Proposed Maximum Residue Limit

PMRL2016-08

Fludioxonil

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) is proposing to establish maximum residue limits (MRLs) for fludioxonil on leaf petioles (CSG 4B), pomegranates, black sapotes, canistels, papayas and star apples to permit the import and sale of foods containing such residues.

Fludioxonil is a fungicide currently registered in Canada for use on various commodities.

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when fludioxonil is used according to label directions in the exporting country, and that such residues will not be a concern to human health. This quantity is then legally established as an MRL on the corresponding imported commodity. 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 fludioxonil 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 are also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point.

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

 Table 1
 Proposed Maximum Residue Limits for Fludioxonil

Common Name	Residue Definition	MRL (ppm) ¹	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 <i>H</i> -pyrrole-3-carbonitrile	15 ²	Leaf petioles (Crop Subgroup 4B)
		5.0^{3}	Pomegranates, black sapotes, canistels, papayas, star apples

ppm = parts per million.

² This proposed MRL will replace the currently established MRL of 0.01 ppm on CSG 4B.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

³ This proposed MRL will replace the currently established MRL of 1.7 ppm on pomegranates, and of 0.45 ppm on black sapotes, canistels, papayas, and star apples.

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

The MRLs proposed for fludioxonil in Canada are the same as corresponding American tolerances as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Table 2 compares the MRL proposed for fludioxonil on pomegranates in Canada with the corresponding Codex MRL¹ listed on the Codex Alimentarius Pesticide Residues in Food webpage. Currently there are no Codex MRLs listed for fludioxonil in or on celery or other leaf petiole commodities, black sapotes, canistels, papayas and star apples.

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

Food Commodity	Canadian MRL (ppm)	Codex MRL (ppm)	
Pomegranates	5.0	2.0	

Next Steps

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

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 fludioxonil in celery and pomegranate were submitted to support the maximum residue limits on imported leaf petioles (CSG 4B), pomegranates, black sapotes, canistels, papayas, and star apples.

Maximum Residue Limits

The recommendation for maximum residue limits (MRLs) for fludioxonil was based upon the residues observed in crop commodities treated according to label directions in the exporting country, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRLs for imported leaf petioles (CSG 4B), pomegranates, black sapotes, canistels, papayas, and star apples.

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

Commodity	Application Method/ Maximum Application Rate	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Celery	Broadcast foliar; 1.00 kg ai/ha ¹	0	2.0	8.5	None
Pomegranates	$74 \text{ g ai}/100 \text{ L}^2$ (double dip)	0	1.3	2.0	None

¹ kg ai/ha = kilograms of fludioxonil ingredient per hectare.

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

 $^{^{2}}$ g ai/100 L = grams of fludioxonil per 100 L of water.