Proposed Maximum Residue Limit PMRL2023-02

Spiropidion

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Purpose of consultation

Maximum residue limits (MRLs)[1] for **imported** commodities are being proposed for the pesticide spiropidion as part of the following application under submission number 2020-4760, in order to permit the import and sale of food in Canada that could contain spiropidion residues.

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 spiropidion on imported commodities of cantaloupe/muskmelon, watermelon, cucumber, winter squash, pumpkin, tomatoes, bell peppers, non-bell peppers, potatoes and soybeans to control white flies.

Spiropidion is an insecticide not currently registered for use in Canada.

Health Canada has determined the quantity of residues that may remain in or on the imported commodities when spiropidion 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 health 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).

[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.

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.

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 spiropidion on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for spiropidion 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 for spiropidion are summarized in Table 1.

Table 1 Proposed maximum residue limits for spiropidion

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Spiropidion	3-(4-chloro-2,6-dimethylphenyl)-8-methoxy-1-methyl-2-oxo-1,8-diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate and its metabolite 3-(4-chloro-2,6-dimethylphenyl)-4-hydroxy-8-methoxy-1-methyl-1,8-diazaspiro[4.5]dec-3-en-2-one, expressed as parent equivalents.	7.0	Dried tomatoes
		5.0	Potato flakes
		3.0	Dry soybeans
		1.5	Potatoes, tomato paste
		1.0	Bell peppers, non-bell peppers
		0.9	Cantaloupes, muskmelons (other than those listed in this item), pumpkins, watermelons, winter squash
		0.8	Cucumbers, tomatoes

[1] ppm = parts per million

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 spiropidion in Canada with corresponding American tolerances and proposed Codex MRLs.[2] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Once established, a listing of established Codex MRLs will be available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity.

Table 2 Comparison of proposed Canadian MRLs, American tolerances and Codex MRLs

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Bell peppers, non-bell peppers	1.0	1.5	1 (peppers, subgroup of (except martynia, okra, roselle))
Dried tomatoes	7.0	Not established	7
Tomato paste	1.5	Not established	1.5
Potato flakes	5.0	Not established	5
Cantaloupes, muskmelons, watermelons, winter squash, pumpkins	0.9	0.9 (muskmelon, pumpkin, watermelon)	0.9 (melons (except watermelon), pumpkins, watermelon, winter squash)
Dry soybeans	3.0	3	3
Potatoes	1.5	1.5	1.5
Cucumbers	0.8	0.8	0.8
Tomatoes	0.8	0.8	0.8

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

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for spiropidion 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 for spiropidion were submitted to support the maximum residue limits on imported cantaloupes, cucumbers, tomatoes, bell peppers, non-bell peppers, potatoes and soybeans. In addition, processing studies in treated potatoes, soybeans, and tomatoes were reviewed to determine the potential for concentration of residues of spiropidion in processed commodities.

Dietary risk assessment results

Acute dietary (food only) intake estimates indicated that the general population and all population subgroups (except females 13 to 49 years of age) are exposed to less than 6% of the acute reference dose, and therefore there are no health concerns. Acute dietary (food only) intake estimates indicated that females 13 to 49 years of age are exposed to less than 18% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food only) intake estimates indicated that the general population and all population subgroups are exposed to 5% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for total combined residues of spiropidion and the metabolite SYN547305 on imported commodities was based upon the residues observed in crop commodities treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported cantaloupes, watermelons, cucumbers, winter squash, tomatoes, bell peppers, non-bell peppers, potatoes and soybeans.

Table A1 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
Potatoes	Foliar applications/ 343–373	6–8	0.02	0.896	**Potato Flakes** *Spiropidion*: No concentration in processed fraction. *SYN547305*: 3.5×
Soybean seeds	Foliar applications/ 348–375	10–16	0.02	1.76	*Spiropidion:* no concentration in soybean flour and soybean oil.

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
					SYN547305: soybean flour - 1.6×; no concentration in soybean oil
Tomatoes	Foliar applications/ 530–565	1	0.029	0.503	**Tomato paste** *Spiropidion*: 0.3× *SYN547305*: 3.7× **Dried tomato** *Spiropidion*: 2.9× *SYN547305*: 12.2×
Bell peppers	Foliar applications/ 539–563	1	0.106	0.493	Not required
Non-bell peppers	Foliar applications/ 534–554	1	0.073	0.693	Not required
Cucumbers	Foliar applications/ 532–550	1	0.115	0.440	Not required
Cantaloupes	Foliar applications/ 536–558	1	0.117	0.526	Not required

[1] g a.i./ha = grams of active ingredient per hectare
[2] Total combined residues of spiropidion and the metabolite SYN547305, expressed as parent equivalents

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover total combined residues of spiropidion and the metabolite SYN547305, expressed as parent equivalents. Dietary risks from exposure to total combined residues of spiropidion in these imported crop commodities 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
3161375	2019, SYN546330 SC (A20262B) - Magnitude of the Residues in or on Potato as a Representative Crop of Tuberous and Corm Vegetables, Subgroup 1C - USA 2017, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
3161376	2019, SYN546330 SC (A20262B) - Magnitude of the Residues in Soybeans USA 2017, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
3161377	2019, SYN546330 SC (A20262B) - Magnitude of the Residue in or on Tomatoes, Peppers, and Eggplant (Representative Commodities of Fruiting Vegetables Crop Group 8) and Tomato Processed Commodities USA, 2017 and 2018, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
3161378	2019, SYN546330 (A20262B) - Magnitude of the Residues in Cucumber, Cantaloupe, and Summer Squash Representative Crops for Crop Group 9 - Cucurbit Vegetables, USA 2017, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1
3161379	2019, SYN546330 SC (A20262B) - Magnitude of the Residues in or on Potato as a Representative Crop of Tuberous and Corm Vegetables, Subgroup 1C - CAN 2017, DACO: 7.4.1,7.4.2,7.4.6,IIA 6.3.1