Proposed Maximum Residue Limit PMRL2019-14

Fluxapyroxad

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

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of the new use on annual canarygrass for human consumption to the product label, Insure Cereal FX4, containing technical grade pyraclostrobin, fluxapyroxad, triticonazole and metalaxyl, is acceptable. The specific uses approved in Canada are detailed on the label of Insure Cereal FX4, *Pest Control Products Act* Registration Number 33210.

The evaluation of this fluxapyroxad application indicated that the end-use product has value and the human health and environmental risks associated with the new use are acceptable. A revision to the MRL for rice bran is also proposed under this PMRL.

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 fluxapyroxad is being conducted via this document (see Next Steps). MRL consultation for the other active ingredients, pyraclostrobin, triticonazole and metalaxyl, present in Insure Cereal FX4, is being consulted under separate actions. 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 fluxapyroxad, are as follows.

Table 1 Proposed Maximum Residue Limits for Fluxapyroxad

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Fluxapyroxad	3-(difluoromethyl)-1-methyl-*N*-(3′,4′,5′-trifluoro[1,1′-biphenyl]-2-yl)-1*H*-pyrazole-4-carboxamide	8.5[2]	Rice bran
		0.01	Annual canarygrass seeds

[1] ppm = parts per million;
[2] The MRL for rice bran is being revised from the current MRL of 4.5 ppm.

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

Table 2 compares the MRLs proposed for fluxapyroxad 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. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Index webpage, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Rice bran	8.5	8.5	Not Established
Annual canarygrass seeds	0.01	Not Established	Not Established

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fluxapyroxad 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

Previously reviewed residue data from field trials conducted in/on wheat and barley (translated to annual canarygrass) were reassessed in the framework of this petition. In addition, processing studies in treated barley and rice were also reassessed to determine the potential for concentration of residues of fluxapyroxad into processed commodities.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fluxapyroxad was based upon the previously reviewed 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 annual canarygrass seeds and rice bran.

Table A1 Summary of Field Trial and Processing Data Used to Support the 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
Barley grain	Foliar application / 200	20-27	<0.01	1.2[2]	Barley flour: 0.2×
Wheat grain			0.09	0.19[2]	
Rice grain	Ground spray / 288-309	28-29	0.22	3.84	Rice bran: 2.4×

[1] g a.i./ha = grams of active ingredient per hectare.
[2] Based on the degree of exaggeration (200-fold) of a foliar application, it was determined that residues resulting from a seed treatment at 1 g a.i./ha would not be quantifiable.

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