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Proposed Maximum Residue Limit

PMRL2022-07

# Topramezone

*(publié aussi en français)*

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## Purpose of Consultation

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide topramezone, as part of the following application for Canadian use, under submission number 2018-4844.

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 commodity of canola to the product label of Certitude A Herbicide, containing technical grade topramezone, to control volunteer canola and suppress kochia in fields to be seeded to canola. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Number [33908](#).

The evaluation of this topramezone application indicated that the end-use product has value, and the human health and environmental risks associated with the new use is acceptable. Dietary risks from the consumption of foods listed in Table 1 were shown to be acceptable when topramezone 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 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 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).

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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.

Consultation on the proposed MRLs for topramezone is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRLs for topramezone 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 topramezone, are summarized in Table 1.

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

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Topramezone	3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1 <i>H</i> -pyrazol-4-yl)methanone	0.05	Fat and meat byproducts of poultry <sup>2</sup>
		0.01	Rapeseeds <sup>3</sup> (crop subgroup 20A) (revised); eggs and meat of poultry <sup>2</sup>

<sup>1</sup> ppm = parts per million

<sup>2</sup> From poultry consumption of feed treated with topramezone

<sup>3</sup> Canola is a variety of rapeseed

An MRL is proposed for each commodity included in the listed crop groupings in accordance with 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

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. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 compares the MRLs proposed for topramezone in Canada with corresponding American tolerances. American tolerances are 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 topramezone in or on any commodity on the Codex Alimentarius [Pesticide Index](#) webpage.

**Table 2 Comparison of proposed Canadian MRL, American Tolerance and Codex MRL (where different)**

<b>Food commodity</b>	<b>Canadian MRL (ppm)</b>	<b>American Tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
Meat byproducts of poultry	0.05	0.02	Not Established
Fat of poultry	0.05	Not Established	Not Established
Rapeseeds (crop subgroup 20A) (revised); eggs, meat of poultry	0.01	Not Established	Not Established

### Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for topramezone 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](#).

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<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.

## Appendix I

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

Residue data for topramezone in canola were submitted to support the use of Certitude A Herbicide on canola. In addition, a processing study in treated canola was reviewed to determine the potential for concentration of residues of topramezone 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 25% 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 54% of the acceptable daily intake, and therefore are not a health concern.

### Maximum residue limits

The recommendation for maximum residue limits (MRLs) for topramezone was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data used to calculate the proposed MRL for rapeseeds (crop subgroup 20A, revised).

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

Commodity	Application method/ Total application rate (g a.i./ha) <sup>1</sup>	Preharvest interval (days)	Lowest average field trial residues (ppm)	Highest average field trial residues (ppm)	Experimental processing factor
Canola seed	Soil preplant application/ 5.60–6.73	84–163	<0.01	<0.01	No quantifiable residues observed when treated at exaggerated rates.

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

Based on the dietary burden and residue data, MRLs of 0.01 ppm in eggs and meat of poultry, and MRLs of 0.05 ppm in fat and meat byproducts of poultry to cover residues of topramezone are also proposed.

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of topramezone. Dietary risks from exposure to residues of topramezone in these crop and livestock 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**

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