Proposed Maximum Residue Limit

Santé

Canada

PMRL2020-37

Tetraconazole

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

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



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Under the authority of the <u>Pest Control Products Act</u>, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product labels of Mettle 210 ME Fungicide and Mettle 125 ME Fungicide, containing technical grade tetraconazole, is acceptable. The specific uses approved in Canada are detailed on the labels of Mettle 210 ME Fungicide and Mettle 125 ME Fungicide, <u>Pest Control Products Act Registration Numbers 32042</u> and 30673, respectively.

The evaluation of this tetraconazole application indicated that the end-use products have value and the human health and environmental risks associated with the new uses 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 MRLs for tetraconazole is being conducted via this document (see Next steps). 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 <u>World Trade Organization</u>, as coordinated by the <u>Canada's Notification Authority and Enquiry Point</u>.

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

 Table 1
 Proposed maximum residue limits for tetraconazole

Common name	Residue definition	MRL (ppm) ¹	Food commodity
Tetraconazole	1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1 <i>H</i> -1,2,4-triazole	2.0	Liver of cattle, goats, horses and sheep ²
		1.0	Barley bran
		0.9	Rapeseeds (crop subgroup 20A) (revised)
		0.5	Barley flour; milk fat; wheat germ
		0.3	Barley; fat of cattle, goats, horses and sheep ³ ; fruiting vegetables (crop group 8-09)
		0.15	Cucurbit vegetables (crop group 9); wheat bran

Common name	Residue definition	MRL (ppm) ¹	Food commodity
		0.09	Dried shelled pea and bean (except soybean) (crop subgroup 6C)
		0.08	Meat byproducts of cattle, goats, horses and sheep (except liver), ⁴ wheat flour
		0.06	Milk ⁵
		0.05	Wheat
		0.03	Fat of poultry
		0.02	Meat and meat byproducts of poultry
		0.01	Eggs, field corn, popcorn grain

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 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. For livestock commodities, differences in MRLs can also be due to different livestock feed items and practices.

Table 2 compares the MRLs proposed for tetraconazole in Canada with corresponding American tolerances and Codex MRLs. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs listed for tetraconazole in or on any commodity on the Codex Alimentarius Pesticide Index webpage.

² The MRL is proposed to replace the currently established MRL of 0.05 ppm.

³ The MRL is proposed to replace the currently established MRL of 0.02 ppm.

⁴ The MRL is proposed to replace the currently established MRL of 0.02 ppm.

⁵ The MRL is proposed to replace the currently established MRL of 0.01 ppm.

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

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

Food commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Liver of cattle, goats, horses and sheep	2.0	1.5	Not established
Milk fat	0.5	0.75	Not established
Fat of cattle, goats, horses and sheep	0.3	0.15	Not established
Meat byproducts of cattle, goats, horses and sheep (except liver)	0.08	0.15	Not established
Fat of poultry	0.03	0.05	Not established
Meat byproducts of poultry	0.02	0.05	Not established
Meat of poultry	0.02	0.01	Not established
Eggs	0.01	0.02	Not established

Next steps

The PMRA invites the public to submit written comments on the proposed MRLs for tetraconazole 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 maximum residue limits

Residue data for tetraconazole in various crops were submitted to support the domestic use of Mettle 210 ME Fungicide and Mettle 125 ME Fungicide.

Maximum residue limits

The recommendation for maximum residue limits (MRLs) for tetraconazole was based upon the submitted field trial data, and the guidance provided in the <u>OECD MRL Calculator</u>. Table A1 summarizes the residue data used to calculate the proposed MRLs for various crops.

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
Wheat	Foliar/220–235	30–51	0.01	0.039	Wheat bran: 3.7× Wheat flour: 2.0× Wheat germ: 10.6×
Barley	Foliar/217–236	28–51	<0.01	0.248	Barley bran ² : 3.7× Barley flour ² : 2.0×
Dry pea	Foliar/219-228	13–18	< 0.01	0.048	Not required
Dry bean	Foliar/223-229	13–15	< 0.01	0.070	Not required
Rapeseed (canola)	Foliar/224–236	20–22	< 0.012	0.870	Refined oil: 0.1×
Field corn	Foliar/95–105	29–95	<0.01	<0.01	No quantifiable residues observed at exaggerated rates
Cucumber	Foliar/217-223		< 0.01	0.080	Not required
Cantaloupe	Foliar/216-220	0	0.014	0.077	Not required
Summer squash	Foliar/217–231	U	<0.01	0.047	Not required
Bell pepper	Foliar/144-149		0.014	0.059	Not required
Non-bell pepper	Foliar/147–148	0	0.040	0.110	Not required
Tomato	Foliar/144–153	U	0.016	0.097	Paste: 0.3× Puree: 0.2× Juice: 0.1×

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

Based on the dietary burden and residue data, MRLs are also proposed in Table A2 to cover residues of tetraconazole in livestock commodities.

² Processing factor extended from wheat bran and wheat flour

Table A2 Proposed MRLs in livestock commodities

Commodity	Proposed MRLs (ppm)
Liver of cattle, goats, horses and sheep	2.0
Milk fat	0.5
Fat of cattle, goats, horses and sheep	0.3
Meat byproducts of cattle, goats, horses and sheep (except liver)	0.08
Milk	0.06
Fat of poultry	0.03
Meat and meat byproducts of poultry	0.02
Eggs	0.01

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