CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF DECEMBER 14, 2005

SCHEDULE NO. 1436 (1-METHYLCYCLOPROPENE)

P.C. 2005-2222 OF NOVEMBER 28, 2005

SOR/2005-397 OF NOVEMBER 28, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)[1] of the *Food and Drugs Act*, hereby makes the annexed Regulations Amending the Food and Drug Regulations (1436 — 1-Methylcyclopropene).

[1] S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1436 — 1-METHYLCYCLOPROPENE)

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations*[2] is amended by adding the following after item M.7.1:

	I	II	III	IV
Item No.	**Common Chemical Name**	**Chemical Name of Substance**	**Maximum Residue Limit p.p.m.**	**Foods**
M.7.1.1	1-methylcyclopropene	1-methylcyclopropene	0.01	Apples

COMING INTO FORCE

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

[2] C.R.C., c. 870

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

Description

Under authority of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA), of Health Canada, has approved an application for the registration of the pest control product (pesticide) 1-methylcyclopropene as a plant growth regulator in apples as a post-harvest treatment. This regulatory amendment will establish a Maximum Residue Limit (MRL) under the *Food and Drugs Act* for residues of 1-methylcyclopropene resulting from this use in apples, in order to permit the sale of food containing these residues.

Before making a registration decision regarding a new pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. Pest control products will be registered if: the data requirements for assessing value and safety have been adequately addressed; the evaluation indicates that the product has merit and value; and the human health and environmental risks associated with its proposed use are acceptable.

The human health risk assessment includes an assessment of dietary risks posed by expected residues of the pest control product, as determined through extensive toxicological studies. An acceptable daily intake (ADI) and/or acute reference dose (ARfD) 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 food when the pest control product is used according to the proposed label and the intake of that food from both domestic and 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 ARfD 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 an MRL for 1-methylcyclopropene of 0.01 parts per million (ppm) in apples would not pose an unacceptable health risk to the public.

International Situation and Trade Implications

The Canadian MRL proposed in this regulatory amendment differs from the tolerance established in the United States

.../4

(U.S.) (http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html) and Codex MRL (http://www.mrldatabase.com). These differences are outlined in the following table:

Foods	Canada	U.S.	Codex*
Apple	0.01	Exempted**	None established

* Codex is an international organization under the auspices of the United Nations which develops international food standards, including MRLs.

** Exempted from the requirement of a tolerance.

MRLs may vary from one country to another for a number reasons including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. MRL/tolerance harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRL proposed in this regulatory amendment is necessary. The differences in MRLs/tolerances outlined above are not expected to negatively impact businesses or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

Alternatives

Under the *Food and Drugs Act*, the sale of food containing residues of pest control products at a level less than or equal to 0.1 ppm is permitted unless a lower MRL has been established in Table II, Division 15, of the *Food and Drug Regulations*. In the case of 1-methylcyclopropene, establishment of an MRL is necessary to support the use of a pest control product which has been shown to be both safe and effective, while at the same time preventing the sale of food with unacceptable residues.

Benefits and Costs

The use of 1-methylcyclopropene will provide joint benefits to consumers and the agricultural industry as a result of improved management of pests. In addition, 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.

.../5

Some costs may be incurred related to the implementation of analytical methods for analysis of 1-methylcyclopropene in the food 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 March 26, 2005. Interested parties were invited to make representations concerning the proposed amendment. No responses were received.

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the MRL for 1-methylcyclopropene is adopted.

Contact

Francine Brunet, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9. (Tel.: (613) 736-3678; Fax: (613) 736-3659; E-mail: pmra_regulatory_affairs-affaires_réglementaires_arla@hc-sc.gc.ca)

October 24, 2005