchewan Ministry of Agriculture regarding the turf application rate being used to model the estimated environmental concentrations. They proposed that lower, agricultural rates, would be more realistic.

Health Canada response

Refer to the environmental assessment response to this question (see comment 2.7). The dietary assessment continues to use the estimated environmental concentrations from the turf use, as provided from the environmental assessment.

1.2.2 Differences between Health Canada assessment and international regulatory reviews

Comments were received from various individuals, registrants, and grower groups expressing concern regarding the differences between the Health Canada assessment and those of international regulatory bodies.

Health Canada response

International reviews are considered as part of the Health Canada assessment. For the dietary assessment of lambda-cyhalothrin, the residue inputs used in the risk assessment are specific to the Canadian use pattern, including Canadian monitoring data, Canadian percent crop treated, and information on the origin of the Canadian food supply. Additionally, differences in the inputs from toxicology and the environmental assessment affect the dietary assessment. It is therefore expected that the Health Canada risk assessment will have outcomes that are unique to Canada.

1.2.3 Registrant comments on the inputs to the risk assessment

Comments were received from Syngenta Canada Inc. with a number of suggestions for refinements to the inputs of the dietary risk assessment. The comments are summarized below:

1. Use of surrogate monitoring data for various commodities
2. Removal of certain commodities from the risk assessment (cranberries, and some caneberries) as they are not treated in Canada nor do they have a Canadian MRL or an American Tolerance established.
3. Use of the "essentially zero" concept for residues in milk, based on the available United States Pesticide Data Program (PDP) monitoring data, or mitigation that would restrict the possibility of residues in milk
4. Use of the "essentially zero" concept for residues in or on canola, pulses, soybean, cereals, and corn based on submitted historic data from the Canadian Grain Commission Cargo Monitoring Results.
5. Use of the "essentially zero" concept for residues in or on potato, based on the available Canadian Food Inspection Agency (CFIA) monitoring data

Health Canada response

The suggested refinements have been considered for incorporation into the revised risk assessments.

Use of surrogate monitoring data for the following commodities was considered to be acceptable and incorporated into the revised assessment: beef muscle translated to goat meat, pork meat, and sheep meat; beef fat translated to goat fat, sheep fat, and pork fat (where other data were not available); tomato translated to tomatillo, and orange translated to citron and citrus hybrids.

The following commodities that were included in the PRVD assessment are grown in Canada but not treated with lambda-cyhalothrin and do not have a Canadian MRL or American Tolerance: Sugar beet, blackberry, blueberry, boysenberry, chicory, cranberry, currant, ginseng, gooseberry, horseradish, huckleberry, parsnip, radish, raspberry, and turnip. They have been removed from the revised risk assessments.

There are certain cases where Health Canada may consider the residues in a commodity to be negligible, and remove that commodity from the risk assessment ("essentially zero"). This rationale is considered to be an ultimate refinement, and it must be considered carefully in the context of the residue chemistry information and the risk assessment. Use of this rationale introduces uncertainty and may underestimate risk. In the context of lambda-cyhalothrin's risk assessment, which is driven by acute risks from low levels of residues in various commodities, it is difficult to justify the complete removal of any commodities. However, the submitted data has been reviewed and certain refinements have been made based on the "essentially zero" rationale.

For lambda-cyhalothrin residues in milk, there is evidence in the PDP monitoring data for milk and heavy cream that residues exist and can be detected if the method of analysis is sensitive (low limit of detection). This is consistent with the understanding of animal metabolism and the available data for animal commodities. Milk is therefore maintained at the same residue inputs as in the assessment performed to support the PRVD.

The registrant proposed revisions to the residue estimates for canola, pulses, soybean, cereals, and corn based on submitted historic data (1998 to 2016) from the Canadian Grain Commission Cargo Monitoring Results. Unlike CFIA or PDP monitoring data, Canadian Grain Commission data is not designed for risk assessment purposes. Canadian Grain Commission data is for exported cargo samples and may not be representative of commodities destined for Canadian use. It will not be representative of imports. It is not known whether the commodities may have been held in storage for an extended period of time prior to vessel loading and sampling, which may affect residues. These limitations, as well as the other available residue chemistry information for each commodity, were considered.

After analysing the data provided, the rationale for negligible residues was not accepted for any of the commodities; however, the analysis provided the following refinements: Canola was revised using the limit of quantification for the Canadian portion of the food supply, and translated to flax seed. As the data was for lambda-cyhalothrin only, the limit of quantification was doubled to represent the epimer portion of the residue definition; the limit of detection was not provided. Dry peas were revised using the limit of quantification for the Canadian portion of the food supply, and translated to chickpeas and lentils. Wheat was revised using the 2018 PDP data for wheat flour and was translated to barley, buckwheat, rye, and triticale.

For lambda-cyhalothrin residues in potato, there is substantial monitoring data available that would support the rationale for negligible residues. However, potato commodities had very little impact on the overall acute risk assessment in the PRVD assessment (based on the CFIA monitoring data). As true zero is considered to be an ultimate refinement, and adds uncertainty, it is not applied to potato at this time, as it would add uncertainty without improving the overall risk assessment outcomes. Therefore, the residue inputs used in the PRVD assessment for potato were retained.

1.2.4 Registrant prioritization of commodities for refining the dietary risk assessment

A comment was received from Syngenta Canada Inc. providing a list of registered uses of lambda-cyhalothrin in order of priority for the purpose of refining the dietary risk assessments as follows.

The commodities of highest priority were:

1. Canola, pulses (Crop Group 6C), corn, soybean, and cereals

The commodity of second priority was:

2. Potato

The commodities of third priority were:

3. a. Remaining Crop Group 6 commodities
   b. Mustard, and flax
   c. Cover crops, alfalfa, and timothy (non-feed uses only)
   d. Brassica/cole crops (Crop Group 5A)
   e. Fruiting vegetables (Crop Group 8)
   f. Cucurbit vegetables (Crop Group 9)

g. Apple, pear
h. Cherry, peach, nectarine, plum
i. Strawberry
j. Celery
k. Asparagus
l. Sweet potato and remaining Crop Group 1 commodities
m. Carrot
n. Saskatoon berry
o. Tree nuts (Crop Group 14-11)

All other commodities were grouped together, with specific comments provided for meats, offal, head and leaf lettuce (Crop Group 4), bulb vegetables (Crop Group 3), sunflower, safflower, citrus hybrids, olives, and tea. Prioritization within this group was not provided.

Health Canada response

The priority list has been taken into consideration in the revised risk assessment. Crop Group 1 commodities that were included were arrowroot, carrot, cassava, dasheen, garden beet, ginger, Jerusalem artichoke, potato, sweet potato, tanier corms, turmeric, yam bean, and yam.

The comments provided for the remaining commodities and the availability of alternatives were considered. As a result, beef commodities (not including milk) were included in the mitigated risk assessment.

The subset of commodities included in the mitigated dietary risk assessment that showed acceptable risk are: Crop Group 5-13: *Brassica* Head and Stem Vegetable Group; Crop Group 6: Legume Vegetables (Succulent or Dried); Crop Group 8-09: Fruiting Vegetables; Crop Group 9: Cucurbit Vegetables; Crop Group 14-11: Tree Nuts; Crop Group 15: Cereal Grains; alfalfa; apple; arrowroot; asparagus; beef cattle commodities; carrot; cassava; celery; cherry; Chinese broccoli; cover crops; dasheen; flax; garden beet; ginger; Jerusalem artichoke; kohlrabi; mustard seeds (oilseed type); nectarine; peach; pear; plum; potato; rapeseed (including canola); Saskatoon berry; strawberry; sweet potato; tanier corms; timothy; turmeric; yam bean; and yam. Continued registration of these commodities is acceptable. When treated, these commodities are not permitted to be used as livestock feed. Importation continues to be permitted for these commodities at their currently established MRLs, if applicable.

1.2.5 Registrant comments regarding the external application uses on beef cattle and non-lactating dairy cattle

Comments were received from a registrant, Intervet Canada Corp., suggesting that external application uses on beef cattle and non-lactating cattle are not risk drivers and poses minimal contribution to dietary exposure. A recommendation was made suggesting that Health Canada use residues from the external application studies instead of MRLs for meat byproducts of cattle.

Health Canada response

As a result of the comments received during consultation, external application to beef cattle and non-lactating dairy cattle are acceptable for continued registration.

It is noted that the dietary risk assessment does not typically separate animal commodity residues by source (feeding, external application, or structural application) unless the uses can be mitigated to avoid residues. Otherwise, the use that results in the highest residue, based on the available data, is incorporated into the risk assessment. In the case of lambda-cyhalothrin, as per the Syngenta priority list (please refer to 1.2.4), feed uses are not considered to be a priority. Additionally, label statements that limit the possibility of residues from structural uses will be required. Therefore, in this case, as the mitigated risk assessment does not include animal feed uses, residues from external animal application studies have been used to refine inputs for meat byproducts of cattle.

1.2.6 Comments regarding commodities that are now recommended for continued registration

Comments were received from various individuals, registrants, and grower groups regarding commodities that are now recommended for continued registration, such as apples, beans, beef commodities, brassica vegetables, canola, carrot, celery, cereals, cherries, cucurbit vegetables, peas, potato, and strawberries.

For cereals, a comment was received from Cereals Canada proposing that the impact of blended commodities (that is, commodities that are co-mingled from different sources on a large scale) be considered in the risk assessment.

Health Canada response

As a result of the revised dietary risk assessment based on comments and additional information received during consultation, many food uses are now acceptable for continued registration, and applicable Canadian MRLs will be maintained. Please refer to the list under “Re-evaluation decision of Lambda-Cyhalothrin” (page 2), for the full list of commodities that will be retained on the labels.

Regarding cereals, Health Canada considers the blending classification for commodities in the risk assessment and choses residue inputs accordingly. This includes the use of highest average residues rather than maximum residues, and the use of percent crop treated as an adjustment factor where appropriate. In the case of this assessment, data from the Canadian Grain Commission was also used to refine the cereals inputs (please refer to 1.2.3 for additional information).

1.2.7 Proposed mitigation via changes to the application rates of lambda-cyhalothrin

Comments were received from various individuals, registrants, and grower groups proposing mitigation based on changes to the use pattern, including cases where the typical use is lower than the maximum label rate.

Health Canada response

For the dietary assessment of lambda-cyhalothrin, many of the residue inputs are based on Canadian monitoring data. This is the most highly refined residue data available, and is reflective of the actual use of the product on commodities that are in the Canadian food supply.

For commodities that do not have monitoring data, the residue inputs are typically based on field trial data supplied by the registrants at the maximum application rate

1.2.8 Comments on lettuce and onion

Comments were received regarding the value of lambda-cyhalothrin application to lettuce (Canadian Horticultural Council and Consortium PRISME) and onion (Canadian Horticultural Council) commodities, which were proposed for cancellation as a result of the dietary assessment.

Health Canada response

Lettuce and onion were not identified by the registrants as priority commodities; however, they were identified as commodities with limited alternatives. These uses were included in the risk assessment using highly refined residue inputs (monitoring data) that are reflective of the actual residues in the food supply; however, their inclusion showed risks of concern and these uses will therefore be cancelled.

1.2.9 Revocation of MRLs

Comments were received from the Canadian Potato Council and the Canadian Horticultural Council indicating that the revocation of MRLs would result in commodities being regulated under the General MRL (GMRL) of 0.1 ppm, and that Canadian consumers would continue to be exposed to lambda-cyhalothrin via imported foods.

Health Canada response

As a result of the updated risk assessment based on comments received during consultation, many food uses are now acceptable for continued registration and applicable Canadian MRLs will be maintained. Please refer to the list under “Re-evaluation decision of Lambda-Cyhalothrin” (page 2), for the full list of commodities that will be retained on the labels.

For commodities that will require MRLs revisions due to dietary risks of concern, it will be proposed that these MRLs be set at 0.01 ppm, via an MRL for “All other food commodities (other than those listed in this item).” It will be proposed to extend the current MRL of 0.01 ppm for “All food commodities (other than those already covered by a higher MRL as a result of use on growing crops) in food-handling establishments where food products are held, processed or prepared” to be broadly applicable to all food commodities that do not have specific established MRLs, and thereby also not require the revocation and reliance on the GMRL for these commodities.

Changes to MRLs will be published in a PMRL document for consultation. Recommendations for changes to MRLs are included in Appendix V.

1.3 Comments related to occupational/residential exposure

1.3.1 Comment concerning turf transferable residues

A registrant commented that a turf transferable residue study was available and should be used to refine the postapplication dermal and incidental oral exposure and risk assessments for uses on turf.

Health Canada response

The use of the turf transferrable residue (TTR) study was revisited by Health Canada. The study was considered acceptable for estimating TTR values for lambda-cyhalothrin. It was not used to update the incidental oral hand-to-mouth residential risk assessment for turf as a chemical-specific hand press study was available and considered acceptable to estimate hand residue loading for children (1<2 years). As discussed in Appendix VI, these chemical-specific studies were used in the updated postapplication assessments for turf, and risks were shown to be acceptable, provided the use pattern changes and mitigation measures outlined in Appendix X are followed.

1.3.2 Comment concerning the application rate used for outdoor ornamentals treated with a mechanically-pressurized handgun

A comment was received from a registrant that stated the application rate used in the PRVD risk assessment for application to outdoor ornamentals with a mechanically-pressurized handgun was incorrect.

Health Canada response

Health Canada reviewed the label information and agree that the application rate was incorrect. The correct application rate was included in the updated assessment and risks were shown to be acceptable, provided the mitigation measures outlined in Appendix X are followed.

1.3.3 Comments concerning mitigation proposed for occupational mixer/loader and applicator assessment

Comments were received from a technical registrant regarding proposed mitigation for custom groundboom application and airblast, and mechanically-pressurized handgun applications to outdoor ornamentals. The registrant noted that risks associated with custom groundboom application were driven by inhalation and proposed the addition of a respirator for mixing/loading activities as opposed to the use of a closed-cab tractor. For airblast application to outdoor ornamentals, the registrant proposed the addition of a chemical-resistant hat to mitigate exposure during application. This mitigation was proposed by Health Canada in the PRVD. For application to outdoor ornamentals via mechanically-pressurized handgun, the registrant indicated that the incorrect application rate was used in the risk assessment (See comment 1.3.2) and proposed the use of an updated application rate as well as the use of a respirator to mitigate risks.

Health Canada response

The occupational risk assessment was updated to include new data from the Agricultural Handlers Exposure Assessment Task Force (AHETF). As a result, the additional personal protective equipment (chemical-resistant hat) proposed in PRVD2017-03 is no longer required for airblast application to outdoor ornamentals. However, it is required for conifer seed orchards, a new use that was not assessed in the PRVD. For custom groundboom application, based on the updated risk assessment, risks are shown to be acceptable if either a closed cab tractor is used or a respirator is worn in an open cab tractor. Risks were not shown to be acceptable for all custom groundboom applications when a respirator was only used for mixing/loading activities. These mitigation measures are comparable to what was proposed by the registrant. For mechanically-pressurized handgun applications to outdoor ornamentals, when using the updated application rate (See comment 1.3.2 and Health Canada's response), risks were shown to be acceptable if a respirator was worn, which is consistent with the registrant's suggestion.

1.3.4 Comment concerning the scenarios assessed for indoor residential applications

Comments were received from a technical registrant in consultation with the Canadian Pest Management Association (CPMA) that the risk assessment included uses/applications that are not on the label, specifically, perimeter (band) and spot treatments, including for treating bedbugs for indoor uses. For liquid commercial-class products, it was requested that the risk assessment only be conducted for crack and crevice applications, as it is stated on product labels that only crack and crevice applications are to be made using these products.

Health Canada response

For liquid commercial-class products, the label language for application to control indoor pests is unclear or contradictory. All labels state for "crack and crevice applications"; however, use directions on some labels include wording that could be interpreted as spot treatment or treatment beyond Health Canada's current definition of crack and crevice treatment (see PMRA Guidance Document, *Structural Pest Control Products: Label Updates*).

The commercial-class pressurized (aerosol) product label does not indicate that uses are restricted to crack and crevice application only. Labels indicate when various application types (crack and crevice, spot, perimeter) may be used. No comments were received during the PRVD consultation period with respect to the risk assessment for the pressurized product.

Considering the current label directions, Health Canada has maintained the different types of treatment in the updated assessment.

Based on the comments received and the PMRA Guidance Document, *Structural Pest Control Products: Label Updates*, label modifications are required for products used to control indoor pests. These label changes are also required to clarify label directions to reduce the likelihood of product misuse by pest control applicators and minimize unnecessary exposure to occupants living in, working in or entering treated areas.

Specifically for liquid products, which the registrant commented is only to be used for crack and crevice applications, Health Canada requires that the definition of crack and crevice application, as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* be

added to product labels, and a label statement must be added prohibiting indoor broadcast, perimeter and spot applications in residential structures. A definition of residential structures will also be added to the label. In addition, any label instructions that could be interpreted as applications in residential structures beyond crack and crevice must be removed from all product labels.

For pressurized (aerosol) products, Health Canada requires that the definition of crack and crevice application and spot application, as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* be added to product labels, and a label statement must be added prohibiting indoor broadcast and perimeter applications in residential structures. A definition of residential structures will also be added to the label. In addition, any label instructions that could be interpreted as applications beyond crack and crevice and spot treatments in residential structures must be removed from all pressurized product labels.

See Appendices VI and X for details on the required label modifications.

1.3.5 Comment concerning refinements to the residential postapplication exposure and risk assessment for indoor environments

A comment was received from a technical registrant suggesting various refinements for the dermal and incidental oral exposure and risk assessment for children (1 < 2 years). For the indoor dermal assessment, these refinements included using the 50th percentile transfer coefficient for children (1 < 2 years). For the indoor incidental oral (hand-to-mouth) assessment, these refinements included reducing the exposure time on carpets from 4 hours to 2 hours to match the exposure time used on hard surfaces and increasing the replenishment interval from 14 minutes to 30 minutes for both hard and soft surfaces.

Health Canada response

The indoor postapplication dermal and incidental oral exposure and risk assessments for children (1<2 years) were updated to include revised application rates for indoor uses and updated exposure equations, as described in Appendix VI. Based on these changes, risks were shown to be acceptable for indoor uses and the refinements suggested by the registrant were not used.

1.3.6 Comments concerning the use of non-Canadian data to inform the residential risk assessment

Comments were received from the Canadian Pest Management Association (CPMA) and other users that the risk assessment was based on data from the USEPA Residential SOPs (2012). There is concern that since use patterns are different in Canada compared to the United States, relying on data from the USEPA does not reflect the Canadian use of lambda-cyhalothrin products. The comment also enquired whether the CPMA pyrethroid survey information previously provided to Health Canada had been used in the risk assessment for lambda-cyhalothrin.

Health Canada response

The USEPA Residential SOPs provide models and inputs to estimate exposures to people in residential areas from application of pesticides and from postapplication exposures following treatment to areas of the home. The models and inputs are based on scientific exposure studies, as well as survey information related to exposure factors (for example, body weight). The SOPs are used in a manner, which considers the use pattern of a pesticide (for example, application rate). When the PMRA conducted the risk assessment, Canadian-specific use information was incorporated into the exposure model estimates. For example, all exposure estimates were based on Canadian application rates. In addition, the pyrethroid survey data previously submitted to Health Canada was used to the extent possible in the updated exposure and risk assessments for lambda-cyhalothrin. For example, in the selection of application equipment used for structural scenarios, and in the assumption of the area treated in a home for crack and crevice bedbug application.

1.3.7 Comments concerning the postapplication cancer risk assessment

Comments were received from the registrant suggesting that only crack and crevice applications be assessed for the cancer exposure and risk assessment as current label language states that applications are crack and crevice only.

Health Canada response

Regarding the use pattern that was assessed for indoor environments in the updated risk assessment, refer to the Health Canada response to comment 1.3.4. With respect to the cancer assessment, as discussed in the Health Canada response to comment 1.1.2, a threshold approach was undertaken in the updated risk assessment and therefore a q_1* is no longer warranted for lambda-cyhalothrin.

2.0 Comments related to the environmental risk assessment

Comments were received from the registrant, Syngenta Canada Inc., the general public, and the Ministry of Agriculture in Saskatchewan.

2.1 Comment: One registrant suggested that Heath Canada use the organic carbon-water partitioning co-efficient, K_{oc}, determined from either solid phase microextraction (SPME) or updated liquid-liquid extraction (LLE) techniques, for risk assessment. A K_{oc} derived from SPME would represent the freely dissolved chemical, which the registrant suggests is the bioavailable fraction and the most relevant for determining aquatic EECs used in the risk assessment. Alternatively, they suggest that a K_{oc} based on updated LLE methods would be a better refinement of what is currently used by Health Canada in aquatic risk assessments.

Health Canada response

Health Canada acknowledges that SPME can be used to determine a K_{oc} that is specific to the freely dissolved chemical only. However, the amount of the chemical found in the freely dissolved fraction can be highly variable, depending on various environmental factors (for example, quantity and quality of DOC, pH, ionic strength, temperature). This is evidenced in the data reported in the Pyrethroid Working Group study (PMRA# 2805496). In two water/sediment

systems tested, the K_{oc} (SPME) for lambda-cyhalothrin differed significantly (2 056 000 ± 117,000 in one and 3 024 000 ± 485 000 in the other). In a study that compared sorption behavior in three artificial and five natural water/sediment systems (PMRA# 2805493) calculated K_{DOC} values were based on differences between concentrations measured using LLE and SPME methods and DOC in the supernatant. On average, K_{DOC} was about three times higher than K_{oc} (SPME) with greater variability. The study authors concluded that the source and characteristics of organic carbon have profound influence on the magnitude of freely dissolved concentrations as well as the amount associated with DOC. Furthermore, the K_{oc} (SPME) was not determined from adsorption isotherms in either study. Therefore, the resulting K_{oc} (SPME) is not of sufficient quality to replace the K_{oc} values generated from regular guideline studies.

The commenter had also requested that Health Canada use two K_{oc} values based on updated LLE methods as outlined in the Pyrethroid Working Group study report (PMRA# 2805496). Similar to the SPME tests, the K_{oc} (LLE) was determined at a single concentration. As such, the resulting K_{oc} (LLE) is not of sufficient quality to replace the K_{oc} values generated from standard guideline studies.

In addition, test concentrations for laboratory-based toxicity endpoints for lambda-cyhalothrin were not measured specifically for freely dissolved chemical. The commenter suggested that water used in guideline laboratory studies will have a TOC of less than 2 mg/L and that most is present as dissolved organic carbon (DOC). As levels of carbon are expected to be low, the commenter suggested that most of the test chemical will be present as freely dissolved. Although the TOC could be low at test initiation, some bound chemical would be expected and could increase over the test duration as carbon could be added to the test system if food is introduced (for example, chronic studies) or by the accumulation of feces produced by test organisms. Given this, a direct comparison of a toxicity value to an estimated concentration in water, which is based on freely dissolved chemical in the water is not possible from these data.

2.2 Comment: One registrant suggested that Health Canada should reconsider the data used to characterize the persistence of lambda-cyhalothrin in soil, taking into account updated information from the reassessment of lambda-cyhalothrin by the European Union (EU).

Health Canada response

The comment refers to data reviewed by the EU in the updated Renewal Assessment Report (RAR) for lambda-cyhalothrin (PMRA# 3146679). Health Canada has reconsidered the use of the results from two soils that were previously included in the assessment (Lohimngen and Gartenacker soil). Please see the science section of this document for additional details.

2.3 Comment: One registrant proposed that spray buffer zones for the protection of marine/estuarine habitats should be determined using an acute marine endpoint (mysid shrimp, 4.2 ng/L) rather than a chronic endpoint (mysid shrimp, 0.22 ng/L). As lambda-cyhalothrin is short lived in the water column due to rapid partitioning, a short-term (acute) endpoint would be more appropriate.

Health Canada response

Health Canada agrees with using the acute (96-hour) endpoint for mysid shrimp for the calculation of spray buffer zones for marine/estuarine habitats. Health Canada has revised the spray buffer zones based on the new end point for marine and estuarine habitats, and using the maximum single application rate only.

2.4 Comment: One registrant commented that, for pesticides with low solubility in water, aquatic exposure should be based on the freely dissolved fraction in water only as this is the fraction of the chemical that is bioavailable to organisms. The commenter proposed using an equation, based on equilibrium partition theory, for calculation of freely dissolved chemical.

Health Canada response

Health Canada considered additional information provided by the registrant regarding the bioavailability of chemicals in aquatic systems. Several laboratory toxicity studies demonstrated that dissolved, particulate and sediment bound organic carbon can decrease uptake and toxicity of pyrethroids (for example, PMRA# 2275726, 2281474, 2677240). In some cases, however, the effects from DOC and/or POC on reducing bioavailability and toxicity of pyrethroids are variable and are not always large (for example, PMRA# 2666881, 2666879, 2666972). Additional evidence shows that the presence of DOC at low environmentally relevant levels (<10 mg/L) may increase bioavailability of some pesticides with low solubilities, including pyrethroids (PMRA# 3146680, 3146687). A recent comprehensive literature review demonstrates that the bioavailability and toxicity of pesticides to aquatic organisms in the presence of particles cannot always be predicted by only considering the partitioning of pesticides between water and particles using the K_{oc} (PMRA# 3146689).

Possible reasons for the disparities observed in the bioavailability and toxicity of low solubility chemicals may originate from differences in water chemistry and DOC/POC characteristics that can enhance water solubility and potential bioavailability of non-polar chemicals. Aqueous chemistry, factors such as water pH, ionic strength, hardness and presence of other cation constituents, can play an important role in controlling the polarity and the conformation of the fulvic and humic molecules and preferential binding sites for organic pollutants (for example, PMRA# 3146691, 3146685, 3146690, 3146683). In addition, characteristics of the dissolved organic matter (for example, concentration, molecular configuration, size, structure and hydrophobicity), factors which can differ spatially and change over time, can affect the binding potential and strength of chemical binding in a particular water body (PMRA# 3146684, 3146685, 3146686, 3146682, 3146692).

The equation proposed by the commenter would estimate “freely dissolved lambda-cyhalothrin” EECs using K_{oc}-DOC and K_{oc}-POC values derived from static controlled equilibrium laboratory conditions and generic/median carbon concentration (DOC/POC) across various waterbody types based on American data; this method assumes that DOC and POC bound pesticide is not bioavailable. As discussed above, the effect of DOC/POC on bioavailability and toxicity of hydrophobic chemicals is complex and not fully understood, unpredictable, and is likely site specific. It is uncertain if EEC values generated from the proposed model would be sufficiently representative or conservative (in other words, worst case scenario) for the protection of aquatic environments or would underestimate the exposure potential of low solubility chemicals to aquatic organisms. The proposed model also considers “freely dissolved chemical” as the only

route of exposure and ignores the potential for bioaccumulation (for example, exposure of secondary producers feeding on bacteria and algae to which organic pesticides can bind and contribute to toxicity). The physiology of aquatic organisms, for example, feeding behaviour (for example, filter feeder and/or capable of ingesting particulate matter, is pelagic or benthic) and digestion, invariably influence both bioaccumulation and toxicity of pesticides. Bioaccumulation of several pyrethroids including lambda-cyhalothrin in aquatic food webs is documented (PMRA# 3146680).

For these reasons, Health Canada has determined that the proposed method could underestimate the potential for exposure to organisms living in aquatic environments. Health Canada currently calculates an EEC in the entire water column (15 or 80 cm scenarios) and does not consider partitioning among the compartments (DOC, POC, or freely dissolved). The approach used by Health Canada is protective of aquatic habitats.

2.5 Comment: One registrant suggested that the species sensitivity distribution (SSD) curve for lambda-cyhalothrin should be based on combined freshwater and marine data and for multiple pyrethroids, rather than using a single curve to determine HC_5 values for individual pyrethroids.

Health Canada response

When there is a sufficient amount of data available for a pesticide chemical, Health Canada conducts risk assessments for individual chemicals. Health Canada's current policy for pesticides is to calculate SSD curves for freshwater and marine aquatic species separately, and for individual chemicals only.

2.6 Comment: Two eye-witness accounts, related to an incident report implicating aerial drift of lambda-cyhalothrin onto a lake in central Canada, were provided. The anecdotal information provided a chronological sequence of events from the suggested timing of exposure, observed mortality of aquatic organisms and reporting to the authorities.

Health Canada response

Health Canada has reviewed and analyzed the information available related to this incident report. Lambda-cyhalothrin was not detected in water, sediment, and tissue samples of affected organisms taken soon after the reported event. Estimates of the environmental concentration of lambda-cyhalothrin in the lake based on the application rate and presumed buffer zones that were followed indicated that levels would be several orders of magnitude less than those needed to cause acute/lethal effects to invertebrates and fish. However, based on a LOD that is higher than the acute toxicity endpoints, exposure cannot be fully discounted. Health Canada concluded that it was possible that lambda-cyhalothrin contributed to the death of the crayfish and water beetles. However, based on an almost identical mortality event involving crayfish at a different lake in the same region (located 18 km to the east) a week earlier, which had no link to pesticide use, other factors (such as low dissolved oxygen) could also have contributed to the observed mortalities.

2.7 Comment: A comment provided by the Saskatchewan Ministry of Agriculture expressed concern that applying the turf rate (in other words, the highest label rate) for modeling lambda-cyhalothrin is an overestimation of the actual use patterns in agricultural area. The commenter states that rates used in agricultural crops are less than one-third those used in turf applications.

Health Canada response

The highest cumulative application rate is used as a worst case maximum exposure scenario for the screening level risk assessment. For runoff water modelling specifically, the highest rates (turf), second highest rate (multiple crops), and lowest label rate (tobacco) were all modelled. For buffer zone modeling, all application rates are considered to determine crop-specific spray buffer zones.

2.8 Comment: The Saskatchewan Ministry of Agriculture suggested that additional mitigative options should be considered wherever possible before making a final re-evaluation decision that might involve complete cancellation of registrations. Specific examples were highlighted:

> **2.8.1:** Increased buffer zones around sensitive areas should mitigate problems with the insecticide entering into these areas.

Health Canada response

Health Canada uses a scientific approach for determining spray buffer zones to mitigate the exposure of sensitive aquatic and terrestrial habitats to spray drift from the application of pesticides. The input parameters used for modelling spray buffer zones include endpoints for the most sensitive non-target aquatic and terrestrial organisms, crop-specific application rates, application frequency, methods of application and consideration of the dissipation of the chemical in water over time. An arbitrary increase in the size of the spray buffer zone would not be based on an assessment of available scientific information.

Pesticides may also enter waterbodies through overland runoff. Mitigative measures to reduce aquatic exposure through this route include the implementation of a 10 m vegetative filter strip.

> **2.8.2:** Lambda-cyhalothrin and other synthetic pyrethroids should be applied later in the evening when there is less chance of negatively impacting pollinators. An evening application is also recommended since synthetic pyrethroids tend to lose efficacy at higher temperatures (generally greater than 25 degrees Celsius).

Health Canada response

Label statements for mitigating risk to pollinators are required on updated product labels (see Appendix X).

> **2.8.3:** Product labels should be revised to address concerns with respect to run-off from treated fields to nearby water bodies, such as “Do not apply if heavy precipitation is in the forecast”.

Health Canada response

Label statements for mitigating runoff will be required on updated product labels (see Appendix X). Mitigative measures to reduce aquatic exposure through this route include the implementation of a 10 m vegetative filter strip.

3.0 Comments related to the value assessment

Comment

Comments were received from registrants, growers, grower groups, agricultural stakeholders, and provincial governments indicating the need for lambda-cyhalothrin to manage multiple insect pests across several use sites, including agricultural, horticultural, beef and non-lactating dairy cattle, and structural use sectors. In addition, stakeholders commented on the impact the loss of lambda-cyhalothrin will have on economic competitiveness, resistance management, and alternative pest management solutions, especially considering proposed cancellation of neonicotinoid and pyrethroid active ingredients.

Health Canada response

Consideration of comments and new information resulted in a revision to the dietary risk assessment, thereby permitting the continued application of lambda-cyhalothrin on most food commodities, as well as beef and non-lactating dairy cattle, and for structural uses. Based on this, growers and users will retain the use of lambda-cyhalothrin to manage economically important insect pests in most use sectors.

3.1 Lettuce

Comment

The Canadian Horticultural Council, Consortium PRISME, and Association des producteurs maraîchers du Québec commented on the impact the proposed cancellation of lambda-cyhalothrin would have on lettuce production. Stakeholders outlined the need for lambda-cyhalothrin to manage cabbage loopers in greenhouse lettuce, as well as tarnished plant bugs, cabbage loopers, darksided and white cutworms in field lettuce. Concerns were raised since limited greenhouse alternatives are registered to manage cabbage loopers, and many of the registered alternatives for the other pests are under re-evaluation, proposed for phase out, or are have a high toxic profile to the environment (carbaryl).

Health Canada response

Health Canada recognizes the value of lambda-cyhalothrin to the production of lettuce. However, dietary risks of concern remain (see comment 1.2.8), and therefore, both the greenhouse and field use on lettuce are cancelled.

3.2 Bulb vegetables

Comment

Comments from the Canadian Horticultural Council, Association des producteurs maraîchers du Québec and Peak of the Market were received in response to the proposed cancellation of lambda-cyhalothrin on bulb vegetables, specifically the importance of managing onion thrips and leek moth on garlic, leek, onions, green onions and shallots. Stakeholders indicated lambda-cyhalothrin was valued as a broad-spectrum insecticide with good efficacy against these insects, and that there were limited viable alternatives to manage leek moth on onions and garlic.

Health Canada response

Health Canada recognizes the value of lambda-cyhalothrin to the production of bulb vegetables. However, dietary risks of concern remain (see comment 1.2.8), and therefore, this use is cancelled. Several other alternatives from various modes of action are also registered and are not currently under re-evaluation.

Appendix IV Revised toxicology reference values for lambda-cyhalothrin

[Note: Shaded cells indicate exposure scenarios which have been modified by Health Canada following consideration of the comments received on PRVD2017-03]

Exposure Scenario	Study	Point of Departure (POD) and Endpoint	CAF or Target MOE [1]
Acute Dietary	two acute oral neurotoxicity studies with lambda-cyhalothrin - rat	$BMDL_{20}$ = 0.28 mg/kg bw (↓ motor activity)	300
ARfD = 0.0009 mg/kg bw			
Repeated Dietary	1-year oral (capsule) toxicity study with lambda-cyhalothrin - dog	NOAEL = 0.1 mg/kg bw/day (neurotoxic signs, liquid feces)	300
ADI = 0.0003 mg/kg bw/day			
Short-, Intermediate- and Long-term Dermal	21-day dermal toxicity study with lambda-cyhalothrin - rat	NOAEL = 10 mg/kg bw/day (neurotoxic signs, ↓ bw, ↓ rel ovary wt, ↓ abs testes wt)	300
Short-, Intermediate-and Long-term Inhalation	21-day inhalation toxicity study with lambda-cyhalothrin - rat	NOAEL = 0.08 mg/kg bw/day (neurotoxic signs, ↓ bw, ↑ liver wt, ↓ cholesterol, punctate foci of cornea)	300
Short- and Intermediate-Term Non-Dietary Incidental Oral Ingestion	two acute oral neurotoxicity studies with lambda-cyhalothrin - rat	$BMDL_{20}$ = 0.28 mg/kg bw (↓ motor activity)	300
Short- and Intermediate-term Aggregate Risk (Oral, Dermal, Inhalation)	**oral:** two acute oral neurotoxicity studies with lambda-cyhalothrin - rat **dermal:** 21-day dermal toxicity study with lambda-cyhalothrin – rat **inhalation:** 21-day inhalation toxicity study with lambda-cyhalothrin - rat	**Common Endpoint:** neurotoxicity oral $BMDL_{20}$ = 0.28 mg/kg bw dermal NOAEL = 10 mg/kg bw/day inhalation NOAEL = 0.08 mg/kg bw/day (0.3 µg/L)	 300 300 300
Long-term Aggregate Risk (Oral, Dermal, Inhalation)	**oral:** 1-year oral (capsule) toxicity study with lambda-cyhalothrin – dog	**Common Endpoint:** neurotoxicity oral NOAEL = 0.1 mg/kg bw/day dermal NOAEL = 10 mg/kg bw/day	 300 300

Exposure Scenario	Study	Point of Departure (POD) and Endpoint	CAF or Target MOE [1]
	dermal: 21-day dermal toxicity study with lambda-cyhalothrin - rat **inhalation:** 21-day inhalation toxicity study with lambda-cyhalothrin - rat	inhalation NOAEL = 0.08 mg/kg bw/day (0.3 µg/L)	300
Cancer	Treatment-related increase in the incidence of mammary gland adenocarcinomas and the combined incidence of uterine leiomyomas/leiomyosarcomas in female mice. A linear low-dose extrapolation approach for the assessment of oncogenic risk is considered to be unnecessarily conservative and a threshold approach was employed. The margin from the ADI to the NOAEL for mammary gland and uterine tumours in female mice is considered to be sufficiently health protective.		

[1] CAF (Composite assessment factor) refers to the total uncertainty and PCPA factors for dietary and residential risk assessment; MOE refers to the target margin of exposure for occupational and residential assessments.

Appendix V Dietary exposure and risk estimates for lambda-cyhalothrin

Details for the revised risk assessment are included in this appendix. Please refer to PRVD2017-03 for additional information.

Table 1 Summary of dietary exposure and risk from lambda-cyhalothrin's full use pattern

Population Subgroup	Acute Probabilistic, Food and Water		Chronic (Cancer and Non-Cancer), Food and Water	
	Dietary Exposure (mg/kg bw/day)	%ARfD[1]	Dietary Exposure (mg/kg bw/day)	%ADI[2]
General Population	0.004457	495	0.000169	56
All Infants (<1 year old)	0.001262	140	0.000129	43
Children 1–2 years old	0.001677	186	0.000278	93
Children 3–5 years old	0.001662	185	0.000199	66
Children 6–12 years old	0.000924	103	0.000121	40
Youth 13–19 years old	0.004544	505	0.000094	32
Adults 20–49 years old	0.004953	550	0.000216	72
Adults 50–99 years old	0.003719	413	0.000132	44
Female 13–49 years old	0.003538	393	0.000113	38

[1] Acute Reference Dose (ARfD) of 0.0009 mg/kg bw.
[2] Acceptable Daily Intake (ADI) of 0.0003 mg/kg bw/day.

Table 2 Summary of dietary exposure and risk from lambda-cyhalothrin's mitigated use pattern

Population Subgroup	Acute Probabilistic, Food and Water		Chronic (Cancer and Non-Cancer), Food and Water	
	Dietary Exposure (mg/kg bw/day)	%ARfD[1]	Dietary Exposure (mg/kg bw/day)	%ADI[2]
General Population	0.000492	55	0.000027	9
All Infants (<1 year old)	0.000888	99	0.000060	20
Children 1–2 years old	0.000857	95	0.000092	31
Children 3–5 years old	0.000490	54	0.000066	22
Children 6–12 years old	0.000477	53	0.000040	13
Youth 13–19 years old	0.000273	30	0.000023	8
Adults 20–49 years old	0.000441	49	0.000022	7
Adults 50–99 years old	0.000422	47	0.000019	6
Female 13–49 years old	0.000449	50	0.000020	7

[1] Acute Reference Dose (ARfD) of 0.0009 mg/kg bw.
[2] Acceptable Daily Intake (ADI) of 0.0003 mg/kg bw/day.

Maximum residue limits

Changes to MRLs will be published in a PMRL document for consultation. Recommendations based on the revised risk assessment are included below.

Table 3 Maximum residue limits recommended to be subject to a 0.01 ppm MRL for all other food commodities

Food Commodity	Canadian MRL (ppm)[1]	American Tolerance (ppm)	Codex MRL (ppm)
Apricots	0.5	0.50	0.5
Avocados	0.2	0.20	Not established
Cardoon	0.3	Not established	Not established
Chinese onions	0.1	0.1	0.2
Chokecherries	0.5	Not established	Not established
Dry bulb onions	0.1	0.1	0.2
Eggs	0.01	0.01	Not established
Fat of goats	5	3.0	3 (Meat (from mammals other than marine mammals), on a fat basis)
Fat of hogs	0.5	0.2	3 (Meat (from mammals other than marine mammals), on a fat basis)
Fat of horses	5	3.0	3 (Meat (from mammals other than marine mammals), on a fat basis)
Fat of poultry	0.01	0.03	Not established
Fat of sheep	5	3.0	3 (Meat (from mammals other than marine mammals), on a fat basis)
Fresh Florence fennel leaves and stalks	0.3	Not established	Not established
Garlic	0.1	0.1	0.2
Grapes	0.2	Not established	0.2
Great headed garlic	0.1	0.1	0.2
Green onions	0.1	Not established	0.2
Head lettuce	2	2.0	Not established
Leaf lettuce	2	2.0	Not established
Leeks	0.15	Not established	0.2
Meat byproducts of goats	0.2	0.2	0.2 (kidney) 0.05 (liver)
Meat byproducts of hogs	0.01	0.02	0.2 (kidney) 0.05 (liver)
Meat byproducts of horses	0.2	0.2	Not established
Meat byproducts of poultry	0.01	0.01	Not established
Meat byproducts of sheep	0.2	0.2	0.2 (kidney) 0.05 (liver)
Meat of goats	0.2	0.2	3 (Meat (from mammals other than marine mammals), on a fat basis)
Meat of hogs	0.01	0.01	3 (Meat (from mammals other than marine mammals), on a fat basis)
Meat of horses	0.2	0.2	3 (Meat (from mammals other than marine mammals), on a fat basis)
Meat of poultry	0.01	0.01	Not established
Meat of sheep	0.2	0.2	3 (Meat (from mammals other than marine mammals), on a fat basis)

Food Commodity	Canadian MRL (ppm)[1]	American Tolerance (ppm)	Codex MRL (ppm)
Milk	0.5	0.4 [2]	0.2
Milk fat	12	10.0	Not established
Olives	0.5	Not established	1
Oranges	0.2	Not established	0.2
Peanuts	0.05	0.05	0.2
Potato onions	0.1 [1]	0.1	Not established
Rhubarb	0.3	Not established	Not established
Satsuma mandarins	0.2	Not established	0.2
Shallots	0.1	0.1 (bulb only)	0.2
Sugarcane cane	0.05	0.05	0.05
Sunflower oil	0.3	0.30	Not established
Sunflower seeds	0.2	0.2	0.2
Swiss chard	0.3	Not established	Not established
Tea (dried leaves)	2	Not established	Not established
Tree onion tops	0.1	Not established	0.2
Undelinted cotton seeds	0.05	0.05	0.2
Welsh onion tops	0.1	Not established	0.2

[1] All food commodities listed in this table will be proposed to be regulated under the MRL of 0.01 ppm for "All food commodities (other than those listed in this item)."
[2] Based on the American tolerance for "Milk, fat (reflecting 0.4 ppm in whole milk)."

Residue Definition

No change is proposed to the compounds included in the residue definition as a result of the re-evaluation. However, for clarity, the wording of the Canadian residue definition will be revised. The bolded text below highlights the new wording in the residue definition:

> **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, a 1:1 mixture of** (*R*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*R*,3*R*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-α-cyano-3-phenoxybenzyl (*Z*)-(1*S*,3*S*)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate **(expressed as parent equivalents)**

Appendix VI Revised occupational and residential exposure and risk assessments for lambda-cyhalothrin

Details for the revised risk assessment are included in this appendix. Please refer to PRVD2017-03 for additional information.

Toxicology reference values
The toxicology reference values have been revised since PRVD2017-03 (Appendix IV). The short-to-intermediate incidental oral scenario for postapplication and aggregate scenarios were updated and the q_1* value was removed. All human health risk assessments have been updated as necessary using the revised values.

Use pattern
The full use pattern was revisited for the updated occupational and residential exposure assessment. For the occupational agricultural assessment some new uses/crops, crop group expansions and rate increases are included in the updated risk assessment. For the residential postapplication exposure and risk assessment, updated application rates for indoor uses are included in the updated risk assessment.

Mixer/loader/applicator unit exposures
Several unit exposure values have been revised since PRVD2017-03. For agricultural scenarios, the open cab groundboom, open cab airblast, closed aerial cockpit and open mixing/loading of liquid scenarios were updated using the values provided by Agricultural Handlers Exposure Task Force (AHETF). Unit exposures for handheld airblast/mistblowers were also included in this updated risk assessment. For non-agricultural/structural scenarios, unit exposures from a pest control operator applicator study were used.

Dislodgeable foliar residue (DFR)
The occupational postapplication risk assessment for field crops was updated using peak DFR and dissipation rate values from three chemical-specific DFR studies conducted on corn, bell pepper and cotton. These studies were not considered appropriate to estimate DFR for tree and orchard crops, due to different crop morphology and application equipment; therefore, standard outdoor peak DFR and dissipation rate values were maintained. The current standard greenhouse peak DFR and dissipation rate values were also used. These have been updated from the values used in the PRVD2017-03. Values used to estimate DFR in the postapplication assessment are noted in the footnotes of Appendix VI, Table 7.

Turf transferable residue (TTR)
The occupational and residential postapplication risk assessments were updated using a chemical-specific turf transferable residue study. Based on this study, TTR was estimated using a peak value of 1.1% of application rate after each application, with a 23.3% dissipation rate per day). This is a refinement to the standard values used in PRVD2017-03.

Turf hand residue data
The residential turf postapplication hand-to-mouth incidental oral exposure assessment was updated using a chemical-specific hand press study on treated turf. The hand residue value was estimated using 2.3% of the application rate based on the average value in this study. This is a refinement to the standard model used in PRVD2017-03.

Occupational exposure and risk assessment
The results of the updated occupational mixer/loader/applicator and postapplication assessments are summarized in Appendix VI, Tables 2–17. See Appendix VI, Table 1 for a summary of mitigation required as a result of the updated risk assessment. The mitigation required for mixers/loaders/applicators is comparable to that proposed in PRVD2017-03. The restricted-entry intervals (REIs) are shorter than the REIs proposed for some crops in PRVD2017-03. As per the PRVD2017-03, the occupational non-agricultural/structural postapplication exposure assessment is addressed by the residential postapplication exposure and risk assessment.

Residential postapplication exposure and risk assessment
For application of commercial-class products to residential areas, the residential postapplication assessments for turf and indoor environments were updated to reflect current exposure equations and the updated short-to intermediate-term incidental oral toxicology reference value. The turf assessment was also updated to include chemical-specific TTR and hand residue data. The indoor assessment also included refined inputs for pyrethroids and updated application rates received from registrants. For treated gardens and trees, there are no changes from the PRVD2017-03 risk assessment, where risks were shown to be acceptable.

The results of the updated assessments are summarized in Appendix VI, Tables 8–16.

Outdoor uses

For turf, postapplication risks were shown to be acceptable for the current use pattern. However, as noted in the Science evaluation update, section 1.4, the retreatment interval must be extended from 7 days to 14 days to mitigate aggregate risks.

For outdoor structural uses in residential areas, postapplication risks were assessed qualitatively. Risks were acceptable for outdoor uses in residential areas when applied as a perimeter, void, spot, or crack and crevice treatment provided the definitions in Appendix X, section 2.2.4 and 2.2.5 are implemented.

Indoor uses

For indoor uses, risks are shown to be acceptable for crack and crevice applications in both non-residential and residential areas for all formulations assessed. This risk outcome is different from the PRVD, which only allowed crack and crevice applications to non-residential areas.

In the PRVD, Health Canada also conducted an assessment for perimeter (band) and spot treatment for all formulations, based on use directions on some labels. These use directions include the term "spot treatment" on some labels, as well as wording that could be interpreted as spot treatment or treatment beyond Health Canada's current definition of crack and crevice treatment (see PMRA Guidance Document, *Structural Pest Control Products: Label Updates*). Therefore, Health Canada maintained these types of treatment in the updated assessment. Risks were shown to be acceptable for these types of treatment.

Comments were received from a registrant in consultation with the CPMA that the risk assessment should only be conducted for crack and crevice applications as it is stated on liquid commercial-class product labels that only crack and crevice applications are to be made using these products. Health Canada notes that liquid products do have a label statement to limit application to crack and crevice treatment. Therefore, as a result of the comment provided by the registrant, Health Canada requires that the definition of crack and crevice application, as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* be added to the liquid product labels, as well as a label statement prohibiting indoor broadcast, perimeter and spot applications in residential structures. A definition of residential structures will also be added to the label. In addition, any label instructions that could be interpreted as applications beyond crack and crevice in residential structures must be removed from all liquid product labels. For example, under the directions for use for controlling cluster flies, label directions state the following:

> "In winter and spring when cluster flies become active and are emerging, interior crack-and-crevice treatment can help reduce the infestation, **along with general surface application in infested attics or unoccupied lofts**."

These label changes are required to clarify label directions to reduce the likelihood of product misuse by pest control applicators and minimize unnecessary exposure to occupants living in, working in or entering treated areas.

For the pressurized products, label directions indicate indoor treatments are to be made as crack and crevice or spot applications depending on the location being treated and the pest being controlled. Therefore, Health Canada requires that the definition of crack and crevice application and spot application, as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* be added to the pressurized product labels, as well as a label statement prohibiting indoor broadcast and perimeter applications in residential structures. A definition of residential structures will also be added to the label. In addition, any label instructions that could be interpreted as applications beyond crack and crevice and spot treatments in residential structures must be removed from all pressurized product labels. These label additions are required to clarify label directions to reduce the likelihood of product misuse by pest control applicators and minimize unnecessary exposure to occupants living in, working in or entering treated areas.

For all products (liquid and pressurized products), in addition to the label changes required above, further label revisions as per the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* are required. These include ventilation and other best practice statements aimed at reducing post application exposure. Also, given the ongoing concern for product misuse by PCOs, a registrant-implemented national product stewardship program is required with the aim to encourage and promote the proper handling and use of commercial class lambda-cyhalothrin product in indoor residential sites.

Bystander exposure and risk assessment

A bystander assessment was conducted using available air concentration data from the literature. The assessment was conducted assuming bystanders would be exposed for an intermediate-term duration to the maximum air concentration from the study. This is considered to be a conservative assessment that uses an upper bound estimate of exposure. Results are summarized in Table 17. MOEs were greater than the target MOE and risks were shown to be acceptable. Since bystander exposure was very low compared to other routes of exposure (over 100-fold lower exposure), it was considered qualitatively in the aggregate risk assessment.

Table 1 Occupational and residential assessment mitigation summary

Scenario	Mitigation[a]
Groundboom application	When handling more than 7.15 kg a.i., use a closed cab OR use an open cab and wear a respirator.
Airblast application to conifer seed orchards	Wear a chemical-resistant hat during application.
Mechanically-pressurized handgun application	Wear a respirator when handling more than 0.11 kg a.i. per day.
Handheld airblast/mistblower application	Chemical-resistant coveralls over long pants and long-sleeved shirt, chemical-resistant gloves and a respirator. Restrict the amount handled to 5.1 g a.i. per day.
Application to turf	Increase minimum retreatment interval from 7 days to 14 days.
Occupational agricultural postapplication	Restricted-entry intervals (REIs) of greater than 12 hours are required for the following crops: Corn (seed, sweet) = 3 days Conifer seed orchards = 1 day See the REI table in Appendix X.
Outdoor non-agricultural/structural treatment using mechanically pressurized or power operated handheld equipment.	Wear chemical-resistant coveralls and a respirator. Restrict the amount handled to 0.72 kg a.i. per day.
Indoor non-agricultural/structural uses: all formulations	All registered uses maintained. Add precautionary statements and definitions from the PMRA Structural Guidance document.

[a] Mitigation in this table for mixers/loaders/applicators is based on a single layer of personal protective equipment (long pants and long-sleeved shirt with chemical-resistant gloves) unless otherwise specified.

Table 2 Groundboom: Mixer/loader/applicator exposure and risk assessment for agricultural scenarios

Crops [a]	Max. Appl. Rate (g a.i./ha)	ATPD [b] (ha)	Exposure[c] (µg/kg bw/day)		MOE (Target = 300)		
			Dermal	Inhal.	Dermal[d]	Inhal.[e]	Combined[f]
Single layer PPE, CR gloves; Open mix/load; Open-cab							
Chokecherry shelterbelts	7.08	26	0.193	0.005	51800	15100	11700
Poplar and willow plantings	10.13	107	1.136	0.031	8800	2560	1980
Cereals and grains - Crop Group 15 (except corn)	10.13	360	3.826	0.105	2620	760	590
Alfalfa/grass mixture, summer fallow, unimproved pastures; Timothy (grown for hay or seed)		107	1.136	0.031	8800	2560	1980
Corn (field, pop, sweet, seed)	25	140	3.672	0.101	2720	791	613
		80	2.098	0.058	4770	1380	1070
Oilseeds – Crop Group 20A and	11.25	360	4.247	0.117	2350	684	530

Crops [a]	Max. Appl. Rate (g a.i./ha)	ATPD [b] (ha)	Exposure[c] (µg/kg bw/day)		MOE (Target = 300)		
			Dermal	Inhal.	Dermal[d]	Inhal.[e]	Combined[f]
Crop Group 20B		107	1.262	0.035	7920	2300	1780
Tuberous and corm vegetables – Crop Group 1C	25	360	9.439	0.260	1060	308	239
		107	2.805	0.077	3560	1040	803
Legumes – Crop Group 6	28.43	360	10.732	0.295	932	271	210
		107	3.190	0.088	3130	911	706
Fruiting vegetables – Crop Group 8-09	25	26	0.682	0.019	14700	4260	3300
Brassica – Crop subgroup 5A							
Cucurbit Vegetables – Crop Group 9	28.43	26	0.775	0.021	12900	3750	2900
Lettuce (head and leaf), celery, ferns of asparagus, carrots, Tobacco (post-planting and soil treatment)[g]	10.13	26	0.276	0.008	36200	10500	8150
Garlic, great headed (elephant garlic), Leek, Onion (dry bulb, green, welch, shallot)	22.94	26	0.625	0.017	16000	4650	3600
Strawberries, Saskatoon berries	12.69	26	0.346	0.010	28900	8400	6510
Outdoor ornamentals	27	26	0.736	0.020	13600	3950	3060
Turf – Sod farms	37	30	1.164	0.032	8590	2500	1930
Turf – Golf courses, homes, industrial and commercial lawns		16	0.621	0.017	16100	4680	3630
Single layer PPE, CR gloves; Open M/L with respirator; Open-cab[h]							
Tuberous and corm vegetables – Crop Group 1C	25	360	9.443	0.196	1060	408	295
Legumes – Crop Group 6	28.43		10.732	0.223	932	359	259
Single layer PPE, CR gloves; Open M/L; Open-cab with respirator[h]							
Tuberous and corm vegetables – Crop Group 1C	25	360	9.443	0.090	1060	891	484
Legumes – Crop Group 6	28.43		10.732	0.102	932	784	426
Single layer PPE; Open M/L; Closed-cab[h]							
Tuberous and corm vegetables – Crop Group 1C	25	360	7.828	0.078	1280	1030	571
Legumes – Crop Group 6	28.43		8.897	0.088	1120	906	502

Shaded cells indicate that risks were not shown to be acceptable.

Max. = maximum; Appl. = application; ATPD = area treated per day; Inhal. = inhalation; PPE = personal protective equipment; Single layer = long-sleeved shirt with long pants; CR = chemical-resistant; M/L = mix/load; BW = body weight.

[a] Refer to Residue Chemistry Crop Groups for a list of crops included in each crop group.

[b] When two different ATPD values are listed for the same crop, the larger ATPD value is used to assess custom application. Custom application may not be practiced for every crop within a given crop group. Values for some crops have been updated from PRVD2017-03.

[c] Exposure = unit exposure × ATPD × max. appl. Rate / 80 kg body weight.

[d] Dermal MOE = dermal NOAEL/dermal exposure. Based on a NOAEL of 10 mg/kg bw/day from a 21-day dermal toxicity study in rats and a target MOE of 300.

[e] Inhalation MOE = inhalation NOAEL/inhalation exposure. Based on a NOAEL of 0.08 mg/kg bw/day from a 21-day inhalation toxicity study in rats and a target MOE of 300.

[f] Combined MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)].

[g] Includes field and cover crop treatments.

[h] This mitigation is to address risks to custom applicators and will only be required when handling more than 7.15 kg of active ingredient per day.

Table 3 Airblast: Mixer/loader/applicator exposure and risk assessment for agricultural scenarios

Crops	Max. Appl. Rate (g a.i./ha)	ATPD (ha)	Exposure[a] (µg/kg bw/day)		MOE (Target = 300)		
			Dermal	Inhal.	Dermal[b]	Inhal.[c]	Combined[d]
Single layer PPE, CR gloves; Open mix/load; Open cab							
Chokecherry shelterbelts	7.08	20	6.771	0.017	1480	4660	1120
Poplar and willow plantings; Pears	10.13		9.690	0.025	1030	3250	784
Apples, nectarines, peaches, plums, cherries; Saskatoon berries; Crop group 14 – Tree nuts[e]	12.69		12.142	0.031	824	2600	625
Outdoor ornamentals	27		25.838	0.066	387	1220	294
Conifer seed orchards[f]	58.56	11	30.821	0.078	324	1020	246
Single layer PPE, CR gloves.CR hat worn during application; Open mix/load; Open cab							
Conifer seed orchards[f]	58.56	11	3.812	0.078	2620	1020	736

Shaded cells indicate that risks were not shown to be acceptable.
Max. = maximum; Appl. = application; ATPD = area treated per day; Inhal. = inhalation; PPE = personal protective equipment; Single layer = long-sleeved shirt with long pants, CR gloves; CR = chemical-resistant; BW = body weight.
[a] Exposure = unit exposure × ATPD × max. appl. rate / 80 kg body weight.
[b] Dermal MOE = dermal NOAEL/dermal exposure. Based on a NOAEL of 10 mg/kg bw/day from a 21-day dermal toxicity study in rats and a target MOE of 300.
[c] Inhalation MOE = inhalation NOAEL/inhalation exposure. Based on a NOAEL of 0.08 mg/kg bw/day from a 21-day inhalation toxicity study in rats and a target MOE of 300.
[d] Combined MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)].
[e] Refer to Residue Chemistry Crop Groups for a list of crops included in each crop group.
[f] Includes Douglas fir, hemlocks, spruces, larches, pines and true firs.

Table 4 Aerial application: Mixer/loader/applicator exposure and risk assessment for agricultural scenarios

Crops[a]	Max. Appl. Rate (g a.i./ha)	Scenario (M/L or A)	ATPD (ha)	Exposure[b] (µg/kg bw/day)		MOE (Target = 300)		
				Dermal	Inhal.	Dermal[c]	Inhal.[d]	Combined[e]
Single layer PPE; CR gloves (not required in cockpit); Open mix/load; Closed cockpit								
Poplar and willow plantings	9.96	M/L	400	2.913	0.031	3430	2550	1460
		A		0.133	0.0005	75200	166000	51700
Alfalfa/grass mixture, summer fallow, unimproved pastures; Cereals - Crop Group 15 (excluding corn)		M/L		2.913	0.031	3430	2550	1460
		A		0.133	0.0005	75200	166000	51700
Oilseeds – Crop Group 20A and Crop Group 20B	11.25	M/L		3.291	0.035	3040	2260	1300
		A		0.150	0.001	66600	147000	45800
Corn (field, pop, sweet, seed); Tuberous and corm vegetables – Crop Group 1C	25	M/L		7.313	0.0079	1370	1020	583
		A		0.334	0.001	30000	66000	20600
Legumes – Crop Group 6	27.25	M/L		7.971	0.086	1250	932	535
		A		0.364	0.001	27500	60600	18900

Max. = maximum; Appl. = application; M/L = mixing/loading; A = application; ATPD = area treated per day; Inhal. = inhalation; PPE = personal protective equipment; Single layer = long-sleeved shirt with long pants; CR = chemical-resistant; BW = body weight.
[a] Refer to Residue Chemistry Crop Groups for a list of crops included in each crop group.
[b] Exposure = unit exposure × ATPD × max. appl. rate / 80 kg body weight.
[c] Dermal MOE = dermal NOAEL/dermal exposure. Based on a NOAEL of 10 mg/kg bw/day from a 21-day dermal toxicity study in rats and a target MOE of 300.

[d] Inhalation MOE = inhalation NOAEL/inhalation exposure. Based on a NOAEL of 0.08 mg/kg bw/day from a 21-day inhalation toxicity study in rats and a target MOE of 300.
[e] Combined MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)].

Table 5 Handheld Equipment: Mixer/loader/applicator exposure and risk assessment for agricultural scenarios

Crops [a]	Max. Appl. Rate (g a.i./L)	HH equip.	ATPD (g/L)	Exposure[b] (µg/kg bw/day)		MOE (Target = 300)		
				Dermal	Inhal.	Dermal [c]	Inhal. [d]	Combined[e]
MPHW, MPHG, Backpack = Single layer PPE, CR gloves, no respirator; HH AB/MB = CR coveralls over single layer for M/L/A, respirator for applicator								
Greenhouse lettuce	0.020	MPHG	3800	5.373	0.145	1860	551	425
		MPHW	150	0.036	0.002	279000	46600	39900
		Backpack		0.207	0.002	48400	33900	19900
		HH AB/MB		1.239	0.150	8070	535	501
Greenhouse tobacco seedlings	0.007	MPHG	3800	1.769	0.048	5650	1670	1290
		MPHW	150	0.012	0.001	848000	142000	121000
		Backpack		0.068	0.001	147000	103000	60600
		HH AB/MB		0.408	0.049	24500	1620	1520
Poplar and willow plantings	0.101	MPHG	3800	28.865	0.726	372	110	85
		MPHW	150	0.179	0.009	55800	9320	7990
		Backpack		1.034	0.012	9670	6790	3990
		HH AB/MB		6.193	0.748	1610	107	100
Chokecherry shelterbelts	0.0071	ROW	3800	0.306	0.002	32700	42300	18400
		MPHW	150	0.013	0.001	799000	133000	114000
		Backpack		0.072	0.001	138000	97100	57100
		HH AB/MB		0.433	0.052	23100	1530	1440
Conifer seed orchards	0.073	MPHG	3800	19.421	0.525	515	152	118
		MPHW	150	0.129	0.006	77200	12900	11000
		Backpack		0.747	0.009	13400	9390	5520
		HH AB/MB		4.477	0.541	2230	148	139
Fruiting vegetables – Crop Group 8-09 Brassica – Crop subgroup 5A	0.167	MPHW	150	0.295	0.014	33900	5660	4850
		Backpack		1.702	0.019	5880	4120	2420
Cucurbit Vegetables – Crop Group 9	0.283	Backpack	150	2.903	0.033	3450	2420	1420
		MPHW		0.503	0.024	19900	3320	2850
Lettuce (head & leaf), celery	0.020	Backpack	150	0.207	0.002	48400	33900	19900
		MPHW		0.036	0.002	279000	46600	39900
Ferns of asparagus, carrots	0.101	Backpack	150	1.034	0.012	9670	6790	3990
		MPHW		0.179	0.009	55800	9320	7990
Garlic, great headed (elephant garlic); Onion (leek, dry bulb, green, welch, shallot)	0.046	Backpack	150	0.468	0.005	21300	15000	8800
		MPHW		0.081	0.004	123000	20600	17600
Tobacco (post-planting & soil treatment)	0.068	Backpack	150	0.689	0.008	14500	10200	5980
		MPHW		0.119	0.006	93700	14000	12000

Crops [a]	Max. Appl. Rate (g a.i./L)	HH equip.	ATPD (g/L)	Exposure[b] (µg/kg bw/day)		MOE (Target = 300)		
				Dermal	Inhal.	Dermal [c]	Inhal. [d]	Combined[e]
Apples, nectarines, peaches, plums, cherries; Tree nuts [f]	0.127	Backpack	150	1.296	0.015	7720	5420	3180
		MPHW		0.224	0.011	44600	7440	6380
		HH AB/MB		7.760	0.937	1290	85	80
Strawberries	0.127	Backpack	150	1.296	0.015	7720	5420	3180
		MPHW		0.224	0.011	44600	7440	6380
Saskatoon berries	0.063	Backpack	150	0.648	0.007	15400	10800	6360
		MPHW		0.112	0.005	89100	14900	12700
		HH AB/MB		3.881	0.469	2580	171	160
Pears	0.0101	Backpack	150	1.034	0.012	9670	6790	3990
		MPHW		0.179	0.009	55800	9320	7990
		HH AB/MB		6.193	0.748	1610	107	100
Outdoor ornamentals	0.036	MPHG	3800	9.551	0.258	1050	310	239
		Backpack	150	0.368	0.004	27200	19100	11200
		MPHW		0.064	0.003	157000	26200	22500
		HH AB/MB		2.202	0.266	4540	301	282
Turf (sod farm, golf course, home, industrial and commercial lawns)	37 g/ha	Turf gun	2 ha	0.726	0.004	13800	21600	8410
Livestock – beef cattle and calves less than 256 kg[f]	0.097 g/animal	MPHW	470 animals	0.538	0.026	18600	3110	2660
		Backpack		3.103	0.035	3220	2260	1330
Livestock – beef cattle and calves greater than 256 kg[f]	0.146 g/animal	MPHW		0.809	0.039	12400	2060	1770
		Backpack		4.671	0.053	2140	1500	883
Single layer PPE, respirator. [g]								
Outdoor ornamentals	0.036	MPHG	3800	9551	0.026	1060	3100	783
Poplar and willow plantings	0.101			26.865	0.073	372	1100	278
Conifer seed orchards	0.073			19.421	0.053	515	1520	385
CR coveralls over single layer PPE, respirator for applicator and limit amount handled per day to 5.1 g a.i.[h]								
Poplar and willow plantings Conifer seed orchards Apples, nectarines, peaches, plums, cherries, pears, Saskatoon berries, Crop group 14 - Tree nuts	NA[h]	HH AB/MB	NA[i]	2.079	0.251	4810	318	300

Shaded cells indicate that risks were not shown to be acceptable.

Max. = maximum; Appl. = application; HH = handheld; ATPD = area treated or volume of spray solution handled per day; Inhal. = inhalation; PPE = personal protective equipment; Single layer = long-sleeved shirt with long pant; CR = chemical-resistant; MPHG = mechanically pressurized hand gun; MPHW= manually pressurized hand wand; HH AB/MB = handheld airblast/mistblower; BW = body weight; NA = not applicable.

[a] Refer to Residue Chemistry Crop Groups for a list of crops included in each crop group.

[b] Exposure = unit exposure × ATPD × max. appl. rate / 80 kg body weight.

[c] Dermal MOE = dermal NOAEL/dermal exposure. Based on a NOAEL of 10 mg/kg bw/day from a 21-day dermal toxicity study in rats and a target MOE of 300.

[d] Inhalation MOE = inhalation NOAEL/inhalation exposure. Based on a NOAEL of 0.08 mg/kg bw/day from a 21-day inhalation toxicity study in rats and a target MOE of 300.

[e] Combined MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)].

[f] Equipment listed on the label for use on livestock are automatic dipper gun and pour-on applications. MPHW and backpack sprayer equipment was used as a surrogate for these types of application equipment. This is not expected to underestimate exposure.

[g] This mitigation is to address risks to applicators using MPHG equipment and will only be required when handling more than 0.11 kg of active ingredient per day.

[h] The amount handled per day (product of the application rate and the ATPD) was set to 5.1 g a.i./day. This is the maximum amount that could be handled in a day where risks are shown to be acceptable.

Table 6 Mixer/loader/applicator exposure and risk assessment for indoor and outdoor non-agricultural/structural scenarios

Site (s)	Form.	Max. Appl. Rate	App. Equip.	ATPD[a]	Exposure [b] (µg/kg bw/day)		MOE (Target = 300)		
					Dermal	Inhal.	Dermal [c]	Inhal. [d]	Combined [e]
Indoor and outdoor structural uses (Use-site category 12, 20, 21, 27)									
Liquid open pour, mixing/loading/application; Single layer PPE, CR gloves									
Indoor structural uses including: Residential, industrial/commercial buildings Modes of transportation Food handling establishments Pet kennels Livestock/poultry houses	MS EC	0.3 g a.i./L	MPHW (PCO)	40 L	12.877	0.049	777	1623	525
Outdoor structural uses			Backpack	150 L	3.063	0.035	3260	2290	1350
			MPHW		0.531	0.025	18800	3150	2700
			MPHG	3800 L	79.59	2.152	126	37	29
Liquid open pour, mixing/loading/application; CR coveralls over single layer PPE, CR gloves, respirator.									
Outdoor structural uses	MS EC	0.3 g a.i./L	MPHG	3800 L	26.037	0.215	384	372	182
				Restriction on AHPD.[f]	16.396	0.136	610	590	300
Single layer PPE, CR gloves									
Indoor and outdoor structural uses (Residential, industrial/commercial buildings) Modes of transportation, Pet kennels Livestock/poultry houses In-ground service boxes Stumps, utility poles, fences, inside trees, Aerial termite cartons in trees, Wasp and hornet nets	PP	0.298 g a.i./can[g]	Aerosol spray can	14 cans	7.632	0.086	1310	934	545

Max. = maximum; Appl. = application; HH = handheld; ATPD = area treated per day; Inhal. = inhalation; PPE = personal protective equipment; Single layer = long-sleeved shirt with long pants; CR = chemical-resistant; MPHW= manually pressurized handwand; MPHG = mechanically pressurized handgun; PCO = pest control operator; BW = body weight; MS = microencapsulated suspension; EC = emulsifiable concentrate; PP = pressurized product; form = formulation; AHPD = amount handed per day

[a] Values for some crops have been updated from PRVD2017-03.

[b] Exposure = unit exposure × ATPD × max. appl. rate / 80 kg body weight..

[c] Dermal MOE = dermal NOAEL/dermal exposure. Based on a NOAEL of 10 mg/kg bw/day from a 21-day dermal toxicity study in rats and a target MOE of 300.

[d] Inhalation MOE = inhalation NOAEL/inhalation exposure. Based on a NOAEL of 0.08 mg/kg bw/day from a 21-day inhalation toxicity study in rats and a target MOE of 300.

[e] Combined MOE = 1 / [(1/dermal MOE) + (1/inhalation MOE)].

[f] The amount handled per day (AHPD; product of the application rate and the ATPD) is restricted to 0.72 kg a.i. per day. This is the maximum amount that could be handled in a day where risks are shown to be acceptable.

[g] Rate was calculated based on the product guarantee of 0.05% and the largest can size of 595g.

Table 7 Occupational postapplication risk assessment for agricultural scenarios

Surrogate/ Representative Crops[a]	Crops Assessed[b]	Max. Rate (g ai/ha)	Max. No. Apps.	Min. RTI (days)	Activity[c]	TC[d] (cm^2/hr)	Day 0 DFR/TTR[e]	Day 0 MOE[f] (Target = 300)	REI[g] (days)
Greenhouse Crops (Use-site category 5)									
Greenhouse lettuce	Lettuce	10.13	2	7	All activities	230	0.05	9190	12 hours
	Tobacco Seedlings	30	1	NA			0.08	5800	
Trees and shelterbelts (Use-site category 4, 16)									
Forestry	Poplar and willow plantings	10.126	3	7	Harvest (seedling production)	6700	0.04	345	12 hours
					Irrigation (hand set)	1750		1320	
					Hand pruning, scouting	580		3990	
					Transplanting	230		10100	
					Hand weeding	100		23100	
	Conifer seed orchards	58.56	3	10	Irrigation (hand set)	1750		265	1
					Harvest (conifer seed cones)	1400		332	12 hours
					Hand pruning, scouting	580		801	
					Transplanting	230		2020	
					Hand weeding	100		4650	
	Chokecherry shelterbelts	7.08	1	-	Irrigation (hand set)	1750	0.02	3230	12 hours
					Scouting	580		9750	
					Transplanting	230		24600	
					Hand weeding	100		56500	
Field Crops (Use-site category 7, 13, 14)									
Forage crop	Alfalfa, grass mixtures, summer fallow, unimproved pastures, Timothy (grown for hay or seed)	10.13	3[h]	7	Irrigation (hand set)	1750	0.026	2170	12 hours
					Scouting	1100		3450	
Spring/Winter wheat, sorghum, forage crop	Grains – Crop group 15 (excluding corn and teosinte)	10.13	3	4	Irrigation (hand set)	1750	0.026	2170	12 hours
					Scouting (full)	1100		3450	
					Scouting (full)	210		18100	
					Hand weeding	70		54300	
Field corn	Teosinte	10.13	3	4	Irrigation (hand set)	1750	0.026	2170	12 hours
					Scouting (full)	1100		3450	
					Scouting (min)	210		18100	
					Hand weeding	70		54300	
Field corn	Corn (field, pop)	25	3	4	Irrigation (hand set)	1750	0.058	993	12 hours
					Scouting (full)	1100		1580	
					Scouting (min)	210		8280	
					Hand weeding	70		24800	
Seed/Sweet corn	Corn (seed, sweet)	25	3	4	Hand detasseling/Hand harvesting	8800	0.058	198	3
					Irrigation (hand set)	1750		993	12 hours
					Scouting (full)	1100		1580	
					Scouting (min)	210		9390	
					Hand weeding	70		24800	
Canola, sunflower, safflower, parsley	Oilseeds – Crop Group 20A/20B	11.25	3	7	Irrigation (hand set)	1750	0.029	1950	12 hours
					Scouting (full), hand harvesting (parsley)	1100		3110	
					Transplanting	230		14900	
					Scouting (all)	210		16300	
					Bird Control,	90		38800	

Surrogate/ Representative Crops[a]	Crops Assessed[b]	Max. Rate (g ai/ha)	Max. No. Apps.	Min. RTI (days)	Activity[c]	TC[d] (cm^2/hr)	Day 0 DFR/TTR[e]	Day 0 MOE[f] (Target = 300)	REI[g] (days)
					Scouting (sunflower)				
					Thinning, hand weeding	70		48800	
Chickpea, green pea, dry bean, soybean	Legumes – Crop Group 6	28.43	3	4	Irrigation (hand set)	1750	0.074	773	12 hours
					Scouting, hand harvesting	1100		1230	
					Scouting (green pea)	210		6440	
					Hand weeding	70		19300	
Asparagus, carrot, leaf lettuce	Asparagus fern, leaf lettuce, head lettuce, celery, carrot	10.13	3	7	Irrigation (hand set)	1750	0.026	2170	12 hours
					Hand harvesting	1100		3450	
					Transplanting	230		16500	
					Scouting (all)	210		18100	
					Thinning, hand weeding	70		54300	
Turnip, potato, sweet potato	Tuberous and corm vegetables – Crop Group 1C	25	2	7	Irrigation (hand set)	1750	0.065	879	12 hours
					Roguing, hand harvesting	1100		1400	
					Transplanting	230		5020	
					Scouting (all)	210		7330	
					Hand thinning/weeding	70		22000	
Broccoli, Brussels sprouts, cauliflower	Brassica Crop Group 5A (excluding cabbages and kohlrabi)	25	3	7	Hand harvesting	5150	0.065	299	12 hours
					Hand weeding	4400		350	
					Scouting (full), topping, tying/training	4000		385	
					Irrigation (hand set)	1750		879	
					Scouting (min), hand thinning plants	1300		1180	
					Transplanting	230		6990	
Cabbage	Cabbage, Chinese cabbage (napa), Chinese mustard cabbage (gai choi), kohlrabi	25	3	7	Hand weeding	4400	0.065	350	12 hours
					Irrigation (hand set)	1750		879	
					Hand/MA harvesting, scouting, hand thinning plants	1300		1180	
					Transplanting	230		6990	
Cucumber, watermelon	Cucurbit Vegetables – Crop Group 9	28.43	3	7	Irrigation (hand set)	1750	0.074	773	12 hours
					Hand/MA harvesting, training, turning	550		2460	
					Transplanting	230		5880	
					Scouting, hand thinning plants, hand weeding, hand pruning	90		15000	
Onion (bulb, green)	Bulb onion, onion (green, shallot, Welch), leek, garlic, great headed (elephant) garlic	22.94	3	7	Hand weeding	4400	0.060	381	12 hours
					Irrigation (hand set)	1750		958	
					Hand harvesting, scouting, hand thinning plants	1300		1290	
Bell pepper, tomato	Fruiting Vegetables – Crop Group 8-09 (except eggplant and garden huckleberry)	25	2	7	Irrigation (hand set)	1750	0.065	879	12 hours
					Hand harvesting, tying/training	1100		1400	
					Transplanting	230		6690	
					Scouting (all)	210		7330	
					Hand pruning/weeding	70		22000	

Surrogate/ Representative Crops[a]	Crops Assessed[b]	Max. Rate (g ai/ha)	Max. No. Apps.	Min. RTI (days)	Activity[c]	TC[d] (cm^2/hr)	Day 0 DFR/TTR[e]	Day 0 MOE[f] (Target = 300)	REI[g] (days)
Eggplant	Eggplant (including African, pea, scarlet)				Irrigation (hand set)	1750	0.065	879	12 hours
					Hand harvesting, tying/training	550		2800	
					Transplanting	230		6690	
					Scouting, hand pruning/weeding, hand thinning plants	90		17100	
High bush blueberry	Garden huckleberry				Irrigation (hand set)	1750	0.065	879	12 hours
					Hand harvestings	1400		1100	
					Bird control, frost control, scouting, hand pruning/weeding	640		2400	
					Transplanting	230		6690	
Tobacco	Tobacco	10.13	1	-	Irrigation (hand set)	1750	0.026	2170	12 hours
					Canopy management, hand/MA harvesting	800		4750	
					Transplanting	230		16500	
					Scouting, hand weeding	90		42200	
Tree fruit/nuts and berries (Use-site category 14)									
Saskatoon Berry	Saskatoon berry	12.69	2	10	Irrigation (hand set)	1750	0.033	1730	12 hours
					Hand harvesting	1400		2170	
					Bird control, frost control, scouting, hand pruning/weeding	640		4740	
					Transplanting	230		13200	
Strawberry	Strawberry	12.69	3	7	Hand harvesting	1100	0.033	2760	12 hours
					Transplanting	230		13200	
					Scouting	210		14400	
					Canopy management, hand weeding	70		43300	
Apple, cherry (sweet), plum	Apple, peach, plum, nectarine, cherry (sweet, sour)	12.69	3	7	Hand thinning fruit	3000	0.05	616	12 hours
					Hand harvesting	1400		1320	
					Scouting, training, hand pruning	580		3180	
					Transplanting	230		8030	
					Orchard maintenance, propping, weeding	100		18500	
Pear	Pear	10.13	1	-	Hand thinning fruit	3000	0.03	1320	12 hours
					Hand harvesting	1400		2820	
					Scouting, training, hand pruning	580		6810	
					Transplanting	230		17200	
					Orchard maintenance, propping, weeding	100		39500	
Hazelnut, walnut	Hazelnut (filbert), walnut (English, black), beechnut, butternut, chestnut, chinquapin, hickory nut	12.69[h]	3	7	Scouting, hand pruning	580	0.05	3180	12 hours
					Transplanting	230		8030	
					Mechanical harvesting (shaking)	190		9720	
					Orchard maintenance, poling, hand weeding	100		18500	
Ornamentals and Turf (Use-site category 27, 30)									
Floriculture	Cut flowers	27	3	7	Disbudding, hand harvesting, hand pruning	4000	0.07	356	12 hours
					All other activities	230		6190	

Surrogate/ Representative Crops[a]	Crops Assessed[b]	Max. Rate (g ai/ha)	Max. No. Apps.	Min. RTI (days)	Activity[c]	TC[d] (cm^2/hr)	Day 0 DFR/TTR[e]	Day 0 MOE[f] (Target = 300)	REI[g] (days)
Floriculture, Nursery crop (outdoor)	Outdoor ornamentals, Non-cut flowers	27	3	7	Irrigation (hand set)	1750		814	
					Container moving, pinching, plant support/staking, scouting, transplanting, hand weeding	250		6190	
Sod farms, Golf courses	Turf (sod, golf course, home, industrial/commercial lawns)	37	4	7	Harvesting (slab), Transplanting/planting	6700	0.005	3100	12 hours
					Irrigating, mowing, watering, cup changing, miscellaneous grooming, irrigation repair	3500		5940	
					Aerating, fertilizing, hand pruning, mechanical weeding, scouting, seeding	1000		20800	

Shaded cells indicate those calculated MOEs that are below the target MOE of 300 on the day of the last application (day 0) and risks were not shown to be acceptable.

Apps = applications; RTI = Re-treatment Interval; DFR = Dislodgeable Foliar Residue; TTR = turf transferrable residue; REI = Restricted-entry interval; TC = transfer coefficient; MOE = margin of exposure; MA = mechanically-assisted harvesting; full = full foliage; min = minimum foliage; all = includes both full and min foliage

[a] Surrogate or representative crops were chosen to reflect the appropriate postapplication activities and associated TCs for several crops. Crop groups were assessed together using several surrogate or representative crops for the crop group. Some activities listed may not be performed for some crops within the crop group. In some cases, surrogate crops were not available for registered crops, in those cases postapplication exposure was considered to be addressed by the other crops in the crop group. This is an uncertainty in the risk assessment.

[b] In some cases crop groups are listed. Refer to Residue Chemistry Crop Groups for a list of crops included in each crop group.

[c] When multiple surrogate/representative crops were used to assesse a crop group, there may be several different TC clusters listed for the scouting activity, since all activities from all representative crops were used to assess the crop group in a tier one approach. For some crop groups, scouting was included twice. This is due to the use of multiple surrogate crops that had different scouting TCs.

[d] Transfer coefficients (TC) are from the PMRA Agricultural TC memo. Activities that have minimal postapplication exposure to treated foliage and do not have a transfer coefficient are not included in this table.

[e] Day 0 DFR = Dislodgeable Foliar Residues on Day 0 after all applications. Dislodgeable foliar residue values for field crops, except for corn, were calculated using the peak DFR of 26% of the application rate after the final application and 14% dissipation per day based on chemical-specific data. For corn, a peak DFR of 23% of the application rate after the final application and 12% dissipation per day were used to calculated DFR based on chemical-specific data. For greenhouse ornamental crops, the default peak of 25% of the application rate after each application and dissipation rate of 2.0% per day was used. For trees (forestry, fruit trees, tree nuts), DFR was estimated using standard DFR values of 25% of the application rate after each application for peak and a 10% dissipation rate per day.

[f] Dermal MOE on Day 0 = NOAEL/ ($DFR_{Day\ 0}$ × Transfer Coefficient × 8 hr / 80 kg). MOE on day 0 after application; based on the NOAEL of 10 mg/kg bw/day from the 21-day dermal rat toxicity study, target MOE of 300. This toxicology reference value is applicable for all durations.

[g] Day at which the dermal exposure results in an MOE greater than or within range of the target MOE (300) and risks are shown to be acceptable.

[h] A lower registration rate for these crops with 4 applications is also registered; however, the calculated DFR is not higher than the calculated DFR presented in this table.

Table 8 Short-to intermediate-term dermal postapplication exposure from indoor treatment of hard and soft surfaces

Exposure Scenario		Lifestage	DR ($\mu g/cm^2$)[a]	TR ($\mu g/cm^2$)[b]	TC (cm^2/hr)[c]	ET (hr/day)[c]	Dermal Exposure (mg/kg bw/day)[d]	Dermal MOE[e] (Target = 300)
Liquid Product Formulation								
Perimeter/spot/ bedbug	Soft surface	Adults	0.24	0.0096	6800	8	0.0065	1500
		Children 1 < 2 years	0.24	0.0096	1800	4	0.0063	1600
	Hard	Adults	0.24	0.0144	6800	2	0.0024	4100

Exposure Scenario		Lifestage	DR (µg/cm^2)[a]	TR (µg/cm^2)[b]	TC (cm^2/hr)[c]	ET (hr/day)[c]	Dermal Exposure (mg/kg bw/day)[d]	Dermal MOE[e] (Target = 300)
	surface	Children 1 < 2 years	0.24	0.0144	1800	2	0.0047	2100
Crack and crevice (bedbug only)	Soft surface	Adults	0.12	0.0048	6800	8	0.0033	3100
		Children 1 < 2 years	0.12	0.0048	1800	4	0.0031	3200
	Hard surface	Adults	0.12	0.0072	6800	2	0.0012	8200
		Children 1 < 2 years	0.12	0.0072	1800	2	0.0024	4200
Crack and crevice (all other pests)	Soft surface	Adults	0.05	0.0019	6800	8	0.0013	7700
		Children 1 < 2 years	0.05	0.0019	1800	4	0.0013	8000
	Hard surface	Adults	0.05	0.0029	6800	2	0.0005	20000
		Children 1 < 2 years	0.05	0.0029	1800	2	0.0009	11000
Pressurized Product Formulation								
Perimeter/spot/bedbug	Soft surface	Adults	0.42	0.0166	6800	8	0.0113	890
		Children 1 < 2 years	0.42	0.0166	1800	4	0.0109	920
	Hard surface	Adults	0.42	0.0249	6800	2	0.0042	2400
		Children 1 < 2 years	0.42	0.0249	1800	2	0.0081	1200
Crack and crevice (bedbug only)	Soft surface	Adults	0.21	0.0083	6800	8	0.0056	1800
		Children 1 < 2 years	0.21	0.0083	1800	4	0.0054	1800
	Hard surface	Adults	0.21	0.0125	6800	2	0.0021	4700
		Children 1 < 2 years	0.21	0.0125	1800	2	0.0041	2500
Crack and crevice (all other pests)	Soft surface	Adults	0.08	0.0033	6800	8	0.0023	4400
		Children 1 < 2 years	0.08	0.0033	1800	4	0.0022	4600
	Hard surface	Adults	0.08	0.0050	6800	2	0.0008	12000
		Children 1 < 2 years	0.08	0.0050	1800	2	0.0016	6100

C/C = crack and crevice; NOAEL = no observed adverse effect level; MOE = margin of exposure;

[a] DR = Deposited residues (µg/cm^2) were calculated based on the indoor surface-directed application rates using the USEPA Residential SOPS (2012) algorithms for all scenarios. For perimeter/spot/bedbug applications, it is assumed that the deposited residues are 50% of the application rate, 25% for C/C bed bug treatment and 10% for C/C treatment. The calculated application rates for the liquid and pressurized product formulations are 0.0048 g a.i./m^2 and 0.0083 g a.i./m^2, respectively. These application rates were calculated based on label information, registrant provided information and assumptions from the USEPA Residential SOPS (2012).

[b] TR = transferable residue (µg/cm^2) = deposited residue (µg/cm^2) × fraction transferred (%).The fraction transferred was 0.06 for hard surfaces and 0.04 for soft surfaces based on pyrethroid data presented in the USEPA Residential SOPs (2012).

[c] TC = Transfer coefficients (cm^2/hr) and ET = exposure time (hr/day) are standard values obtained form the USEPA Residential SOP (2012).

[d] Dermal exposure (mg/kg bw/day) = TR (µg/cm^2) × 0.001mg/µg × TC (cm^2/hr) × ET (hr/day) / BW (kg). Body weights of 80 and 11 kg were used for adults and children (1<2 years) respectively, as stated in the USEPA Residential SOPs (2012).

[e] MOE = NOAEL / exposure. The NOAEL is 10 mg/kg bw/day from a 21-day dermal toxicity study in rats, and a target MOE of 300. This toxicology reference value is applicable for all durations.

Table 9 Long-term dermal postapplication exposure from indoor treatment of hard and soft surfaces

Exposure Scenario		Lifestage	DR (µg/cm^2) [a]	TR (µg/cm^2) [b]	TC (cm^2/hr) [c]	ET (hr/day)[c]	Dermal Exposure (mg/kg bw/day)[d]	Dermal MOE[e] (Target = 300)
Liquid Product Formulation								
Perimeter/Spot/bedbug	Soft surface	Adults	0.24	0.0048	4700	8	0.0023	4400
		Children 1 < 2 years	0.24	0.0048	1300	4	0.0023	4400
	Hard surface	Adults	0.24	0.0072	4700	4	0.0008	12000
		Children 1 < 2 years	0.24	0.0072	1300	2	0.0017	5900
Crack and crevice (bedbug only)	Soft surface	Adults	0.12	0.0024	4700	8	0.0011	8900
		Children 1 < 2 years	0.12	0.0024	1300	4	0.0011	8800
	Hard surface	Adults	0.12	0.0036	4700	2	0.0004	24000
		Children 1 < 2 years	0.12	0.0036	1300	2	0.0009	12000
Pressurized Product Formulation								
Perimeter/Spot/bedbug	Soft surface	Adults	0.42	0.0083	4700	8	0.0039	2600
		Children 1 < 2 years	0.42	0.0083	1300	4	0.0039	2500
	Hard surface	Adults	0.42	0.0125	4700	2	0.0015	6800
		Children 1 < 2 years	0.42	0.0125	1300	2	0.0029	3400
Crack and crevice (bedbug only)	Soft surface	Adults	0.21	0.0042	4700	8	0.0020	5100
		Children 1 < 2 years	0.21	0.0042	1300	4	0.0020	5100
	Hard surface	Adults	0.21	0.0062	4700	2	0.0007	14000
		Children 1 < 2 years	0.21	0.0062	1300	2	0.0015	6800

C/C = crack and crevice; NOAEL = no observed adverse effect level; MOE = margin of exposure;

[a] DR = Deposited residues (µg/cm^2) were calculated based on the indoor surface-directed application rates using the USEPA Residential SOPS (2012) algorithms for all scenarios. For perimeter/spot/bedbug applications, it is assumed that the deposited residue available is 50% of the application rate, and 25% for C/C bedbug treatment. The calculated application rates for the liquid and pressurized formulations are 0.0048 g a.i./m^2 and 0.0083 g a.i./m^2, respectively. These application rates were calculated based on label information, registrant provided information and assumptions from the USEPA Residential SOPS (2012).

[b] TR = transferable residue (µg/cm^2) = deposited residue (µg/cm^2) × Fraction transferred (%).The fraction transferred was 0.03 for hard surfaces and 0.02 for soft surfaces based on the 50th percentile of data presented in the USEPA Residential SOPs (2012).

[c] TC = Transfer coefficient (cm^2/hr) are 50th percentile values and exposure times (ET, hr/day) are standard values obtained from the USEPA Residential SOP (2012).

[d] Dermal exposure (mg/kg bw/day) = TR (µg/cm^2) × 0.001mg/µg × TC (cm^2/hr) × ET (hr/day) / BW (kg). Body weights of 80 and 11 kg were used for adults and children (1<2 years) respectively, as stated in the USEPA Residential SOPs (2012).

[e] MOE = margin of exposure; MOE = NOAEL / exposure. The NOAEL is 10 mg/kg bw/day from a 21-day dermal toxicity study in rats, with a target MOE of 300. This toxicology reference value is applicable for all durations.

Table 10 Short-to intermediate dermal postapplication exposure from treated lawns and turf

Activities	Lifestage	Appl. Rate (g a.i./ha)	TTR_t (µg/cm^2)[a]	TC (cm^2/hr)[b]	ET (hr/day)[b]	Dermal Exposure (mg/kg bw/day)[c]	Dermal MOE[d] (Target = 300)
4 applications, 7 day RTI							
High contact lawn activities	Adults	37	0.0048	180 000	1.5	1.63E-02	610
	Children 1 < 2 years			49 000	1.5	3.22E-02	310
Mowing Turf	Adults			5500	1	3.31E-04	30000
	Youth 11 < 16 years			4500	1	3.81E-04	26000
Golfing	Adults			5300	4	1.28E-05	7800
	Youth 11 < 16 years			4400	4	1.49E-05	6700
	Children 6 < 11 years			2900	4	1.75E-05	5700
4 applications, 14 day RTI[f]							
High contact lawn activities	Children 1 < 2 years	37	0.0041	49 000	1.5	2.72E-02	370

Appl. = application; RTI = retreatment interval; TTR_t = turf transferable residue at time (t); TC = transfer coefficient; ET = exposure time; MOE = margin of exposure; BW = body weight; NOAEL = no observed adverse effect level.

[a] Peak TTR of 1.1% of the application rate and a dissipation rate of 23.3% per day was used to model multiple applications based on chemical-specific data. This is a refinement from the PRVD2017-03.

[b] Standard TC and ET values from the USEPA Residential SOPs (2012).

[c] Dermal exposure (mg/kg bw/day) = DFR_t (µg/cm^2) × 0.001 mg/µg × TC (cm^2/hr) × ET (hr/day) / BW (kg). Body weights of 80, 57, 32 and 11 kg were used for adults, youth, children (6 < 11 years) and children (6 < 11 years), respectively, as stated in the USEPA Residential SOPs (2012).

[d] MOE = NOAEL/exposure. The NOAEL is 10 mg/kg bw/day from a 21-day dermal toxicity study in rats and the target MOE is 300.

[f] During consultation of the PRVD2017-03, the registrant supported an extension in the RTI from 7 days to 14 days. While risks are shown to be acceptable for the postapplication dermal assessment for all lifestages, dermal exposure for children (1 < 2 years) was also assessed at a 14 day RTI, as a longer RTI was required to mitigate the aggregate risk assessment.

Table 11 Short-to intermediate postapplication HtM exposure for children from indoor environments

Exposure Scenario		Dermal Exposure[a] (mg/hr)	Hand Residue Loading [b] (mg/hr)	Oral Exposure [c] (mg/kw bw/day)	Incidental Oral MOE[d] (Target = 300)
Liquid Formulation					
Perimeter/spot/bedbug	Soft surfaces	0.017	0.0013	5.89E-05	4800
	Hard surfaces	0.026	0.0019	4.42E-05	6300
Crack and crevice (bedbug only)	Soft surfaces	0.009	0.0006	2.95E-05	9500
	Hard surfaces	0.013	0.0010	2.21E-05	13000
Crack and crevice (all other pests)	Soft surfaces	0.003	0.0003	1.18E-05	24000
	Hard surfaces	0.005	0.0004	8.84E-06	32000
Pressurized Product Formulation					
Perimeter/spot/bedbug	Soft surfaces	0.030	0.0022	1.02E-04	2700
	Hard surfaces	0.045	0.0034	7.64E-05	3700

Exposure Scenario		Dermal Exposure[a] (mg/hr)	Hand Residue Loading [b] (mg/hr)	Oral Exposure [c] (mg/kw bw/day)	Incidental Oral MOE[d] (Target = 300)
Crack and crevice (bedbug only)	Soft surfaces	0.015	0.0011	5.10E-05	5500
	Hard surfaces	0.022	0.0017	3.82E-05	7300
Crack and crevice (all other pests)	Soft surfaces	0.006	0.0004	2.04E-05	14000
	Hard surfaces	0.009	0.0007	1.53E-05	18000

MOE = margin of exposure; HtM = hand-to-mouth; BMDL = benchmark dose lower confidence limit.
[a] Dermal exposure (mg/hr) = dermal exposure (mg/kw bw/day) × body weight (11 kg) / exposure time (hr/day), where dermal exposure and exposure time are from Table 8.
[b] Hand loading residue (mg/hr) = HR = dermal exposure (mg/hr) × fraction on hands (0.15) / 2 hands. Fraction on hands is the amount of a.i. on a hand compared to the whole body and is a point estimate from the USEPA Residential SOPs (2012).
[c] Oral exposure (mg/kg bw/day) = $[(HR \times F_m) \times (ET \times N) \times (1-(1-SE)^{FreqHtM / N})]$ / BW. The following point estimates from the USEPA Residential SOP (2012) were used to calculate oral exposure: exposure times (ET) for soft and hard surfaces were 4 and 2 hours, respectively; fraction mouthed (F_m) is the fraction of hand surface area mouthed per event (0.13); the replenishment interval per hour (N) was 4; the saliva extraction factor (SE) was 0.48; the frequency of hand-to-mouth events per hour (FreqHtM) was 20; and the body weight for children (1 < 2 years) was 11 kg.
[d] Incidental Oral MOE = $BMDL_{20}$ / oral exposure. The $BMDL_{20}$ is 0.28 mg/kg bw from acute oral neurotoxicity studies in rats. The target MOE is 300.

Table 12 Long-term postapplication HtM exposure for children from indoor environments

Exposure Scenario		Dermal Exposure[a] (mg/hr)	Hand Residue Loading [b] (mg/hr)	Oral Exposure [c] (mg/kw bw/day)	Incidental Oral MOE[d] (Target = 300)
Liquid Formulation					
Perimeter/Spot/Bedbug	Soft surfaces	0.006	0.0005	1.84E-05	5400
	Hard surfaces	0.009	0.0007	1.38E-05	7300
Crack and crevice (bedbug only)	Soft surfaces	0.003	0.0002	9.18E-06	11000
	Hard surfaces	0.005	0.0004	6.88E-06	15000
Pressurized Product Formulation					
Perimeter/spot/bedbug	Soft surfaces	0.011	0.0008	3.17E-05	3200
	Hard surfaces	0.016	0.0012	2.38E-05	4200
Crack and crevice (bedbug only)	Soft surfaces	0.005	0.0004	1.59E-05	6300
	Hard surfaces	0.008	0.0006	1.19E-05	8400

MOE = margin of exposure; NOAEL = no observed adverse effect level; HtM = hand-to-mouth;
[a] Dermal exposure (mg/hr) = dermal exposure (mg/kw bw/day) × body weight (11 kg) / exposure time (hr/day), where dermal exposure and exposure time are from Table 9.
[b] Hand loading residue (mg/hr) = HR =dermal exposure (mg/hr) × fraction on hands (0.15) / 2 hands. Fraction on hands is the amount of a.i. on a hand compared to the whole body and is a point estimate from the USEPA Residential SOPs (2012).
[c] Oral exposure (mg/kg bw/day) = $[(HR \times F_m) \times (ET \times N) \times (1-(1-SE)^{FreqHtM / N})]$ / BW. The following point estimates from the USEPA Residential SOP (2012) were used to calculate oral exposure: exposure times (ET) for carpets and hard surfaces were 4 and 2 hours, respectively; fraction mouthed (F_m) is the fraction of hand surface area mouthed per event (0.12; 50th percentile value); the replenishment interval per hour (N) was 4; the saliva extraction factor (SE) was 0.48; the frequency of hand-to-mouth events per hour (FreqHtM) was 14 (50th percentile value); and the body weight for children (1 < 2 years) was 11 kg.
[d] Incidental Oral MOE = NOAEL / oral exposure. The NOAEL is 0.1 mg/kg bw/day from a 1-year oral toxicity study in dogs. The target MOE is 300.

Table 13 Short- to intermediate-term postapplication HtM exposure for children from lawns and turf

Application rate (g/ha)	# of appls.	RTI (days)[a]	Hand loading residue[b] (mg/cm^2)	Oral Exposure[c] (mg/kw bw/day)	Incidental Oral MOE[d] (Target = 300)
37	4	7	1.01×10^{-5}	9.63E-05	2900
		14	8.51×10^{-6}	8.13E-05	3400

MOE = margin of exposure; BW = body weight; $BMDL_{20}$ =benchmark dose limit; HtM = hand-to-mouth; BMDL = benchmark dose lower confidence level; RTI = re-treatment interval

[a] While risks are shown to be acceptable for a 7 day RTI, a 14 day RTI assessment was also included as a longer RTI was required to mitigate the aggregate risk assessment.

[b] Hand loading residue (HR) was calculated as 2.3% of the application rate based on a chemical-specific hand transfer residue study. For the 7 days RTI, HR after 4 applications was modelling using the dissipation rate of 23.3% per day from a chemical-specific turf transferable residue study. For the 14 day RTI, turf residues dissipated between applications so it was not necessary to model a multiple application scenario.

[c] Oral exposure (mg/kg bw/day) = $[(HR \times F_m) \times (ET \times N) \times (1-(1-SE)^{FreqHtM / N})] / BW$. The following point estimates from the USEPA Residential SOP (2012) were used to calculate oral exposure: exposure times (ET) for high contact lawn activities was 1.5 hours; fraction mouthed (F_m) is the fraction of hand surface area mouthed per event (0.13); the replenishment interval per hour (N) was 4; the saliva extraction factor (SE) was 0.48; the frequency of hand-to-mouth events per hour (FreqHtM) was 14; and the body weight for children (1<2 years) was 11 kg.

[d] MOE = $BMDL_{20}$/ oral exposure. The $BMDL_{20}$ is 0.28 mg/kg bw from acute oral neurotoxicity studies in rats. The target MOE is 300.

Table 14 Short-to intermediate-term postapplication OtM exposure for children from indoor environments

Exposure Scenario		DR ($\mu g/cm^2$) [a]	Fraction Transferred[b]	OR ($\mu g/cm^2$) [c]	ET (hr/day)[d]	Oral Exposure (mg/kg bw/day)[e]	Incidental Oral MOE[f] (Target = 300)
Liquid Formulation							
Perimeter/spot/bedbug	Soft surface	0.24	0.04	0.010	4	1.25E-04	2200
	Hard surface	0.24	0.06	0.014	2	9.41E-05	3000
Crack and crevice (bedbug only)	Soft surface	0.12	0.04	0.005	4	6.27E-05	4500
	Hard surface	0.12	0.06	0.007	2	4.71E-05	6000
Crack and crevice (all other pests)	Soft surface	0.048	0.04	0.002	4	2.51E-05	11000
	Hard surface	0.048	0.06	0.003	2	1.88E-05	15000
Pressurized Product Formulation							
Perimeter/spot/bedbug	Soft surface	0.42	0.04	0.017	4	2.171E-03	1300
	Hard surface	0.42	0.06	0.025	2	1.63E-04	1700
Crack and crevice (bedbug only)	Soft surface	0.21	0.04	0.008	4	1.08E-04	2600
	Hard surface	0.21	0.06	0.012	2	8.14E-05	3400
Crack and crevice (all other pests)	Soft surface	0.08	0.04	0.003	4	4.34E-05	6500
	Hard surface	0.08	0.06	0.005	2	3.25E-05	8500

OtM = object-to-mouth; BMDL = benchmark dose lower confidence limit.

[a] DR = Deposited residues ($\mu g/cm^2$) are the same as those determined for dermal postapplication assessment, which is consistent with the USEPA Residential SOPS (2012). See Table 8 for details.

[b] Fraction transferred is the fraction of deposited residues (DR) expected to transfer from a hard or soft object. These values are refined from the USEPA Residential SOPs (2012) using data from pyrethroid studies and are the same values used for the dermal postapplication. assessment. See Table 8 for details

[c] OR = Object residue ($\mu g/cm^2$) = deposited residue ($\mu g/cm^2$) × fraction transferred (%).

[d] ET = Exposure times (hr/day) are standard values obtained form the USEPA Residential SOP (2012).

[e] Oral exposure (mg/kg bw/day) = $[(OR \times SAM) \times (ET \times N) \times (1-(1-SE)^{FreqOtM / N})] / BW$. The following point estimates from the USEPA Residential SOP (2012) were used to calculate oral exposure: SAM is the object surface area mouthed per event (10 cm^2/event); the replenishment interval per hour (N) was 4; the saliva extraction factor (SE) was 0.48; the frequency of object-to-mouth events per hour (FreqOtM) was 14; and the body weight for children (1 < 2 years) was 11 kg.

[f] MOE = $BMDL_{20}$/ oral exposure. The $BMDL_{20}$ is 0.28 mg/kg bw from acute oral neurotoxicity studies in rats. The target MOE is 300.

Table 15 Long-term postapplication OtM exposure for children (1 < 2 years) from indoor environments

Exposure Scenario		DR (µg/cm^2) [a]	Fraction Transferred[b]	OR (µg/cm^2) [c]	ET (hr/day)[d]	Oral Exposure (mg/kg bw/day)[e]	Incidental Oral MOE[f] (Target = 300)
Liquid Formulation							
Perimeter/spot/bedbug	Soft surface	0.24	0.02	0.005	4	6.00E-05	1700
	Hard surface	0.24	0.03	0.007	2	4.50E-05	2200
Crack and crevice (begbug only)	Soft surface	0.12	0.02	0.002	4	3.00E-05	3300
	Hard surface	0.12	0.03	0.004	2	2.25E-05	4400
Pressurized Product Formulation							
Perimeter/spot/bbug	Soft surface	0.42	0.02	0.008	4	1.04E-04	960
	Hard surface	0.42	0.03	0.012	2	7.78E-05	1300
Crack and crevice (bed bug only)	Soft surface	0.21	0.02	0.0045	4	5.19E-05	1900
	Hard surface	0.21	0.03	0.006	2	3.89E-05	2600

OtM = object-to-mouth; NOAEL = no observed adverse effect level

[a] DR = Deposited residues (µg/cm^2) are the same as those determined for dermal postapplication assessment. This is based on the USEPA Residential SOPS (2012). See Table 9 for details.

[b] Fraction transferred is the fraction of DR expected to transfer to a hard or soft object. These values are the 50th percentile values from the USEPA Residential SOPs (2012) and not specific to pyrethroids.

[c] OR = Object residue (µg/cm^2) = deposited residue (µg/cm^2) × Fraction transferred (%).

[d] ET = Exposure times (hr/day) are standard values obtained form the USEPA Residential SOP (2012).

[e] Oral exposure (mg/kg bw/day) = $[(OR \times SAM) \times (ET \times N) \times (1-(1-SE)^{FreqOtM / N})] / BW$. The following point estimates from the USEPA Residential SOP (2012) were used to calculate oral exposure: SAM is the object surface area mouthed per event (10 cm^2/event); the replenishment interval per hour (N) was 4; the saliva extraction factor (SE) was 0.48; the frequency of object-to-mouth events per hour (FreqOtM) was 12 (50th percentile); and the body weight for children (1 < 2 years) was 11 kg.

[f] Incidental Oral MOE = NOAEL / oral exposure. The NOAEL is 0.1 mg/kg bw/day from a 1-year oral toxicity study in dogs. The target MOE is 300.

Table 16 Short-to intermediate-term postapplication OtM exposure for children (1<2 years) from lawns and turf

Application rate (g/ha)	Number of appls.	RTI (days)[a]	Object residue[b] (µg/cm^2)	Oral Exposure[c] (mg/kw bw/day)	Incidental Oral MOE[d] (Target = 300)
37	4	7	4.82×10^{-5}	2.03×10^{-5}	14000
	4	14	4.07×10^{-3}	1.71×10^{-5}	16000

OtM = object-to-mouth; Appl. = application; RTI = retreatment interval; MOE = margin of exposure; BW = body weight; $BMDL_{20}$ =benchmark dose lower confidence limit.

[a] Risk from object-to-mouth (OtM) exposure was assessed with the registered RTI of 7 days. A 14 day RTI was also assessed as a longer RTI was required to mitigate the aggregate risk assessment.

[b] Object residue is the same as the TTR values determined for dermal postapplication assessment, which is consistent with the USEPA Residential SOPs (2012). This is based on a chemical-specific TTR study. See Table 10 for details.

[c] Oral exposure (mg/kg bw/day) = $[(\text{object residue} \times SAM) \times (ET \times N) \times (1-(1-SE)^{FreqOtM / N})] / BW$. The following point estimates from the USEPA Residential SOP (2012) were used to calculate oral exposure: SAM is the object surface area mouthed per event (10 cm^2/event); exposure time (ET) was 1.5 hrs/day, the replenishment interval per hour (N) was 4; the saliva extraction factor (SE) was 0.48; the frequency of object-to-mouth events per hour (FreqOtM) was 9; and the body weight for children (1 < 2 years) was 11 kg.

[d] MOE = $BMDL_{20}$/ oral exposure. The $BMDL_{20}$ is 0.28 mg/kg bw from acute oral neurotoxicity studies in rats. The target MOE is 300.

Table 17 Postapplication short-to intermediate duration bystander inhalation exposure

Lifestage	Maximum Air Concentration (µg/m^3)[a]	Inhalation rate (m^3/ hr)	ET (hr/day)	Inhalation Exposure (mg/kg bw/day)[d]	Inhalation MOE[e] (Target = 300)
Adult	0.00046	0.64	1.5	5.52×10^{-6}	14 000 000
Youth		0.63	1.7	8.64×10^{-6}	9 300 000
Toddler		0.23	2.3	2.70×10^{-5}	3 000 000

ET = exposure time; MOE = margin of exposure; BW = body weight; NOAEL = no observed adverse effect level.
[a] Maximum value from literature study.
[b] Inhalation exposure = maximum air concentration × inhalation rate × exposure time × conversion factor (µg/1 × 10^{-3}mg) / body weight.
[e] MOE = NOAEL/exposure. NOAEL of 0.08 mg/kg bw/day from a 21-day inhalation toxicity study in rats with a target MOE of 300.

Appendix VII Revised aggregate exposure and risk assessments for lambda-cyhalothrin

Table 1 Aggregate exposure and risk assessment for indoor environments

Scenario		Life stage	Dermal Exposure[a] (mg/kg bw/day)	Dermal MOE[b]	Dietary Exposure[c] (mg/kg bw/day)	Incidental Oral Exposure[d] (mg/kg bw day)	Total oral Exposure[e] (mg/kg bw/day)	Oral MOE[f]	Aggregate MOE[g]
			Target MOE = 300						
Liquid formulation; short-to-intermediate-term duration									
Perimeter/spot/ bedbug	Soft surfaces	Adults	6.53E-03	1500	2.10E-05	-	2.10E-05	13 000	1400
		Children (1 < 2 years)	6.28E-03	1600	9.00E-05	1.25E-04	2.15E-04	1300	720
	Hard surfaces	Adults	2.45E-03	4100	2.10E-05	-	2.10E-05	13 000	3100
		Children (1 < 2 years)	4.71E-03	2100	9.00E-05	9.41E-05	1.84E-04	1500	890
Crack and crevice (bedbug only)	Soft surfaces	Adults	3.26E-03	3100	2.10E-05	-	2.10E-05	13 000	2500
		Children (1 < 2 years)	3.14E-03	3200	9.00E-05	6.27E-05	1.53E-04	1800	1200
	Hard surfaces	Adults	1.22E-03	8200	2.10E-05	-	2.10E-05	13 000	5100
		Children (1 < 2 years)	2.36E-03	4200	9.00E-05	4.71E-05	1.37E-04	2000	1400
Crack and crevice (all other pests)	Soft surfaces	Adults	1.31E-03	7700	2.10E-05	-	2.10E-05	13 000	4900
		Children (1 < 2 years)	1.26E-03	8000	9.00E-05	2.51E-05	1.15E-04	2400	1900
	Hard surfaces	Adults	4.90E-04	20 000	2.10E-05	-	2.10E-05	13 000	8100
		Children (1 < 2 years)	9.43E-04	11 000	9.00E-05	1.88E-05	1.09E-04	2600	2100
Liquid formulation; long-term duration									
Perimeter/spot/ bedbug	Soft surfaces	Adults	2.26E-03	4400	2.10E-05	-	2.10E-05	4800	2300
		Children (1 < 2 years)	2.27E-03	4400	9.00E-05	6.00E-05	1.50E-04	670	580
	Hard surfaces	Adults	8.46E-04	12 000	2.10E-05	-	2.10E-05	4800	3400
		Children (1 < 2 years)	1.70E-03	5900	9.00E-05	4.50E-05	1.35E-04	740	660
Crack and crevice (bedbug only)	Soft surfaces	Adults	1.13E-03	8900	2.10E-05	-	2.10E-05	4800	3100
		Children (1 < 2 years)	1.13E-03	8800	9.00E-05	3.00E-05	1.20E-04	830	760
	Hard surfaces	Adults	4.23E-04	24 000	2.10E-05	-	2.10E-05	4800	4000
		Children (1 < 2 years)	8.51E-04	12 000	9.00E-05	2.25E-05	1.13E-04	890	830
Pressurized product formulation[h]; short-to-intermediate-term duration									
Perimeter/spot/ bedbug	Soft surfaces	Adults	1.13E-02	890	2.10E-05	-	2.10E-05	13000	830
		Children (1 < 2 years)	1.09E-02	920	9.00E-05	2.17E-04	3.07E-04	910	460
	Hard surfaces	Adults	4.23E-03	2400	2.10E-05	-	2.10E-05	13 000	2000
		Children (1 < 2 years)	8.15E-03	1200	9.00E-05	1.63E-04	2.53E-04	1100	580

Scenario		Life stage	Dermal Exposure[a] (mg/kg bw/day)	Dermal MOE[b]	Dietary Exposure[c] (mg/kg bw/day)	Incidental Oral Exposure[d] (mg/kg bw day)	Total oral Exposure[e] (mg/kg bw/day)	Oral MOE[f]	Aggregate MOE[g]
			Target MOE = 300						
Crack and crevice (bedbug only)	Soft surfaces	Adults	5.64E-03	1800	2.10E-05	-	2.10E-05	13 000	1600
		Children (1 < 2 years)	5.43E-03	1800	9.00E-05	1.08E-04	1.98E-04	1400	800
	Hard surfaces	Adults	2.12E-03	4700	2.10E-05	-	2.10E-05	13 000	3500
		Children (1 < 2 years)	4.07E-03	2500	9.00E-05	8.14E-05	1.71E-04	1600	980
Crack and crevice (all other pests)	Soft surfaces	Adults	2.26E-03	4400	2.10E-05	-	2.10E-05	13 000	3300
		Children (1 < 2 years)	2.17E-03	4600	9.00E-05	4.34E-05	1.33E-04	2100	1400
	Hard surfaces	Adults	8.47E-04	12000	2.10E-05	-	2.10E-05	13 000	6300
		Children (1 < 2 years)	1.63E-03	6100	9.00E-05	3.25E-05	1.23E-04	2300	1700
Pressurized product formulation [h]; long-term duration									
Perimter/spot/ bedbug	Soft surfaces	Adults	3.90E-03	2600	2.10E-05	-	2.10E-05	4800	1700
		Children (1 < 2 years)	3.92E-03	2500	9.00E-05	1.04E-04	1.94E-04	510	430
	Hard surfaces	Adults	1.46E-03	6800	2.10E-05	-	2.10E-05	4800	2800
		Children (1 < 2 years)	2.94E-03	3400	9.00E-05	7.78E-05	1.68E-04	600	510
Crack and crevice (bedbug only)	Soft surfaces	Adults	1.95E-03	5100	2.10E-05	-	2.10E-05	4800	2500
		Children (1 < 2 years)	1.96E-03	5100	9.00E-05	5.19E-05	1.42E-04	700	620
	Hard surfaces	Adults	7.31E-04	14 000	2.10E-05	-	2.10E-05	4800	3500
		Children (1 < 2 years)	1.47E-03	6800	9.00E-05	3.89E-05	1.29E-04	780	700

MOE = margin of exposure; " – " = not applicable; NOAEL = no observed adverse effect level; $BMDL_{20}$ = benchmark dose lower confidence limit

[a] Dermal exposure as calculated for each lifestage in the postapplication risk assessment for indoor environments. (Appendix VI, Tables 8 and 9).

[b] Dermal MOE = NOAEL / dermal exposure. NOAEL is 10 mg/kg bw/day from a 21-day dermal toxicity study in rats.

[c] Dietary exposure is from the dietary risk assessment and includes chronic exposure from food uses and drinking water.

[d] Incidental oral exposure is calculated for children (1 < 2 years) in the postapplication risk assessments for indoor environments. The object-to-mouth incidental oral scenario was used in the aggregate assessment as it had the highest incidental oral exposure from all oral postapplication scenarios (Appendix VI, Tables 14 and 15).

[e] Total oral exposure = dietary exposure + incidental oral exposure. Target MOE = 300

[f] Oral MOE = NOAEL or $BMDL_{20}$ / total oral exposure. For short-to intermediate duration, the $BMDL_{20}$ is 0.28 mg/kg bw from acute oral neurotoxicity studies in rats and the target MOE is 300. For long-term durations the NOAEL is 0.1 mg/kg bw/day from a 1-year oral toxicity study in dogs. The target MOE is 300.

[g] Aggregate MOE = 1 / [1/MOE(dermal) + 1/MOE(oral)].

Table 2 Aggregate exposure and risk assessment for outdoor environments

Scenario	Life stage	Dermal Exposure[a] (mg/kg bw/day)	Dermal MOE[b]	Dietary Exposure[c] (mg/kg bw/day)	Incidental Oral Exposure[d] (mg/kg bw/day)	Total Oral Exposure[e] (mg/kg bw/day)	Oral MOE[f]	Aggregate MOE[g]
Gardens and Trees; Short-to intermediate-term duration; 3 applications, 7 day RTI								
Gardens and Trees	Adults	2.45E-03	4080	2.10E-05	-	2.10E-05	13 000	3100
	Children (6 < 11 years)	1.67E-03	5970	4.40E-05	-	4.40E-05	6400	3100
Lawns and Turf; Short-to intermediate-term duration; 4 applications, 7 day RTI								
High contact lawn activities	Adults	1.63E-02	610	2.10E-05	-	2.10E-05	13 000	590
	Children (1 < 2 years)	3.22E-02	310	9.00E-05	9.63E-05	1.86E-04	1500	260
Mowing Turf	Adults	3.31E-04	30 000	2.10E-05	-	2.10E-05	13 000	9200
	Youth (11 < 16 years)	3.81E-04	26 000	2.60E-05	-	2.60E-05	11 000	7600
Golfing	Adults	1.28E-03	7800	2.10E-05	-	2.10E-05	13 000	4900
	Youth (11 < 16 years)	1.49E-03	6700	2.60E-05	-	2.60E-05	11 000	4100
	Children (6 < 11 years)	1.75E-03	5700	4.40E-05	-	4.40E-05	6400	3000
Lawns and Turf; Short-to intermediate-term duration; 4 applications, 14 day RTI								
High contact lawn activities	Children (1 < 2 years)	2.72E-02	370	9.00E-05	8.13E-05	1.71E-04	1600	300

Shaded cells identify risks that were not shown to be acceptable.
MOE = margin of exposure; " – " = not applicable; NOAEL = no observed adverse effect level; $BMDL_{20}$ = benchmark dose lower confidence limit

[a] Dermal exposure as calculated for each lifestage in the postapplication risk assessment for outdoor environments (Gardens and Trees, PRVD2017-03; Lawn and Turf. Appendix VI, Table 10.
[b] Dermal MOE = NOAEL / dermal exposure. NOAEL is 10 mg/kg bw/day from a 21-day dermal toxicity study in rats. Target MOE = 300.
[c] Dietary exposure is from the dietary risk assessment and includes chronic exposure from food uses and drinking water.
[d] Incidental oral exposure is calculated for children (1 <2 years) in the postapplication risk assessments for lawn and tree scenarios. The hand-to-mouth incidental oral scenario was used in the aggregate assessment as it had the highest incidental oral exposure from all postapplication scenarios (Appendix VI, Table 13).
[e] Total oral exposure = dietary exposure + incidental oral exposure.
[f] Oral MOE = $BMDL_{20}$/ oral exposure. The $BMDL_{20}$ is 0.28 mg/kg bw from acute oral neurotoxicity studies in rats. The target MOE is 300.
[g] Aggregate MOE = 1 / [1/MOE(dermal) + 1/MOE(oral)].

Appendix VIII Revised environmental risk assessment

Table 1 Level 1 estimated environmental concentrations of lambda-cyhalothrin in potential drinking water sources

Crop (use pattern)	Groundwater EEC (µg a.i./L)		Surface Water EEC (µg a.i./L)	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]
Turf (4 × 37 g a.i./ha, at 7-day intervals)	**0**	**0**	**0.68**	**0.081**

Notes:
[1]90th percentile of daily average concentrations
[2]90th percentile of 365-day moving average concentrations
[3]90th percentile of the peak concentrations from each year
[4]90th percentile of yearly average concentrations

Table 2 Refined risk assessment for aquatic organisms based on spray drift deposition using lowest rates of application for 6% ground boom, 23% aerial, 59% late season airblast and 74% early season airblast

Organism	Exposure	Endpoint value[1]	Lowest Application rate	EEC µg a.i./L	RQ			
					6%	23 %	59 %	74%
Freshwater Species								
Invertebrates	Acute	HC_5 from SSD (0.00094 µg a.i./L)	5.04 g a.i./ha (ground boom, sunflower/cole crops/various crops)	0.04	**43**	NA	NA	NA
			6.96 g a.i./ha (airblast, cherry, poplar and willow)	0.5 (59%, late season), 0.6 (74%, early season)	NA	NA	**532**	**638**
			9.96 g a.i./ha (aerial, sunflower/canola/mustard)	0.3	NA	**319**	NA	NA
Water flea (*Daphnia magna*)	Chronic	21-d NOEC = 0.00198 µg a.i./L	5.04 g a.i./ha	0.04	**20**	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	**253**	**303**
			9.96 g a.i./ha	0.3	NA	**152**	NA	NA
Fish	Acute	HC_5 = 0.113 µg a.i./L	5.04 g a.i./ha	0.04	0.4	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	**4.5**	**5.3**
			9.96 g a.i./ha	0.3	NA	**2.7**	NA	NA
Fathead minnow	Chronic	30-d NOEC = 0.031 µg a.i./L	5.04 g a.i./ha	0.04	**1.2**	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	**16**	**19**
			9.96 g a.i./ha	0.3	NA	**9.7**	NA	NA
Aquatic plant	No data available							
	Acute		5.04 g a.i./ha	0.04	0.02	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	0.2	0.24

Organism	Exposure	Endpoint value[1]	Lowest Application rate	EEC µg a.i./L	RQ			
					6%	23 %	59 %	74%
Algae (*Selenastrum capricornutum)*		72-h EC_{50} = 2.5 µg a.i./L	9.96 g a.i./ha	0.3	NA	0.12	NA	NA
Amphibians[2]	Acute	0.113 µg a.i./L	5.04 g a.i./ha	0.2	**1.8**	NA	NA	NA
			6.96 g a.i./ha	2.7/ 3.4	NA	NA	**24**	**30**
			9.96 g a.i./ha	1.5	NA	**13**	NA	NA
Amphibians[2]	Chronic	30-d NOEC= 0.031 µg a.i./L	5.04 g a.i./ha	0.2	**6.5**	NA	NA	NA
			6.96 g a.i./ha	2.7(59%) 3.4(74%	NA	NA	**87**	**110**
			9.96 g a.i./ha	1.5	NA	**48**	NA	NA
Marine/Estuarine Species								
Invertebrates Mysid shrimp (*Mysidopsis bahia*)	Acute	96-h LC_{50} = 0.0021 µg ai/L)	5.04 g a.i./ha	0.04	**19**	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	**238**	**286**
			9.96 g a.i./ha	0.3	NA	**143**	NA	NA
	Chronic	28-d NOAEC = 0.00022 µg ai/L	5.04 g a.i./ha	0.04	**182**	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	**2273**	**2727**
			9.96 g a.i./ha	0.3	NA	**1364**	NA	NA
Fish (*Cyprinodon variegates*)	Acute	24-h LC_{50} = 0.081 µg ai/L	5.04 g a.i./ha	0.04	0.5	NA	NA	NA
			6.96 g a.i./ha	0.5/0.6	NA	NA	**6.2**	**7.4**
			9.96 g a.i./ha	0.3	NA	**3.7**	NA	NA
Algae	No data available							

[1)] Where applicable, endpoints were divided by an Uncertainty Factor to account for varying protection goals (in other words, protection at the community, population, or individual level)
[2)] Endpoints from fish used as surrogate
Values in bold exceed Level of concern (≥ 1)
NA = not applicable

Table 3 Refined risk assessment for aquatic organisms based on spray drift deposition using highest rates of application for 6% ground boom, 23% aerial, 59% late season airblast and 74% early season airblast. (Only taxonomic groups where RQs were less than the LOC at the lowest rates are considered for the highest rates)

Organism	Exposure	Endpoint value[1]	Lowest Application rate	EEC µg a.i./L	RQ			
					6%	23 %	59 %	74%
Freshwater Species								
Fish	Acute	HC_5 = 0.113 µg ai/L	37 g a.i./ha × 4 (ground boom, turf)	0.9	**8.0**	**NA**	**NA**	**NA**
			12.688 g a.i./ha × 3 (airblast, various fruit crops)	2.5 (59%) 3.1 (74%)	NA	**NA**	**22**	**27**

Organism	Exposure	Endpoint value[1]	Lowest Application rate	EEC µg a.i./L	RQ			
					6%	23 %	59 %	74%
			58.56 g a.i./ha × 3 (airblast, conifer seed orchard)	10.8 (59%) 13.5 (74%)	NA	**NA**	**96**	**119**
			19.08 g a.i./ha × 3 (aerial)	1.4	**NA**	**12**	**NA**	**NA**
Algae (*Selenastrum capricornutum)*	Acute	72-h EC_{50} = 2.5 µg ai/L	37 g a.i./ha × 4 (ground boom)	0.9	0.4	**NA**	**NA**	**NA**
			12.688 g a.i./ha × 3 (airblast)	2.5 (59%) 3.1(74%)	NA	**NA**	1	**1.2**
			19.08 g ai/ha × 3 (aerial)	1.4	**NA**	0.6	**NA**	**NA**
Marine/Estuarine Species								
Fish (*Cyprinodon variegates*)	Acute	24-h LC_{50} = 0.081 µg ai/L	37 g a.i./ha (ground boom, single app. on turf)	0.3	**4**	**NA**	**NA**	**NA**
			12.688 g a.i./ha (airblast, single app on various fruit crops)	0.9 (59%) 1.2 (74%)	**NA**	**NA**	**11**	**15**
			58.56 g a.i./L (airblast, single application on conifer seed orchard)	4.3 (59%) 5.4 (74%)	**NA**	**NA**	**53**	**67**
			19.08 g a.i./ha (aerial, single app on soybean[3])	0.6	**NA**	**7**	**NA**	**NA**
			25 g a.i./ha (aerial, single app on corn[3])	0.7	**NA**	**9**	**NA**	**NA**

[1)] Where applicable, endpoints were divided by an Uncertainty Factor to account for varying protection goals (in other words, protection at the community, population, or individual level)
[2)] Endpoints from fish used as surrogate
[3)] Both soybean and corn are considered for marine assessment, as corn has a higher single application than soybean but not a higher cumulative rate.
Values in bold exceed Level of concern (≥ 1)
NA = Not applicable

Table 4 Refined risk assessment for aquatic organisms based on runoff

Organism	Endpoint value[1]	Scenario	EEC (µg a.i./L)[2]	RQ	LOC Exceeded
Freshwater Species					
Invertebrates	Acute HC_5 from SSD (0.00094 µg ai/L)	Turf (37 g a.i./ha × 4)	0.13	**138**	**Yes**
		Soybean (28.4 g a.i./ha × 3)	0.92	**979**	**Yes**
		Tobacco (5.04 g a.i./ha × 1)	0.021	**22**	**Yes**
Water flea (*Daphnia magna*)	Chronic 21-day NOEC = 0.00198 µg ai/L	Turf	0.005	**2.5**	**Yes**
		Soybean	0.033	**16.7**	**Yes**
		Tobacco	<0.001	0.5	No
Note: the level of concern (LOC = 1) was not exceeded for fish (acute), algae and amphibians[3] (acute). The LOC was marginally exceeded (highest RQ = 1.1) for chronic toxicity to fish (fathead minnow) and amphibians[3].					
Marine Species					
Estuarine/marine Invertebrates Mysid shrimp (*Mysidopsis bahia*)	Acute 96-h LC_{50}=0.00205 µg a.i./L	Turf	0.011	**54**	**Yes**
		Soybean	0.071	**35**	**Yes**
		Tobacco	0.002	**1**	**Yes**
	Chronic 28-d NOAEC= (0.00022 µg a.i./L)	Turf	0.005	**23**	**Yes**
		Soybean	0.033	**150**	**Yes**
		Tobacco	<0.001	**4.5**	**Yes**
Note: the level of concern (LOC = 1) was not exceeded for marine fish (acute and ELS, *Cyprinodon variegates*)					

[1)] Endpoints were divided by an Uncertainty Factor to account for varying protection goals (in other words, protection at the community, population, or individual level)
[2)] EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.
[3)] Endpoints from fish used as surrogate for amphibian assessment

Table 5 Revised Toxic Substances Management Policy Considerations

Toxic Substances Management Policy Considerations Comparison to TSMP Track 1 Criteria for Lambda-cyhalothrin and its transformation products (Ia, X, XV)						
TSMP Track 1 Criteria	**TSMP Track 1 Criterion Value**		**Are criteria met?**			
			Lambda-cyhalothrin	**Ia**	**X**	**XV**
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes	N/A		
Predominantly anthropogenic[2]	Yes		Yes	Yes	Yes	Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Yes: 16 to 417 days based on laboratory data	No: all expected to be <182 d		
	Water	Half-life ≥ 182 days	No: 0.28 days	No: limited data available but all expected to be <182 d		
	Whole system (Water + Sediment)	Half-life ≥ 365 days	No: 12.6 – 60 days			

Toxic Substances Management Policy Considerations Comparison to TSMP Track 1 Criteria for Lambda-cyhalothrin and its transformation products (Ia, X, XV)						
TSMP Track 1 Criteria	**TSMP Track 1 Criterion Value**		**Are criteria met?**			
			Lambda-cyhalothrin	**Ia**	**X**	**XV**
	Air	Half-life ≥ 2 days or evidence of long range transport	Volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (2×10^{-4} mPa) and Henry's law constant (1.8×10^{-7}atm m^3/mole).	No data available		
Bioaccumulation[4]	Log $K_{ow} \geq 5$		Yes: 7	No: 3.85[6]	No: 3.93[6]	Yes: 6.37[6]
	BCF ≥ 5000		No: 3275 to 3635[5]	No: BCF values for TP's unavailable. However, based on TP estimated[6] Log K_{ow}'s < lambda-cyhalothrin parent, and parent has BCF < 5000, bioconcentration of TP's is also expected to be <5000		
	BAF ≥ 5000		Not available	Not available		
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			**No, does not meet all TSMP Track 1 criteria.**	**No, does not meet all TSMP Track 1 criteria.**		

[1] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).
[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4] Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{ow}).
[5] as per values used by EFSA
[6] As per EFSA, estimated using EPI Suite v4.10

Appendix IX Update on the water monitoring data of Lambda-cyhalothrin

For the re-evaluation of lambda-cyhalothrin (PRVD2017-03), Health Canada considered monitoring information to assess potential risks to human health (from drinking water) and non-target organisms (from ecologically relevant water). Monitoring information and data used in the re-evaluation were available from the United States and Canada. Available data from Canada (Quebec, Nova Scotia, New Brunswick, Prince Edward Island and British Columbia) was limited. The majority of the data considered in the re-evaluation was from the United States. Available data suggested that lambda-cyhalothrin was rarely detected in water in Canada and the United States. During the consultation period, additional data and monitoring information were submitted to Health Canada (an additional 1857 samples). Available information and data were reviewed and the assessment has been updated. Additional information and data were available from the United States, Quebec, Atlantic Region (Prince Edward Island, New Brunswick and Nova Scotia), Ontario and Alberta.

Lambda-cyhalothrin was not detected in groundwater in Canada or the United States.

For surface water sources of drinking water, lambda-cyhalothrin is infrequently detected (27,499 samples, 108 detection, 0.3% detection frequency), with a maximum concentration of 0.66 µg/L from Quebec.

For the ecological risk assessment, lambda-cyhalothrin was detected more frequently in American data. Available Canadian data shows lambda-cyhalothrin is infrequently detected (2,923 samples, 12 detections, 0.4% detection) with a maximum concentration of 0.66 µg/L from Quebec.

Appendix X Label amendments for products containing lambda-cyhalothrin

Information on approved labels of currently registered products should not be removed unless it contradicts the label statements provided below.

CANCELLED USES TO BE REMOVED FROM PRODUCT LABELS

- lettuce,
- mustard seed (condiment type),
- all feed uses,
- all registered commodities from Crop Group 3-07: Bulb Vegetables, and
- all registered commodities from Crop Group 20: Oilseeds (Revised), **except for** flax seed, mustard seed (oilseed type), and rapeseed (including canola).

HEALTH

1.0 Label amendments for technical class products containing lambda-cyhalothrin

The following statement is required on all technical-grade active ingredient labels under the section entitled **TOXICOLOGICAL INFORMATION**:

"Skin exposure may cause transient sensations (tingling, burning, itching, numbness)."

2.0 Label amendments for commercial-class end-use products containing lambda-cyhalothrin

The following statement is required on all commercial-class product labels under the section entitled **TOXICOLOGICAL INFORMATION**:

"Skin exposure may cause transient sensations (tingling, burning, itching, numbness)."

Removal of uses from the labels:

The uses and use instructions for the following crops/uses must be removed from the product labels:

- Lettuce, mustard seed (condiment type), all feed uses, all registered commodities from Crop Group 3-07: Bulb Vegetables, and all registered commodities from Crop Group 20: Oilseeds (Revised), **except for** flax seed, mustard seed (oilseed type), and rapeseed (including canola).

Clarification of label language for indoor uses:

The following label changes are required to clarify label directions to reduce the likelihood of product misuse by pest control applicators and minimize unnecessary exposure to occupants living in, working in or entering treated areas.

- Remove label statements on liquid commercial-class products that can be interpreted as applications beyond the definition of crack and crevice treatment for residential indoor uses as outlined in the PMRA Guidance Document, *Structural Pest Control Products: Label Updates*. Add a label statement prohibiting indoor broadcast, perimeter and spot applications.
- Remove label statements on pressurized (aerosol) commercial-class products that can be interpreted as applications beyond the definitions of crack and crevice or spot treatments for residential indoor uses as outlined in the PMRA Guidance Document, *Structural Pest Control Products: Label Updates*. Add a label statement prohibiting indoor broadcast and perimeter applications.

2.1 PRECAUTIONS

2.1.1 Liquid commercial class end-use products for agricultural uses

The following label amendments are for products that are registered for agricultural uses (for example, application to field crops, outdoor ornamentals, trees, and turf). Some labels may have one or more of these uses registered.

General label improvements:

Under **PRECAUTIONS**, the following statements must be amended (or added if not present) on all commercial-class end-use products with agricultural, outdoor ornamentals and turf uses:

- "Apply only when the potential for drift beyond the area to be treated is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings."

Personal protective equipment:
Personal protective equipment (PPE) label statements must be amended (or added if not present) to include the following directions under **PRECAUTIONS**, unless the current mitigation is more restrictive. Should the PPE on the label be more restrictive (for example, respirator, chemical-resistant coveralls), then those PPE should be incorporated into the applicable statement(s) below.

- "Wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair, unless otherwise specified below. Gloves are not required during application within a closed cab [or cockpit]." The text in square brackets should only be included when the product is registered for aerial application.
- "For applications using an open-cab groundboom equipment, when handling more than [7.15 kg a.i. to be reported in product equivalent value] per person per day, also wear a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides OR use a closed cab tractor that provides both a physical barrier and respiratory protection (such as dust/mist filtering and/or vapour/gas purification system). The closed cab must have a chemical-resistant barrier that totally surrounds the occupant and prevents contact with pesticides outside the cab. Respirator and gloves are not required to be worn during application within a closed cab. These restrictions are in place to minimize exposure to individual applicators. Application may need to be performed over multiple days or using multiple applicators." As indicated by the square brackets above, the active ingredient amount in this statement (in other words, 7.15 kg a.i.) is to be converted into the corresponding amount of product by the registrant for each product label.

- "For open cab airblast application to conifer seed orchards, also wear chemical-resistant headgear. Chemical-resistant headgear includes sou'wester hat, chemical-resistant rain hat or large-brimmed waterproof hat and hood with sufficient neck protection." Note: this statement is only required to be added to product labels that are registered for use on conifer seed orchards.
- "When handling more than [0.11 kg a.i. to be reported in product equivalent value] per person per day using mechanically-pressurized handheld equipment, also wear a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides during mixing, loading and application." As indicated by the square brackets above, the active ingredient amount in this statement (in other words, 0.11 kg a.i.) is to be converted into the corresponding amount of product by the registrant for each product label.
- "For application using handheld airblast/mistblower equipment, wear chemical-resistant coveralls with a chemical-resistant hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks, chemical-resistant footwear and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides. DO NOT handle more than [5.1 g a.i. to be reported in product equivalent value] per person per day. This restriction is required to minimize exposure to the worker. Applications may be required over multiple days or using multiple applicators." As indicated by the square brackets above, the amount of active ingredient in the statement (in other words, 5.1 g a.i) is to be converted into the corresponding amount of product by the registrant for each product label.
- Add "For all applications using handheld equipment, wear eye, head and respiratory protection when applying above waist height, including overhead."

Restricted-entry intervals (REIs):
For labels with all agricultural uses (for example, application to field crops, ornamentals, and trees), the REI text under **PRECAUTIONS** on the label should be modified as follows:

- "**DO NOT** enter or allow worker entry into treated areas during the intervals specified in the following table:"

Table 2.1 below, must be added to the label under **PRECAUTIONS.** Remove any crops from the table that are not registered on that specific product label or are cancelled as a result of the re-evaluation.

For products that are **not** co-formulated with other active ingredients (in other words, lambda-cyhalothrin is the only registered active ingredient) REIs currently on the label should be changed (increased or decreased) to match the values in Table 2.1. REIs currently on other parts of the label (for example, under crop specific directions for use) should be removed and added to the REI table if the activity is not currently specified in the REI table. Values should not be lower than those specified in Table 2.1.

For products that are co-formulated with other active ingredients (for example, registration numbers 30325 and 30404), the REIs currently on the label should not decrease; however, they must increase to match the values in Table 2.1. If there are longer REIs currently on the label, they must replace the corresponding REIs in Table 2.1. It may be necessary to add crops to this table on specific labels to include REIs specified for crops addressed by "all other crops" and for activities addressed by "all other activities."

Table 2.1 Restricted-entry intervals (REI) for lambda-cyhalothrin

Crop(s)	Postapplication Activity	REI
Conifer seed orchards	Hand set/hand line irrigation related activities involving foliar contact	1 day
	All other activities	12 hours
Corn (sweet)	Hand harvesting	3 days
	All other activities	12 hours
Corn (seed)	Hand detasseling	3 days
	All other activities	12 hours
Golf courses	All activities	Until sprays have dried
All other crops	All activities	12 hours

2.1.2 Liquid commercial class end-use products for structural uses

The following label amendments are for products that are registered for structural uses. These include, but are not limited to application to surfaces in residential, industrial, institutional, and commercial buildings, modes of transport, pet kennels, and livestock/poultry barns.

Personal protective equipment:

Personal protective equipment label statements must be amended (or added if not present) to include the following directions under **PRECAUTIONS**, unless the current mitigation is more restrictive. Should the PPE on the label be more restrictive (for example, respirator, chemical-resistant coveralls), then those PPE should be incorporated into the applicable statement(s) below.

- "When mixing, loading and applying, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, unless otherwise specified below."
- "For applications using mechanically-pressurized or power operated hand-held equipment, also wear chemical-resistant coveralls and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH-approved canister approved for pesticides during mixing, loading and application. DO NOT handle more than [0.72 kg a.i. to be reported in product equivalent value] per day. This restriction is required to minimize exposure to the worker. Applications may be required over multiple days or using multiple applicators." As indicated by the square brackets above, the active ingredient amount in this statement (in other words, 0.75 kg a.i.) is to be converted into the corresponding amount of product by the registrant for each product label.

2.1.3 Pressurized (aerosol) commercial class end-use products for structural uses

The following label amendments are for products that are registered for structural uses. These include, but are not limited to application to surfaces in residential, industrial, institutional, and commercial buildings, modes of transport, pet kennels, livestock/poultry barns, in-ground service boxes, stumps, utility poles, fences, inside trees, subterranean ant nests and bee/wasp/hornet nests.

Personal Protective Equipment:

Personal protective equipment label statements must be amended (or added if not present) to include the following directions under **PRECAUTIONS**, unless the current mitigation is more restrictive. Should the PPE on the label be more restrictive (for example, respirator, chemical-resistant coveralls), then those PPE should be incorporated into the applicable statement(s) below.

- "When applying, wear a long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes."

2.1.4 Additional label modifications for liquid and pressurized (aerosol) commercial class end–use products for structural uses

The following label amendments are for products that are registered for structural uses. These include, but are not limited to application to surfaces in residential, industrial, institutional, and commercial buildings, modes of transport, pet kennels, and livestock/poultry barns (animal housing).

These statements are for surface applications for **liquid and pressurized (aerosol) commercial-class products**, which encompass the lambda-cyhalothrin structural products that are registered at this time.

The following label statements must be amended (or added if not present) under **PRECAUTIONS**:

- **"DO NOT** apply as a space spray"
- **"DO NOT** apply to overhead areas or in confined spaces without appropriate respiratory and eye protection."
- "Ventilate treated areas during and after application either by opening windows and doors or using fans, where required, to aid in the circulation of air. Air exchange/ventilation systems confirmed to be operational may also be used."
- **"DO NOT** allow spray to drip or allow drift onto non-target surfaces."
- "Care should be taken to avoid the pesticide exiting the void. Any residue deposits on non-target surfaces must be removed by the applicator."
- "**DO NOT** apply when a food/feed processing facility is in operation."
- "**DO NOT** apply to surfaces that may come into contact with food/feed."
- "**DO NOT** apply when people or pets or livestock are present."
- "**DO NOT** allow people or pets or livestock to enter treated areas until sprays have dried."
- "Cover or remove all food/feed. Cover all food/feed processing surfaces, equipment and utensils or thoroughly wash them following treatment."

The following statements are for **liquid commercial-class products**, which encompass the lambda-cyhalothrin structural products that are registered at this time.

The following label statements must be amended (or added if not present) under **PRECAUTIONS:**

- "DO NOT apply as a broadcast, perimeter or spot application for indoor applications to residential structures. A residential structure is one where the general public, including children, could be exposed during or after application. Residential structures include, but are not limited to, homes, garages, schools, restaurants, hotels/motels, public buildings or any other structures where the general public including children may potentially be exposed."
- "**DO NOT** apply to soft surfaces of furniture, mattresses, linens, pet bedding, toys or clothing."
- "For hard surface furniture, treatments to bed frames, headboards, dressers or other areas (for example, closets) listed on the labels where clothes, toys, towels and other items are stored, apply only to junction points and cracks and crevices. Broadcast, perimeter or spot treatments are not permitted. Remove all objects before treatment. Any residues deposited on non-target surfaces must be removed by the applicator. Treated areas must be dry before replacing stored items."

The following statements are for **pressurized (aerosol) commercial-class products**, which encompass the lambda-cyhalothrin structural products that are registered at this time. The following label statements must be amended (or added if not present) under **PRECAUTIONS:**

- "For indoor applications to residential structures, **DO NOT** apply as a broadcast or perimeter application. A residential structure is one where the general public, including children, could be exposed during or after application. Residential structures include, but are not limited to, homes, garages, schools, restaurants, hotels/motels, public buildings or any other structures where the general public including children may potentially be exposed."
- "**DO NOT** apply to soft surfaces of furniture, mattresses, linens, pet bedding, toys or clothing."
- "For hard surface furniture, treatments to bed frames, headboards, dressers or other areas (for example, closets) listed on the labels where clothes, toy, towels and other items are stored, apply to junction points, cracks and crevices and as a spot treatment. Spot treatment is up to 10% of the surface of the treated item. Broadcast and perimeter treatments are not permitted. Remove all objects before treatment. Any residues deposited on non-target surfaces must be removed by the applicator. Treated areas must be dry before replacing stored items."

2.2 DIRECTIONS FOR USE

2.2.1 Feed uses

All commodities that remain on the label and have the potential to be used for animal feed are to include label wording (see bullets in next paragraph) to prevent application to commodities destined to be used as animal feed. Example commodities that may be used for feed and require label language to disallow feed use are: alfalfa; barley; canola (rape); corn, field; corn, pop; corn, sweet; cowpea/faba bean; flax; grass; lupin; millet; oats; pea, field; rye; sorghum; soybean; summerfallow; timothy; unimproved pasture; wheat/triticale. Note for these commodities that any non-feed uses remain acceptable for continued registration.

The following wording must be added where applicable. Any label wording implying or allowing feed uses must be removed (for example, "Crops treated may be fed to non-lactating dairy animals and other livestock following a 14 day interval from application to harvest or foraging").

- "DO NOT cut treated fields for hay/forage."
- "DO NOT graze treated fields."
- "For grasses/non-grasses grown for seed production only, DO NOT feed seed screenings and aftermath to livestock."
- Add "(for seed production only)" to crop names where applicable

2.2.2 Pour-on and ear tag application to beef cattle

The following wording must be added to the ear tag and pour-on application products: "DO NOT apply to lactating dairy cattle."

2.2.3 Liquid commercial class end-use products for agricultural uses

For products that currently have tank-mix partners label statements, remove the current label statement and replace it with the following under **DIRECTIONS FOR USE**:

- "When tank-mixes are permitted, read and observe all label directions, including rates and restrictions for each product used in the tank-mix. Follow the more stringent label precautionary measures for mixing, loading and applying stated on both product labels."

The following statements must be added to or remain on the label under **DIRECTIONS FOR USE:**

- **"DO NOT** apply by air, unless otherwise specified in the crop-specific use directions."
- **"DO NOT** apply in greenhouses, unless otherwise specified in the crop-specific use directions."

2.2.4 Liquid commercial class end-use products for structural uses

The following label statements must be added to the label under **DIRECTIONS FOR USE**:

"DO NOT apply as a broadcast, perimeter or spot treatment No exposed surfaces should be treated."

The label must contain clear instructions that define areas and locations that can be treated. Include the following definitions under "**DIRECTIONS OF USE**." The following definitions are from the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* (28 February 2020) must be added to the label when relevant uses are registered on the product label.

For commercial-class liquid products:	
Outdoor perimeter	Outdoor perimeter application is 1 m or less out from the building's foundation and to a maximum height of 1 m starting where the foundation meets the ground.
Outdoor spot	Apply to small areas of exterior surfaces of structures.
Crack and crevice (indoor or outdoor)	Crack and crevice is an application directly into narrow openings on the surface of the structure. It does not include the treatment of exposed surfaces. Narrow openings typically occur at expansion joints, utility entry points and along baseboards and mouldings.
Furniture treatment including but not limited to hard surface furniture such	Crack and crevice: Crack and crevice applications are to junction points on items.

as bed frames, headboards, dressers, cupboards etc.	
Residential structure	A residential structure is one where the general public, including children, could be exposed during or after application. Residential structures include, but are not limited to, homes, garages, schools, restaurants, hotels/motels, public buildings or any other structures where the general public including children may potentially be exposed.

As indicated in Section 2.0 of this Appendix, the following label changes are required to clarify label directions to reduce the likelihood of product misuse by pest control applicators and minimize unnecessary exposure to occupants living in, working in or entering treated areas.

- Remove label statements on liquid commercial-class products that can be interpreted as applications beyond the definition of crack and crevice treatment for residential indoor uses as outlined in the PMRA Guidance Document, *Structural Pest Control Products: Label Updates*. Add the label statement prohibiting indoor broadcast, perimeter, and spot applications.

For Use Direction Tables specific to Animal Housing, add the following statement:

- For indoor applications to residential areas (where the general public, including children may be exposed), **DO NOT** apply as a broadcast, perimeter or spot treatment.

2.2.5 Pressurized (aerosol) commercial class end-use products for structural uses

The following label statements must be added to the label under **DIRECTIONS FOR USE**:

"DO NOT apply as a broadcast or perimeter treatment to indoor areas."

The label must contain clear instructions that define areas and locations that can be treated. Include the following definitions under "**DIRECTIONS OF USE**." The following definitions are from the PMRA Guidance Document, *Structural Pest Control Products: Label Updates* (28 February 2020) must be added to the label when relevant uses are registered on the product label.

For commercial-class pressurized products:	
Outdoor spot	Apply to small areas of exterior surfaces of structures.
Indoor spot	Spot application is localized to a surface area not more than 0.2 m^2. Spots are not to be adjoining. The combined area of spots is not to exceed 10% of the total surface area of a room.
Crack and crevice (indoor and outdoor)	Crack and crevice is an application directly into narrow openings on the surface of the structure. It does not include the treatment of exposed surfaces. Narrow openings typically occur at expansion joints, utility entry points and along baseboards and mouldings.
Void (outdoors)	Void application applies to inaccessible, enclosed empty spaces of a structure. For example, aerial termite cartridges and subterranean ant nests.

Furniture treatment including but not limited to hard surface furniture such as bed frames, headboards, dressers, cupboards etc.	Spot: Spot application is up to 10% of the surface of the treated item. Crack and crevice: Crack and crevice applications are to junction points on items.

As indicated in Section 2.0 of this Appendix, the following label changes are required to clarify label directions to reduce the likelihood of product misuse by pest control applicators and minimize unnecessary exposure to occupants living in, working in or entering treated areas.

- Remove label statements on pressurized (aerosol) commercial-class products that can be interpreted as applications beyond the definitions of crack and crevice or spot treatments for residential indoor uses as outlined in the PMRA Guidance Document, *Structural Pest Control Products: Label Updates*. Add the label statement prohibiting indoor broadcast and perimeter applications.

ENVIRONMENT

3.0 Label amendments for lambda-cyhalothrin technical grade active ingredient labels:

The following statements must be added to the section entitled ENVIRONMENTAL PRECAUTIONS:

TOXIC to aquatic organisms.

DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

The following statements must be added to the section entitled DISPOSAL:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal and provincial regulations. For additional details and clean up of spills, contact the manufacturer and the provincial regulatory agency.

4.0 Label amendments for commercial class products containing lambda-cyhalothrin:

Under the ENVIRONMENTAL PRECAUTIONS section, the following statements are required:

For products with outdoor agricultural uses, including turf and ornamentals:

Toxic to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.

Toxic to small wild mammals.

Toxic to bees. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. Avoid application during the crop blooming period. If applications must be made during the crop blooming period, restrict applications to the evening when most bees are not

foraging. Avoid applications when bees are foraging in the treatment area in ground cover containing blooming weeds. To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying – Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/pollinators).

Toxic to certain beneficial arthropods (which may include predatory and parasitic insects, spiders, and mites). Minimize spray drift to reduce harmful effects on beneficial arthropods in habitats next to the application site such as hedgerows and woodland.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

To reduce risk to aquatic organisms from runoff, a vegetative filter strip of at least 10 metres wide between the field edge and adjacent, downhill aquatic habitats must be observed, as specified under DIRECTIONS FOR USE

For product formulations that contain aromatic petroleum distillates, the following statement is required:

This product contains (an) active ingredient(s) and aromatic petroleum distillates, which are toxic to aquatic organisms.

For all outdoor products used to treat structures and for perimeter (barrier) treatment, the following statement is required under the ENVIRONMENTAL PRECAUTIONS section:

Toxic to aquatic organisms.

In addition, for all outdoor structural products with perimeter (barrier) treatment, the following statement is required under the ENVIRONMENTAL PRECAUTIONS section:

Toxic to bees. Avoid application around blooming plants.

For pour-on products add only the following statement under the ENVIRONMENTAL PRECAUTIONS section:

Toxic to aquatic organisms.

For product labels with greenhouse uses:

Greenhouse use: Toxic to beneficial arthropods (which may include predatory and parasitic insects, spiders, and mites). May harm beneficial arthropods, including those used in greenhouse production. Avoid application when beneficial arthropods are in the treatment area.

Under the DIRECTIONS FOR USE section, the following statements are required:

The following statements are required for all products with outdoor agriculture (including turf and ornamentals) uses and for structural products with perimeter (barrier) treatment:

As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

To protect pollinators, follow the instructions regarding bees in the Environmental Precautions section.

For all products that have agricultural uses, including turf and ornamentals:

A Vegetative Filter Strip (VFS) of at least 10 metres wide must be constructed and maintained. The VFS is required between the field edge and adjacent, downhill aquatic habitats to reduce risk to aquatic organisms from run-off. Aquatic habitats include, but are not limited to, lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, and estuaries.

The VFS is to be composed of grasses and may also include shrubs, trees, or other vegetation. Additional guidance can be found on the PMRA Environmental Risk Mitigation webpages.

Both VFS and spray drift buffer zones must be observed.

Where there are no aerial uses, add the following sentence:
DO NOT apply by air.

For all outdoor structural (spot treatment) products:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

For products applied by field sprayer, airblast and/or aerial application equipment, where applicable, add the following under DIRECTIONS FOR USE:

> Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 8 km/h at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Air-induction nozzles must be used for the ground application of this product. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 8 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium-coarse classification. DO NOT apply under weather conditions of less than 50% relative humidity and temperatures greater than 20°C. Nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing- or rotorspan.

Apply only by fixed-wing or rotary aircraft equipment which has been functionally and operationally calibrated for the atmospheric conditions of the area and the application rates and conditions of this label.

Label rates, conditions and precautions are product specific. Read and understand the entire label before opening this product. Apply only at the rate recommended for aerial application on this label. Where no rate for aerial application appears for the specific use, this product cannot be applied by any type of aerial equipment.

Ensure uniform application. To avoid streaked, uneven or overlapped application, use appropriate marking devices.

Use Precautions

Apply only when meteorological conditions at the treatment site allow for complete and even crop coverage. Apply only under conditions of good practice specific to aerial application as outlined in the National Aerial Pesticide Application Manual, developed by the Federal/Provincial/Territorial Committee on Pest Management and Pesticides.

SPRAY BUFFER ZONES

A spray buffer zone is NOT required for:

- Uses with hand-held application equipment permitted on this label

The spray buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	PCP #	Crop	Spray Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Field sprayer	24984, 33576, 26837, 29052, 32427	Barley, buckwheat, pearl millet, proso millet, oats, rice, rye sorghum, teosinte, triticale, wheat, wild rice, carrots, celery, flax, mustard (oilseed type), canola, summer-fallow, poplar and willow, sweet potato, timothy (for seed production only), ferns of asparagus.	10	5	3	1
	24984, 33576	Alfalfa/grass mixtures				
	26837	Alfalfa				
	30325	Flax seed, mustard seed (oilseed type), rapeseed (including canola)				
	29052, 32427	Alfalfa	15	5	3	1
	30325	Crop Group 6 – Legumes (Succulent or Dried): Bean (Lupinus spp.), bean (Phaseolus spp.), bean (Vigna spp.), Broadbean (fava bean), chickpea (garbanzo bean), guar, jack bean, lablab bean, lentils, pea (pisum spp), pigeon pea, soybean, soybean (immature seed), sword bean	25	10	5	2
	24984, 33576, 29052, 32427, 26837	Crop Group 6 Legume Vegetables: Soybean, Succulent and Dry Edible Beans, Succulent and Dry Peas, Fava Beans (broad beans) and chickpeas, lentils Peas, succulent: peas (includes dwarf pea, edible-pod pea, snow pea, sugar snap pea, English pea, garden pea, green pea), pigeon pea. Peas, dry: Peas (Pisum spp.) (includes field pea)	30	15	5	3
	30404	Soybeans and Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans and chickpeas)	20	10	4	2
	26837 , 33576, 24984, 29052, 32427, 30325	Crop Group 5A – head and stem brassica; Broccoli, Chinese broccoli (gai lon), brussel sprouts, cabbage, Chinese cabbage (napa), cauliflower, and kohlrabi),	25	10	5	3
	26837, 29052, 32427, 24984, 33576	Corn (including field, pop and sweet types, and crops grown for seed production)	25	10	5	3
	27428, 28946, 29052, 32427	Outdoor ornamentals				
	26837, 24984, 33576, 30325	Crop Group 9 – Cucurbit Vegetables: Chayote (fruit), Chinese waxgourd, citron melon, cucumber, gherkin, edible gourd (includes hyotan, cucuzza, hechima, Chinese okra), momordica spp., muskmelon, pumpkin, summer squash, winter squash, watermelon				

Method of application	PCP #	Crop		Spray Buffer Zones (metres) Required for the Protection of:			
				Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
				Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
	30325	Corn (including field, pop and sweet types, and crops grown for seed production) Crop Group 1C Tuberous and Corm Vegetables (Arrowroot, Chinese Artichoke, Jerusalem Artichoke, Edible Canna, Chufa, Dasheen (taro), Potato, Sweet Potato, True Yam) Crop Group 8-09 – Fruiting vegetables: Eggplant, African eggplant, pea eggplant, scarlet eggplant, garden huckleberry, goji berry, groundcherry, martynia, okra, pepino, bell pepper, non-bell pepper, sunberry, tomatillo, tomato, currant tomato, bush tomato, cocona, naranjilla, roselle, tree tomato and cultivars, varieties and hybrids of these commodities		20	10	5	3
	24984, 33576, 26837, 29052, 32427	Potatoes Tomatoes		10	5	4	2
	27428, 28946	Turf (sod, golf course, home, industrial and commercial lawns)		40	20	10	3
	24984, 33576, 26837, 29052, 32427	Strawberry		15	5	3	2
		Field tobacco		2	1	1	1
		Tobacco (soil treatment), tobacco (post planting treatment)		5	2	3	1
		Rye or wheat (tobacco cover crop treatment)		3	1	2	1
Airblast	26837, 24984	CONIFER SEED ORCHARDS (Douglas-fir, hemlocks, spruces, larches, pines and true firs)	Early growth stage	85	75	70	60
			Late growth stage	75	65	60	50
	24984, 33576, 26837, 29052, 32427	Chokecherry, shelterbelts	Early growth stage	55	45	50	40
			Late growth stage	45	35	40	30
	24984, 33576, 26837	Poplar (Populus spp.) and willow (Salix spp.) plantings, including Short-Rotation-Intensive-Culture (SRIC), their hybrids and their planting stock	Early growth stage	70	60	50	40
			Late growth stage	60	50	40	35
	24984, 33576, 26837, 29052, 32427	Pears	Early growth stage	60	50	50	40
			Late growth stage	50	40	40	35
	24984, 33576, 26837	Saskatoon berries	Early growth stage	65	60	55	45
			Late growth stage	55	50	45	35

Method of application	PCP #	Crop		Spray Buffer Zones (metres) Required for the Protection of:			
				Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
				Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
	Tree fruits and strawberry: 24984, 33576, 26837, 29052, 32427 Tree nuts: 24984, 33576, 26837	Apples, cherries, nectarines, peaches, plums, strawberries	Early growth stage	70	60	55	45
		Tree Nuts (Excluding Ginkgo, Monkey puzzle nut and Pine nuts) - Beechnut, Bur Oak, Butternut, Chestnut, Chinquapin, Hazelnut (Filbert), Heartnut, Hickory nut, Japanese horse-chestnut, Black walnut, English walnut, Yellowhorn, walnut, butternut, heartnut	Late growth stage	60	50	45	35
	27428, 29052, 32427, 28946	Outdoor ornamentals	Early growth stage	80	70	60	50
			Late growth stage	70	60	50	40

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
Aerial	**PCP 24984, 33576:** Alfalfa, flax, canola, mustard (oilseed type), grass mixtures, summer-fallow	Fixed wing	375	150	175	55
		Rotary wing	375	125	175	35
	PCP 29052, 32427: Alfalfa, flax,	Fixed wing	375	150	175	55
		Rotary wing	375	150	175	40
	PCP 24984, 33576: Buckwheat, pearl millet, proso millet, rice, rye sorghum, teosinte, triticale, wild rice.	Fixed wing	800	300	175	55
		Rotary wing	550	300	175	35
	PCP 24984, 33576: Lentils, potatoes, barley, wheat, oats, succulent and dry edible beans, succulent peas, field peas, dry peas and soybeans	Fixed wing	800	300	175	55
		Rotary wing	550	300	175	35
	PCP 29052, 32427: Lentils, potatoes, barley, wheat, oats, succulent and dry edible beans, succulent peas, field peas, dry peas and soybeans.	Fixed wing	800	300	175	55
		Rotary wing	575	300	175	40

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
	PCP 24984, 33576: Canola, mustard (oilseed type) 1 Application	Fixed wing	375	150	175	55
		Rotary wing	375	125	175	35
	PCP 29052, 32427: Canola, mustard (oilseed type) 3 Applications	Fixed wing	800	400	175	55
		Rotary wing	700	400	175	40
	PCP 24984, 33576: Crop Group 6 Legume Vegetables Dwarf pea, edible-pod pea, snow pea, sugar snap pea, English pea, garden pea, green pea, pigeon pea. Peas (*Pisum* spp.) (includes field peas), chickpeas, succulent and dry edible beans, fava beans, soybeans	Fixed wing	800	300	175	55
		Rotary wing	550	300	175	35
	PCP 29052, 32427: Crop Group 6 Legume Vegetables Dwarf pea, edible-pod pea, snow pea, sugar snap pea, English pea, garden pea, green pea, pigeon pea. Peas (*Pisum* spp.) (includes field peas), chickpeas, succulent and dry edible beans, fava beans, soybeans	Fixed wing	800	300	175	55
		Rotary wing	575	300	175	40
	PCP 24984, 33576: Corn (including field, pop and sweet types, and crops grown for seed production)	Fixed wing	800	800	800	225
		Rotary wing	800	575	475	225
	PCP 29052, 32427: Corn (including field, pop and sweet types, and crops grown for seed production)	Fixed wing	800	800	800	250
		Rotary wing	800	675	400	225
	PCP 30325: Corn (including field, pop and sweet types, and crops grown for seed production)	Fixed wing	800	800	800	550
		Rotary wing	800	725	400	225
	PCP 30404:	Fixed wing	800	800	800	225

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:			
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m
	Soybeans, and Dried Shelled Beans (Phaseolus spp., Lupinus spp., Vigna spp., dry fava beans, dry lablab beans and chickpeas)	Rotary wing	800	725	425	225
	PCP 24984, 33576: Poplar (*Populus* spp.) and willow (*Salix* spp.) plantings, including short-rotation-intensive-culture (sric), their hybrids and their planting stock	Fixed wing	775	300	175	55
		Rotary wing	550	300	175	35
	PCP 30325: Crop Group 1C Tuberous and Corm Vegetables (Arrowroot, Chinese Artichoke, Jerusalem Artichoke, Edible Canna, Chufa, Dasheen (taro), Potato, Sweet Potato, True Yam),	Fixed wing	800	800	800	550
		Rotary wing	800	725	400	225
	PCP 30325: Crop Group 6 Legumes (Succulent and Dried) (Bean (Lupinus spp.), bean (Phaseolus spp.), bean (Vigna spp.), Broadbean (fava bean), chickpea (garbanzo bean), guar, jackbean, lablab bean, lentil, pea (pisum spp), pigeon pea, soybean, soybean (immature seed), sword bean)	Fixed wing	800	800	800	575
		Rotary wing	800	425	475	250
	PCP 30325: Flax seed, mustard seed (oilseed type), rapeseed (including canola)	Fixed wing	800	275	325	125
		Rotary wing	500	275	325	125

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) spray buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The spray buffer zones for airblast application of this product can be modified based on weather conditions and spray equipment configuration by accessing the Spray Buffer Zone Calculator on the Pest Management Regulatory Agency web site. Spray buffer zones for field sprayer or aerial application CANNOT be modified using the Spray Buffer Zone Calculator.

For product labels with greenhouse uses, add the following statement:

DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Under the STORAGE section, the following statements are required:

Store this product away from food or feed.

Under the DISPOSAL section where the container is recyclable (except ear tag packaging), the following statements are required:

DO NOT reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.

2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

For ear tag products:

Dispose of packaging and any used tags in accordance with provincial requirements.
VALUE

General label updates:

- On principal panel, replace “Guarantee” with “Active Ingredient”.

(A) Agricultural Uses

- For certain Crop Groups, individual crops were removed for mitigation purposes. Due to this, label revisions are required to delete reference to the Crop Group, and replace it with a list of the supported crops. Example: All references to CROP SUBGROUP 5A (Head and Stem Brassica Subgroup) must be deleted and replaced with a list of the supported Brassica crops.

(B) Animal Use Products

- Revise the current resistance management section wording to reflect latest Directive (DIR2013-04).

(C) Structural Use Products

Note: For all commercial class structural product labels, the following general changes are required:

- Labels with structural uses must be amended to include the definitions for application types outlined in the PMRA publication "*PMRA Guidance Document, Structural Pest Control Products: Label Updates*". The types of application methods permitted should appear in the DIRECTIONS FOR USE section under the header "How to Apply".
- All resistance management labelling must be updated as per "*DIR2013-04, Pesticide Resistance Management Labelling Based on Target Site / Mode of Action*". For products with structural uses, the plant protection terminology must be amended to reflect the structural use (for example, change "field" to "location"; removal of "certified crop advisors" if there are no crop uses on the label).
- Statements that provide reapplication instructions and minimum retreatment intervals must be updated to ensure consistency within and across labels.
    - Replace "Re-apply as necessary" and "Re-apply when re-infestation occurs" with: "If pest problem persists or reoccurs, treatment must only be repeated after 21 days. Maximum of 4 applications per year."
    - For liquid commercial products, replace "Apply directly to bedbugs" with "To enhance effectiveness of this product, apply this product directly to bedbugs within cracks and crevices. Treatment must only be repeated after 21 days if pest problem persists or reoccurs. Maximum of 4 applications per year."
    - For pressurised products, whenever direct contact with insects is mentioned, include the following statement: "However, this product must be used as per the definitions provided in the 'How to Apply' table."

Appendix XI References Considered Following Publication of PRVD2017-03

Note that the following includes only references that were not previously considered in PRVD2017-03.

A. Information Considered in the Updated Toxicology Assessment

List of Studies/Information Submitted by the Registrant

PMRA Document Number	Reference
2918244	Elmore, Susan A. and Shyamal D. Peddada, 2009, Points to consider on the statistical analysis of rodent cancer bioassay data when incorporating historical control data. Toxicologic Pathology, Volume 37, Pages 672 676, DACO: 4.8
2918247	Kitsche, A., L.A. Hothorn, and F. Schaarschmidt, 2012, The use of historical controls in estimating simultaneous confidence intervals for comparison against a concurrent control - Computational Statistics and Data Analysis, Volume 56, Pages 3865 to 3875, DACO: 4.8
2918245	Klimisch, H.J., Andrae, M. and Tillmann, U., 1997, A systemic approach for evaluating the quality of experimental toxicological and ecotoxicological data - Regulatory Toxicology and Pharmacology, Volume 25, Pages 1 to 5, DACO: 4.8
2918240	Krewski D, Gaylor D, Szyszkowicz M., 1991, A model-free approach to low-dose extrapolation - Environmental Health Perspectives, Volume 90, Pages 279 to 285, DACO: 4.8
2805473	2017, Lambda-cyhalothrin Weight of Evidence Assessment for Carcinogenicity Position Statement Response to PMRA PRVD2017-03, DACO: 4.4.4
2918243	Schneider, Klaus et al, 2009, ToxRTool, a new tool to assess the reliability of toxicological data - Toxicology Letters, Volume 189, Pages 138 to 144, DACO: 4.8

Additional Information Considered

Published Information

PMRA Document Number	Reference
2918246	Boobis, Alan R. et al, 2017, IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans - Critical Reviews in Toxicology, Volume 36, Number 10, Pages 781 to 792 , DACO: 4.8
2918242	European Food Safety Authority, 2016, Update: use of the benchmark dose approach in risk assessment. Dated November 17, 2016. EFSA Journal 15(1), DACO: 4.8

PMRA Document Number	Reference
2918189	Makinen, Netta et al, 2017, Characterization of MED12, HMGA2 and FH alterations reveals molecular variability in uterine smooth muscle tumors - Molecular Cancer Volume 16, DACO: 4.8
2918190	Matsubara, A. et al, 2013, Taniguchi, H., Kushima, R., Tsuda, H and Kani, Y. 2013. Prevalence of MED12 mutations in uterine and extrauterine muscle tumours - Histopathology, Volume 62, Pages 657 to 661, DACO: 4.8
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2684920	2014, Residential Use Survey of Actives in Pyrethroid/Permethrin Cluster (REV2011-05), DACO: 5.2
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PMRA Document Number	Reference
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2805488	Bondarenko, S., Gan, J., Spurlock, F., 2008, Solid-Phase Microextraction (SPME) Methods to Measure Bioavailable Concentrations in Sediment, DACO: 8.2.4.2
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