

Proposed Maximum Residue Limit

PMRL2007-14

Metalaxyl

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Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the <u>Pest Control Products Act</u> (PCPA), has concluded that revisions to previously proposed maximum residue limits (MRLs) for metalaxyl are required.

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 pose a unacceptable health risk. This quantity is then legally established as an MRL which 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.

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 <u>Bill C-28</u>, 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.

MRLs have been legally established in Canada for metalaxyl on a number of crops and additional MRLs were proposed in PMRL2006-01, including MRLs for fat kidney, liver, meat and meat byproducts (except kidney and liver) of cattle, goats, hogs, horses, poultry and sheep. Based on ruminant feeding data and maximum theoretical dietary burden (MTDB) estimates, the Agency has determined that the MRL proposed in PMRL2006-01 for kidney of cattle, goats, hogs, horses and sheep should be increased from 0.7 ppm to 0.85 ppm. An MRL of 0.7 ppm remains for kidney of poultry.

Consultation on the proposed revised MRLs for metalaxyl 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.

Ruminant kidney MRLs for metalaxyl proposed in PMRL2006-01 to be revised are as follows:

Table 1 Proposed Maximum Residue Limits for Metalaxyl

Common Chemical Name	Chemical Name of Substance	Food Commodities	MRL Proposed in PMRL2006-01 (ppm)	Proposed MRL (ppm)
Metalaxyl	N-(2,6-dimethylphenyl)-N- (methoxyacetyl)-DL-alanine methyl ester, including metabolites that can be converted to the 2,6-dimethylaniline moiety, each expressed as metalaxyl equivalents	Kidney of cattle, goats, hogs, horses and sheep	0.70	0.85

A complete list of all MRLs established in Canada can be found in <u>Table II, Division 15</u> 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 <u>MRL webpage</u>, which will be updated to include the MRLs listed in this document.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons. For livestock commodities, differences in MRLs can be due to different livestock feed items and practices. Table 2 identifies differences among MRLs in Canada, tolerances in the United States and Codex¹ MRLs. The proposed MRLs in Canada differ from the corresponding tolerances in the United States as listed in 40 CFR 180 (searchable by pesticide). Currently, there are no Codex MRLs established for metalaxyl on livestock commodities (Codex MRLs searchable by pesticide or commodity).

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs

Food	Canadian MRL	American Tolerance (ppm)	Codex MRL
Commodities	(ppm)		(ppm)
Kidney of cattle, goats, hogs, horses and sheep	0.85	0.4	No Codex MRLs have been established for metalaxyl on livestock commodities.

Codex 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 metalaxyl 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 metalaxyl and before posting an Established Maximum Residue Limit document on the PMRA's website once the amendments to the FDA are in force.