Proposed Maximum Residue Limit

PMRL2023-27

Flumioxazin

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide flumioxazin, as part of the following application for Canadian use, under submission number 2019-6673.

Under the authority of the <u>Pest Control Products Act</u>, Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested application to add the new commodities of various edible-podded and succulent shelled peas to the product label of Flumioxazin 51 WDG Herbicide containing technical grade flumioxazin, to control or suppress certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 29235.

The evaluation of this flumioxazin application indicated that the end-use product has value, and the human health and environmental risks associated with the new use are acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when flumioxazin 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. 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 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).

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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.

Consultation on the proposed MRLs for flumioxazin is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for flumioxazin 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 be added to the MRLs already established for flumioxazin, are summarized in Table 1.

Table 1 Proposed maximum residue limits for flumioxazin

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Flumioxazin	2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propyn-1-yl)-2 <i>H</i> -1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1 <i>H</i> -isoindole-1,3(2 <i>H</i>)-dione	0.02	Edible-podded dwarf peas, edible-podded peas, edible-podded pigeon peas, edible-podded snow peas, edible-podded sugar snap peas, succulent shelled English peas, succulent shelled garden peas, succulent shelled green peas, succulent shelled peas, succulent shelled pigeon peas

 $^{1 \}text{ ppm} = \text{parts per million}$

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

Currently, there are no American tolerances for flumioxazin in or on the petitioned commodities listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide, nor are there Codex MRLs² listed for flumioxazin in or on the petitioned commodities on the Codex Alimentarius Pesticide Index webpage.

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

Next steps

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

Appendix I

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

Residue data for flumioxazin were submitted to support the use of Flumioxazin 51 WDG Herbicide on edible-podded peas and succulent shelled peas.

Dietary risk assessment results

There were no acute or short-term health effects observed in the flumioxazin toxicology data for the general population, and therefore an acute reference dose (ARfD) was not necessary for this group. Acute dietary (food plus drinking water) intake estimates indicated females 13 to 49 years of age are exposed to less than 100% 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 57% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for flumioxazin 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 edible-podded and succulent shelled peas.

Table A1 Summary of field trial 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)
Edible-podded peas	Pre-emergent/ 68.4–74.9	48–58	<0.02	<0.02
Succulent shelled peas	Pre-emergent/ 69.3–77.0	54–65	<0.02	<0.02

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

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover residues of flumioxazin. Dietary risks from exposure to residues of flumioxazin 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
3060983	2019, Flumioxazin: Magnitude of the Residue on Succulent Peas,
	DACO: 7.3, 7.4.1, 7.4.2.