Proposed Maximum Residue Limit PMRL2024-20

Spiromesifen

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Purpose of consultation

Maximum residue limits (MRLs)[1] for **imported** commodities are being proposed for the pesticide spiromesifen as part of the following application under submission number 2022-6469, in order to permit the import and sale of food in Canada that could contain spiromesifen 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 MRLs for spiromesifen on imported oranges to control or supress certain insects.

Spiromesifen is an insecticide currently registered in Canada for use on various commodities.

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

Before registering a pesticide for food use in Canada, Health Canada must determine the quantity of residues that could remain in or on the food when the pesticide is used according to label directions 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 approved label directions is not a health concern. The proposed MRL is then subject to consultation to legally specify it as an MRL.

[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 for certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for spiromesifen on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for spiromesifen in accordance with the process outlined in the How to get involved 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 spiromesifen, are summarized in Table 1.

Table 1 Proposed maximum residue limits for spiromesifen

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Spiromesifen	2-oxo-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutanoate, including the metabolite 4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one	30	Citrus oil
		0.15	Oranges

[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 geographic locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for spiromesifen in Canada with corresponding tolerances in the United States (U.S.) and Codex MRLs.[2] U.S. tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity.

Table 2 Comparison of proposed Canadian MRLs, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Codex MRL (ppm)
Citrus oil	30	10 (Orange subgroup 10-10A, oil)	30 (Orange oil, edible)
Oranges	0.15	0.15	0.15 (Oranges, sweet, sour (including Orange-like hybrids) subgroup)

How to get involved

Health Canada invites the public to submit written comments on the proposed MRL for spiromesifen up to 75 days from the date of publication of this document (by 10 December 2024). Please forward your comments to Publications. 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 response to comments document found in Pesticides and pest management consultations. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

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

Appendix I

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

Residue data for spiromesifen on oranges were submitted to support the maximum residue limit on oranges. In addition, a processing study in treated oranges was reviewed to determine the potential for concentration of residues of spiromesifen in processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of spiromesifen is not likely to cause acute health effects in the general population (including infants and children).

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 57% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for spiromesifen on oranges and citrus oil 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 for spiromesifen and the metabolite spiromesifen-enol used to calculate the proposed MRLs for oranges and citrus oil.

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
Oranges	Foliar/137–149	21	<0.020	0.103	*Citrus Oil*: Spiromesifen: 210× Spiromesifen-enol: 9.2×

[1] g a.i./ha = grams of active ingredient per hectare

[2] Sum of residues of spiromesifen plus spiromesifen-enol, expressed as parent equivalents

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover total residues of spiromesifen and the metabolite spiromesifen-enol. Dietary risks from exposure to total residues of spiromesifen and the metabolite spiromesifen-enol in oranges and citrus oil 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 Number	Citation
3417237	2016, Amendment n° 01 to the final report - Determination of the residues of spiromesifen and its metabolite spiromesifen-enol in/on citrus (fruits) after spraying of Oberon in the field in Brazil, DACO: 7.4.1,7.4.2
3417238	2018, Oberon 240 SC - Magnitude of the residues in/on citrus; import tolerances, DACO: 7.4.1,7.4.2
3417239	2020, Determination of the residues of spiromesifen in/on orange (fruit and juice) after spraying of FTB: 102000026994 in the field in Brazil, DACO: 7.4.1,7.4.2
3417240	2020, Determination of the residues of abamectin and spiromesifen in/on orange (fruit) after spraying of FTB:102000031748 in the field in Brazil, DACO: 7.4.1,7.4.2
3417241	2018, Oberon 240 SC (Spiromesifen) - Magnitude of the residue in/on citrus processed commodities, DACO: 7.4.5