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Proposed Maximum Residue Limit

PMRL2025-20

# Fluoxapiprolin

*(publié aussi en français)*

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## Purpose of consultation

Maximum Residue Limits (MRLs)<sup>1</sup> are being proposed for the pesticide fluoxapiprolin as part of the following applications for Canadian use, under submission numbers 2022-1814 and 2022-1816.

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 Fluoxapiprolin 95 TC and the end-use product Xivana Prime for new uses on several commodities in Canada, to control or suppress various fungal diseases (please refer to Table 1).

The evaluation of these fluoxapiprolin applications indicated that the end-use product has 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 PRD2025-07, *Fluoxapiprolin and Xivana Prime*, posted to the Pesticides and pest management section of the Canada.ca website on 12 September 2025. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when fluoxapiprolin 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). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2), 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

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<sup>1</sup> 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.

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

Consultation on the proposed MRLs for fluoxapiprolin is being conducted via this document and PRD2025-07. Health Canada invites the public to submit written comments on the proposed MRLs for fluoxapiprolin in accordance with the process outlined in the How to get involved Section of this document, and with the process outlined in PRD2025-07.

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 fluoxapiprolin are summarized in Table 1.

**Table 1 Proposed maximum residue limits for fluoxapiprolin**

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Fluoxapiprolin	2-[3,5-bis(difluoromethyl)-1 <i>H</i> -pyrazol-1-yl]-1-[4-[4-[5-[2-chloro-6-[(methylsulfonyl)oxy]phenyl]-4,5-dihydro-3-isoxazolyl]-2-thiazolyl]-1-piperidinyl]ethanone	6.0	Leafy vegetables (crop group 4-13, except head lettuce)
		2.0	Green onions (crop subgroup 3-07B)
		1.5	Leaf petioles vegetables (crop subgroup 22B)
		0.8	<i>Brassica</i> head and stem vegetable group (crop group 5-13); head lettuce
		0.5	Raisins
		0.2	Small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F); dried tomatoes
		0.07	Cucurbit vegetables (crop group 9)
		0.06	Fruiting vegetables (crop group 8-09)
		0.03	Bulb onions (crop subgroup 3-07A)
0.01	Tuberous and corm vegetables (crop subgroup 1C); fat, meat and		

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
			meat byproducts of cattle, goats, hogs, horses, poultry and sheep; eggs, milk, strawberries

<sup>1</sup> 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 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, human health, and food safety 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

Fluoxapiprolin is a new active ingredient that is concurrently being registered in Canada and the United States (U.S.). The MRLs proposed for fluoxapiprolin in Canada are the same as corresponding tolerances to be promulgated in the U.S., except for livestock commodities, in accordance with Table 2, for which differences in MRLs/tolerances may be due to different livestock feed items and practices.

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

Currently, there are no Codex MRLs<sup>2</sup> listed for fluoxapiprolin in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

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

Food commodity	Proposed Canadian MRL (ppm)	Proposed U.S. tolerance (ppm)	Established Codex MRL (ppm)
Leafy vegetables (crop group 4-13, except head lettuce)	6.0	6.0	Not established
Green onions (crop subgroup 3-07B)	2.0	2.0	Not established
Leaf petioles vegetables (crop subgroup 22B)	1.5	1.5	Not established

<sup>2</sup> The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

<b>Food commodity</b>	<b>Proposed Canadian MRL (ppm)</b>	<b>Proposed U.S. tolerance (ppm)</b>	<b>Established Codex MRL (ppm)</b>
<i>Brassica</i> head and stem vegetable group (crop group 5-13); head lettuce	0.8	0.8	Not established
Raisins	0.5	0.5	Not established
Small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)	0.2	0.2	Not established
Dried tomatoes	0.2	Not established	Not established
Cucurbit vegetables (crop group 9)	0.07	0.07	Not established
Fruiting vegetables (crop group 8-09)	0.06	0.06	Not established
Bulb onions (crop subgroup 3-07A)	0.03	0.03	Not established
Tuberous and corm vegetables (crop subgroup 1C)	0.01	0.01	Not established
Fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep; eggs, milk	0.01	Not established	Not established
Strawberries	0.01	Not established	Not established

ppm = parts per million

## How to get involved

Health Canada invites the public to submit written comments on the proposed MRLs for fluoxapiprolin up to 75 days from the date of publication of this document (12 September 2025). Please forward your comments to the Pest Management Regulatory Agency Publications Section. 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.