Proposed Maximum Residue Limit PMRL2024-06

Picarbutrazox

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Purpose of consultation

Maximum residue limits (MRLs)[1] are being proposed for the pesticide picarbutrazox, as part of the following applications for Canadian use, under submission numbers 2021-6643 and 2021-6665.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the requested applications to add various commodities to the product labels of Vibrance Total (containing technical grade picarbutrazox co-formulated with thiabendazole, sedaxane, Metalaxyl-M and S-isomer, and fludioxonil) and Vayantis Seed Treatment, containing technical grade picarbutrazox, to control certain fungal diseases. The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Numbers 34890 and 34138, respectively.

The evaluation of these picarbutrazox applications indicated that the end-use products have 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. An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except for certain

[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.

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. Residues of picarbutrazox in/on animal commodities are covered under the MRLs currently established for eggs; fat, meat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep; and milk, all at 0.01 ppm. As MRLs are currently established for thiabendazole, sedaxane, metalaxyl-M and S-isomer, and fludioxonil on all the petitioned commodities and in animal commodities, separate PMRL actions are not required.

Health Canada invites the public to submit written comments on the proposed MRLs for picarbutrazox 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 replace or 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)[1]	Food commodity
Picarbutrazox	1,1-dimethylethyl *N*-[6-[[[(Z)-[(1-methyl-1*H*-tetrazol-5-yl)phenylmethylene] amino]oxy]methyl]-2-pyridinyl]carbamate	0.01	Dried shelled pea and bean (except soybean) (crop subgroup 6C); cereal grains (crop group 15)[2]; rapeseeds (revised) (crop subgroup 20A)

[1] ppm = parts per million

[2] The MRL is proposed to replace the currently established MRLs of 0.01 ppm in/on field corn, popcorn grain, and sweet corn kernels plus cob with husks removed with a single crop group 15 MRL at the same value. This will result in a single MRL that will be applicable to all commodities within crop group 15.

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

The MRLs proposed for picarbutrazox in Canada are the same as corresponding U.S. tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[2] listed for picarbutrazox in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

Next steps

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 30 July 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

No field trial data on human food commodities were submitted to support the uses of Vibrance Total on dried shelled beans, dried shelled peas, chickpeas, lentils, lupins and faba beans; or for Vayantis Seed Treatment on crop subgroup 6C – dried shelled pea and bean (except soybean), crop subgroup 20A – rapeseeds (revised), and crop group 15 – cereal grains. Since the proposed seed treatment rates of Vibrance Total and Vayantis Seed Treatment on each of the requested crops are below 10 g a.i./100 kg seed, no field trial data on human foods are required (as per SPN2018-01), as no quantifiable residues of picarbutrazox are expected as result of the proposed seed treatment uses.

Residue data on relevant animal feed commodities from field trials conducted in Canada and the United States were submitted to support the use of Vibrance Total on dried shelled beans, dried shelled peas, chickpeas, lentils, lupins and faba beans; and the use of Vayantis Seed Treatment on crop subgroup 6C – dried shelled pea and bean (except soybean), and crop group 15 – cereal grains. Picarbutrazox was applied to dried beans, dried peas, wheat, and barley at exaggerated rates and harvested at normal commercial harvest.

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 dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 4% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limits

As no quantifiable residues of picarbutrazox are expected as result of the proposed seed treatment uses on crop subgroup 6C – dried shelled pea and bean (except soybean), crop subgroup 20A – rapeseeds (revised), and crop group 15 – cereal grains, the recommendation for proposed maximum residue limits (MRLs) for picarbutrazox was based upon the limit of quantitation for the enforcement method (0.01 ppm), as per SPN2018-01.

Following the review of all available data, the MRLs proposed in Table 1 are recommended to cover residues of picarbutrazox. Dietary risks from exposure to residues of picarbutrazox in these commodities at the proposed and established 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 Document Number	Reference
3401299	2021, Picarbutrazox (A20597B) - Magnitude of the Residues in or on Barley Hay and Straw only Following Seed Treatment, Canada, 2019, DACO: 7.4.1
3401300	2021, Picarbutrazox (A20597B) - Magnitude of the Residues in or on Dry Pea Vines (forage) and Hay only Following Seed Treatment, Canada 2019, DACO: 7.4.1
3401301	2021, Picarbutrazox (A20597B) - Magnitude of the Residues in or on Wheat following seed treatment, USA, 2019, DACO: 7.4.1
3401302	2020, Picarbutrazox (A20597B) - Magnitude of Residues in or on Dry Bean Vines and Hay Following Seed Treatment, USA, 2019, DACO: 7.4.1