Proposed Maximum Residue Limit PMRL2022-19

# Florylpicoxamid

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## Purpose of consultation

Maximum residue limits (MRLs)[1] are being proposed for the pesticide florylpicoxamid as part of the following applications for Canadian use under submission numbers 2020-1404, 2020-1405 and 2020-1406.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the uses requested under the above-noted applications to register the technical grade florylpicoxamid and the end-use products GF-3840 Fungicide and GF-4017 Fungicide (co-formulated with the technical grade pyraclostrobin) for use in Canada on canola, lentils, sugar beets and wheat to control or suppress various fungal diseases.

The evaluation of these florylpicoxamid applications indicated that the end-use products have value, and the human health and environmental risks associated with their proposed uses are acceptable. Details regarding these applications can be found in Proposed Registration Decision PRD2022-14, *Florylpicoxamid*, posted to the Canada.ca website on the 3rd November 2022. Dietary risks from the consumption of foods 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 these uses are safe to eat, and MRLs are being proposed as a result of this assessment.

## 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

[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.

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

Consultation on the proposed MRLs for florylpicoxamid is being conducted via PRD2022-14. The end-use product GF-4017 also contains pyraclostrobin. The currently established MRLs for pyraclostrobin of 0.45 ppm on canola (rapeseeds) and of 0.5 ppm on dry lentils, dry field peas and dry chickpeas are sufficient to cover residues resulting from this new co-formulation and are therefore unaffected by this MRL action. Health Canada invites the public to submit written comments on the proposed MRLs for florylpicoxamid in accordance with the process outlined in the Next steps section of this document, and with the process outlined in PRD2022-14.

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 Canada's Notification Authority and Enquiry Point.

## Proposed MRLs

The proposed MRLs for florylpicoxamid are summarized in Table 1.

**Table 1 Proposed maximum residue limits 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 | 0.015 | Rapeseeds (crop subgroup 20A) (revised) |
| | | 0.01 | Dried shelled beans, except soybeans (crop subgroup 6-21E); dried shelled peas (crop subgroup 6-21F); wheat (crop subgroup 15-21A); sugar beet roots |
| | (1*S*)-2,2-bis(4-fluorophenyl)-1-methylethyl *N*-[[3-(acetyloxy)-4-methoxy-2-pyridinyl]carbonyl]-*L*-alaninate including the metabolite (2*S*)-1,1-bis(4-fluorophenyl)propan-2-yl *N*-[(3-hydroxy-4-methoxypyridin-2-yl)carbonyl]-*L*-alaninate (expressed in parent equivalents) | 0.02 | Eggs; fat, meat, and meat byproducts of cattle, goats, horses, hogs, poultry and sheep; milk |

[1] ppm = parts per million

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

Florylpicoxamid is a new active ingredient that is concurrently being registered in Canada and the United States. The MRLs proposed for florylpicoxamid in Canada are the same as corresponding tolerances to be promulgated in the United States.

Once established, the American tolerances for florylpicoxamid will be listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs[2] listed for florylpicoxamid in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

## Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for florylpicoxamid 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 MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are 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.