Proposed Maximum Residue Limit PMRL2024-25

Florylpicoxamid

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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

A maximum residue imit (MRL)[1] is being proposed for the pesticide florylpicoxamid, as part of the following application for Canadian use, under submission number 2023-1121.

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 barley, chickpeas, field peas, faba beans (also known as broad beans) and wheat to the product label of Zetigo PRM Fungicide containing technical grade florylpicoxamid and pyraclostrobin, to control or suppress a broad range of diseases, as a foliar postemergent use. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 34701.

The evaluation of this florylpicoxamid 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 florylpicoxamid 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 florylpicoxamid is being conducted via this document.

MRLs are currently established for florylpicoxamid on pulses, dried shelled beans, except soybeans (crop subgroup 6-21E) which includes dry broad beans; pulses, dried shelled peas (crop subgroup 6-21F) which includes dry chickpeas and dry field peas; and wheat (under the wheat crop subgroup 15-21A) at 0.01 ppm each, and no further action is required. MRLs are currently established for pyraclostrobin on dry chickpeas, dry field peas and dry broad beans at 0.5 ppm each, on barley at 1.4 ppm and on wheat at 0.2 ppm; accordingly, a separate PMRL action is not required.

Health Canada invites the public to submit written comments on the proposed MRL for florylpicoxamid in accordance with the process outlined in the How to get involved 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 florylpicoxamid, is summarized in Table 1.

Table 1 Proposed maximum residue limit for florylpicoxamid

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Florylpicoxamid	(1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-*L*-alaninate	0.03	Barley (crop subgroup 15-21B)

[1] ppm = parts per million

The commodities included in the listed crop subgroup can be found on the Residue Chemistry Crop Groups webpage in the Pesticides and pest management 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

As reported in Table 2, there are currently no tolerances in the United States (U.S.) for florylpicoxamid in or on the petitioned commodities listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide, nor are there Codex MRLs[2] listed for florylpicoxamid in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Table 2 Comparison of proposed Canadian MRL, U.S. tolerance and Codex MRL

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Barley (crop subgroup 15-21B)	0.03	Not established	Not established

How to get involved

Health Canada invites the public to submit written comments on the proposed MRL for florylpicoxamid up to 75 days from the date of publication of this document (by 9 February 2025). 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.

[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

Previously reviewed residue data for florylpicoxamid from field trials conducted in/on barley were reassessed in the framework of this petition. In addition, a processing study in treated barley was also reassessed to determine the potential for concentration of residues of florylpicoxamid into processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relative to dietary exposure. Consequently, a single dose of florylpicoxamid 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 74% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for maximum residue limit (MRL) for florylpicoxamid was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for florylpicoxamid used to calculate the proposed MRL for barley (crop subgroup 15-21B).

Table A1 Summary of field trial and processing 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)	Experimental processing factor
Barley grain	Foliar / 157-167	30-86	<0.010	0.024	No quantifiable residues observed at exaggerated rates.

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

Based on the dietary burden and residue data, the established MRLs of 0.02 ppm in meat, fat and meat by-products of cattle, goats, hogs, horses, poultry and sheep, milk and eggs are expected to cover residues of florylpicoxamid in/on livestock commodities as a result of this action.

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