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Proposed Maximum Residue Limit

PMRL2024-12

Trifloxystrobin

(publié aussi en français)

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Purpose of consultation

Maximum residue limits (MRLs)¹ are being proposed for the pesticide trifloxystrobin, as part of the following applications for Canadian use, under submission numbers 2018-2941 and 2018-7028.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has accepted the requested applications to add the commodities of bulb vegetables (crop group 3-07) and honeysuckle to the product label of Flint Fungicide, containing technical grade trifloxystrobin, to suppress certain fungal diseases. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 30619.

The evaluation of these trifloxystrobin applications 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 trifloxystrobin 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 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 MRLs for trifloxystrobin is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for trifloxystrobin 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 trifloxystrobin, are summarized in Table 1.

Table 1 Proposed maximum residue limits for trifloxystrobin

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Trifloxystrobin	methyl (α,E)- α -(methoxyimino)-2-[[[(E)-1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetate, including the metabolite (α,E)- α -(methoxyimino)-2-[[[(E)-1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetic acid (expressed as parent equivalents)	1.5	Green onions (crop subgroup 3-07B); honeysuckle
		0.04	Bulb onions (crop subgroup 3-07A)

¹ ppm = parts per million

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

Table 2 compares the MRLs proposed for trifloxystrobin 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 Canadian MRLs, U.S. tolerances and Codex MRLs

Food commodity	Proposed Canadian MRL (ppm)	Established U.S. tolerance (ppm)	Codex MRL (ppm)
Honeysuckle	1.5	Not Established	Not Established
Green onions (crop subgroup 3-07B)	1.5	1.5	0.7 (Leek)
Bulb onions (crop subgroup 3-07A)	0.04	0.04	Not Established

Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for trifloxystrobin up to 75 days from the date of publication of this document (by 2 September 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 MRLs. Comments received will be addressed in a response to comments document found in Pesticides and pest management consultations. 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

Residue data for trifloxystrobin on dry bulb onions, green onions and highbush blueberries were submitted to support the use of Flint fungicide on bulb vegetables (crop group 3-07) and honeysuckle.

Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of trifloxystrobin 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 66% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for trifloxystrobin was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for trifloxystrobin and its metabolite, (α,E)- α -(methoxyimino)-2-[[[(E)-[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetic acid, used to calculate the proposed MRLs for bulb vegetables and honeysuckle.

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) ²	Highest average field trial residues (ppm) ²
Dry bulb onions	Foliar/ 555–590	6-8	<0.020	<0.031
Green onions	Foliar/ 558–569	6-8	<0.050	0.886
Highbush blueberries	Foliar/ 311–328	0	0.143	0.562

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

² Sum of residues of trifloxystrobin plus metabolite (α,E)- α -(methoxyimino)-2-[[[(E)-[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetic acid, in parent equivalents.

Following the review of all available data, the MRLs proposed in Table 1 are recommended in order to cover total residues of trifloxystrobin. Dietary risks from exposure to residues of trifloxystrobin 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
2948341	2018, Trifloxystrobin: Magnitude of the Residue on Blueberry (Highbush and lowbush), DACO: 7.4.1,7.4.2
2900604	2018, Trifloxystrobin: Magnitude of the Residue on Dry Bulb Onion, DACO: 7.4.1,7.4.2
2900605	2017, Trifloxystrobin: Magnitude of the Residue on Green Onion, DACO: 7.4.1,7.4.2