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Proposed Maximum Residue Limit

PMRL2025-17

# Picarbutrazox

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## Purpose of consultation

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide picarbutrazox, as part of the following application for Canadian use, submitted by Syngenta Canada Inc. under submission number 2023-6118.

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 various commodities to the product label of Vayantis Seed Treatment containing the technical grade active picarbutrazox, to control certain fungal diseases as a seed treatment use. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number 34138.

The evaluation of this picarbutrazox 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 picarbutrazox 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.

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<sup>1</sup> 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 picarbutrazox is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for picarbutrazox 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 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 picarbutrazox, are summarized in Table 1.

**Table 1 Proposed maximum residue limits for picarbutrazox**

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Picarbutrazox	1,1-dimethylethyl N-[6-[[[(Z)-[(1-methyl-1H-tetrazol-5-yl) phenylmethylene] amino]oxy]methyl]-2-pyridinyl]carbamate	0.01	Root vegetable (crop subgroup 1A); tuberous and corm vegetables (except potato) (crop subgroup 1D); leaves of root and tuber vegetables (human food or animal feed) (crop group 2); bulb vegetables (crop group 3-07); leafy vegetables (crop group 4-13); <i>Brassica</i> head and stem vegetable group (crop group 5-13); edible-podded legume vegetables (crop subgroup 6A); succulent shelled pea and bean (crop subgroup 6B); fruiting vegetables (crop group 8-09); cucurbit vegetables (crop group 9); stalk, stem, and leaf petioles (crop group 22); herbs (crop group 25); spices (crop group 26)

<sup>1</sup> 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 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

As reported in Table 2, The MRLs proposed for picarbutrazox in Canada are the same as corresponding tolerances in the United States (U.S.) as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs<sup>2</sup> listed for picarbutrazox in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

**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)
Root vegetable (crop subgroup 1A); tuberous and corm vegetables (except potato) (crop subgroup 1D); leaves of root and tuber vegetables (human food or animal feed) (crop group 2); bulb vegetables (crop group 3-07); leafy vegetables (crop group 4-13); <i>Brassica</i> head and stem vegetable group (crop group 5-13); edible-podded legume vegetables (crop subgroup 6A); succulent shelled pea and bean (crop subgroup 6B); fruiting vegetables (crop group 8-09); cucurbit vegetables (crop group 9); stalk, stem, and leaf petioles (crop group 22); herbs (crop group 25); spices (crop group 26)	0.01	0.01	Not established

## How to get involved

Health Canada invites the public to submit written comments on the proposed MRLs for picarbutrazox up to 75 days from the date of publication of this document (by 2 November 2025). 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.

<sup>2</sup> The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

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## Appendix I

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

In lieu of residue data on human food and livestock feed commodities, the applicant submitted a scientific rationale based on the decision tree in Appendix I of Health Canada's *Guidance on Streamlined Residue Chemistry Data Requirements for Seed Treatment Uses and Potato Seed-piece Applications* (Science Policy Note SPN2018-01).

Given that the proposed seed treatment rates of Vayantis Seed Treatment on each of the requested crops are at or below 10 g a.i./100 kg seed, no residue data on human foods are required. In addition, previously reviewed residue data from field trials on various cereal and legume crops conducted at exaggerated application rates are adequate to demonstrate that quantifiable residues of picarbutrazox are not expected in/on livestock feed commodities associated with the new crops.

### Dietary risk assessment results

Studies in laboratory animals showed no acute health effects relevant to dietary exposure. Consequently, a single dose of picarbutrazox is not likely to cause acute health effects in the general population (including infants and children).

Chronic (non-cancer and cancer) dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 6% of the acceptable daily intake, and therefore there are no health concerns.

### Maximum residue limits

As no quantifiable residues of picarbutrazox are expected as a result of the proposed seed treatment uses, the recommendation for proposed maximum residue limits (MRLs) for picarbutrazox in/on these crop commodities was based upon the limit of quantitation for the enforcement method (in other words, 0.01 ppm). Similarly, no quantifiable residues of picarbutrazox are expected in/on livestock commodities as a result of the proposed seed treatment uses and will be covered under the MRLs currently established for this active ingredient (in other words, 0.01 ppm in/on eggs milk; fat, meat and meat byproducts).

Following the review of all available data, the MRLs proposed in Table 1 are recommended, in order to cover residues of picarbutrazox. Dietary risks from exposure to residues of picarbutrazox 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.

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**References**

<b>PMRA number</b>	<b>Citation</b>
3519556	2023, Seed-Treatment Use of Picarbutrazox in Root Vegetables except potato (CSG 1A and CSG 1D), Bulb Vegetables (CG 3-07), Leafy Vegetables except watercress (CG 4-13), Edible-Podded Legume Vegetables (CSG 6A), Succulent Shelled Pea and Bean (CSG 6B), Fruiting Vegetables (CG 8-09), Cucurbit Vegetables (CG 9), Brassica Head and Stem Vegetables (CG 5-13), Stalk, Stem and Leaf Petioles (CG 22), Herbs and Spices (CG 25, CG 26), DACO: 6.1,6.2,6.3,7.1,7.3,7.4,7.4.1