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Proposed Maximum Residue Limit

PMRL2007-13

# Fludioxonil

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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of Section 10 of the [Pest Control Products Act](#) (PCPA), is proposing to establish maximum residue limits (MRLs) for fludioxonil in or on imported citrus fruits (Crop Group 10), kiwifruits, pomegranates and true yam tubers. See Appendix I for a list of the citrus crop group commodities.

Fludioxonil is a fungicide used to control specific disease organisms on the imported commodities and is currently registered for use in Canada on a number of food crops.

The PMRA has determined the quantity of residues that are likely to remain in or on the imported commodities when fludioxonil is used according to label directions in the exporting country. The Agency has also determined such residues will not pose an unacceptable dietary health risk, and is proposing to legally establish corresponding import MRLs. 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.

Details regarding the establishment of these import MRLs can be found in the corresponding Evaluation Report that is available on the [PMRA website](#), under Public Registry, Product Information, Current Applications<sup>1</sup>.

Currently, MRLs are legally established under the Food and Drug Regulations (FDR) after consultation through the Canada Gazette. Amendments to the *Food and Drugs Act* (FDA), via [Bill C-28](#), anticipated to come into force in 2007, will allow pesticide MRLs to be legally established under the PCPA without their having to be adopted by regulation under the FDA, resulting in a more efficient means of establishing, revising and revoking pesticide MRLs.

Consultation on the proposed MRLs for fludioxonil is being conducted via this document (see Next Steps). This action is being taken in advance of Bill C-28 coming into force to allow the MRLs to be legally established as soon as possible after the FDA is amended.

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<sup>1</sup> The relevant report can be accessed by selecting the Applications/All/All tabs and opening the Evaluation Report found under Application Number 2005-0741.

The proposed import MRLs for fludioxonil in Canada in or on food, to be added to those MRLs already legally established, are as follows:

**Table 1 Proposed Maximum Residue Limits for Fludioxonil**

Common Chemical Name	Chemical Name of Substance	MRL (ppm)	Food Commodities
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 <i>H</i> -pyrrole-3-carbonitrile	10	Citrus fruits (Crop Group 10)
		500	Citrus oil
		20	Kiwifruits
		1.7	Pomegranates
		8.0	True yam tubers*

\* PMRL2006-01 proposed an MRL of 0.02 ppm which is to be revised as a result of this action due to the addition of a post-harvest dip application to the seed treatment use pattern in the exporting country.

A complete list of all MRLs established in Canada can be found in [Table II, Division 15](#) of the FDR. Once the amendments to the FDA via Bill C-28 are in force, the list of legally established Canadian MRLs will be available on the PMRA's [MRL webpage](#), which will be updated to include the MRLs listed in this document.

## International Situation and Trade Implications

The proposed MRLs in Canada are the same as corresponding tolerances established in the United States (listed in [40 CFR 180](#) by pesticide), with the exception of pomegranate. Table 2 identifies differences between Canadian MRLs, American tolerances and Codex<sup>2</sup> MRLs ([Codex MRLs](#) searchable by pesticide or commodity).

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<sup>2</sup> Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

**Table 2 Differences between Canadian MRLs, American tolerances and Codex MRLs**

<b>Food Commodities</b>	<b>Canadian MRLs (ppm)</b>	<b>American Tolerances (ppm)</b>	<b>Codex MRLs (ppm)</b>
Citrus fruits (Crop Group 10)	10	10	7
Citrus oil	500	500*	No Codex MRL established
Kiwifruits	20	20	15
Pomegranates	1.7	5.0	No Codex MRL established
True yam tubers	8.0	8.0	No Codex MRL established

\* US tolerance is established on "Grapefruit, oil" in 40 CFR 180.516.

### **Next Steps**

The PMRA invites the public to submit written comments on the proposed import MRLs for fludioxonil within 75 days from the date of publication of this document. Please forward your comments to Publications (see contact information on the cover page of this document). Health Canada will consider all comments received before making a final decision on the proposed MRLs for fludioxonil and before posting an Established Maximum Residue Limit document on the PMRA's website once the amendments to the FDA are in force.

**Appendix I****Crop Groups: Numbers and Definitions**

<b>Crop Group Number</b>	<b>Name of the Crop Group</b>	<b>Food Commodities Included in the Crop Group</b>
10	Citrus fruits	Calamondins Citrus citrons Citrus hybrids Grapefruits Kumquats Lemons Limes Oranges Pummelos Satsuma mandarins Tangerines