Proposed Maximum Residue Limit PMRL2019-29

Ethylene Oxide

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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 maximum residue limits (MRLs) for ethylene oxide on dried vegetables and sesame seeds to permit the sale of foods containing such residues.

Ethylene oxide is an insecticide currently registered in Canada for use on whole or ground spices and processed natural seasonings.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when ethylene oxide 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 an 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 where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for ethylene oxide is being conducted via this document (see Next Steps). 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 Canada's Notification Authority and Enquiry Point.

The proposed MRLs, to be added to the MRLs already established for ethylene oxide and its degradation product, ethylene chlorohydrin, are as follows.

Table 1 Proposed Maximum Residue Limits

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Ethylene oxide	Oxirane	7	Dried vegetables, sesame seeds
Ethylene chlorohydrin	2-Chloroethanol	940	Dried vegetables, sesame seeds

[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

The MRLs proposed for ethylene oxide and the degradation product, ethylene chlorohydrin, in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[1] listed for ethylene oxide and the degradation product, ethylene chlorohydrin, in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for ethylene oxide and the degradation product, ethylene chlorohydrin, 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.

[1] 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 from fumigation trials conducted in the United States were submitted to support the additional MRLs for dried vegetables and sesame seeds. Ethylene oxide was applied to several dried vegetables and sesame seeds at rates within the registered rate, and collected according to label directions.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for ethylene oxide and its degradation product ethylene chlorohydrin was based upon the submitted fumigation trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for dried vegetables and sesame seeds.

Table A1 Summary of Field Trial and Processing Data Used to Support the MRLs

Analyte	Application Method/ Total Application Rate (mg a.i./L)/Duration[1]	Post-treatment Interval (hours)	Lowest Average Field Trial Residues[2] (ppm)	Highest Average Field Trial Residues[2] (ppm)	Experimental Processing Factor
ethylene oxide	Fumigation / 300 / 6 hours	24	<LOD	0.255	None
ethylene chlorohydrin		24	<LOD	167	

[1] mg a.i./L = milligrams of active ingredient per litre.
[2] The residues reported are from trials conducted on dried vegetables and sesame seeds.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of ethylene oxide and its degradation product ethylene chlorohydrin. Residues of ethylene oxide and its degradation product ethylene chlorohydrin in these commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.