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Proposed Maximum Residue Limit

PMRL2014-24

# Spiromesifen

*(publié aussi en français)*

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Publications  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6604-E2  
Ottawa, Ontario K1A 0K9

Internet: [pmra.publications@hc-sc.gc.ca](mailto:pmra.publications@hc-sc.gc.ca)  
[healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra)  
Facsimile: 613-736-3758  
Information Service:  
1-800-267-6315 or 613-736-3799  
[pmra.infoserv@hc-sc.gc.ca](mailto:pmra.infoserv@hc-sc.gc.ca)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish a Maximum Residue Limit (MRL) for spiromesifen on dry tea leaves to permit the import and sale of tea containing such residues.

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

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when spiromesifen is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as a MRL on the corresponding imported commodity. A MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for spiromesifen is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to be added to the MRLs already established for spiromesifen, are as follows:

**Table 1 Proposed Maximum Residue Limits for Spiromesifen**

Common name	Residue definition	MRL (ppm) <sup>1</sup>	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	60	Tea (dried leaves)

<sup>1</sup> 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

Table 2 compares the MRL proposed for spiromesifen in Canada with the corresponding American tolerance and Codex MRL.<sup>1</sup> American 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 Residues in Food website, by pesticide or commodity.

**Table 2 Comparison of Canadian Maximum Residue Limits, American Tolerances and Codex MRLs (where different)**

<b>Food Commodity</b>	<b>Canadian MRL (ppm)</b>	<b>American tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
Tea (dried leaves)	60	40	No MRL is established

## Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spiromesifen 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). The PMRA will consider all comments received before 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.

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<sup>1</sup> 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 in tea were submitted to support the MRL on imported dry tea leaves. In addition, processing data was reviewed to determine the potential for concentration of residues of spiromesifen into tea processed commodities.

#### Maximum Residue Limits

The recommendation for MRLs for spiromesifen was based on the residues observed in tea treated according to label directions in the exporting country, and the guidance provided in the Organisation for Economic Co-operation and Development's MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported tea.

**Table A1. Summary of Field Trial and Processing Data Used to Support the Maximum Residue Limits**

Commodity	Application Method/ Total application rate (g a.i./ha)	Preharvest Interval (days)	Residues <sup>1</sup> (ppm)		Experimental processing factor
			Min	Max	
Fresh tea leaves	Foliar/600	7	0.64	9.99	3.26 (black tea)
Crude green tea leaves	Foliar/600	7	6.32	21.07	None
Crude green tea leaves	Foliar/600	7	6.16	21.75	None

<sup>1</sup> Total residues of spiromesifen and the -enol metabolite

Following the review of all available data, the MRLs as proposed in Table 1 is recommended to cover total residues of spiromesifen. Total residues of spiromesifen in this imported commodity at the proposed MRLs will not pose an unacceptable risk to any segment of the population.