Proposed Maximum Residue Limit PMRL2024-13

Abamectin

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1.0 Pesticides in Canada

Pesticides provide both organic and conventional growers in Canada with a variety of options to help minimize damage from pests to their crops and livestock. Pesticides help protect crops from pests such as weeds, fungi, and insects. This allows people in Canada to access high-quality nutritious foods all year long.

All pesticides, for both organic and conventionally grown crops, that are approved for use in Canada are regulated by Health Canada's Pest Management Regulatory Agency (PMRA). This includes regulating pesticide residues that may be present on food commodities **imported** into Canada. Health Canada reviews all new pesticide applications and re-evaluates existing pesticides on a regular basis to help ensure the protection of human health.

Maximum residue limits

A maximum residue limit (MRL) is the highest amount of a specific pesticide residue allowed on a particular food commodity when a pesticide is used according to label directions.

Health Canada scientists set (or specify) MRLs after a robust scientific review of the pesticide, and provided that the risks meet Health Canada's requirements for the protection of human health. This means that the scientists first make sure the amount of pesticide residue on or in food commodities is low enough that there are no effects on human health. Health Canada is responsible for setting MRLs on food commodities grown domestically or imported into Canada. Different food commodities can have different MRLs for the same pesticide due to differences in how the pesticide is used for each crop or food commodity.

An MRL is a scientific calculation that estimates the maximum potential concentration of residues on food commodities. It is not a measurement of pesticide toxicity or safety. It accounts for the highest potential amount of residue that may remain on a food commodity when label directions are followed. More information about these calculations is in Section 5.0 Calculating the proposed MRL. Often, the residues that remain are much lower than the MRL under typical use conditions. If the use directions change for a given pesticide, the MRL can also change. However, before any change to an MRL is proposed, the risks must meet Health Canada's requirements for the protection of human health.

MRLs are legal limits that are enforced by the Canadian Food Inspection Agency (CFIA). The latest National Chemical Residue Monitoring Program and Chemistry Food Safety report that uses MRLs to determine compliance rates can be requested on the Food safety testing reports and journal articles page on Canada.ca.

When setting MRLs on related food commodities, Health Canada uses crop groups. Individual crops can be allocated to a crop group based on botanical or taxonomic criteria as well as on cultivation practices. Crop groups simplify the establishment of MRLs by using residue data for crops that are representative of the whole group to extend to all crops within the crop group. Crop groups can also contain smaller and more closely related crop subgroups.

Imported food commodities

To set MRLs on imported food commodities, Health Canada evaluates multiple studies from various scientific disciplines on human health. As directed in Section 10(3) of the *Pest Control Products Act*, only health risks are assessed for imported food commodities, and only for potential exposure in the diet.

This is because the pesticide is applied in the country from which the food commodity is imported. People in Canada could only be exposed to the residue from that imported food commodity through their diet. Canadian workers, such as a grower will not be exposed, and no exposure to the Canadian environment is expected. An exporting country may have different pests, different climates, or regulate pesticides differently than Canada. After conducting a thorough scientific assessment and finding no health concerns, Health Canada may align the Canadian MRL with the established MRL or tolerance of the exporting country, to allow the imported food commodity to be sold in Canada.

However, if the pesticide is registered for other uses in Canada, Health Canada would conduct a full health, environment and value assessment before making any registration decision for those uses. This assessment sets the conditions for that pesticide in Canada to help ensure there are no health or environmental concerns, and confirms that the pesticide use has value.

2.0 Purpose of this consultation

Health Canada is consulting the public and seeking your feedback on proposed new and revised MRLs to address potential abamectin residues on various imported food commodities.

Abamectin is an insecticide currently registered for use in Canada on hops and various fruit and vegetable commodities. The proposed new and revised MRLs listed below were requested by Syngenta Canada Inc. to align Canada's new abamectin MRL with the Japanese MRL on tea (for tea grown in Japan); to revise Canada's existing abamectin MRLs to align with the United States (U.S.) tolerances (another name for MRLs) on papayas and fruiting vegetables (except tomatoes) grown in the U.S.; and to align Canada's new abamectin MRLs with the U.S. tolerances on specific food commodities grown in the U.S.. These MRL changes, including new MRLs, would allow these food commodities, or any of their derived processed food commodities that may contain abamectin residues, to be imported and sold in Canada.

Health Canada is proposing to accept these MRL changes (including new MRLs). This is because Health Canada conducted a thorough scientific assessment and found because that the health risk from eating food commodities treated with abamectin meets Health Canada's requirements for the protection of human health. The main health assessment required for this consultation was the dietary risk assessment and it was conducted in accordance with Sections 10 and 11 of the *Pest Control Products Act*. This assessment involves a thorough evaluation of health risks that considered the toxicity and dietary exposure of abamectin, and follows strict regulatory standards. Further details on the dietary risk assessment can be found in Section 3.0 Dietary risk assessment.

Proposed Canadian MRLs for abamectin

These MRL changes will not change the Canadian registered labels for abamectin, how the pesticide is used in Canada, or increase the amount of pesticide residues in the food grown in Canada.

Table 1 summarizes the proposed new and revised MRLs for abamectin, as well as the reason for each proposed MRL.

MRLs are based on a residue definition that typically includes the pesticide itself and may also include one or more degradation products referred to as metabolites. A searchable residue definition table is available on the Residue Definitions for Chemicals with Maximum Residue Limits Regulated Under the Pest Control Products Act page on Canada.ca.

Please note that recently updated residue definitions, including abamectin, will appear in the next version of the searchable residue definition table.

The following MRLs are based on the following residue definition: 5-O-demethylavermectin A1a

Table 1 Proposed maximum residue limits (MRLs) for abamectin

Food commodity	Current MRL (ppm)[1]	Proposed MRL (ppm)[1]	Reason for the proposed MRL
Tea (dried leaves)	None	1.0	**New MRL** on tea (dried leaves), based on the registered use in the exporting country. The tea may then be imported into Canada.
Papayas	0.03	0.4	**Increase MRL** on papayas, as a result of an increased application rate in the exporting country. The papayas may then be imported into Canada.

Food commodity	Current MRL (ppm)[1]	Proposed MRL (ppm)[1]	Reason for the proposed MRL
Stone fruits (crop group 12-09)	0.09 (original crop group 12)	0.09	**Apply current MRL** on the original crop group 12 (stone fruits) **to the food commodities without MRLs** in the updated crop group 12-09 (stone fruits), based on the registered crop group use in the exporting country. These food commodities may then be imported into Canada.
Fruiting vegetables (crop group 8-09)	0.07 (tomatoes) 0.02 (all other crops in crop group 8-09)	0.07	**Increase MRL** on fruiting vegetables (except tomatoes), which will include all imported fruiting vegetables (from field and greenhouse uses) from the exporting country. These food commodities may then be imported into Canada.
Low growing berries (crop subgroup 13-07G)	0.05 (strawberries only)	0.05	**Apply current MRL** on strawberries **to the food commodities without MRLs** in crop subgroup 13-07G (low growing berries), based on the registered crop subgroup use in the exporting country. These food commodities may then be imported into Canada.
Carrot roots	None	0.03	**New MRL** on carrot roots, based on the registered use in the exporting country. The carrot roots may then be imported into Canada.

Food commodity	Current MRL (ppm)[1]	Proposed MRL (ppm)[1]	Reason for the proposed MRL
Citrus fruits (crop group 10) (revised)	0.02 (original crop group 10)	0.02	**Apply current MRL** on the original crop group 10 (citrus fruits) **to the food commodities without MRLs** in the updated crop group 10-revised, based on the registered crop group use in the exporting country. These food commodities may then be imported into Canada.
Pome fruits (crop group 11-09)	0.02 (apples and pears only)	0.02	**Apply current MRL** on apples and pears **to the food commodities without MRLs** in crop group 11-09 (pome fruits), based on the registered crop group use in the exporting country. These food commodities may then be imported into Canada.
Small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)	0.02 (grapes only)	0.02	**Apply current MRL** on grapes **to the food commodities without MRLs** in crop subgroup 13-07F (small fruits vine climbing, except fuzzy kiwifruit), based on the registered crop subgroup use in the exporting country. These food commodities may then be imported into Canada.
Dried chive leaves	None	0.02	**New MRL** on dried chive leaves, based on the registered use in the exporting country. The dried chive leaves may then be imported into Canada.

Food commodity	Current MRL (ppm)[1]	Proposed MRL (ppm)[1]	Reason for the proposed MRL
Guavas, pineapples	None	0.015	**New MRL** on guavas and pineapples, based on the registered use in the exporting country. The guavas and pineapples may then be imported into Canada.
Tree nuts (crop group 14-11)	0.01 (original crop group 14)	0.01	**Apply current MRL** on almonds and pecans **to the food commodities without MRLs** in crop group 14-11 (tree nuts), based on the registered crop group use in the exporting country. These food commodities may then be imported into Canada.
Tropical and subtropical fruits; small fruits; inedible peel (crop subgroup 24A), sweet corn kernels plus cob with husks removed	None	0.01	**New MRL** on certain tropical and subtropical fruits; small fruits; inedible peel (crop subgroup 24A) and sweet corn, based on the registered use in the exporting country. These food commodities may then be imported into Canada.

[1] ppm = parts per million

Based on the results from the dietary risk assessment, Health Canada is proposing to accept the new and revised MRL requests for abamectin. This is because these new and revised MRLs meet Health Canada's requirements for the protection of human health.

3.0 Dietary risk assessment

Before an MRL can be set, Health Canada scientists make sure the amount of pesticide residue on or in food commodities is low enough that there are no effects on human health. They evaluate the relevant scientific information on the toxicity and dietary exposure of the pesticide. This process is called a dietary risk assessment.

Overview of the dietary risk assessment process

The **dietary risk assessment** process involves four distinct steps:

1. Evaluate the relevant scientific data and information and then identify the toxicology hazards of the pesticide;

2. Determine the **acute reference dose (ARfD)** and the **acceptable daily intake (ADI)**, where applicable.

   ARfD: the amount of a specific pesticide residue that a person can eat and drink **on any given day** without any negative health effects. The ARfD is used to estimate acute dietary risk, which considers the potential for health effects after a single day of exposure to the pesticide.

   ADI: the amount of a specific pesticide residue a person could eat and drink **every** day over their entire lifetime without any negative health effects. The ADI is used to estimate chronic dietary risk, which considers the potential for health effects after a lifetime of exposure to the pesticide.

   Health Canada scientists estimate both acute (single day) and chronic (lifetime) dietary intakes, where applicable, for the general population and several sub-populations such as pregnant people, infants, children and seniors.

3. Estimate the **potential daily intake (PDI)**.

   PDI: the total amount of a specific pesticide residue that might be eaten. When determining the PDI for a pesticide, scientists consider **all** food commodities (both registered (domestic) and imported), drinking water (where applicable), and how diets can vary between people in Canada. The PDI is the potential dietary exposure to a specific pesticide.

4. Characterize the **acute dietary risk** by comparing the PDI with the ARfD, and characterize the **chronic dietary risk** by comparing the PDI with the ADI, where applicable.

If the PDI is lower than both the ARfD and the ADI (where applicable), Health Canada scientists conclude that all food commodities that could be treated with this pesticide are safe to eat.

Summary of the dietary risk assessment results for abamectin

This summary focuses on key aspects of the dietary risk assessment that are potentially of greatest interest to people in Canada. It is intended to help improve the understanding of Health Canada's pesticide decisions. Technical details and how to request additional information about the dietary risk assessment can be found in Section 7.0 Next steps and in Appendix I.

The results from the dietary risk assessment show that, when abamectin is used according to the Japanese and American registered label directions, the dietary risks from abamectin on food commodities continue to meet Health Canada's requirements for the protection of human health. The toxicology information for abamectin relevant to the dietary risk assessment is reported in Table A1-1 of Appendix I.

The acute dietary risk assessment results showed that exposure to abamectin is **less than 31%** of the ARfD. **This means that acute exposure to abamectin will not affect your health.** The dietary risk for each subpopulation is reported in Table A1-2 of Appendix I.

- Health Canada considers that acute risk may be of concern when exposure is greater than 100% of the ArfD. When the acute dietary risk assessment is lower than 100% of the ArfD, it means that on a given day there are no human health concerns from eating foods treated with abamectin.

The chronic dietary risk assessment results showed that exposure to abamectin is **less than 30%** of the ADI level. **This means that chronic exposure to abamectin will not affect your health**. The dietary risk for each subpopulation is reported in Table A1-3 of Appendix I.

- Health Canada considers that chronic risk may be of concern when exposure is greater than 100% of the ADI. When the chronic dietary risk assessment is lower than 100% of the ADI, it means that there are no human health concerns from eating foods treated with abamectin every day over a person's lifetime.

For more information on how Health Canada assesses and manages risk from pesticides, refer to this guidance document:

- PMRA Guidance Document, A framework for risk assessment and risk management of pest control products

For more information on the MRL process, refer to Section 19 *Maximum Residue Limits* found within this guideline:

- Residue chemistry guidelines: Revised 2022 PMRA guidance document – Canada.ca

7.0 Summary of residue data to support the proposed MRLs

Health Canada scientists reviewed the residue data from field trial studies for abamectin on imported crops that were submitted to support the proposed MRLs on the following food commodities: carrots, sweet corn, pineapples, guavas, papayas, lychees, tea and dried chive leaves. Scientists also re-assessed previously reviewed residue data from field trials conducted on tomatoes, bell peppers, non-bell peppers, oranges, grapefruit, lemons, apples, pears, sweet cherries, tart cherries, peaches, plums, grapes, strawberries, almonds and pecans.

In addition, scientists reviewed experimental processing data that were submitted on treated fresh chive leaves, and selected an experimental processing factor.

An **experimental processing factor** is the ratio of residue levels in a processed food commodity to residue levels in the raw food commodity. This factor is used to determine whether pesticide residues concentrate in a processed food commodity. An experimental processing factor that is less than onefold means that residues of the pesticide do not concentrate in the processed food commodity. A separate MRL does not need to be set for the processed food commodity, because residues will be addressed by the proposed MRL for the raw food commodity.

Scientists also re-assessed previously reviewed experimental processing data on treated tomatoes, citrus fruits, apples, plums and grapes and confirmed the processing factors. Examples of processed food commodities are juice or oil from oranges, paste or puree from tomatoes, juice from apples, and chips or flakes from potatoes.

Table 2 summarizes the residue data used to calculate the proposed MRLs for the various imported food commodities.

Table 2 Summary of field trial and processing data used to support the MRLs

Food commodity	Application method	Total application rate (g a.i./ha)[1,6]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2,5]	Highest average field trial residues (ppm)[2,5]	Experimental processing factor[3]	Proposed MRL (ppm)
Carrot roots	Seed treatment	0.016–0.017 mg a.i./seed[4]	71–128	<0.006	0.019	Not required	0.03
Fresh chive leaves	Foliar	64–66	5–7	<0.004	0.0042	Dried leaves: 3.0-fold [3.0 × 0.0042 ppm (which is the highest average concentration of residues (HAFT) in treated fresh chives) = 0.013 ppm]	0.02 Dried Chive leaves (0.01 Fresh chive leaves MRL is already established)
Papayas	Foliar	83–91	3–5	<0.005	0.131	Not required	0.4
Pineapples	Foliar	52–53	78–112	<0.004	<0.004	Not required	0.015
Guavas	Foliar	82–83	8	<0.004	0.005	Not required	0.015
Sweet corn kernels plus cob with husks removed	Seed treatment + Foliar	56–89	6–7	<0.006	<0.006	Not required	0.01

Food commodity	Application method	Total application rate (g a.i./ha)[1,6]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2,5]	Highest average field trial residues (ppm)[2,5]	Experimental processing factor[3]	Proposed MRL (ppm)
Dried tea leaves	Foliar	108	7	0.072	0.477	Not required	1.0 Tea (dried leaves)
Tomatoes (standard size and cherry tomatoes)	Foliar	66–70	1	0.006	0.041	Paste: 1.0-fold [1.0 × 0.041 ppm (which is the highest average concentration of residues (HAFT) in treated tomatoes) = 0.041 ppm] Purée: 0.63-fold [0.63 × 0.041 ppm (which is the highest average concentration of residues (HAFT) in treated tomatoes) = 0.026 ppm]	0.07 Fruiting vegetables (crop group 8-09)
Non-bell peppers	Foliar	62–64	7	<0.006	<0.01	Not required	0.07 Fruiting vegetables (crop group 8-09)
Bell peppers	Foliar	63–66	7	<0.006	<0.012	Not required	0.07 Fruiting vegetables (crop group 8-09)

Food commodity	Application method	Total application rate (g a.i./ha)[1,6]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2,5]	Highest average field trial residues (ppm)[2,5]	Experimental processing factor[3]	Proposed MRL (ppm)
Oranges	Foliar	51–54	7	<0.004	<0.007	Orange juice: 0.25-fold [0.25 × 0.007 ppm (which is the highest average concentration of residues (HAFT) in treated oranges) = 0.002 ppm]	0.02 Citrus fruits (crop group 10) (revised)
Grapefruits	Foliar	51–53	6–7	<0.004	<0.006	Not applicable	0.02 Citrus fruits (crop group 10) (revised)
Lemons	Foliar	52–53	7	<0.004	<0.008	Citrus oil: 7-fold [7 × 0.008 ppm (which is the highest average concentration of residues (HAFT) in treated lemons) = 0.056 ppm]	0.02 Citrus fruits (crop group 10) (revised) (0.1 citrus oil MRL is already established)

Food commodity	Application method	Total application rate (g a.i./ha)[1,6]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2,5]	Highest average field trial residues (ppm)[2,5]	Experimental processing factor[3]	Proposed MRL (ppm)
Apples	Foliar	54–56	28	<0.004	0.013	Apple juice: 0.4-fold [0.4 × 0.013 ppm (which is the highest average concentration of residues (HAFT) in treated apples) = 0.005 ppm]	0.02 Pome fruits (crop group 11-09)
Pears	Foliar	54	21	<0.004	0.011	Not required	0.02 Pome fruits (crop group 11-09)
Sweet cherries	Foliar	52	21	<0.006	<0.019	Not required	0.09 Stone fruits (crop group 12-09)
Tart cherries	Foliar	52	21	<0.008	0.053	Not required	0.09 Stone fruits (crop group 12-09)
Peaches	Foliar	52	21 – 22	<0.004	0.026	Not required	0.09 Stone fruits (crop group 12-09)
Plums	Foliar	54	21	<0.004	<0.006	Dried prune plums: 1.9-fold [1.9 × 0.006 ppm (which is the average concentration of residues in treated fresh plums) = 0.011 ppm]	0.09 Stone fruits (crop group 12-09)

Food commodity	Application method	Total application rate (g a.i./ha)[1,6]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2,5]	Highest average field trial residues (ppm)[2,5]	Experimental processing factor[3]	Proposed MRL (ppm)
Grapes	Foliar	42–44	28	<0.004	<0.008	Grape juice: 0.1-fold [0.1× 0.008 ppm (which is the highest average concentration of residues (HAFT) in treated grapes) = 0.001 ppm] Raisins: 0.6-fold [0.6 × 0.008 ppm (which is the highest average concentration of residues (HAFT) in treated grapes) = 0.005 ppm]	0.02 Small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)
Strawberries	Foliar	88	3	0.009	0.027	Not required	0.05 Low growing berries (crop subgroup 13-07G)
Almonds	Foliar	81	21	<0.01	<0.01	Not required	0.01 Tree nuts (crop group 14-11)
Pecans	Foliar	81	21	<0.01	<0.01	Not required	0.01 Tree nuts (crop group 14-11)

Food commodity	Application method	Total application rate (g a.i./ha)[1,6]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2,5]	Highest average field trial residues (ppm)[2,5]	Experimental processing factor[3]	Proposed MRL (ppm)
Lychees	Foliar	54–56	8–13	<0.002	0.0027	Not required	0.01 Tropical and subtropical fruits, small fruits, inedible peel (crop subgroup 24A)

[1] g a.i./ha = grams of active ingredient per hectare
[2] ppm = parts per million
[3] An experimental processing factor that is less than onefold means that residues of the pesticide do not concentrate in the processed food commodity. A separate MRL does not need to be set for the processed food commodity, because residues will be addressed by the proposed MRL for the raw food commodity.
[4] mg a.i./seed = milligrams of active ingredient per seed
[5] Represents total residues of Avermectin B1a + 8,9-Z isomer of Avermectin B1a + Avermectin B1b. The residue definition for abamectin is revised to 5-O-demethylavermectin A1a (also known as Avermectin B1a), as per PRVD2023-01. Since residues of 8,9-Z isomer of avermectin B1a and avermectin B1b do not contribute significantly to the total residues, no numeric adjustments to the values cited in this table or to the proposed MRLs are being requested.
[6] The application rates of abamectin used in the field trials align (within onefold) with the application rates on the registered labels from the exporting country for all listed food commodities, except for tea leaves, almonds and pecans. The application rates in the tea leaves, almond and pecan field trials are approximately 1.5-fold higher than those on the corresponding Japanese and American registered labels. When field trial study application rates are 1.0-fold or higher, the proposed MRLs determined from these studies will address the potential residues of abamectin resulting from the product used at the registered label rates.

5.0 Calculating the proposed MRLs

Health Canada scientists calculated the proposed MRLs for abamectin using the residues observed in the residue trials, and the guidance provided in the OECD MRL Calculator. Many international regulatory authorities use this statistical calculator to set MRLs on food commodities that are either grown domestically or imported from different countries. Full residue datasets are required to run the OECD MRL calculator, not just the highest and lowest residues reported in Table 2 above.

Pesticide MRLs established for each food commodity, including those imported into Canada, may be found using the Maximum Residue Limit Database. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, for pesticides or food commodities.

6.0 International considerations

Internationally, MRLs are used to facilitate trade of food commodities between countries. Canadian MRLs are established or amended on the basis of a robust scientific risk assessment that demonstrates safety for people in Canada.

While MRLs may be aligned to the extent possible with the Codex MRLs and U.S. tolerances (provided that the risks meet Health Canada's requirements for the protection of human health), MRLs may vary from one country to another for several reasons, which may include:

- differences in the way pesticides are used between countries
- different geographical locations of the field residue studies
- different environmental and weather conditions and pests between the countries.

For abamectin, the differences are based on different application rates or new or additional crop residue data for these food commodities in the U.S. and Japan (see bullet 1 above).

Table 3 compares the MRLs proposed for abamectin in Canada with the corresponding U.S. tolerances and international Codex MRLs. The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

The U.S. tolerances are listed by pesticide in the Electronic Code of Federal Regulations, 40 CFR Part 180.

The Codex MRLs are listed by pesticide or food commodity on the Codex Alimentarius Pesticide Index.

Table 3 Comparison of proposed Canadian MRLs, U.S. Tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)[1]	Established U.S. Tolerance (ppm)[1]	Established Codex MRL (ppm)[1]
Fruiting vegetables (crop group 8-09)	0.07	0.07	0.09 (peppers, sweet including pimento or pimiento)
			0.05 (tomato, egg plant)
			0.005 (peppers chili)
Citrus fruits (crop group 10, revised)	0.02	0.02	0.02
Pome fruits (crop group 11-09)	0.02	0.02	0.01

Food commodity	Proposed Canadian MRL (ppm)[1]	Established U.S. Tolerance (ppm)[1]	Established Codex MRL (ppm)[1]
Stone fruits (crop group 12-09)	0.09	0.09	0.07 (cherries subgroup); 0.03 (peaches including apricots and nectarine subgroup); 0.005 (plums including fresh prunes subgroup)
Small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)	0.02	0.02	0.03 (grapes)
Low growing berries (crop subgroup 13-07G)	0.05	0.05	0.15 (strawberry)
Tree nuts (crop group 14-11)	0.01	0.01	0.005
Tropical and subtropical fruits, small fruits inedible peel (crop subgroup 24A)	0.01	0.01	Not established
Carrot roots	0.03	0.03	Not established
Sweet corn kernels plus cob with husks removed	0.01	0.01	0.002 (sweet corns subgroup)
Pineapples	0.015	0.015	0.002
Guavas	0.015	0.015	Not established
Dried chive leaves	0.02	0.02	0.08
Tea (dried leaves)	1.0	1.0	Not established
Papayas	0.4	0.40	0.01

[1] ppm = parts per million

International consultation on the proposed MRLs also occurs as a result of Canada notifying the World Trade Organization. This is coordinated by Canada's Notification Authority and Enquiry Point to comply with Canada's international trade obligations.

7.0 Next steps

Health Canada invites the public to submit written comments on the proposed MRL changes for abamectin up to 75 days from the date of publication of this document.

Please submit your comments to the PMRA Publications Section.

Health Canada considers all comments received up to 75 days from the date of publication of this document (by 9 September 2024) before making a final science-based decision about the proposed MRLs. Comments received within this 75 day period will be addressed in a response to comments document found in Pesticides and pest management consultations. If no comments are received, or the comments do not result in a change to the proposed MRLs, the MRLs will be set and legally in effect on the date they are entered into the Maximum Residue Limit Database.

If you would like to request additional information on the supporting scientific documents for these proposed MRLs, here is the information you will need to identify the request:

- Active ingredient: abamectin
- Published document number: PMRL2024-13
- Submission number: 2020-5848
- Related re-evaluation documents PRVD2023-01

Appendix I Excerpt of the dietary risk assessment

Table A1-1 Summary of toxicology information for abamectin for use in dietary exposure assessment

Exposure scenario	Toxicology reference value used in risk assessment	Study	Toxicological endpoint
Acute Dietary General Population	NOAEL[1] = 0.5 mg/kg bw CAF[1] = 300[2] ARfD[1] = 0.0017 mg/kg bw	Acute neurotoxicity study in rats, supported by 12-week study in dogs	LOAEL[1] = 1.5 mg/kg bw/day Based on decreased splay reflex in rats; and based on mydriasis observed in dogs at ≥1.0 mg/kg bw/day (in other words, threefold greater dose than the NOAEL)
Repeated Dietary General population	NOAEL[1] = 0.12 mg/kg bw/day CAF[1] = 300[3] ADI[1] = 0.0004 mg/kg bw/day	Developmental neurotoxicity study	LOAEL[1] = 0.2 mg/kg bw/day Based on decreased pup body weight (in other words, 1.7-fold greater dose than the NOAEL)

[1]ARfD = Acute Reference Dose; NOAEL = No Observed Adverse Effect Level; LOAEL = Lowest Observed Adverse Effect Level; CAF = Composite Assessment Factor; ADI = Acceptable Daily Intake; bw = body weight; PCPA = *Pest Control Products Act*. Reference values and endpoints cited in PRVD2023-01.

[2] To account for uncertainties and provide extra protection of sensitive subpopulations, a CAF of 300-fold (10-fold for differences between animals and humans, 10-fold for variations between humans, and a threefold PCPA factor) was applied to the NOAEL for decreased splay reflex in rats and mydriasis observed in dogs to calculate the ARfD. Therefore, NOAEL÷CAF = 0.5 mg/kg bw ÷300 = 0.0017 mg/kg bw (rounded value). This is 882-fold lower than the dose where toxicological effects were observed in the rat (LOAEL÷ARfD = 1.5 mg/kg bw/day ÷ 0.0017 mg/kg bw) or 588-fold lower than the dose at which mydriasis was observed in the dog.

[3] To account for uncertainties and provide extra protection of sensitive subpopulations, a CAF of 300-fold (10-fold for differences between animals and humans, 10-fold for variations between humans, and a threefold PCPA factor) was applied to the NOAEL for decreased pup body weight to calculate the ADI. Therefore, NOAEL ÷ CAF = 0.12 mg/bw/day ÷300 = 0.0004 mg/kg bw/day. This is 500-fold lower than the dose where toxicological effects were observed in animals (LOAEL÷ADI = 0.2 mg/kg bw/day ÷ 0.0004 mg/kg bw/day).

Dietary exposure assessments are conducted using a database called the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID) which is explained in Science Policy Note SPN2014-01, *General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments*. This is a food recipe and consumption database used by Canada and the U.S. for dietary exposure modelling for pesticides that incorporates food

consumption data from the U.S. National Health and Nutritional Examination Survey, What We Eat in America (NHANES/WWEIA) dietary survey. This survey is made available through the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The NHANES survey, which uses interviews and physical examinations to assess the health and nutritional status of adults and children in the United States, is updated periodically and is also reflective of the large variety of food consumption patterns in the Canadian population.

Results of the acute dietary risk assessment

Table A1-2 shows that the PDI is less than 100% of the ARfD (see Section 3.0), therefore there are no acute dietary risks of concern. The DEEM-FCID (NHANES) analyses estimate the dietary exposure of the general population and various population subgroups. The results reported in Table A1-2 are for the general population (all ages), all infants (<1 year old), children 1–2 years old, children 3–5 years old, children 6–12 years old, youth 13–19 years old, adults 20-49 years old, females 13–49 years old and adults 50+ years old. When including the use of abamectin on the various food commodities, the estimated dietary exposure to abamectin for all population subgroups is less than 31% of the ARfD. This means that potential acute exposure to abamectin will not affect your health.

Table A1-2 Summary of acute dietary risk for abamectin

Population subgroup	Food and drinking water[1,2] – previous assessment	Food and drinking water[1,2] – Updated to include the proposed MRLs
	%ARfD[3,5]	%ARfD[3,4,6]
General Population	11.6	**12.4**
All Infants	22.2	**30.8**
Children 1–2 years old	24.6	**22.3**
Children 3–5 years old	21.3	**17.0**
Children 6–12 years old	12.6	**12.1**
Youth 13–19 years old	8.2	**9.0**
Adults 20–49 years old	9.7	**11.0**
Adults 50+ years old	9.9	**9.9**
Females 13–49 years old	10.2	**11.3**

Bolded values indicate updated risk assessments

[1] "Food and Drinking Water" represents all Canadian-grown and imported foods that could be treated with abamectin, as well as the dietary contribution from consuming water that may be impacted by Canadian agricultural uses of abamectin.

[2] For the previous assessment, the "Estimated Environmental Concentrations" (EECs) of abamectin were calculated for drinking water at 1.4 µg a.i./L from surface water. For the updated assessment, the "Estimated Environmental Concentrations" (EECs) of abamectin were calculated for drinking water at 2.5 µg a.i./L from surface water. Note: for imported food commodities, the pesticide for that specific import use is not applied in Canada and will not impact drinking water. As noted in footnote 1, potential exposure via drinking water is considered for the overall risk assessment, which includes both Canadian registered uses and imports.

[3] Values are below 100% (PDI ÷ARfD × 100), therefore, there are no dietary concerns for any segment of the population.

[4] Includes updated monitoring data for some food commodities, which were not previously available. The use of this updated monitoring data can result in lower potential dietary exposures in some population subgroups compared to the previous risk assessment. Monitoring data from Canada (CFIA) or the U.S. (United States Department of

Agriculture) consider residues taken when the crops are imported into Canada, or when crops are on the way to the marketplace.
[5] Previous assessment is from submission 2013-4347. Published documents can be accessed in the link by choosing "Application Number" in the "Filter" field, and entering the submission number in the "Value" field.
[6] Updated assessment is from PRVD2023-01.

Results of the chronic dietary risk assessment

Table A1-3 shows that the PDI is less than 100% of the ADI (see Section 3.0), therefore there are no chronic dietary risks of concern. The DEEM-FCID (NHANES) analyses estimate the dietary exposure of the general population and various population subgroups. The results reported in Table A1-3 are for the general population (all ages), all infants (<1 year old), children 1–2 years old, children 3–5 years old, children 6–12 years old, youth 13–19 years old, adults 20–49 years old, females 13–49 years old and adults 50+ years old. When including the use of abamectin on the various food commodities, the estimated dietary exposure to abamectin for all population subgroups is less than 30% of the ADI. This means that potential chronic exposure to abamectin will not affect your health.

Table A1-3 Summary of chronic dietary risk for abamectin

Population subgroup	Food and drinking water[1,2] – previous assessment	Food and drinking water[1,2] – Updated to include the proposed MRLs
	%ADI[3,4]	%ADI[3,5]
General Population	7.7	**10.3**
All Infants	16.6	**29.6**
Children 1–2 years old	20.2	**26.2**
Children 3–5 years old	15.3	**18.3**
Children 6–12 years old	9.3	**10.9**
Youth 13–19 years old	5.9	**7.2**
Adults 20–49 years old	6.7	**9.1**
Adults 50+ years old	6.5	**9.2**
Females 13-49 years old	6.4	**8.8**

Bolded values indicate updated risk assessments
[1] "Food and Drinking Water" represents all Canadian-grown and imported foods that could be treated with abamectin, as well as the dietary contribution from consuming water that may be impacted by Canadian agricultural uses of abamectin.
[2] For the previous assessment, the "Estimated Environmental Concentrations" (EECs) of abamectin were calculated for drinking water at 0.49 µg a.i./L from surface water. For the updated assessment, the "Estimated Environmental Concentrations" (EECs) of abamectin were calculated for drinking water at 0.91 µg a.i./L from surface water. Note: for imported food commodities, the pesticide for that specific import use is not applied in Canada and will not impact drinking water. As noted in footnote 1, potential exposure via drinking water is considered for the overall risk assessment, which includes both Canadian registered uses and imports.
[3] Values are below 100% (PDI ÷ ADI × 100), therefore, there are no dietary concerns for any segment of the population.
[4] Previous assessment from submission 2013-4347. Published documents can be accessed in the link by choosing "Application Number" in the "Filter" field, and entering the submission number in the "Value" field.
[5] Updated assessment is from PRVD2023-01.