Proposed Maximum Residue Limit PMRL2022-06

Flutriafol

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Purpose of consultation

Maximum Residue Limits (MRLs)[1] for **imported** commodities are being proposed for the pesticide flutriafol as part of the following application under submission number 2020-1216, in order to permit the import and sale of food in Canada that could contain flutriafol 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 *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify maximum residue limits (MRLs) for flutriafol on the imported commodities of hops and almonds, to control or suppress certain fungal diseases.

Flutriafol is a fungicide currently registered in Canada for use on apples, grapes, strawberries, and soybeans.

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

[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.

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

Table 1 Proposed maximum residue limits for flutriafol

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Flutriafol	*α*-(2-fluorophenyl)-*α*-(4-fluorophenyl)-1*H*-1,2,4-triazole-1-ethanol	20	Hops (dried cones)
		0.6	Almond nuts

[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 flutriafol 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[2] listed for flutriafol in or on the petitioned commodities on the Codex Alimentarius Pesticide Index webpage.

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

Next steps

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

Appendix I

Summary of field trial data used to support the proposed maximum residue limits

Residue data for flutriafol were submitted to support the maximum residue limits on imported hops and almonds.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups are less than 83% of the acute reference dose, and therefore, are not a health concern.

Chronic dietary (food plus drinking water) intake estimates for the general population and all population subgroups are less than 78% of the acceptable daily intake, and therefore, are not a health concern.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for flutriafol was based upon the residues observed in crop commodities treated according to label directions or 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 hops and almonds.

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

Commodity	Application method/ Total application rate (g a.i./ha)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Hops (dried cones)	Foliar/510	7-8	4.14	7.96
Almond nuts	Foliar /766–771	14	<0.01	0.295

[1] g a.i./ha = grams of active ingredient per hectare

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

References

PMRA#	Citation
3106752	2011, Magnitude and Decline of Flutriafol and Metabolite Residues in/on Raw Agricultural Commodities of Tree Nuts Following Six Applications of Flutriafol 125 g/l SC with a 7-day Retreatment Interval and a 14-day PHI, DACO: 7.2.1,7.4.1,7.4.2,7.4.5
3106751	2014, Magnitude and Decline of Flutriafol and Metabolite Residues in/on Hops Raw Agricultural Commodities Following Four Foliar Applications of Flutriafol 125 g/l SC (2013), DACO: 7.2.1,7.4.1,7.4.2,7.4.5