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Proposed Maximum Residue Limit

PMRL2021-31

Flutianil

(publié aussi en français)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed as part of the following applications under pesticide submission numbers 2019-0595 and 2019-0600 for Canadian uses, and submission number 2019-0598 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 uses requested under the above-noted applications to register the technical grade flutianil and the end-use product GATTEN for new uses on cucurbit vegetables (crop group 9), cherries (crop subgroup 12-09A), and small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F) in Canada, to control various species of powdery mildew.

The evaluation of these flutianil 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 PRD2021-09, *Flutianil and GATTEN*, posted to the Health Canada website on 21 December 2021. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when flutianil is used according to the supported label directions. Therefore, foods containing residues at these levels are safe to eat, and MRLs are being proposed as a result of this assessment.

In addition, Health Canada is proposing acceptability of the request to specify MRLs for flutianil on imported low growing berries (crop subgroup 13-07G) and apples, to control or suppress various fungal diseases, in order to permit the import and sale of food that could contain such residues. Health Canada has determined the quantity of residues that are likely to remain in or on the imported commodities, when flutianil is used according to label directions in the exporting country, and that such residues will not be a concern to human health. Details regarding the proposed MRLs on imported commodities can also be found in PRD2021-09, Section 3.8.

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 a 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.

¹ A Maximum Residue Limit (MRL) is the maximum amount of residue that is expected to remain in or on food when a pesticide is used according to label directions.

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's determination is that the consumption of this amount of residue is safe. This quantity 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 where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for flutianil is being conducted via this document and PRD2021-09. Health Canada invites the public to submit written comments on the proposed MRLs for flutianil in accordance with the guidance reported in the Next Steps section of this document, and with the guidance found in PRD2021-09.

To comply with Canada's international trade obligations, consultation on the proposed MRLs are 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 flutianil are summarized in Table 1.

Table 1 Proposed maximum residue limits for flutianil

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Flutianil	(2Z)-2-[[2-fluoro-5-(trifluoromethyl)phenyl]thio]-2-[3-(2-methoxyphenyl)-2-thiazolidinylidene]acetonitrile	0.7	Small fruits vine climbing, except fuzzy kiwifruit (crop subgroup 13-07F)
		0.5	Low growing berries (crop subgroup 13-07G)
		0.4	Cherries (crop subgroup 12-09A)
		0.2	Squash/cucumber (crop subgroup 9B)
		0.15	Apples
		0.07	Melon (crop subgroup 9A)

¹ ppm = parts per million

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

The MRLs proposed for flutianil in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs² listed for flutianil 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 flutianil 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.