Proposed Maximum Residue Limit PMRL2023-15

Pyrethrins

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Purpose of consultation

Revocation of the maximum residue limit (MRL)[1] for the pesticide pyrethrins on raw cereals is being proposed as part of the re-evaluation decision under submission number 2004-0238. The objective of the proposed revocation is to address potential dietary risk concerns by limiting residues of pyrethrins on cereals. This proposed MRL revocation accompanies the cancellation of pyrethrins use for the direct application to bulk or bagged stored grain according to the health risk mitigation measures indicated in the re-evaluation decision RVD2023-06.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) determined that continued registration of products containing pyrethrins for sale and use in Canada are acceptable when used according to revised conditions of registration. The revised conditions of registration includes new mitigation measures and the cancellation of certain uses.

The evaluation of pyrethrins was published in the PRVD2020-08. Health Canada had proposed cancellation of the use of pyrethrins for the direct application to bulk or bagged stored grain and the revocation of the MRL for cereal grains due to unacceptable dietary risks. Comments on the evaluation were received through the consultation process, which were considered in the re-evaluation decision (RVD2023-06). However, these did not result in changes to the dietary risk assessment and the re-evaluation decision for pyrethrins cancels the post-harvest use of pyrethrins on bulk or bagged stored cereals. Therefore, the associated MRL for pyrethrins on raw cereals is proposed for revocation.

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.

[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.

Before registering a pesticide for food use in Canada or allowing continued registration, 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 above the acceptable level (developed in Step 2 above), Health Canada concludes that consuming residues resulting from use according to approved label directions is a health concern and that mitigation measures are required to address the risk issue. If the risk mitigation measures require the revocation of an MRL, the proposed MRL revocation is then subject to consultation to legally remove it as an MRL.

The dietary risk assessment for pyrethrins published in PRVD2020-08 indicated risks were not acceptable when the direct application to bulk or bagged stored grain was considered. The proposed mitigation measures included cancellation of this use and revocation of the associated MRL for raw cereals. RVD2023-06 confirmed the dietary risk assessment and mitigation measures, and effected the cancellation of the post-harvest use of pyrethrins on bulk or bagged stored grains. This mitigation does not impact any other of the currently registered food or feed uses of pyrethrins. Based on the identified risk, the MRL for pyrethrins on treated raw cereals is proposed for revocation. Following the revocation of this MRL, these crops will be regulated under subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues not exceed 0.1 ppm.

Consultation on the proposed MRL revocation for pyrethrins on raw cereals is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL change for pyrethrins 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 MRL proposed for revocation is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

MRL proposed for revocation

The MRL proposed for revocation for pyrethrins is summarized in Table 1.

Table 1 Maximum residue limit proposed for revocation for pyrethrins

Common name	Residue definition[1]	Current MRL (ppm)[2,3]	MRL after revocation (ppm) [2,3]	Food commodity
Pyrethrins	The sum of (1*S*)-2-methyl-4-oxo-3-(2*Z*)-2,4-pentadien-1-yl-2-cyclopenten-1-yl (1*R*,3*R*)-2,2-dimethyl-3-(2-methyl-1-propen-1-yl)cyclopropanecarboxylate and (1*S*)-2-methyl-4-oxo-3-(2*Z*)-2,4-pentadien-1-yl-2-	3.0	0.1[4]	Raw cereals

Common name	Residue definition[1]	Current MRL (ppm)[2,3]	MRL after revocation (ppm) [2,3]	Food commodity
	cyclopenten-1-yl (1*R*,3*R*)-3-[(1*E*)-3-methoxy-2-methyl-3-oxo-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate.			

[1] Residue definition revised as per Appendix IV of PRVD2020-08
[2] ppm = parts per million
[3] MRL as pyrethrin 1 and pyrethrin 2
[4] Following the revocation of this MRL, these crops will not appear in the MRL database, but will be regulated under subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues not exceed 0.1 ppm.

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

To mitigate human health risks associated with the dietary exposure to pyrethrins, an MRL is proposed for revocation. Table 2 compares the MRL proposed for revocation in Canada for pyrethrins with corresponding American tolerances and Codex MRLs.

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

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food Commodity	Canadian MRL[1,2,3] (ppm)	American Tolerance[4] (ppm)	Codex MRL[5] (ppm)
Raw cereals	3	Not established	Not established directly, but covered under ‘Cereal grains’
Barley, grain, postharvest	Not established directly, but covered under “Raw cereals”	3	
Buckwheat, grain, postharvest		3	
Corn, field, grain, postharvest		3	
Corn, pop, grain, postharvest		3	
Oat, grain, postharvest		1	

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

Food Commodity	Canadian MRL[1,2,3] (ppm)	American Tolerance[4] (ppm)	Codex MRL[5] (ppm)
Rice, grain, postharvest		3	
Rye, grain, postharvest		3	
Sorghum, grain, grain, postharvest		1	
Wheat, grain, postharvest		3	
Cereal grains (from postharvest treatment)		Not established	0.3

[1] ppm = parts per million
[2] Following the revocation of the MRLs, all crops will be regulated under subsection B.15.002(1) of the Food and Drug Regulations, which requires that residues not exceed 0.1 ppm.
[3] MRL as sum of pyrethrin 1 and pyrethrin 2
[4] Tolerances for residues of the insecticide pyrethrins: pyrethrin 1, pyrethrin 2, cinerin 1, cinerin 2, jasmolin 1, and jasmolin 2, the insecticidally active principles of Chrysanthemum cinerariaefolium, which are measured as cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1
[5] For compliance with MRLs and estimation of dietary intake for plant and animal commodities: Total pyrethrins, calculated as the sum of pyrethrins 1 and 2, cinerins 1 and 2, and jasmolins 1 and 2, determined after calibration with the World Standard pyrethum extract.

Next steps

Health Canada invites the public to submit written comments on the proposed revocation of the MRL for pyrethrins 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 revocation of the MRL. Comments received will be addressed in a separate document linked to this PMRL. The revocation of the MRL will be legally in effect as of the date that it is removed from the Maximum Residue Limit Database. The revocation of the MRL will take effect 36 months from the publication of RVD2023-06, to allow sufficient time for legally treated commodities to clear the channels of trade.

Appendix I

Summaries of the residue chemistry data and references used are reported in PRVD2020-08 and RVD2023-06. Additional information on the dietary risk assessment is provided in PRVD2020-08.

Dietary risk assessment results

As reported in PRVD2020-08, acute dietary (food plus drinking water) refined intake estimates (including cereal commodities) indicated that there were no acute dietary health concerns, as the general population and all population subgroups may be exposed to less than 100% of the acute reference dose (ARfD). Chronic dietary (food plus drinking water) refined intake estimates (including cereals commodities) indicated potential health risks, as the general population and various population subgroups may be exposed to over 100% of the acceptable daily intake (ADI). Cereal commodities were the risk drivers for the most exposed subpopulation (children 1-2 years old) and for the general population, accounting for over 85% of the total exposure.

When applying the mitigation measures of cancelling the post-harvest use of pyrethrins on bulk or bagged stored grains and revoking the MRL for raw cereals, the assessment indicated that there were no acute or chronic dietary health concerns, as the acute dietary (food plus drinking water) risks for the general population and all population subgroups are less than 34% of the ARfD, and the chronic dietary (food plus drinking water) risks to the general population and all population subgroups are less than 70% of the ADI.

Following the review of all available data, the MRL revocation for pyrethrins on raw cereals listed in Table 1 is proposed. Dietary risks from exposure to residues of pyrethrins in the remaining commodities were shown to be acceptable for the general population and all subpopulations, including infants, children, adults, and seniors, and are considered safe to eat.