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Proposed Maximum Residue Limit

PMRL2022-11

Fluensulfone

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@hc-sc.gc.ca

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Purpose of consultation

Maximum residue limits (MRLs)¹ for imported commodities are being proposed for the pesticide fluensulfone, as part of the following application under submission number 2020-1209, in order to permit the import and sale of food in Canada that could contain fluensulfone residues. This import MRL proposal does not result in a change of the current approved conditions of use in Canada.

Under the authority of the [Pest Control Products Act](#), Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify maximum residue limits (MRLs) for fluensulfone on various imported commodities, for the management of certain nematode species.

Fluensulfone is an insecticide currently registered in Canada for use on fruiting vegetables (crop group 8-09) and cucurbits (crop group 9).

Health Canada has determined the quantity of residues that may remain in or on the imported commodities when fluensulfone is used according to the label directions of the exporting country, and that such residues will not be a concern to human health. Therefore, the foods containing residues resulting from this use are safe to eat, and MRLs are being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRLs can be found in [Appendix I](#).

Dietary health assessment

In assessing the risk of a pesticide, Health Canada combines information on pesticide toxicity with information on the degree and duration of dietary exposure to the pesticide residue from food. The risk assessment process involves four distinct steps:

- 1) Identifying the toxicology hazards posed by the pesticide;
- 2) Determining the "acceptable dietary level" for Canadians (including all vulnerable populations), which is protective of adverse health effects;
- 3) Estimating human dietary exposure to the pesticide from all applicable sources (domestic and imported commodities); and
- 4) Characterizing human risk by comparing the estimated human dietary exposure to the acceptable dietary level.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, and that such residues will not be a concern to human health (Steps 3 and 4 above). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2 above), Health Canada concludes that consuming residues resulting from use according to label directions approved in the foreign country is not a health concern. The proposed MRL is then subject to consultation to legally specify the MRL on the corresponding imported commodity.

¹ A maximum residue limit (MRL) is the maximum amount of residue that may remain in or on food when a pesticide is used according to label directions.

An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for fluensulfone on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for fluensulfone in accordance with the process outlined in the Next Steps section of this document.

To comply with Canada’s international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the [World Trade Organization](#), as coordinated by [Canada’s Notification Authority and Enquiry Point](#).

Proposed MRLs

The proposed MRLs, to be added to the MRLs already established for fluensulfone, are summarized in Table 1.

Table 1 Proposed maximum residue limits for fluensulfone

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Fluensulfone	5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and the metabolite 5-fluoro-3,4-bis(fluoromethyl)-3-pentene-1-sulfonic acid (expressed as parent equivalents)	20	Leafy <i>Brassica</i> greens (crop subgroup 5B)
		15	Citrus oil
		4.0	Root vegetable (except sugar beet) (crop subgroup 1B), leafy vegetables (except <i>Brassica</i> vegetables) (crop group 4)
		2.0	Potato chips, potato flakes
		1.5	Head and stem <i>Brassica</i> (crop subgroup 5A), raisins
		0.9	Dried apples
		0.8	Tuberous and corm vegetables (crop subgroup 1C), small fruits vine climbing (crop subgroup 13-07D)
		0.5	Low growing berries (crop subgroup 13-07G)
		0.4	Pome fruits (crop group

Common name	Residue definition	MRL (ppm) ¹	Food commodity
			11-09)
		0.3	Citrus fruits (crop group 10) (revised), sugarcane molasses
		0.15	Stone fruits (crop group 12-09)
		0.06	Sugarcane cane
		0.02	Tree nuts (crop group 14-11)

¹ ppm = parts per million

An MRL is proposed for each commodity included in the listed crop groupings in accordance with the [Residue Chemistry Crop Groups](#) webpage in the [Pesticides section](#) of Canada.ca.

MRLs established in Canada may be found using the [Maximum Residue Limit Database](#) on the [Maximum Residue Limits for Pesticides](#) webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International situation and trade implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the geographical locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for fluensulfone in Canada with corresponding US tolerances and Codex MRLs.² The MRLs proposed for fluensulfone in Canada are the same as corresponding American tolerances as listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide, with the exception of dried apples, where the American tolerance for pome fruit applies. A listing of established Codex MRLs is available on the Codex Alimentarius [Pesticide Index](#) webpage, by pesticide or commodity.

² The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of proposed Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Root vegetable (except sugar beet) (crop subgroup 1B)	4.0	4	4 [beetroot, carrot, celeriac, turnip-rooted chervil, horseradish, parsnip, radish, turnip (garden)]
Leafy vegetables (except <i>Brassica</i> vegetables) (crop group 4)	4.0	4	1 (leafy vegetables) 0.8 (head lettuce) 2 (celery) 4 (spinach)
Raisins	1.5	1.5	Not established
Dried apples	0.9	0.4 (under Fruit, pome)	Not established
Tuberous and corm vegetables (crop subgroup 1C)	0.8	0.8	0.8 (potato, sweet potato)
Small fruits vine climbing (crop subgroup 13-07D)	0.8	0.8	Not established
Pome fruits (crop group 11-09)	0.4	0.4	Not established
Citrus fruits (crop group 10) (revised)	0.3	0.3	Not established
Sugarcane molasses	0.3	0.3	Not established
Stone fruits (crop group 12-09)	0.15	0.15	Not established
Sugarcane cane	0.06	0.06	Not established
Tree nuts (crop group 14-11)	0.02	0.02	Not established

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for fluensulfone up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). Health Canada will consider all comments received and a science-based approach will be applied in making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the [Maximum Residue Limit Database](#).

Appendix I

Summary of field trial data used to support the proposed maximum residue limits

Residue data from field trials conducted in Canada and the United States were submitted to support the maximum residue limits (MRLs) on several imported crops/crop groups. Fluensulfone was applied to crops at rates equivalent to those on the foreign registered labels, and harvested according to label directions. In addition, processing studies in treated crops were reviewed to determine the potential for concentration of residues of fluensulfone into processed commodities.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 12% of the acute reference dose, and therefore are not a health concern.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 42% of the acceptable daily intake, and therefore are not a health concern.

Maximum residue limits

The recommendation for MRLs for fluensulfone on imported commodities was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). MRLs to cover total combined residues of fluensulfone and the BSA metabolite in/on crops and processed commodities are proposed as shown in Table 1. Residues in processed commodities not listed in Table 1 are covered under the proposed MRLs for the raw agricultural commodities (RACs).

Table A1 Summary of field trial and processing data used to support the MRLs

Commodity	Application method/Total application rate (kg a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm) ²	Highest average field trial residues (ppm) ²	Experimental processing factor
Radish roots	PPI ³ /4.01–4.13	34–56	0.13	3.51	Not required
Carrot roots	PPI/4.0–4.2	76–177	<0.02	2.20	
Turnip roots	PPI or DRIP ⁴ /3.97–4.02	83–115	<0.02	0.58	
Potatoes	PPI/4.0–4.3	71–148	0.08	0.60	Potato chips: 1.6× Potato flakes: 2.4×
Head lettuce	PPI or DRIP/3.93–4.07	53–96	<0.02	0.43	Not required

Commodity	Application method/Total application rate (kg a.i./ha)¹	Preharvest interval (days)	Lowest average field trial residues (ppm)²	Highest average field trial residues (ppm)²	Experimental processing factor
Leaf lettuce	PPI or DRIP/3.91–4.02	43–116	<0.02	1.36	
Spinach	PPI or DRIP/3.97–4.13	64–88	<0.02	1.78	
Celery	PPI or DRIP/3.95–4.18	78–104	<0.02	1.03	
Cabbages	PPI or DRIP/3.93–4.13	66–94	0.05	1.11	Not required
Cauliflowers	PPI or DRIP/3.82–3.99	63–137	<0.02	0.28	
Mustard greens	PPI or DRIP/3.97–4.19	34–71	0.12	6.49	
Mizuna	PPI or DRIP/3.93–4.15	36–90	0.78	7.98	
Grapefruits	Chemigation/3.98–4.01	58–60	<0.02	0.08	Juice: <0.3× Oil: <0.5 – >70× Marmalade: <0.2×
Lemons	Chemigation/4.0	60–61	<0.02	0.13	
Oranges	Chemigation/3.99–4.01	58–60	<0.02	0.07	
Apples	Chemigation/3.91–4.16	91–165	<0.02	0.16	Juice: 1.7× Sauce: 1×
Pears	Chemigation/3.91–4.06	62–151	<0.02	0.21	Dried apples: 5.5×
Sweet cherries and tart cherries	Chemigation/3.96–4.07	43–83	<0.02	0.05	Dried plums: 2.9× Plum juice: 1.2× Plum puree: 0.9×
Peaches	Chemigation/3.99–4.02	48–141	<0.02	0.08	
Plums	Chemigation/3.98–4.01	65–144	<0.02	0.03	
Grapes	Chemigation/3.96–4.05	61–143	<0.02	0.49	Raisins: 2.4× Juice: 0.74×
Fuzzy kiwifruit	Chemigation/3.98–4.02	123–157	<0.02	0.32	

Commodity	Application method/Total application rate (kg a.i./ha)¹	Preharvest interval (days)	Lowest average field trial residues (ppm)²	Highest average field trial residues (ppm)²	Experimental processing factor
Strawberries	PPI or DRIP/3.89–4.01	62–199	<0.02	0.28	Not applicable
Almond nuts	Chemigation/3.96–4.02	60–90	<0.02	<0.02	Not applicable
Pecan nuts	Chemigation/3.96–4.02	57–90	<0.02	<0.02	
Sugarcane cane	Chemigation/3.88–4.18	235–265	<0.02	0.04	Molasses: 7.3× Refined sugar: <0.4×

¹ kg a.i./ha = kilograms of active ingredient per hectare

² Total combined residues of fluensulfone and the metabolite BSA, expressed in parent equivalent

³ PPI = Pre-plant incorporated

⁴ DRIP = Drip irrigation

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover total combined residues of fluensulfone and the metabolite BSA, expressed in parent equivalents. Dietary risks from exposure to total combined residues of fluensulfone in these imported crop commodities at the proposed MRLs were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus the imported foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
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3106567	2014, Magnitude of the Residue of MCW-2 in Strawberries, DACO: 7.4.1
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3106569	2014, Magnitude of the Residue of MCW-2 in Radish, DACO: 7.4.1
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3106572	2016, Magnitude of the Residue of MCW-2 in Stone Fruit (Cherry, Peach and Plum), DACO: 7.4.1
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3232680	2016, Magnitude of Residue of MCW-2 in Peanut and Peanut Processed Commodities, DACO 7.4.1