Proposed Maximum Residue Limit PMRL2022-05

Glufosinate-ammonium

(publié aussi en français)

16 March 2022

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

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

Catalogue number: H113-24/2022-5E (print version)
H113-24/2022-5E-PDF (PDF version)

Purpose of consultation

Maximum residue limits (MRLs)[1] for **imported** commodities are being proposed for the pesticide glufosinate-ammonium as part of the following application under submission number 2018-0708, in order to permit the import and sale of food in Canada that could contain glufosinate-ammonium residues. This import MRL proposal does not result in a change of the current approved conditions of use of glufosinate-ammonium in Canada.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the proposed MRLs for glufosinate-ammonium on various imported commodities, which is used to control or suppress certain weeds.

Glufosinate-ammonium is an herbicide 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 glufosinate-ammonium 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 human risk by comparing the estimated human dietary exposure to the acceptable dietary level.

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.

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

Consultation on the proposed MRLs for glufosinate-ammonium on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for glufosinate ammonium 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 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 glufosinate-ammonium are summarized in Table 1.

Table 1 Proposed maximum residue limits for glufosinate-ammonium

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Glufosinate-ammonium	2-amino-4-(hydroxymethylphosphinyl)butanoic acid monoammonium salt, including the metabolites propanoic acid, 3-(hydroxymethylphosphinyl) and 2-(acetylamino)-4-(hydroxymethylphosphinyl) butanoic acid (expressed as glufosinate free-acid equivalents)	0.6	Avocados
		0.5	Tea (dried leaves)
		0.1	Green coffee beans, mangoes

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

Table 2 compares the MRLs proposed for glufosinate-ammonium in Canada with corresponding American tolerances and Codex MRLs.[2] A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity. Currently, there are no American tolerances listed for glufosinate-ammonium in or on the petitioned commodities on the Electronic Code of Federal Regulations, 40 CFR Part 180.

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)
Avocados	0.6	Not established	0.1 (tropical fruits inedible peel)
Tea (dried leaves)	0.5	Not established	Not established
Mangoes	0.1	Not established	0.1 (tropical fruits inedible peel)
Green coffee beans	0.1	Not established	0.1

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for glufosinate-ammonium 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.

[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 glufosinate-ammonium were submitted to support the maximum residue limits on imported avocados, mangoes, green coffee beans and tea (dried leaves). In addition, processing studies in treated green coffee beans and tea (dried leaves) were reviewed to determine the potential for concentration of residues of glufosinate-ammonium into processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of glufosinate-ammonium 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 55% of the acceptable daily intake, and therefore are not a health concern.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for glufosinate-ammonium 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 used to calculate the proposed MRLs for imported avocados, mangoes, green coffee beans, and tea (dried leaves).

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

Commodity	Application method/ Total application rate (kg ai/ha)[1]	Preharvest interval (days)	Lowest average field trial residues[2] (ppm)	Highest average field trial residues[2] (ppm)	Experimental processing factor
Avocados	Ground spray/3.0	0	<0.030	0.300	Not required
Mangoes	Ground spray/2.9–3.1	0	<0.030	<0.030	Not required
Green coffee beans	Post-emergence directed spray along crop line/0.591–0.623	20	<0.030	<0.030	Instant coffee: 1.3× Roasted coffee beans: 1.5×
Tea (dried leaves)	Soil directed spray/2.6–2.7	10-11	<0.030	0.048	Instant tea: 2.0×

[1] kg ai/ha = kilograms of active ingredient per hectare

[2] Total glufosinate, calculated as the sum of glufosinate, glufosinate propanoic acid and *N*-acetyl glufosinate, expressed as glufosinate free-acid equivalents.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover total residues of glufosinate-ammonium. Dietary risks from exposure to total residues of glufosinate-ammonium 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.

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