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Proposed Maximum Residue Limit

PMRL2023-39

# Diflufenican

*(publié aussi en français)*

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Publications  
Pest Management Regulatory Agency  
Health Canada  
2 Constellation Drive  
8<sup>th</sup> floor, A.L. 2608 A  
Ottawa, Ontario K1A 0K9

Internet: [canada.ca/pesticides](http://canada.ca/pesticides)  
[pmra.publications-arla@hc-sc.gc.ca](mailto:pmra.publications-arla@hc-sc.gc.ca)

Information Service:  
1-800-267-6315  
[pmra.info-arla@hc-sc.gc.ca](mailto:pmra.info-arla@hc-sc.gc.ca)

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## Purpose of consultation

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide diflufenican as part of the following applications for Canadian use, under submission numbers 2021-0670, 2021-0639, 2021-0695 and 2021-0697.

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 diflufenican and the end-use products SC500 for new uses on field corn and soybeans; SC617 (co-formulation containing isoxaflutole) for use on field corn, seed corn, and corn grown for silage in Eastern Canada and British Columbia only; and SC600 (co-formulation containing metribuzin) for use on soybeans in Canada; all to provide residual control of redroot pigweed, green pigweed, tall waterhemp and palmer amaranth.

The evaluation of these diflufenican 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 PRD2023-07, *Diflufenican, SC500, SC600, and SC617*, posted to the Pesticides section of the Canada.ca website on 3 August 2023. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when diflufenican 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.

## 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

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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.

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 diflufenican is being conducted via this document and PRD2023-07. MRLs are currently established for metribuzin on dry soybeans at 0.3 ppm and for isoxaflutole on field corn at 0.02 ppm, accordingly, separate PMRL actions are not required. Health Canada invites the public to submit written comments on the proposed MRLs for diflufenican in accordance with the process outlined in the Next steps Section of this document, and with the process outlined in PRD2023-07.

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 diflufenican are summarized in Table 1.

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

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Diflufenican	<i>N</i> -(2,4-difluorophenyl)-2-[3-(trifluoromethyl) phenoxy]-3-pyridinecarboxamide	0.01	Dry soybeans, eggs; fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep; field corn, milk

<sup>1</sup> ppm = parts per million

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

Diflufenican is a new active ingredient that is concurrently being registered in Canada and the United States. The MRLs proposed for diflufenican in Canada are the same as corresponding tolerances to be promulgated in the United States, except for certain livestock commodities as shown in Table 2 for which no tolerances are proposed due to different practices and policies regarding livestock.

Once established, the American tolerances for diflufenican 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 diflufenican in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

**Table 2 Comparison of proposed Canadian MRLs, proposed American tolerances and Codex MRLs**

<b>Food commodity</b>	<b>Canadian MRL (ppm)</b>	<b>American tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
Field corn; dry soybeans	0.01	0.01	Not Established
Eggs, milk; fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep	0.01	Not Established <sup>1</sup>	

<sup>1</sup> As residues in livestock are expected to be insignificant (40 CFR section 180.6 (a)(3)), tolerances for residues of diflufenican in/on livestock commodities are not required at this time.

### Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for diflufenican 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.

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<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.