Proposed Maximum Residue Limit PMRL2023-40

Tolfenpyrad

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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 to their crops and livestock from pests. The reason pesticides are used is to 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). Pesticide residues that may be present on food commodities **imported** into Canada are also regulated. 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 MRLs after a robust scientific review and provided that the risks meet Health Canada's requirements for the protection of human health. Health Canada is responsible for establishing 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 scientifically based 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 5.0 Calculating the proposed MRL. Often, the residues that remain are much lower 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.

Imported food commodities

For the purposes of setting 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 so potential exposure to the residue from that commodity is only through the diet. For example, Canadian workers, such as a grower will not be exposed, and no exposure to the Canadian environment is expected.

However, if the pesticide is registered for other uses in Canada, a full health, environment and value assessment would be conducted prior to any registration decision for those uses. This would ensure there are no health or environmental concerns, and 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 MRLs, as well as proposed MRL increases and decreases to address potential tolfenpyrad residues on various imported food commodities.

Tolfenpyrad is an insecticide not currently registered for use in Canada, and, as such, there are no associated Canadian labels or uses. The proposed new and revised MRLs listed below were requested by Nichino America Inc., to align Canada's new and current MRLs for tolfenpyrad with those of the United States of America (US). This was done so these commodities, or any of their derived processed food commodities that may contain tolfenpyrad residues, can be imported and sold in Canada.

The following outlines the reasons for the proposed new and revised MRLs:

- The proposed MRL **increase** to potential tolfenpyrad residues on **imported** arugula, garden cress and upland cress is due to new data on mustard greens (a representative crop of crop subgroup 4-13B);
- The proposed MRL **decrease** to potential tolfenpyrad residues on **imported** citrus oil and citrus fruits from the US is due to the decreased application rate in the exporting country; and
- The proposed specification of **new** MRLs is due to the potential presence of tolfenpyrad residues on various **imported** food commodities. For example:

    - **extending** Canada's current MRL on potatoes to all tuberous and corm vegetables (crop subgroup 1C).
    - **extending** Canada's current MRLs on leafy vegetables except *Brassica* (crop group 4, except spinach) to the commodities without current MRLs in the updated crop subgroup of leafy greens (crop subgroup 4-13A, except spinach and endive).
    - **extending** Canada's current MRL on undelinted cotton seeds to all commodities within the cottonseed crop subgroup (crop subgroup 20C, revised).
    - **specifying** new MRLs on bulb onions (crop subgroup 3-07A), green onions (crop subgroup 3-07B), *Brassica* leafy greens (crop subgroup 4-13B), fruiting vegetables (crop group 8-09) and pome fruits (crop group 11-09).

The new and revised MRLs are proposed, because the health risk from eating food commodities treated with tolfenpyrad meet 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*.

Proposed Canadian MRLs for tolfenpyrad

Table 1 summarizes the proposed new and revised MRLs for tolfenpyrad.

Table 1 Proposed maximum residue limits for tolfenpyrad

Common name	Residue definition[1]	Current MRL (ppm)[2]	Proposed MRL (ppm)[2]	Food commodity
Tolfenpyrad	4-chloro-3-ethyl-1-methyl-*N*-[[4-(4-methylphenoxy)phenyl] methyl]-1*H* pyrazole-5-carboxamide	30 for arugula, garden cress and upland cress; no current MRLs on other commodities within this crop subgroup	40	*Brassica* leafy greens (crop subgroup 4-13B)
		70 for citrus oil; no current MRL on the other listed commodities.	30	Citrus oil; bitter lettuce, blackjack, cat's whiskers, cham-chwi, cham-na-mul, Chinese amaranth, Chinese violets, chipilin, buckhorn plantain leaves, cosmos, dang-gwi, dol-nam-mul, ebolo, English primrose, escaroles, fameflowers, feather cockscombs, fresh cilantro leaves, fresh dillweed leaves, good King Henry, huauzontles, Indian asters, jute leaves
		None	10	Green onions (crop subgroup 3-07B)
		None	1.5	Fruiting vegetables (crop group 8-09)
		None	1.0	Pome fruits (crop

Common name	Residue definition[1]	Current MRL (ppm)[2]	Proposed MRL (ppm)[2]	Food commodity
				group 11-09, except apples)
		1.5	0.8	Citrus fruits (crop group 10) (revised)
		0.7 for undelinted cotton seeds only	0.7	Cottonseeds (crop subgroup 20C) (revised)
		None	0.09	Bulb onions (crop subgroup 3-07A)
		0.01 for potatoes; no current MRLs on other commodities within this crop subgroup	0.01	Tuberous and corm vegetables (crop subgroup 1C)

[1] Residue Definition upon which MRLs are based typically includes the pesticide itself and sometimes also includes 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.

[2] 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 tolfenpyrad. This is because these new and revised MRLs meet Health Canada's requirements for the protection of human health.

The proposed new and revised MRLs were requested to align Canada's proposed and current MRLs for tolfenpyrad with the US tolfenpyrad tolerances.

- The term "**tolerance**" is used in the US to describe the maximum residue limit.
- The requests are based on new or different application rates registered for use in the US, on commodities that will be imported into Canada.

3.0 Dietary risk assessment

Before an MRL can be set, scientists from Health Canada make sure the amount of pesticide residue on or in food commodities is low enough that there are no effects on human health. Scientists 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 toxicological hazards of the pesticide;

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

   ADI: the amount of a specific pesticide residue a person could eat every day over their entire lifetime without any negative health effects. This is set considering all vulnerable people such as pregnant people, infants, children, and seniors.

   ARfD: the amount of a specific pesticide residue that a person can eat on any given day without any negative health effects. This is set considering all vulnerable people such as pregnant people, infants, children, and seniors.

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

   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), and how diets can vary between people in Canada. The PDI level is the potential dietary exposure to a specific pesticide.

4. Characterize the human health risk by comparing the PDI level with the acceptable daily intake (ADI) level and ARfD level, if applicable.

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

When assessing dietary risk, both acute, if applicable, and chronic dietary intakes are estimated for the general population and several sub-populations such as pregnant people, infants, children, and seniors.

Summary of the dietary risk assessment results for tolfenpyrad

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

The results from the dietary risk assessment show that when tolfenpyrad is used according to the label directions for the various proposed uses registered in the US, the dietary risks continue to meet Health Canada’s requirements for the protection of human health.

The acute or short-term dietary risk assessment results showed that exposure to tolfenpyrad is **less than 67%** of the ARfD level. **This means that acute exposure to tolfenpyrad will not affect your health.** The dietary risk for each subpopulation is reported in Table A1-2 of Appendix I.

- Health Canada's level of concern for acute risk is 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 there are no short-term human health concerns from eating foods treated with tolfenpyrad on a given day.

The chronic or long-term dietary risk assessment results showed that exposure to tolfenpyrad is **less than 6%** of the ADI level. **This means that chronic exposure to tolfenpyrad will not affect your health.** The dietary risk for each subpopulation is reported in Table A1-3 of Appendix I.

- Health Canada's level of concern for chronic risk is 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 long-term human health concerns from eating foods treated with tolfenpyrad 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:

- PMRA Guidance Document, *Updated Residue Chemistry Guidelines: Revised 2022* - Canada.ca

4.0 Summary of residue data to support the proposed MRLs

The required residue data from field trial studies for tolfenpyrad were submitted and reviewed to support the proposed MRLs on the following imported commodities: imported dry bulb onions, green onions, mustard greens, tomatoes, peppers, oranges, lemons, grapefruits, pears and apples (apples are a representative crop for pome fruits). Previously reviewed residue data from field trials conducted on head lettuce, leaf lettuce, and potatoes were re-assessed for this request.

In addition, experimental processing data on treated apples (as a representative crop for pome fruits) and tomatoes were submitted and reviewed. Previously reviewed experimental processing data conducted on oranges and potatoes were re-assessed to determine the potential for concentration of tolfenpyrad residues in processed food commodities. Examples of processed commodities are juice or oil from oranges, paste or puree from tomatoes, juice from apples, and chips or flakes from potatoes.

In the submitted field trial studies, tolfenpyrad was applied in grams of active ingredient per hectare (g a.i./ha) at ranges of:

- 451-477 g a.i./ha for tuberous and corm vegetables (crop subgroup 1C), which aligns with the US registered label rate of 470–492 g a.i./ha.
- 780-809 g a.i./ha for bulb vegetables (crop subgroups 3-07A and 3-07B), which aligns with the US registered label rate of 818–840 g a.i./ha.
- 447-470 g a.i./ha for leafy greens (crop subgroup 4-13A), which aligns with the US registered label rate of 470–493 g a.i./ha.
- 459-465 g a.i./ha for *Brassica* leafy greens (crop subgroup 4-13B), which aligns with the US registered label rate of 470–493 g a.i./ha.
- 453-480 g a.i./ha for fruiting vegetables (crop group 8-09), which aligns with the US registered label rate of 470–493 g a.i./ha.
- 306-325 g a.i./ha for citrus fruits (crop group 10, revised), which aligns with the US registered label rate of 302–314 g a.i./ha.
- 444-461 g a.i./ha for pome fruits (crop group 11-09), which is 0.75-fold the US registered label rate of 605–628 g a.i./ha. Therefore, residues of tolfenpyrad from the field trial study were scaled up by a factor of 1.4-fold to account for the rate difference.
- 454-470 g a.i./ha for cottonseed (crop subgroup 20C, revised), which aligns with the US registered label rate of 470–493 g a.i./ha.

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

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

Commodity	Application method/ Total application rate (g a.i./ha)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2]	Highest average field trial residues (ppm)[2]	Experimental processing factor[3]
Potatoes	Foliar ground application / 451–477	13–14	<0.01	<0.01	Flakes and Chips: No quantifiable residues observed at exaggerated rates
Dry bulb onions	Foliar ground application / 780–809	6–8	<0.01	0.047	Not applicable

Commodity	Application method/ Total application rate (g a.i./ha)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2]	Highest average field trial residues (ppm)[2]	Experimental processing factor[3]
Green onions	Foliar ground application / 787–796	6–8	0.647	4.89	Not applicable
Head lettuce (with wrapper leaves)	Foliar ground application / 447–470	1	0.122	3.59	Not applicable
Leaf lettuce	Foliar ground application / 451–461	1	0.873	13.3	Not applicable
Mustard greens	Foliar ground application / 459–465	1	1.94	18.55	Not applicable
Tomatoes	Foliar ground application / 453–480	1	0.060	0.339	Puree: 0.3-fold [0.3 (unrounded processing factor) × 0.129 ppm (average concentration of residues in treated whole tomatoes) = 0.036 ppm] Paste: onefold [0.9 (unrounded processing factor) × 0.129 ppm (average concentration of residues in treated whole tomatoes) = 0.12 ppm]
Bell peppers	Foliar ground application / 456–463	1	0.046	0.158	Not applicable

Commodity	Application method/ Total application rate (g a.i./ha)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2]	Highest average field trial residues (ppm)[2]	Experimental processing factor[3]
Non-bell peppers	Foliar ground application / 461–465	1	0.125	0.289	Not applicable
Oranges	Foliar ground application / 306–325	3	0.044	0.319	Juice: 0.02-fold [0.02 (unrounded processing factor) × 0.319 ppm (average concentration of residues in treated whole oranges) = 0.01 ppm] Citrus Oil: 82-fold [82 (processing factor) × 0.372 ppm (average concentration of residues in treated whole lemons) = 30.5 ppm[4]]
Lemons	Foliar ground application / 306–316	3	0.129	0.372	
Grapefruits	Foliar ground application / 306–319	3	0.017	0.271	
Apples	Foliar ground application / 445–453	13-14	0.102	0.316	Juice: 0.05-fold [0.05 (unrounded processing factor) × 0.206 ppm (average concentration of residues in treated whole apples) = 0.01 ppm]

Commodity	Application method/ Total application rate (g a.i./ha)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)[2]	Highest average field trial residues (ppm)[2]	Experimental processing factor[3]
Pears	Foliar ground application / 444–461	14	0.049	0.356	Not applicable

[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 indicates that residues of tolfenpyrad do not concentrate in the processed commodity, and a separate MRL does not need to be set for the processed commodity, as residues of tolfenpyrad will be covered off by the proposed MRL for the raw commodity.
[4] The residues of tolfenpyrad in citrus oil exceed the proposed MRL on citrus fruits, therefore a separate MRL on citrus oil is being proposed.

5.0 Calculating the proposed MRLs

The proposed MRLs for tolfenpyrad were calculated using the residues observed in the residue trials and the guidance provided in the OECD MRL Calculator. This statistically based calculator is used by many international regulatory authorities to set MRLs on food commodities 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. 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 tolfenpyrad, the differences are based on different application rates or new or additional crop residue data for these commodities in the US (see bullet 1 above).

Table 3 compares the MRLs proposed for tolfenpyrad in Canada with the corresponding American 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 American tolerance is listed by pesticide in the Electronic Code of Federal Regulations, 40 CFR Part 180

The Codex MRL is listed by pesticide or commodity on the Codex Alimentarius Pesticide Index

Table 3 Comparison of Proposed Canadian MRLs, American tolerances and Codex MRLs

Food commodity	Canadian MRL (ppm)[1]	American tolerance (ppm)[1]	Codex MRL (ppm)[1]
Brassica leafy greens (crop subgroup 4-13B)	**40**	40	Not established
Citrus oil	**30**	30	80
Bitter lettuce, blackjack, cat's whiskers, cham-chwi, cham-na-mul, Chinese amaranth, Chinese violets, chipilin, buckhorn plantain leaves, cosmos, dang-gwi, dol-nam-mul, ebolo, English primrose, escaroles, fameflowers, feather cockscombs, fresh cilantro leaves, fresh dillweed leaves, good King Henry, huauzontles, Indian asters, jute leaves	**30**	30 (leafy greens, subgroup 4-16A)	Not established
Green onions (crop subgroup 3-07B)	**10**	10	Not established
Fruiting vegetables (crop group 8-09)	**1.5**	1.5	0.5 (peppers subgroup)
Pome fruits (crop group 11-09, except apples)	**1.0**	1.0 (including apples)	Not established
Apples	**Not established**	1.0 (Fruit, pome, group 11-10)	Not established

Food commodity	Canadian MRL (ppm)[1]	American tolerance (ppm)[1]	Codex MRL (ppm)[1]
Citrus fruits (crop group 10) (revised)	**0.8**	0.80	0.9 (lemons and limes (including citron) subgroup) 0.9 (mandarins (including mandarin-like hybrids) subgroup) 0.6 (oranges, sweet, sour (including orange-like hybrids) subgroup) 0.6 (pummelo and grapefruits (including shaddock-like hybrids among other grapefruit) subgroup)
Cottonseeds (crop subgroup 20C) (revised)	**0.7**	0.70	Not established
Bulb onions (crop subgroup 3-07A)	**0.09**	0.09	0.09
Tuberous and corm vegetables (crop subgroup 1C)	**0.01**	0.01	0.01 (Potato)

[1] ppm = parts per million

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

7.0 Next steps

Health Canada invites the public to submit written comments on the proposed new and revised MRLs for tolfenpyrad 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 before making a final science-based decision about the proposed MRL. Comments received will be addressed in a separate document linked to this proposed MRL. If no comments are received, or the comments do not result in a change to

the proposed MRL, the established MRL will be legally in effect on the date it is 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 help identify the request:

- Active ingredient: tolfenpyrad
- Published document number: PMRL2023-40
- Submission number: 2019-2759

Appendix I Excerpt of the dietary risk assessment

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

Exposure scenario	Toxicology reference value used in risk assessment	Study	Toxicological endpoint
Acute Dietary **All populations**	NOAEL[1] = 1.6 mg/kg bw CAF[1,2] = 300[2] ARfD[1] = 0.005 mg/kg bw	Two-generation dietary reproductive toxicity study in rats	LOAEL[1] = 3.0 mg/kg bw/day Based on increased pup deaths post-natal days 0 to 4 in the presence of maternal toxicity (in other words, 1.9-fold greater dose than the NOAEL)
Chronic Dietary **All populations**	NOAEL[1] = 1.6 mg/kg bw CAF[1,3] = 300[3] ADI[1] = 0.005 mg/kg bw		LOAEL[1] = 3.0 mg/kg bw/day Based on increased pup deaths post-natal days 0 to 4 in the presence of maternal toxicity (in other words, 1.9-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; PCPA-factor = *Pest Control Products Act*-factor. Reference values cited in submission 2014-1484. 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.

[2] To account for uncertainties including inter- and intra-species variations, a CAF of 300-fold (10-fold for differences between animals and humans, 10-fold for variation between humans, and a threefold PCPA factor) was applied to the NOAEL for potential effects in the young to calculate the ARfD. Therefore, NOAEL÷ CAF = 1.6 mg/kg bw ÷300 = 0.005 mg/kg bw. This is 600-fold (LOAEL÷ARfD) lower than the dose where toxicological effects were observed in animals (at the LOAEL = 3.0 mg/kg bw/day).

[3] To account for uncertainties including inter- and intra-species variations, a CAF of 300-fold (10-fold for differences between animals and humans, 10-fold for variation between humans, and a threefold PCPA factor) was applied to the NOAEL for potential effects in the young to calculate the ADI. Therefore, NOAEL÷CAF = 1.6 mg/kg bw ÷300 = 0.005 mg/kg bw. This is 600-fold (LOAEL÷ADI) lower than the dose where toxicological effects were observed in animals (at the LOAEL = 3.0 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 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

There are no dietary risks of concern when the PDI is less than the ARfD (see Section 3.0), which is the result shown in Table A1-2. 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 tolfenpyrad on the various imported food commodities, the estimated dietary exposure to tolfenpyrad for all population subgroups is less than 67% of the ARfD. **This means that acute exposure to tolfenpyrad will not affect your health.**

Table A1-2 Summary of acute dietary risk for tolfenpyrad

Population subgroup	Refined assessment Food only[1,3] – previous assessment	Refined assessment[5] Food only[1,3] – Updated to include the proposed MRLs[2]
	% ARfD[4,6]	% ARfD[4]
General Population	67.9	**46.0**
All Infants	62.3	**60.4**
Children 1–2 years old	90.0	**58.6**
Children 3–5 years old	77.9	**41.9**
Children 6–12 years old	44.4	**25.7**
Youth 13–19 years old	27.8	**19.0**
Adults 20–49 years old	60.5	**42.3**
Adults 50+ years old	94.0	**66.8**
Females 13–49 years old	66.7	**47.6**

Bolded values indicate updated risk assessments.

1 "Food Only" represents all foods that could be treated with tolfenpyrad, including imported foods.

2 Maximum residues from monitoring data for apples, oranges, potatoes and tomatoes are also included in the risk assessment for their respective processed commodities and associated experimental processing factors.

3 No Estimated Environmental Concentrations (EECs) of tolfenpyrad have been calculated for drinking water, as the pesticide is not applied in Canada, therefore, there will be no impact on drinking water.

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

5 Includes monitoring data for some commodities (maximum value or ½ LOD (limit of detection) when there are no detected residues), which were not previously available. The use of this monitoring data results in lower potential dietary exposures compared to the previous risk assessment. Monitoring data from Canada (CFIA) or the US (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.

6 Previous assessment from submission 2014-1484. 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.

Results of the chronic dietary risk assessment

There are no dietary risks of concern when the PDI is less than the ADI (see Section 3.0), which is the result shown in Table A1-3. 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 tolfenpyrad on the various imported food commodities, the estimated dietary exposure to tolfenpyrad for all population subgroups is less than 6% of the ADI. **This means that chronic exposure to tolfenpyrad will not affect your health.**

Table A1-3 Summary of chronic dietary risk for tolfenpyrad

Population subgroup	Refined assessment Food only[1,3] – previous assessment	Refined assessment[5] Food only[1,3] – Updated to include the proposed MRLs[2]
	% ADI[4,6]	% ADI[4]
General Population	7.2	**2.9**
All Infants	4.3	**4.7**
Children 1–2 years old	11.4	**5.9**
Children 3–5 years old	10.1	**4.2**
Children 6–12 years old	5.9	**2.6**
Youth 13–19 years old	3.4	**2.0**
Adults 20–49 years old	6.7	**2.7**
Adults 50+ years old	9.0	**3.1**
Females 13–49 years old	7.1	**2.6**

Bolded values indicate updated risk assessments.

1 "Food Only" represents all foods that could be treated with tolfenpyrad, including imported foods.

2 Mean residues from the monitoring data for apples, oranges, potatoes and tomatoes are also included in the risk assessment for their respective processed commodities and associated experimental processing factors.

3 No Estimated Environmental Concentrations (EECs) of tolfenpyrad have been calculated for drinking water, as the pesticide is not applied in Canada, therefore, there will be no impact on drinking water.

4 Values are below 100% (PDI ÷ ADI × 100), therefore, there are no dietary concerns for any segment of the population.

5 Includes monitoring data for some commodities (mean value or ½ LOD (limit of detection) when there are no detected residues) and percent imported commodity statistics where appropriate, both of which were not previously available. The use of this monitoring data and percent imported commodity statistics results in lower potential dietary exposures compared to the previous risk assessment. Monitoring data from Canada (CFIA) or the U.S. (United States Department of Agriculture) considers residues taken when the crops are imported into Canada, or when crops are on the way to the marketplace.

6 Previous assessment from submission 2014-1484. 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.