CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

WILL BE PUBLISHED IN CANADA GAZETTE, PART II ON JULY 13, 2005

SCHEDULE NO. 1411 (IMAZETHAPYR)

P.C. 2005-1275 OF JUNE 27, 2005

SOR/2005-209 OF JUNE 27, 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 (1411 — Imazethapyr)*.

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

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REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1411 — IMAZETHAPYR)

AMENDMENT

1. The portion of item I.2.02 of Table II to Division 15 of Part B of the *Food and Drug Regulations*[1] in column IV is replaced by the following:

	IV
Item No.	**Foods**
I.2.02	Kidney beans, lima beans, navy beans, pinto beans, runner beans, snap beans, soybeans, tepary beans, wax beans

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

Imazethapyr is registered under the *Pest Control Products Act* as a herbicide for the control of a variety of broadleaf weeds and grasses in alfalfa grown for seed, chickling vetch for seed production, imazethapyr tolerant canola, imazethapyr tolerant corn, processing peas, snap beans, snow peas, and soybeans in Eastern Canada and in dry beans including adzuki beans, black beans, cranberry beans, dutch brown beans, kidney beans, pink beans, pinto beans, red beans, white beans, and yellow eye beans as pre-plant incorporated, pre-emergent and post-emergent treatments. A Maximum Residue Limit (MRL) has been established under the *Food and Drugs Act* for residues of imazethapyr resulting from this use at 0.1 parts per million (ppm) in kidney beans, lima beans, navy beans, pinto beans, runner beans, snap beans, tepary beans and wax beans. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 ppm.

The Pest Management Regulatory Agency (PMRA), of Health Canada, has recently approved an application to amend the registration of imazethapyr in order to allow its use in soybeans in Manitoba. Following the review of data submitted in connection with this application, this regulatory amendment will establish a specific MRL for residues of imazethapyr resulting from its use 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

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product may be added in the future.

After the review of all available data, the PMRA has determined that an MRL for imazethapyr of 0.1 ppm in soybeans would not pose an unacceptable health risk to the public. This new MRL harmonizes with one established by the United States Environmental Protection Agency.

Alternatives

Even though the sale of food containing residues of pest control products at a level greater than 0.1 ppm would already be prohibited by virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the establishment of an MRL of 0.1 ppm in Table II, Division 15, of the Regulations, for residues of imazethapyr in soybeans will provide more clarity regarding the applicable MRL and will clearly indicate that the appropriate risk assessment has been completed. This is in keeping with current trends towards increased openness and transparency of regulatory processes and is consistent with current practices of most pesticide regulatory agencies throughout the world.

Benefits and Costs

The use of imazethapyr on 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 imazethapyr 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

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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 November 27, 2004. Interested parties were invited to make representation concerning the proposed amendment. No responses were recieved.

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 imazethapyr is adopted.

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