Proposed Maximum Residue Limit PMRL2023-25

Fludioxonil

(publié aussi en français)

4 May 2023

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: H113-24/2023-25E (print version)
H113-24/2023-25E-PDF (PDF version)

Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide fludioxonil, as part of the following application for Canadian use, under submission number 2021-1077.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested application to add the new commodities of crop subgroup 6A (edible-podded legume vegetables) and crop subgroup 6B (succulent shelled pea and bean) to the product label of Vibrance Maxx RFC containing technical grade sedaxane, metalaxyl-M (and S-isomer) and fludioxonil, to control certain fungal diseases. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 32272.

The evaluation of this sedaxane, metalaxyl-M and fludioxonil 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 food listed in Table 1 were shown to be acceptable when fludioxonil is used according to the supported label directions. Therefore, food 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 fludioxonil is being conducted via this document. MRL consultation for sedaxane is being conducted under a separate action. The currently established MRLs for metalaxyl[2] are sufficient to cover residues of metalaxyl-M resulting from this new use and are therefore unaffected by this MRL action. Health Canada invites the public to submit written comments on the proposed MRL for fludioxonil 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 fludioxonil, is summarized in Table 1.

Table 1 Proposed maximum residue limit for fludioxonil

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile	0.01	Succulent shelled cowpeas[2]

[1] ppm = parts per million
[2] MRLs are already established for the other edible-podded legume vegetables and succulent shelled pea and bean included in crop subgroup 6A and 6B.

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.

[2] Metalaxyl is the racemic mixture (containing 1:1 mixture of the *R*- and *S*-enantiomers) of the technical grade active metalaxyl-M (which primarily contains the *R*-enantiomer). Residues of metalaxyl-M are covered by MRLs established for metalaxyl.

Table 2 compares the MRL proposed for fludioxonil in Canada with the corresponding American tolerance and Codex MRL[3]. 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 MRL, American Tolerance and Codex MRL

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Succulent shelled cowpeas	0.01	0.4 (Bean, succulent)	0.4 (Beans, shelled)

Next steps

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

[3] 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 as seed treatments with edible-podded peas, cucumbers, leaf lettuce and radishes were reassessed in the framework of this petition.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects. Consequently, a single dose of fludioxonil is not likely to cause acute health effects in the general population (including infants and children).

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 68% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for fludioxonil was based upon the previously reviewed field trial data. Table A1 summarizes the residue data used to calculate the proposed MRL for succulent shelled cowpeas.

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

Commodity	Application method/Total application rate (g a.i./100 kg seed)[1]	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)
Edible-podded peas	Seed treatment/ 2.9–24.6	58–71	<0.01	<0.01
Cucumbers	Seed treatment/ 2.7–22.1	54–72	<0.01	<0.01
Leaf lettuce	Seed treatment/ 2.6–23.3	55–81	<0.01	<0.01
Radish roots	Seed treatment/ 3.0–22.0	27–54	<0.01	<0.01
Radish leaves			<0.01	<0.01

[1] g a.i./100 kg seed = grams of active ingredient per 100 kilograms of seed

Following the review of all available data, the MRL proposed in Table 1 is recommended in order to cover residues of fludioxonil. Dietary risks from exposure to residues of fludioxonil in this crop commodity at the proposed MRL were 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 is considered safe to eat.

References

None.