Proposed Maximum Residue Limit PMRL2014-63

Difenoconazole

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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 difenoconazole on undelinted cotton seeds, citrus fruits (Crop Group 10 - Revised), citrus oil, stone fruits (Crop Group 12-09), mangoes, tree nuts (Crop Group 14-11), dry soybeans and low growing berries, except cranberries (Crop subgroup 13-07G) to permit the import and sale of foods containing such residues.

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

The PMRA must determine the quantity of residues that are likely to remain in or on the imported food commodities when difenoconazole 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 difenoconazole 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 Standards Council of Canada.

The proposed MRLs, to be added to the MRLs already established for difenoconazole, are as follows.

Table 1 Proposed Maximum Residue Limits for Difenoconazole

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Difenoconazole	1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole	25	Citrus oil
		2.5	Stone fruits (Crop group 12-09); low growing berries, except cranberries (Crop subgroup 13-07G)
		0.80	Citrus fruits (Crop group 10 – revised)
		0.15	Dry soybeans
		0.09	Mangoes
		0.05	Undelinted cotton seeds
		0.03	Tree nuts (Crop group 14-11)

[1] ppm = parts per million

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.

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 difenoconazole 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 Residues in Food website, 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)
Citrus oil	25	25	Not established
Stone fruits (Crop group 12-09)	2.5	2.5	0.2 (cherries) 0.5 (nectarines) 0.5 (peaches) 0.2 (plums/prunes)
Low growing berries, except cranberries (Crop subgroup 13-07G)	2.5	2.5	Not established
Citrus fruits (Crop group 10 – revised)	0.80	0.60	Not established
Dry soybeans	0.15	0.15	0.02 (dry soya bean)
Mangoes	0.09	0.07	0.07
Undelinted cotton seeds	0.05	0.05	Not established

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

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

Appendix I

Summary of Field Trial Data Used to Support the Proposed MRLs

Residue data for difenoconazole in/on cotton, citrus fruits (oranges, grapefruits & lemons), stone fruits (tart cherries, sweet cherries, peaches & plums), mangoes, tree nuts (almonds & pecans), soybeans and strawberries were submitted to support the maximum residue limits (MRLs) on imported crops. In addition, processing studies in treated cotton, citrus fruits (oranges), stone fruits (plums/prunes) and soybeans were reviewed to determine the potential for concentration of residues of difenoconazole into processed commodities.

Maximum Residue Limit(s)

The recommendation for maximum residue limits (MRLs) for difenoconazole 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 the various imported crop commodities.

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits (MRLs)

Commodity	Application Method/ Total Application Rate	Preharvest Interval (days)	Residues (ppm)		Experimental Processing Factor
			Min	Max	
Oranges	Broadcast foliar/ 0.556-0.573 kg ai/ha	0	0.0700	0.650	Citrus oil: 46.8X Citrus juice: no quantifiable residues
Grapefruits	Broadcast foliar/ 0.556-0.576 kg ai/ha	0	0.0700	0.240	
Lemons	Broadcast foliar/ 0.559-0.567 kg ai/ha	0	0.0800	0.240	
Tart cherries	Broadcast foliar/ 0.511-0.524 kg ai/ha	0	0.728	1.01	Not required
Sweet cherries	Broadcast foliar/ 0.517-0.528 kg ai/ha	0	0.284	0.716	Not required
Peaches	Broadcast foliar/ 0.512-0.546 kg ai/ha	0	0.0728	1.02	Not required
Plums	Broadcast foliar/ 0.512-0.520 kg ai/ha	0	0.0700	0.600	Prune: 2.57X
Strawberries	Broadcast foliar/ 0.507-0.529 kg ai/ha	0	0.0704	1.22	Not required
Soybean seeds	Broadcast foliar/ 0.241-0.257 kg ai/ha	0	<0.01	0.152	Refined oil: 0.75X (no concentration observed)
Mangoes	Broadcast foliar/ 0.375 kg ai/ha	7	0.0100	0.0400	Not required
Undelinted cotton seeds	Seed treatment/ 35 g ai/100 kg seed	132 - 189	<0.05	<0.05	Refined oil: no quantifiable residues

Commodity	Application Method/	Preharvest	Residues (ppm)		Experimental
Almond nutmeat	Broadcast foliar/ 0.506-0.517 kg ai/ha	13 - 15	<0.01	<0.01	Not required
Pecan nutmeat	Broadcast foliar/ 0.514-0.521 kg ai/ha	14 - 15	<0.01	0.020	Not required

Following the review of all available data, MRLs as proposed in Table 1 are recommended to cover residues of difenoconazole in/on citrus oil, stone fruits (crop group 12-09), low growing berries, except cranberries (crop subgroup 13-07G), citrus fruits (crop group 10 - revised), dry soybeans, mangoes, undelinted cotton seeds, and tree nuts (crop group 14-11). Residues of difenoconazole 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.