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Proposed Maximum Residue Limit

PMRL2023-20

Prothioconazole

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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

Canada 

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide prothioconazole, 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 prothioconazole and mefentrifluconazole, to control or suppress certain fungal diseases. This application would extend the MRL currently established for crop subgroup 6C (dried shelled pea and bean, except soybean) for prothioconazole to all commodities under the new crop subgroups 6-21E and 6-21F. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [34671](#).

The evaluation of this prothioconazole and mefentrifluconazole 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 prothioconazole is used according to the supported label directions. Therefore, foods containing residues resulting from these uses 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 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 estimated human exposure is less than or equal to the acceptable level (developed in Step 2

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.

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 MRLs for prothioconazole is being conducted via this document. An MRL consultation for mefentrifluconazole is being consulted under a separate action. Health Canada invites the public to submit written comments on the proposed MRLs for prothioconazole 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 the [Canada’s Notification Authority and Enquiry Point](#).

Proposed MRLs

The proposed MRLs, to replace MRLs already established for prothioconazole, are summarized in Table 1.

Table 1 Proposed maximum residue limits for prothioconazole

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Prothioconazole	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3 <i>H</i> -1,2,4-triazole-3-thione, including the metabolite α -(1-chlorocyclopropyl)- α -[(2-chlorophenyl)methyl]-1 <i>H</i> -1,2,4-triazole-1-ethanol	0.9 ²	Dried shelled beans, except soybeans (crop subgroup 6-21E); dried shelled peas (crop subgroup 6-21F)

¹ ppm = parts per million

²The currently established MRL of 0.9 ppm for crop subgroup 6C, except soybeans will be extended to include all commodities within crop subgroup 6-21E (dried shelled beans, except soybeans), and crop subgroup 6-21F (dried shelled peas).

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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the geographic locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for prothioconazole in Canada with corresponding American tolerances and Codex MRLs.² American tolerances are listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius [Pesticide Index](#) webpage, by pesticide or commodity.

Table 2 Comparison of proposed Canadian MRLs, American tolerances and Codex MRLs

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Dried shelled beans, except soybeans (crop subgroup 6-21E)	0.9	0.9 (crop subgroup 6C, except soybean)	1 (pulses group, except dry soya bean)
Dried shelled peas (crop subgroup 6-21F)	0.9		

Next steps

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

Previously reviewed residue data from field trials conducted in/on dried peas and beans were reassessed in the framework of this petition.

Dietary risk assessment results

There were no acute or short-term health effects observed in the prothioconazole toxicology data for the general population, and therefore an acute reference dose (ARfD) was not necessary for this group. Acute dietary (food plus drinking water) intake estimates indicated that females 13 to 49 years of age are exposed to less than 96% 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 34% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for prothioconazole was based upon 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 MRLs for dried shelled beans (except soybean), and dried shelled peas.

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) ²	Highest average field trial residues (ppm) ²
Dry beans	Foliar broadcast/598–650	7–8	<0.05	0.243
Dry peas	Foliar broadcast/595–615	7–8	<0.05	0.661

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

² Total combined residues of prothioconazole and prothioconazole-desthio.

Following the review of all available data, the MRLs proposed in Table 1 are recommended, in order to cover total residues of prothioconazole. Dietary risks from exposure to residues of prothioconazole in these 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 foods that contain residues as listed in Table 1 are considered safe to eat.

References

None