Proposed Maximum Residue Limit PMRL2024-14

Dimethenamid

(publié aussi en français)

11 July 2024

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

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

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

Catalogue number: H113-24/2024-14E (print version)
H113-24/2024-14E-PDF (PDF version)

Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide dimethenamid-P, as part of the following application for Canadian use, under submission number 2022-0353.

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 commodity of dry bulb shallots to the product label of Frontier Max Herbicide containing technical grade dimethenamid-P to control labelled weeds. The specific use approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 29194.

The evaluation of this dimethenamid-P 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 food listed in Table 1 were shown to be acceptable when dimethenamid-P is used according to the supported label directions. Therefore, food containing residues resulting from this use is 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. 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).

[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.

Residues of the resolved isomer dimethenamid-P are covered by MRLs established for dimethenamid, the unresolved isomeric mixture. Consultation on the proposed MRL for dimethenamid is being conducted via this document.

Health Canada invites the public to submit written comments on the proposed MRL for dimethenamid 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 dimethenamid, is summarized in Table 1.

Table 1 Proposed maximum residue limit for dimethenamid

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Dimethenamid	2-chloro-*N*-(2,4-dimethyl-3-thienyl)-*N*-(2-methoxy-1-methylethyl)acetamide	0.01	Shallot bulbs

[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

As per Table 2, the MRL proposed for dimethenamid in Canada is the same as the corresponding tolerance in the United States (U.S.) and Codex MRL[2]. U.S. 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 commodity or pesticide.

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

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

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Shallot bulbs	0.01	0.01	0.01

Next steps

Health Canada invites the public to submit written comments on the proposed MRL for dimethenamid up to 75 days from the date of publication of this document (by 24 September 2024). Please forward your comments to Publications. 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 response to comments document found in Pesticides and pest management consultations. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

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 dry bulb onions 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 3% 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 11% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for a maximum residue limit (MRL) for dimethenamid was based upon the reassessed 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 shallot bulbs.

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)[2]	Highest average field trial residues (ppm)[2]
Dry bulb onion	Foliar broadcast/ 1640–1750	28–31	<0.01	<0.01
Dry bulb onion	Foliar broadcast/ 1640–1750	43–45	<0.01	<0.01

[1] g a.i./ha = grams of active ingredient per hectare.
[2] Residues of dimethenamid, the unresolved isomeric mixture, including dimethenamid-P.

Following the review of all available data, the MRL proposed in Table 1 is recommended, in order to cover residues of dimethenamid. Dietary risks from exposure to residues of dimethenamid in this crop commodity at the proposed MRL was shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the food that contains residues as listed in Table 1 are considered safe to eat.

References

None.