CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1384 (CHLORIMURON-ETHYL)

P.C. 2005-490 OF APRIL 5, 2005

SOR/2005-84 OF APRIL 5, 2005

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 (1384 — Chlorimuron-ethyl)*.

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

.../2

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1384 — CHLORIMURON-ETHYL)

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations*[1] is amended by adding the following after item C.6:

		II	III	IV
Item No.	**Common Chemical Name**	**Chemical Name of Substance**	**Maximum Residue Limit p.p.m.**	**Foods**
C.6.1	Chlorimuron-ethyl	ethyl 2-[[[[(4-chloro-6-methoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]benzoate	0.05	Soybeans

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

Chlorimuron-ethyl is registered under the *Pest Control Products Act* as a herbicide for the control of annual broadleaf weeds in soybeans as a post-emergent treatment. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the Maximum Residue Limit (MRL) for residues of chlorimuron-ethyl in any food is 0.1 parts per million (ppm).

The Pest Management Regulatory Agency (PMRA), of Health Canada, has recently approved an application to amend the registration status of chlorimuron-ethyl from temporary to full. Following the review of additional data received in connection with this application, this regulatory amendment will establish a specific MRL for residues of chlorimuron-ethyl in soybeans.

In order to determine whether proposed MRLs are safe, the PMRA conducts a dietary risk assessment. 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 chlorimuron-ethyl of 0.05 ppm in soybeans will not pose an unacceptable health risk to the public. This new MRL harmonizes with that established by the United States Environmental Protection Agency.

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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 chlorimuron-ethyl, establishment of an MRL for soybeans 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 chlorimuron-ethyl in soybeans 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.

Some costs may be incurred related to the implementation of analytical methods for analysis of chlorimuron-ethyl 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 Organisation for Economic Co-operation 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 September 25, 2004. 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 chlorimuron-ethyl is adopted.

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