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Proposed Maximum Residue Limit

PMRL2024-01

# Tolpyralate

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## Purpose of consultation

Maximum residue limits (MRLs)<sup>1</sup> are being proposed for the pesticide tolpyralate, as part of the following applications for Canadian use, under submission numbers 2021-5974 and 2021-5975.

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 the new commodities of wheat and barley to the product labels of Tolpyralate 400SC Herbicide containing technical grade tolpyralate, and Ondeck Herbicide containing technical grade bromoxynil and tolpyralate, to control or suppress certain weeds. The specific uses approved in Canada are detailed on these product labels, *Pest Control Products Act* Registration Numbers [32901](#) and [34709](#), respectively.

The evaluation of these tolpyralate 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 tolpyralate 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 tolpyralate is being conducted via this document. MRLs are currently established for bromoxynil on barley and wheat at 0.05 ppm; accordingly, a separate PMRL action is not required. Health Canada invites the public to submit written comments on the proposed MRLs for tolpyralate 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 tolpyralate, are summarized in Table 1.

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

Common name	Residue definition	MRL (ppm) <sup>1</sup>	Food commodity
Tolpyralate	1-[[1-ethyl-4-[3-(2-methoxyethoxy)-2-methyl-4-(methylsulfonyl)benzoyl]-1 <i>H</i> -pyrazol-5-yl]oxy]ethyl methyl carbonate	0.01	Barley, wheat

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

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

Currently, there are no American tolerances for tolpyralate in or on the petitioned commodities listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide; nor are there Codex MRLs<sup>2</sup> listed for tolpyralate in or on any commodity on the Codex Alimentarius [Pesticide Index](#) webpage.

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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.

## Next steps

Health Canada invites the public to submit written comments on the proposed MRLs for tolpyralate up to 75 days from the date of publication of this document (by 2 April 2024). 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](#).

## Appendix I

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

Residue data for tolpyralate were submitted to support the use of Tolpyralate 400SC Herbicide and Ondeck Herbicide on barley and wheat. In addition, processing studies in treated barley and wheat were reviewed to determine the potential for concentration of residues of tolpyralate into processed commodities.

#### Dietary risk assessment results

Acute dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 8% of the acute reference dose, and therefore there are no health concerns.

Chronic dietary (food plus drinking water) intake estimates indicated that the general population and all population subgroups are exposed to less than 35% of the acceptable daily intake, and therefore there are no health concerns.

#### Maximum residue limits

The recommendation for maximum residue limits (MRLs) for tolpyralate was based upon the submitted field trial data, and the guidance provided in the [OECD MRL Calculator](#). Table A1 summarizes the residue data for tolpyralate used to calculate the proposed MRLs for barley and wheat.

**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
Barley	Foliar Broadcast/ 37.3–42.4	47–56	<0.01	<0.01	No quantifiable residues observed at exaggerated rates.
Wheat	Foliar Broadcast/ 38.4–41.6	47–58	<0.01	<0.01	No quantifiable residues observed at exaggerated rates.

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

Following the review of all available data, MRLs as proposed in Table 1 are recommended in order to cover residues of tolpyralate. Dietary risks from exposure to residues of tolpyralate 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>
3286724	2021, Magnitude and Decline of the Residue of Tolpyralate in or on Wheat Raw Agricultural and Processed Commodities Following One Foliar Application of Tolpyralate 400 SC - 2019, DACO: 7.1,7.2.1,7.4.1,7.4.2
3286725	2021, Magnitude and Decline of the Residues of Tolpyralate and [CBI REMOVED] in or on Barley Raw Agricultural and Processed Commodities Following One Foliar Application of Tolpyralate 400 SC - 2020, DACO: 7.1,7.2.1,7.4.1,7.4.2