Proposed Maximum Residue Limit PMRL2024-22

Flupyradifurone

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Purpose of consultation

A maximum residue limit (MRL)[1] is being proposed for the pesticide flupyradifurone, as part of the following application for Canadian use, submitted by Bayer CropScience Inc. under submission number 2023-1491.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested application to add the new commodities of mustard seeds (oilseed and condiment) to the product label of BUTEO Start 480 FS containing technical grade flupyradifurone to control flea beetles. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 31451.

The evaluation of this flupyradifurone application indicated that the end-use product has 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 flupyradifurone is used according to the supported label directions. Therefore, foods containing residues resulting from this use are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL 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.

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.

[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.

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 MRL for flupyradifurone on mustard seeds (condiment type) is being conducted via this document. An MRL of 0.03 ppm for flupyradifurone on mustard seeds (oilseed type) is already established, and no further action is required.

Health Canada invites the public to submit written comments on the proposed MRL for flupyradifurone 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 MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

Proposed MRL

The proposed MRL, to be added to the MRLs already established for flupyradifurone, is summarized in Table 1.

Table 1 Proposed maximum residue limit for flupyradifurone

Common name	Residue definition	MRL (ppm)[1]	Food commodity
Flupyradifurone	4-[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]-2(5*H*)-furanone	0.03	Mustard seeds (condiment type)

[1] 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

As reported in Table 2, there are currently no tolerances in the United States (U.S.) for flupyradifurone in or on the petitioned commodity listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide, nor are there Codex MRLs[2] listed for flupyradifurone in or on the petitioned commodity on the Codex Alimentarius Pesticide Index webpage.

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

Table 2 Comparison of proposed Canadian MRL, U.S. tolerance and Codex MRL

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Established Codex MRL (ppm)
Mustard seeds (condiment type)	0.03	Not established	Not established

How to get involved

Health Canada invites the public to submit written comments on the proposed MRL for flupyradifurone up to 75 days from the date of publication of this document (by 24 December 2024). Please forward your comments to Publications. Health Canada will consider all comments received and a science-based approach will be applied in making a final decision on the proposed MRL. Comments received will be addressed in a response to comments document found in Pesticides and pest management consultations. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

Appendix I

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

No new residue data for flupyradifurone were submitted to support the use of BUTEO Start 480 FS on mustard seeds (oilseed and condiment). Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this petition. In addition, previously reviewed processing studies in treated cottonseed and soybeans were also reassessed to determine the potential for concentration of residues of flupyradifurone in processed commodities.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that the general population and all other population subgroups (except females 13–49 years old) are exposed to less than 22% of the acute reference dose, and therefore there are no health concerns.

Acute dietary (food plus drinking water) intake estimates indicated that females 13–49 years old are exposed to less than 36% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 33% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for flupyradifurone was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for flupyradifurone used to calculate the proposed MRL for mustard seeds (condiment type).

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

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
Canola	Seed Treatment/ 56-89 + Foliar application/194–207	60-170	<0.010	0.024	Refined oil: <1× (based on cottonseed and soybean processing factors on refined oils)

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

Following the review of all available data, the MRL proposed in Table 1 is recommended, in order to cover residues of flupyradifurone in/on mustard seeds (condiment type). Dietary risks from exposure to residues of flupyradifurone in this commodity at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the food that contains residues as listed in Table 1 is considered safe to eat.

References

None.