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Proposed Maximum Residue Limit

PMRL2022-08

Pyraclostrobin

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Purpose of consultation

Maximum Residue Limits (MRLs)¹ are being proposed for the pesticide pyraclostrobin, as part of the following application for Canadian use, under submission number 2019-3056.

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 crop subgroup 1B (Root vegetable except sugarbeet), crop group 3 (Bulb vegetables), crop group 4 (Leafy vegetables except *Brassica* vegetables), crop group 9 (Cucurbit vegetables), crop group 11 (Pome fruits), crop group 12 (Stone fruits), blueberries, grapes, and strawberries to the product label of Merivon Fungicide, containing technical grade fluxapyroxad and pyraclostrobin, to control or suppress certain fungal diseases. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 33951.

The evaluation of this pyraclostrobin application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable. MRLs are being proposed only for certain commodities within crop groups 3 and 11, which are listed in Table 1. The remainder of the requested commodities are already covered by existing individual or crop group MRLs. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when pyraclostrobin is used according to the supported label directions. Therefore, foods containing residues 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 1.

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

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.

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 pyraclostrobin is being conducted via this document. The currently established MRLs for fluxapyroxad are sufficient to cover residues resulting from these new uses and are therefore unaffected by this MRL action. Health Canada invites the public to submit written comments on the proposed MRLs for pyraclostrobin 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 pyraclostrobin, are summarized in Table 1.

Table 1 Proposed maximum residue limits for pyraclostrobin

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Pyraclostrobin	methyl <i>N</i> -[2-[[[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-yl]oxy]methyl]phenyl]- <i>N</i> -methoxycarbamate, including the metabolite [2-[[[1-(4-chlorophenyl)-1 <i>H</i> -pyrazol-3-yl]oxy]methyl]phenyl] carbamate	1.5	Azaroles, Chinese quinces, Japanese quinces, medlars, tejocotes
		0.9	Beltsville bunching onions, daylilies, elegans hosta, fritillaria bulbs, fritillaria leaves, fresh Chinese chive leaves, fresh onions, kurrats, lady's leeks, lilies, macrostem onions, pearl onions, serpent garlic, shallot bulbs ² , shallot leaves, wild leeks

¹ ppm = parts per million

² The MRL established for “shallots” at 0.9 ppm will be revised to “shallot bulbs” to reflect current terminology.

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 locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for pyraclostrobin 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)
Crop Group 3	0.9	0.9	1.5 (onion, bulb and spring onion) 0.7 (leek) 0.15 (garlic)
Crop Group 11	1.5	1.5	0.7 (pome fruits)

Next steps

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

Previously reviewed residue data from field trials conducted in/on green onions, bulb onions, apples and pears were reassessed in the framework of this petition. In addition, a processing study in treated apples was also reassessed to determine the potential for concentration of residues of pyraclostrobin into processed commodities.

Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that females 13 to 49 years of age are exposed to less than 55% 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 11% of the acceptable daily intake, and therefore are not a health concern.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for pyraclostrobin was based upon the field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs.

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
Dry bulb onions	Broadcast foliar applications / 1010–1030	6–7	<0.04	0.81	Not applicable
Green onions	Broadcast foliar applications / 1010–1030	6–7	0.70	0.71	Not applicable
Apples	Broadcast foliar applications / 997–1075	0	0.10	0.80	Juice: 1.3× Sauce: 0.7×
Pears	Broadcast foliar applications / 1010–1040	0	0.19	0.93	

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 pyraclostrobin. Dietary risks from exposure to residues of pyraclostrobin in these crops 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

None.