Proposed Maximum Residue Limit PMRL2023-19

Mefentrifluconazole

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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

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Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide mefentrifluconazole, as part of the following application for Canadian use, under submission number 2021-5872.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested application to add the new commodities in crop subgroups 6-21E (dried shelled beans, except soybeans) and 6-21F (dried shelled peas) to the label of the new end-use product RevyPro Fungicide, containing technical grade actives mefentrifluconazole and prothioconazole, to control or suppress certain fungal diseases. This application would extend the MRL currently established for crop group 6 (legume vegetables, except dry lentils and dry soybeans) for mefentrifluconazole to all commodities under the new crop group 6-21 (legume vegetables, except dry lentils and dry soybeans). The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 34671.

The evaluation of this mefentrifluconazole and prothioconazole application indicated that the end-use product has value, and the human health and environmental risks associated with the new uses are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when mefentrifluconazole is used according to the supported label directions. Therefore, foods containing residues resulting from these uses are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL 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.

Before registering a pesticide for food use in Canada, 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

[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.

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 approved label directions is not a health concern. The proposed MRL is then subject to consultation to legally specify it as an MRL. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except for certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRL for mefentrifluconazole is being conducted via this document. An MRL consultation for prothioconazole is being consulted under a separate action. Health Canada invites the public to submit written comments on the proposed MRL for mefentrifluconazole 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 MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

Proposed MRL

The proposed MRL, to replace the MRL already established for mefentrifluconazole, is summarized in Table 1.

Table 1 Proposed Maximum Residue Limit for Mefentrifluconazole

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Mefentrifluconazole	α-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-α-methyl-1*H*-1,2,4-triazole-1-ethanol	0.15[2]	Legume vegetables (crop group 6-21), except dry lentils and dry soybeans

[1]ppm = parts per million

[2]The currently established MRL of 0.15 ppm for crop group 6 (except dry lentils and dry soybeans) will be extended to include all commodities in crop group 6-21 (except dry lentils and dry soybeans). The MRLs already established for dry lentils and dry soybeans at 2.0 ppm and 0.4 ppm, respectively, will not change as a result of this PMRL action.

The commodities included in the listed crop groups/subgroups can be found on the Residue Chemistry Crop Groups webpage in the Pesticides section of Canada.ca.

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 MRL proposed for mefentrifluconazole in Canada is the same as corresponding American tolerance for crop group 6 (except lentil and soybean seed) as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[2] listed for mefentrifluconazole in or on the petitioned commodities on the Codex Alimentarius Pesticide Index webpage.

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for mefentrifluconazole 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 MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is 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 limit

Previously reviewed residue data from field trials conducted in/on legume vegetables were reassessed in the framework of this petition.

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 6% 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 12% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for mefentrifluconazole was based upon the reassessment of previously submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for commodities within crop group 6-21 (except dry lentils and dry soybeans).

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

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)
Edible-podded succulent beans	Foliar/broadcast/449–467	21	<0.01	0.02
Shelled succulent beans	Foliar/broadcast/445–456	21	<0.01	0.02
Edible-podded succulent peas	Foliar/broadcast/444–459	21	<0.01	0.08
Shelled succulent peas	Foliar/broadcast/444–459	21	<0.01	<0.01
Dried beans	Foliar/broadcast/436–461	21	<0.01	0.05
Dried peas	Foliar/broadcast/449–460	21-22	<0.01	0.09

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

Following the review of all available data, the MRL proposed in Table 1 is recommended to cover residues of mefentrifluconazole. Dietary risks from exposure to residues of mefentrifluconazole in these crop commodities at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus the foods that contain residues as listed in Table 1 are considered safe to eat.

References

None