

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1338 (KRESOXIM-METHYL)

P.C. 2004-258 OF MARCH 23, 2004

SOR/2004-49 OF MARCH 23, 2004

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)^a of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1338 — Kresoxim-methyl)*.

^a S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1338 -
KRESOXIM-METHYL)

AMENDMENT

1. The portion of item K.1 of Table II to Division 15 of Part B of the *Food and Drug Regulations*¹ in columns III and IV is replaced by the following:

	III	IV
Item No.	Maximum Residue Limit p.p.m.	Foods
K.1	1.5	Raisins
	1	Grapes
	0.5	Apples, crabapples, loquats, mayhaws, oriental pears, pears, quinces
	0.15	Apple juice, pear juice, pecans
	0.03	Meat and meat by-products of cattle, goats, hogs, horses and sheep
	0.004	Milk

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

¹ C.R.C., c. 870

REGULATORY IMPACT ANALYSIS STATEMENT
(This statement is not part of the Regulation)

Description

Kresoxim-methyl is registered under the *Pest Control Products Act* as a fungicide for the control of apple scab and powdery mildew on apples. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of kresoxim-methyl and its metabolites resulting from its use in Canada and in other countries at 1.5 parts per million (ppm) in raisins, 1.0 ppm in grapes, 0.5 ppm in apples and 0.15 ppm in apple juice and pecans. MRLs have also been established at 0.03 ppm in meat and meat by-products of cattle, goats, hogs, horses and sheep, and 0.004 ppm in milk to cover residues in food derived from animals fed with crops treated with kresoxim-methyl. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 ppm.

This regulatory amendment will establish MRLs for residues of kresoxim-methyl and its metabolites in crabapples, loquats, mayhaws, oriental pears, pear juice, pears and quinces, in order to permit the import and sale of food containing these residues.

In order to determine whether proposed MRLs are safe, the Pest Management Regulatory Agency (PMRA), of Health Canada, conducts a dietary risk assessment. An acceptable daily intake (ADI) and/or acute reference dose (ARD) is calculated by applying a safety factor to a no observable adverse effect level or, in appropriate cases, by applying a risk factor which is calculated based on a linear low-dose extrapolation. The potential daily intake (PDI) is calculated from the amount of residue that remains on each imported food when the pest control product is used according to use instructions in the country of origin and the intake of that food from imported sources in the diet. PDIs are established for various Canadian subpopulations and age groups, including infants, toddlers, children, adolescents and adults. Provided the PDI does not exceed the ADI or ARD for any subpopulation or age group, and the lifetime risk is acceptable, the expected residue levels are established as MRLs under the *Food and Drugs Act* to prevent the sale of food with higher residue levels. Since, in most cases, the PDI is well below the ADI and lifetime risks are very low when MRLs are originally established, additional MRLs for the pest control product may be added in the future.

After the review of all available data, the PMRA has determined that MRLs for kresoxim-methyl, including its metabolites, of 0.5 ppm in crabapples, loquats, mayhaws, oriental pears, pears and quinces, and 0.15 ppm in pear juice would not pose an unacceptable health risk to the public.

Alternatives

Under the *Food and Drugs Act*, it is prohibited to sell food containing residues of pest control products at a level greater than 0.1 ppm unless

a higher MRL has been established in Table II, Division 15, of the *Food and Drug Regulations*. In the case of kresoxim-methyl, establishment of MRLs for crabapples, loquats, mayhaws, oriental pears, pear juice, pears and quinces is necessary to support the import of food containing residues that have been shown to be safe, while at the same time preventing the sale of food with unacceptable residues.

Benefits and Costs

This regulatory amendment will contribute to a safe, abundant and affordable food supply by allowing the importation and sale of food commodities containing acceptable levels of pesticide residues.

Some costs may be incurred related to the implementation of analytical methods for analysis of kresoxim-methyl and its metabolites in the foods mentioned above. Resources required are not expected to result in significant costs to the government.

Consultation

Registration decisions, including dietary risk assessments, made by the PMRA are based on internationally recognized risk management principles, which are largely harmonized among member countries of the Organization for Economic Cooperation and Development. Individual safety evaluations conducted by the PMRA include a review of the assessments conducted at the international level as part of the Joint Food and Agriculture Organization of the United Nations/World Health Organization Food Standards Programme in support of the Codex Alimentarius Commission, as well as MRLs adopted by other national health/regulatory agencies.

This schedule of amendment was published in the *Canada Gazette*, Part I, on May 3, 2003. Interested parties were invited to make representations concerning the proposed amendment. One comment was received requesting the scientific justification and data for setting the MRLs for kresoxim-methyl and its metabolites. The comment also noted that higher MRLs have been set for this pesticide in Japan and the United States.

The MRLs being established through this regulatory amendment are based on information provided by a petitioner to establish MRLs in Canada. Risk assessment methodology used by the PMRA is described in the document Science Policy Notice SPN2000-01, *A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*, which is available on the PMRA web site (www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf). The confidential test data used to conduct the risk assessment cannot be provided, as they are protected from disclosure under the *Access to Information Act*.

Any exporter to Canada who uses a pesticide at application rates and with agricultural practices that would result in residues exceeding these Canadian MRLs can petition the PMRA to establish different MRLs so that

higher residue levels would be permitted. The petitioner must submit the necessary information, including a description of the use of the pesticide and relevant data on residue chemistry and levels.

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the MRLs for kresoxim-methyl and its metabolites are adopted.

Contact

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