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Proposed Maximum Residue Limit

PMRL2025-23

Ethiprole

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Purpose of consultation

A maximum residue limit (MRL)¹ for **imported** commodities is being proposed for the pesticide ethiprole as part of the following application submitted by Bayer CropScience Inc. under submission number 2023-3429, in order to permit the import and sale of food in Canada that could contain ethiprole residues.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing acceptability of the request to specify a maximum residue limit (MRL) for ethiprole on imported sugarcane cane, to control Spittlebug (*Aeneolamia spp.*).

Ethiprole is an insecticide not currently registered for use in Canada.

Health Canada has determined the quantity of residues that may remain in or on imported sugarcane cane when ethiprole is used according to the label directions of the exporting country, and that such residues will not be a concern to human health. Therefore, the foods containing residues resulting from this use are safe to eat, and an MRL is being proposed as a result of this assessment. A summary of the field trial data used to support the proposed MRL 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.

Health Canada must determine the quantity of residues that could remain in or on the imported food commodities when the pesticide is used according to label directions in the exporting country, and that such residues will not be a concern to human health (Step 3 and Step 4). If estimated human exposure is less than or equal to the acceptable level (developed in Step 2), Health Canada concludes that consuming residues resulting from use according to label directions approved in the foreign country is not a health concern. The proposed MRL is then subject to consultation to legally specify the MRL on the corresponding imported commodity.

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 in certain instances where different MRLs are specified for the raw agricultural commodity and its processed product(s).

Consultation on the proposed MRL for ethiprole on imported sugarcane cane is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for ethiprole 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 MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada’s Notification Authority and Enquiry Point.

Proposed MRL

The proposed MRL, to be added to the MRLs already established for ethiprole is summarized in Table 1.

Table 1 Proposed maximum residue limit for ethiprole

| Common name | Residue definition | MRL (ppm) ¹ | Food commodity |
|-------------|---|------------------------|----------------|
| Ethiprole | 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethylsulfinyl)-1H-pyrazole-3-carbonitrile | 0.1 | Sugarcane cane |

¹ ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum residue limits, human health, and food safety 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 geographical locations of the crop field trials used to generate residue chemistry data.

Table 2 compares the MRL proposed for ethiprole in Canada with the corresponding tolerance 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 MRLs² listed for ethiprole in or on - sugarcane cane on the Codex Alimentarius Pesticide Index webpage.

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

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) |
|-----------------------|------------------------------------|---|------------------------------------|
| Sugarcane cane | 0.1 | 0.07 | Not established |

ppm = parts per million

How to get involved

Health Canada invites the public to submit written comments on the proposed MRL for ethiprole up to 75 days from the date of publication of this document (by 21 January 2026). Please forward your comments to the Pest Management Regulatory Agency Publications Section. Health Canada will consider all comments received and a science-based approach will be applied in making a final decision on the proposed MRL. Comments received will be addressed in a response to comments document found in Pesticides and pest management consultations. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

Appendix I

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

Residue data for ethiprole were submitted to support the maximum residue limit on imported sugarcane cane. In addition, a processing study in treated sugarcane cane was reviewed to determine the potential for concentration of residues of ethiprole into processed commodities.

Dietary risk assessment results

Acute dietary (food only) intake estimates indicated that the general population and all population subgroups are exposed to less than 45% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food only) intake estimates indicated that the general population and all population subgroups are exposed to less than 30% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for a maximum residue limit (MRL) for ethiprole on imported sugarcane cane was based upon the residues observed in sugarcane cane treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data for ethiprole to calculate the proposed MRL for imported sugarcane cane.

Table A1 Summary of field trial and processing data used to support the MRL

| 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 |
|----------------|---|----------------------------|---|--|---|
| Sugarcane cane | Foliar /796–831 | 88–120 | <0.002 | 0.054 | Molasses ² : 1.1× Refined sugar: 0.1× |

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

² Anticipated residues of ethiprole in sugarcane molasses are expected to be covered by the proposed MRL of 0.1 ppm for sugarcane cane.

Following the review of all available data, the MRL proposed in Table 1 is recommended, in order to cover residues of ethiprole. Dietary risks from exposure to residues of ethiprole in imported sugarcane cane at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the imported foods that contain residues as listed in Table 1 are considered safe to eat.

References

| PMRA number | Citation |
|--------------------|--|
| 3482542 | 2022, Magnitude of the residues of ethiprole and its metabolites in/on sugarcane after spraying Curbix 200 SC, DACO: 7.4.1,7.4.2 |
| 3482543 | 2022, Magnitude of the residues of ethiprole and its metabolites in/on sugarcane processed commodities after spraying Curbix 200 SC, DACO: 7.4.5 |