Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Proposed Maximum Residue Limit PMRL2022-09

Fluopyram

(publié aussi en français) **28 April 2022**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.info-arla@ hc-sc.gc.ca

Canada

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2022-9E (print version)
H113-24/2022-9E-PDF (PDF version)

Purpose of consultation

Maximum Residue Limits (MRLs)[1] are being proposed for the pesticide fluopyram, as part of the following applications for Canadian use, under submission numbers 2020-0304, 2020-0212, 2020-0367 and 2020-0368; and submission number 2020-0304 for imported commodities.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested applications:

- To add the new commodities of cereal grains (barley, oats, triticale and wheat) to the product label of Prosaro Pro (containing technical grade fluopyram, prothioconazole and tebuconazole), to control or suppress various fungal diseases;

- To add the new commodities of cereal grains (barley, corn, millet, oats, rye, teosinte, triticale and wheat) and soybeans to the product label of USF0411 (containing technical grade fluopyram, prothioconazole and trifloxystrobin), to control or suppress various fungal diseases;

- To add the new commodities of cereal grains (barley, corn, oats, triticale and wheat) and soybeans to the product label of Delaro Complete (containing technical grade fluopyram, prothioconazole and trifloxystrobin), to control or suppress various fungal diseases.

The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Numbers 34093, 34094 and 34095, respectively.

Health Canada's Pest Management Regulatory Agency (PMRA) is also proposing acceptability of the requested application to support the MRL revision resulting from the decreased application rate on rapeseeds (crop subgroup 20A) (revised), currently on the product labels of Propulse and FPY/PTZ Fungicide containing technical grade fluopyram. The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Numbers 33955 and 31729, respectively.

The evaluation of these fluopyram applications indicated that the end-use products have 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 these uses 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.

In addition, Health Canada is proposing acceptability of the request to specify an MRL for fluopyram on green coffee beans to control or suppress various fungal diseases, in order to permit the import and sale of food that could contain such residues.

[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.

Health Canada has determined the quantity of residues that may remain in or on the imported commodity when fluopyram is used according to label directions in the exporting country, and that such residues will not be a concern to human health.

The currently established 0.3 ppm MRL in/on dry soybeans for fluopyram is sufficient to cover residues resulting from this new use and are therefore unaffected by this MRL action.

The currently established 0.35 ppm MRL in/on barley, corn (field and popcorn grain), oats, pearl millet, proso millet, rye, teosinte, triticale, wild rice, buckwheat and wheat; 0.15 ppm MRL in/on dry soybeans; and 0.04 ppm MRL in/on sweet corn kernels plus cob with husks removed for prothioconazole are sufficient to cover residues resulting from this new use and are therefore unaffected by this MRL action.

The currently established 0.1 ppm MRL in/on corn oil (refined); 0.08 ppm MRL in/on dry soybeans; 0.05 ppm MRL in/on barley, corn (field and popcorn grain), oats, pearl millet, proso millet, rye, teosinte, triticale, wild rice, buckwheat and wheat; and 0.04 ppm MRL in/on sweet corn kernels plus cob with husks removed for trifloxystrobin are sufficient to cover residues resulting from this new use and are therefore unaffected by this MRL action.

The currently established 0.5 ppm MRL in/on sweet corn kernels plus cob with husks removed; 0.3 ppm MRL in/on barley; 0.15 ppm MRL in/on oats, rye, triticale and wheat; and 0.05 ppm MRL in/on corn (field and popcorn grain) for tebuconazole are sufficient to cover residues resulting from this new use and are therefore unaffected by this MRL action.

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 human 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 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. 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 replace or 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	*N*-[2-[3-chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide	0.5	Cereal grains (crop group 15), except rice and corn[2,3]
		0.3	Rapeseeds (crop subgroup 20A) (revised)[4]
		0.03	Green coffee beans
		0.02	Field corn, popcorn grain[2]
		0.01	Sweet corn kernels plus cob with husks removed[2]

[1] ppm = parts per million
[2] The MRLs are proposed to replace the currently established 1.5 ppm MRL for cereal grains (crop group 15), except rice.
[3] It is proposed that the existing MRL of 2.0 ppm for wheat bran and germ be revoked. Following the revocation of the 2.0 ppm MRL for wheat bran and germ, these wheat commodities will be regulated under the proposed cereal grains (crop group 15) MRL of 0.5 ppm.
[4] The MRL is proposed to replace the currently established MRL of 1.8 ppm for rapeseeds (crop subgroup 20A) (revised).

An MRL is proposed for each commodity included in the listed crop groupings in accordance with 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

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 American tolerances and Codex MRLs.[2] American 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 proposed Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food commodity	Canadian MRL (ppm)	American tolerance (ppm)	Codex MRL (ppm)
Cereal grains (crop group 15), except rice and corn	0.5	0.5	0.9 (Rye, triticale, wheat) 0.2 (Barley, oats)
Rapeseeds (crop subgroup 20A) (revised)	0.3	0.3	1.0 (rape seed)
Green coffee beans	0.03	0.03	Not established

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. 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.

Appendix I

Summary of field trial data used to support the proposed maximum residue limits

Residue data on barley, sorghum and wheat for fluopyram were submitted to support the use of Prosaro Pro, USF0411, and Delaro Complete, on cereal grains (crop group 15, except rice). Residue data for fluopyram on canola were submitted to support the amendment of the currently established MRL on rapeseeds (crop subgroup 20A) (revised). Residue data were also submitted for fluopyram on coffee to establish a new MRL on imported green coffee beans. Previously reviewed residue data from field trials conducted in/on corn were reassessed in the framework of this petition. In addition, a processing study in treated coffee was reviewed and processing studies in treated wheat and field corn were also reassessed to determine the potential for concentration of residues of fluopyram into processed commodities.

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 37% of the acute reference dose, and therefore are not a health concern.

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 are not a health concern.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for fluopyram was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for cereal grains (crop group 15, except rice), rapeseeds (crop subgroup 20A) (revised) and green coffee beans.

Table A1 Summary of field trial and processing 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)	Experimental processing factor
Barley grain	Foliar/230–260	28–43	<0.011	0.232	Bran: 2.7× Flour: 0.12× Germ: 2.4×
Wheat grain	Foliar/240–320	28–51	<0.01	0.137	
Sorghum grain	Foliar/200–210	28–55	0.054	0.302	Not applicable
Field corn grain	Foliar/492–520	11–14	<0.01	0.018	Starch: 0.15× Refined oil: 0.6× Grits: 0.5× Flour: 0.9× Meal: 0.8× Bran: 2.6×
Sweet corn kernels plus cob with husks removed	Foliar/495–527	0	<0.01	<0.01	

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
Rapeseed (canola) seed	Foliar/293–306	27–29	0.022	0.185	No concentration in processed fractions
Green coffee beans	Drench/491–516	88–90	<0.010	0.012	No quantifiable residues observed at exaggerated rates

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

Following the review of all available data, MRLs as proposed in Table 1 are recommended 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 contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
3080782	2018, An analytical method for the determination of residues of fluopyram (AE C656948) and AE F148815 in crop matrices using LC/MS/MS, DACO: 7.2.1
3080783	2020, Magnitude of fluopyram residues in barley after two foliar applications of fluopyram 500SC (500 g/L) in North America, DACO: 7.4.1,7.4.2
3080784	2019, Magnitude of the residue of fluopyram and prothioconazole in/on sorghum after spray application of fluopyram SC 500 (500 g/L) and prothioconazole SC 480 (480 g/L) in North America, DACO: 7.4.1,7.4.2
3080786	2019, Magnitude of the residue of fluopyram in/on wheat after spray application of fluopyram SC 500 (500 g/L) in North America, DACO: 7.4.1,7.4.2
2478843	2008, Trifloxystrobin 500 SC - Magnitude of the residue in/on field corn, popcorn, and sweet corn, DACO: 7.4.1,7.4.2
3082506	2016, Addendum no. 01 to the final report - Determination of residues of fluopyram and its metabolite in the coffee crop (grains) following the application of fluopyram in trials in Brazil, DACO: 7.4.1,7.4.2
3082507	2017, Fluopyram 500 SC - Magnitude of residues in/on coffee; import tolerances, DACO: 7.4.1,7.4.2
3082508	2019, Amendment no. 01: Magnitude of fluopyram and prothioconazole residues in canola after seed treatment application with fluopyram FS 600 (600 g/L) followed by 2 foliar applications of fluopyram + prothioconazole (200 + 200 g/L) in North America, DACO: 7.4.1,7.4.2
3082509	2017, Amendment 1 to final report - Fluopyram 500 SC - Magnitude of residues in/on coffee processed commodities; import tolerances, DACO: 7.4.5
3082506	2016, Addendum no. 01 to the final report - Determination of residues of fluopyram and its metabolite in the coffee crop (grains) following the application of fluopyram in trials in Brazil, DACO: 7.4.1,7.4.2