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Proposed Maximum Residue Limit

PMRL2026-11

Fludioxonil

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Purpose of consultation

Maximum residue limits (MRLs)¹ for **imported** commodities are being proposed for the pesticide fludioxonil as part of the following application under submission number 2022-6437, in order to permit the import and sale of food in Canada that could contain fludioxonil residues.

Under the authority of the *Pest Control Products Act*, Health Canada is proposing acceptability of the request to specify maximum residue limits for fludioxonil on various imported commodities to control or suppress certain fungal diseases (please refer to Table 1).

Fludioxonil is a fungicide currently registered in Canada for use various commodities.

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

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.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, and that such residues will not be a concern to human health (Step 3 and Step 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 label directions approved in the foreign country is not a health concern. The proposed MRL is then subject to consultation to legally specify the MRL on the corresponding imported commodity. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRLs for fludioxonil on imported commodities is being conducted via this document. Health Canada invites the public to submit written comments directly

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.

related to the residue chemistry data and dietary exposure assessment supporting this proposed MRL action for fludioxonil 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 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, to be added to the MRLs already established for fludioxonil, are summarized in Table 1.

Table 1 Proposed maximum residue limits for fludioxonil

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile	20	Tropical and subtropical fruits; small fruits; inedible peel (crop subgroup 24A); sugar apples
		3.0	Bananas
		0.3	Tree nuts (crop group 14-11, except pecan nuts and pistachio nuts) ²
		0.01	Pecan nuts

¹ ppm = parts per million

² The established MRL of 0.08 ppm for fludioxonil on pistachios, based on previously reviewed pistachio residue data, is not being revised.

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

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the geographical locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for fludioxonil in Canada with corresponding tolerances in the United States (U.S.) and Codex MRLs.² U.S. 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, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Tropical and subtropical fruits; small fruits; inedible peel (crop subgroup 24A)	20	20	Not established
Sugar apples	20	20	Not established
Bananas	3.0	3	2
Tree nuts (crop group 14-11, except pecan nuts and pistachio nuts)	0.3	0.2 (Almond; beechnut; Brazilian pine; bunya; candlenut; chestnut; chinquapin; ginkgo; monkey puzzle; okari nut; peach palm nut; pequi; pili nut; pine nut; tropical almond)	0.3 (Tree nuts group, except Canarium nut, Chilean hazelnut, and pistachios)
Pecan nuts	0.01	0.01 (African tree nut; Brazil nut; bur oak; butternut; cajou; cashew; Guiana chestnut; coconut; hazelnut; heartnut; Japanese horse-chestnut; monkey-pot; coquito nut; dika nut; hickory nut; macadamia nut; mongongo nut; pachira nut; sapucaia nut; pecan; walnut, black; walnut, English; yellowhorn)	

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

How to get involved

Health Canada invites the public to submit written comments that are directly related to this proposed MRL action for fludioxonil, such as comments directed to the residue chemistry data and dietary exposure assessment, up to 75 days from the date of publication of this document (by 13 December 2026). Please forward your comments to the Pesticides Publications Section.

Health Canada considers all comments received that are directly related to the residue chemistry data and dietary exposure assessment supporting the proposed MRL action, 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 consultations. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

Appendix I

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

Residue data for fludioxonil on bananas, almonds and pecans were submitted to support the maximum residue limits on imported bananas and tree nuts (crop group 14-11). Previously reviewed residue data from field trials conducted in/on kiwifruit were also reassessed in the framework of this petition. In addition, a processing study in treated almonds was reviewed to determine the potential for concentration of residues of fludioxonil in processed commodities.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relative to dietary exposure. Consequently, a single dose of fludioxonil 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 70% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for fludioxonil on imported commodities was based upon the residues observed in crop commodities treated according to label directions or exaggerated rates in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for fludioxonil used to calculate the proposed MRLs for imported crops.

Table A1 Summary of field trial and processing data used to support the MRLs

Commodity	Application method/ Total application rate (kg a.i./ha) ¹	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Kiwifruit	Postharvest dip/ 0.23	0	5.25	8.55	Not required
Bananas, whole fruit	Postharvest spray or dip/ 20 g a.i./100 L water	0	0.58	1.18	Not required
Almond, nutmeat	Foliar/ 0.973–0.991	14–15	<0.01	0.147	Oil ² : 1.45×
Pecan, nutmeat	Foliar/ 0.982–0.998	13–14	<0.01	<0.01	Not required

¹ kg a.i./ha = kilograms of active ingredient per hectare

² A separate MRL is not required, as residues of fludioxonil in almond oil are expected to be covered by the proposed 0.3 ppm MRL for Tree nuts [0.147 ppm (HAFT in treated almond nutmeat) × 1.45 processing factor = 0.21 ppm].

Following the review of all available data, the MRLs proposed in Table 1 are recommended, in order to cover residues of fludioxonil. Dietary risks from exposure to residues of fludioxonil in these imported 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 imported foods that contain residues as listed in Table 1 are considered safe to eat.

References

PMRA#	Citation
3415568	A15696C - Magnitude of the Residues of Azoxystrobin and Fludioxonil in Post-Harvest Application to Bananas in Ecuador, 2016
3415570	Fludioxonil WG (A9219B) - Magnitude of the Residues in or on Pecan and Almond Raw Agricultural and Processed Commodities as Representative Crops of the Tree Nuts Crop Group (14-12), USA 2018