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Proposed Maximum Residue Limit

PMRL2019-36

# Fludioxonil

*(publié aussi en français)*

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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 new uses on dried shelled pea and bean (except soybean) – crop subgroup 6C to the product label of Cyproflu Fungicide and Switch 62.5 WG Fungicide, containing technical grade active ingredients fludioxonil and cyprodinil, is acceptable. The specific uses approved in Canada are detailed on the labels of Switch 62.5 WG Fungicide and Cyproflu Fungicide, *Pest Control Products Act* Registration Numbers 28189 and 30185, respectively.

The evaluation of this fludioxonil application indicated that the end-use product has value and the human health and environmental risks associated with the new use are acceptable.

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 MRL for fludioxonil is being conducted via this document (see Next Steps). A summary of the field trial data used to support the proposed MRL can be found in Appendix I. MRL consultation for the other active ingredient, cyprodinil, present in Switch 62.5 WG Fungicide and Cyproflu Fungicide is being conducted under a separate action.

To comply with Canada’s international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the [World Trade Organization](#), as coordinated by the [Canada’s Notification Authority and Enquiry Point](#).

The proposed MRL, to be added to the MRLs already established for fludioxonil, is as follows.

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

Common Name	Residue Definition	MRL (ppm) <sup>1</sup>	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1 <i>H</i> -pyrrole-3-carbonitrile	0.5 <sup>2</sup>	Dried shelled bean and pea (except soybean) (crop subgroup 6C)

<sup>1</sup> ppm = parts per million

<sup>2</sup> The 0.5 ppm MRL is proposed to be extended to all food commodities in crop subgroup 6C.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the [Residue Chemistry Crop Groups](#) webpage in the Pesticides section of the Canada.ca 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

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.

Table 2 compares the MRL proposed for fludioxonil in Canada with corresponding American tolerance and Codex MRLs.<sup>1</sup> 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 the Canadian MRL, American Tolerance and Codex MRLs (where different)**

<b>Food Commodity</b>	<b>Canadian MRL (ppm)</b>	<b>American Tolerance (ppm)</b>	<b>Codex MRL (ppm)</b>
Crop subgroup 6C	0.5	0.4 (dry beans)	0.5 (dry beans) 0.07 (dry peas)

## Next Steps

The PMRA invites the public to submit written comments on the proposed MRL 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 MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the [Maximum Residue Limit Database](#).

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<sup>1</sup> 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 dry pea were submitted to support the domestic use of Cyproflu Fungicide and Switch 62.5 WG Fungicide on crop subgroup 6C. In addition, previously reviewed residue data from field trials conducted on dry beans were reassessed in the framework of this petition

#### Maximum Residue Limit(s)

The recommendation for the maximum residue limit (MRL) for fludioxonil 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 MRL for all commodities of crop subgroup 6C.

**Table A1 Summary of Field Trial Data Used to Support the MRL**

Commodity	Application Method/ Total Application Rate (g a.i./ha) <sup>1</sup>	Preharvest Interval (days)	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)
Dry peas	Foliar application / 734	6–7	0.02	0.17
Dry beans	Foliar application / 1000	5–8	0.02	0.29

<sup>1</sup> g a.i./ha = grams of active ingredient per hectare

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