Proposed Maximum Residue Limit PMRL2023-43

Difenoconazole

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Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide difenoconazole, as part of the following application for Canadian use, under submission number 2021-6200.

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 within leaves of root and tuber vegetables (crop group 2) to the product label of A20259 Fungicide containing technical grade difenoconazole and pydiflumetofen, for the control of alternaria leaf blight (*Alternaria* spp.), powdery mildew (*Erysiphe* spp.) and suppression of white mold (*Sclerotinia sclerotiorum*). The specific use approved in Canada is detailed on this product label, *Pest Control Products Act* Registration Number 33020.

The evaluation of this difenoconazole and pydiflumetofen application indicated that the end-use product has value, and the human health and environmental risks associated with the new use are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when difenoconazole is used according to the supported label directions. Therefore, foods containing residues resulting from this use 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 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.

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

Consultation on the proposed MRL for difenoconazole is being conducted via this document. The consultation on the proposed MRL for pydiflumetofen is being conducted via a separate PMRL action. Health Canada invites the public to submit written comments on the proposed MRL for difenoconazole 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 be added to the MRLs already established for difenoconazole, is summarized in Table 1.

Table 1 Proposed maximum residue limit for difenoconazole

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Difenoconazole	1-[[2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole	8.0	Leaves of root and tuber vegetables (human food or animal feed) (crop group 2, except garden beet tops[2], radish leaves[3] and turnip greens[3])

1 ppm = parts per million

2 Garden beet tops are excluded from this MRL action as an MRL of 8.0 ppm is already established for this commodity.

3 Radish leaves and turnip greens are excluded from this MRL action as an MRL of 35 ppm is already established for these commodities.

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 difenoconazole in Canada is the same as corresponding American tolerance as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[2] listed for difenoconazole in or on the petitioned commodities on the Codex Alimentarius Pesticide Index webpage.

Table 2 Comparison of Proposed Canadian MRL, American Tolerance and Codex MRL

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Leaves of root and tuber vegetables (crop group 2, except garden beet tops, radish leaves and turnip greens)	8.0	8 (Vegetable, leaves of root and tuber, group 2)	Not established

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for difenoconazole 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

No new residue data for difenoconazole in crop group 2 (leaves of root and tuber vegetables) were submitted to support the use expansion of difenoconazole on the A20259 Fungicide label. Previously reviewed residue data from field trials conducted in/on sugar beet tops and radish leaves were reassessed in the framework of this application.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups (except females 13-49 years old) are exposed to less than 20% of the acute reference dose, and therefore there are no health concerns.

Acute dietary (food plus drinking water) intake estimates indicated that females 13 to 49 years old are exposed to less than 19% 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 32% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for difenoconazole was based upon the 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 crops within leaves of root and tuber vegetables (crop group 2).

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)
Radish leaves	Foliar broadcast/ 495–510	7	0.236	3.830
Sugar beet tops[2]	Foliar broadcast/ 513	7	0.180	5.200

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

[2] Data from sugar beet tops were extended to garden beet tops

Following the review of all available data, the MRL proposed in Table 1 is recommended in order to cover residues of difenoconazole. Dietary risks from exposure to residues of difenoconazole 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.