

Proposed Maximum Residue Limit

PMRL2023-03

Methomyl

(publié aussi en français)

19 January 2023

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications Pest Management Regulatory Agency Health Canada 2 Constellation Drive 8th Floor, A.L. 2608 A Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides pmra.publications-arla@hc-sc.gc.ca

Information Service: 1-800-267-6315 pmra.info-arla@hc-sc.gc.ca



ISSN: 1925-0835 (print) 1925-0843 (online)

Catalogue number: H113-24/2023-3E (print version)

H113-24/2023-3E-PDF (PDF version)

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2023

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

Purpose of consultation

Maximum residue limits (MRLs)¹ for **imported** commodities are being proposed for the pesticide methomyl as part of the following application under submission number 2021-1743, in order to permit the import and sale of food in Canada that could contain methomyl 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 <u>Pest Control Products Act</u>, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify MRLs for methomyl on imported commodities of head lettuce and leaf lettuce, to control or suppress certain insects.

Methomyl is an insecticide currently registered in Canada for use on broccoli, Brussels sprouts, cabbage, cauliflower, sweet corn and succulent peas.

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

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.

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. 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 methomyl on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for methomyl 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 <u>World Trade Organization</u>, as coordinated by <u>Canada's Notification Authority and Enquiry Point</u>.

Proposed MRLs

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

Table 1 Proposed maximum residue limits for methomyl

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Methomyl	methyl N-	5.0	Head lettuce,
	[[(methylamino)carbonyl]oxy]ethanimidothioate		leaf lettuce

 $[\]frac{1}{1}$ ppm = parts per million

MRLs established in Canada may be found using the <u>Maximum Residue Limit Database</u> on the <u>Maximum Residue Limits for Pesticides</u> 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 methomyl in Canada with corresponding American tolerances and Codex MRLs.² American tolerances are listed in the <u>Electronic Code of Federal Regulations</u>, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius <u>Pesticide Index</u> webpage, by pesticide or commodity.

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)
Head lettuce, leaf lettuce	5.0	5 (lettuce)	0.2

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for methomyl 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.

⁻

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 methomyl, conducted at exaggerated rates (up to 3.8-fold the United States Good Agricultural Practice application rate), were submitted to support the maximum residue limits on imported lettuce. In addition, a more contemporary lettuce metabolism study was reviewed to confirm the residue definition in plant 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 23% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 48% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for methomyl on imported commodities was based upon the residues observed in crop commodities treated according to exaggerated rates 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 head lettuce and leaf lettuce.

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

Commodity	Application method/Total application rate (kg a.i./ha) ¹	Preharvest interval (days)	Minimum residues (ppm)	Maximum residues (ppm)
Head lettuce	Foliar broadcast/16	8–10	0.3	4.8
Leaf lettuce	Foliar broadcast/15	10	0.3	6.5^2

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

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of methomyl. Dietary risks from exposure to residues of methomyl 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.

² Residues of methomyl in **leaf lettuce** were in exceedance of the proposed 5.0 ppm MRL at some of the trial sites. However, it is not expected that residues would exceed 5.0 ppm when treated at a maximum seasonal application rate of 4.0 kg a.i./ha and harvested at a preharvest interval of 10 days, as per the American registered label.

References

PMRA#	Citation
1731306	1991, Magnitude of residues of methomyl insecticide in leaf and head lettuce. DACO: 7.4.1
3248072	2014, Metabolism of ¹⁴ C-methomyl in Lettuce (Lactuca Sativa), DACO: 6.3