Proposed Maximum Residue Limit PMRL2017-30

Bicyclopyrone

(publié aussi en français)

2 November 2017

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca

Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2017-30E (print version)
H113-24/2017-30E-PDF (PDF version)

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has received applications to register the end-use product Talinor Herbicide (containing technical grade bicyclopyrone, bromoxynil and cloquintocet-mexyl) for use in Canada on wheat (spring and durum) and barley.

The evaluation of this bicyclopyrone application indicated that the end-use product has value and the human health and environmental risks associated with the new uses are acceptable. Based on the application rates and the data submitted, residues of bromoxynil and cloquintocet-mexyl are unlikely to exceed the established MRLs for these actives for wheat and barley grain, from the use of the proposed end-use product on these crops.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to 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. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for bicyclopyrone is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I.

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.

The proposed MRLs, to replace or be added to the MRLs already established for bicyclopyrone, are as follows.

Table 1 Proposed Maximum Residue Limits for Bicyclopyrone

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
		2.0[2]	Meat byproducts of cattle, goats, horses and sheep
		0.5[3]	Meat byproducts of hogs
		0.15	Barley bran
		0.07	Barley, wheat bran
		0.04	Wheat

[1] ppm = parts per million
[2] The MRL is proposed to replace the currently established 1.5 ppm MRL.
[3] The MRL is proposed to replace the currently established 0.2 ppm MRL.

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 MRL proposed for bicyclopyrone in Canada with corresponding American tolerances and Codex MRLs.[1] American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. There are no Codex MRLs established on the proposed commodities for bicyclopyrone, and a listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food and Feed website, by pesticide or commodity.

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

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Hog meat byproducts	0.5	0.4	Not established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for bicyclopyrone 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). The PMRA will consider all comments received before 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.

[1] 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 bicyclopyrone in wheat and barley were submitted to support the domestic use of Talinor Herbicide on these crops. In addition, a processing study in treated wheat was reviewed to determine the potential for concentration of residues of bicyclopyrone into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for bicyclopyrone 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 MRLs for wheat and barley commodities.

Table A1 Summary of Field Trial and Processing Data Used to Support MRLs

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
Wheat grain	Ground foliar application / 47.4-52.5	57-81	<0.01	0.031	2.1-2.3 for bran, 1.4 for germ, 0.2-0.3 for flour
Barley grain	Ground foliar application / 49.2-54.7	57-81	<0.01	0.051	2.1-2.3 for bran, 0.2-0.3 for flour

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

Based on the increase in the dietary burden from the consumption of treated wheat and barley, the MRLs for ruminant byproducts will be revised to 2.0 ppm (from 1.5 ppm), while the MRL for swine meat byproducts will be revised to 0.5 ppm (from 0.2 ppm) to cover residues of bicyclopyrone (and its structurally similar metabolites SYN503780 and CSCD686480, both expressed as bicyclopyrone equivalents).

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover total residues of bicyclopyrone. Total residues of bicyclopyrone in these crop/livestock commodities at the proposed MRLs will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.