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Proposed Maximum Residue Limit

PMRL2024-04

Fluopyram

(publié aussi en français)

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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 fluopyram, as part of the following application for Canadian use, under submission number 2022-0565.

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 of dried shelled beans (except soybeans) and dried shelled peas (crop subgroup 6C) to the product label of Delaro Complete fungicide, containing technical grade fluopyram, prothioconazole and trifloxystrobin, to control certain fungal diseases. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [34095](#).

The evaluation of this fluopyram, prothioconazole and trifloxystrobin 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 fluopyram is used according to the supported label directions. Therefore, foods containing residues resulting from this use 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 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 MRLs for fluopyram is being conducted via this document. MRLs are currently established for prothioconazole on dry crowder peas and dry field beans (in crop subgroup 6-21E) at 0.9 ppm, accordingly a separate PMRL action is not required. Consultation on the proposed MRLs for trifloxystrobin is being addressed under a separate action.

Health Canada invites the public to submit written comments on the proposed MRLs for fluopyram 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 be added to the MRLs already established for fluopyram, are summarized in Table 1.

Table 1 Proposed maximum residue limits for fluopyram

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Fluopyram	<i>N</i> -[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide	0.7	Dry crowder peas, dry field beans ²

¹ ppm = parts per million

² MRLs of 0.7 ppm in/on the remaining commodities in crop subgroup 6C (Dried shelled pea and bean (except soybean) are already established.

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 fluopyram in Canada with corresponding tolerances in the United States (U.S.) and Codex MRLs.² The MRLs proposed for fluopyram in Canada are

² The Codex Alimentarius Commission is an international organization under the auspices of the United

the same as the corresponding U.S. tolerances but are different from the corresponding Codex MRLs.

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 pesticide or commodity.

Table 2 Comparison of Canadian MRLs, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Dry crowder peas, dry field beans	0.7	0.7 (Pea, dried seed; Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6–22E)	0.15 (Dry beans (subgroup)) 0.7 (Dry peas (subgroup))

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for fluopyram up to 75 days from the date of publication of this document (by 21 July 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 MRLs. Comments received will be addressed in a response to comments document found in [Pesticides and pest management consultations](#). The established MRLs will be legally in effect as of the date that they are entered into the [Maximum Residue Limit Database](#).

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 shelled beans and dried shelled peas 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 38% 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 98% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for fluopyram was based upon the reassessed field trial data, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data for fluopyram used to calculate the proposed MRLs for dry field beans and dry crowder 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)	Highest average field trial residues (ppm)
Dry beans	Broadcast foliar/494–514	13–14	<0.01	0.068
Dry peas	Broadcast foliar/494–509	13–14	0.03	0.350

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

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover residues of fluopyram. Dietary risks from exposure to residues of fluopyram 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 contains residues as listed in Table 1 are considered safe to eat.

References

None.