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Proposed Maximum Residue Limit

PMRL2023-35

Bromoxynil

(publié aussi en français)

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Purpose of consultation

A maximum residue limit (MRL)¹ is being proposed for the pesticide bromoxynil, as part of the following applications for Canadian use, under submission number 2020-1763.

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 industrial hemp to the product label of IPCO Brotex 4AT, containing technical grade bromoxynil to control certain weeds. The specific uses approved in Canada are detailed on this product label, *Pest Control Products Act* Registration Numbers [33554](#).

The evaluation of this bromoxynil application indicated that the end-use product has value, and the human health and environmental risks associated with the new use are acceptable. Dietary risks from the consumption of food listed in Table 1 were shown to be acceptable when bromoxynil is used according to the supported label directions. Therefore, food containing residues resulting from this use is 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.

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).

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.

Consultation on the proposed MRL for bromoxynil is being conducted via this document. Health Canada invites the public to submit written comments on the proposed MRL for bromoxynil 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 MRL is also being conducted internationally by notifying the [World Trade Organization](#), as coordinated by the [Canada's Notification Authority and Enquiry Point](#).

Proposed MRL

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

Table 1 Proposed maximum residue limit for bromoxynil

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Bromoxynil	3,5-dibromo-4-hydroxybenzotrile	0.05	Hemp seeds

¹ 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 is no American tolerance for bromoxynil in or on the petitioned commodity listed in the [Electronic Code of Federal Regulations](#), 40 CFR Part 180, by pesticide; nor are there Codex MRLs² listed for bromoxynil 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 MRL for bromoxynil 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 MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is 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 limit

Residue data for bromoxynil were submitted to support the use of IPCO Brotex 4AT on industrial hemp. In addition, a processing study in treated industrial hemp was reviewed to determine the potential for concentration of residues of bromoxynil into hemp hearts, oil, press-cake and flour.

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 9% of the acute reference dose, and therefore there are no health concerns.

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 60% of the acceptable daily intake, and therefore there are no health concerns.

Maximum residue limit

The recommendation for the maximum residue limit (MRL) for bromoxynil 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 hemp seeds.

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
Industrial hemp seeds	Foliar broadcast/ 289–329	54–62	<0.05	<0.05	No concentration in processed fractions

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

Following the review of all available data, the MRL proposed in Table 1 is recommended in order to cover residues of bromoxynil. Dietary risks from exposure to residues of bromoxynil in this crop commodity at the proposed MRL were shown to be acceptable for the general population and all subpopulations, including infants, children, adults and seniors. Thus, the food that contains residues as listed in Table 1 is considered safe to eat.

References

PMRA#	Citation
3118593	2020, Bromoxynil: Magnitude of the residue on industrial hemp, DACO: 7.2.1,7.3,7.4.1,7.4.2,7.4.5