- PREPUBLICATION NOTICE -

TB MEETING OF May 4, 2006

WILL APPEAR IN THE PART I - CANADA GAZETTE - OF May 13, 2006

FOOD AND DRUG REGULATIONS - PROPOSED AMENDMENT

SCHEDULE NO. 1454 (IMAZETHAPYR)

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 numerous crops as pre-plant incorporated, pre-emergent or 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, soybeans, 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 for the control of broadleaf weeds and annual grasses in processing peas in Eastern Canada as pre-emergent or pre-plant incorporated treatments. This proposed regulatory amendment would establish an MRL for residues of imazethapyr resulting from this use in peas, in order to permit the sale of food containing these residues.

Before making a registration decision regarding a new use of a pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. The registration of the pest control product will be amended 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

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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 imazethapyr of 0.1 ppm in peas would not pose an unacceptable health risk to the public. This new MRL harmonizes with the 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 peas would provide more clarity regarding the applicable MRL and would 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 peas will provide joint benefits to consumers and the agricultural industry as a result of improved management of pests. In addition, this proposed 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

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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.

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the proposed MRL for imazethapyr 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-affairs_reglementaires_arla@hc-sc.gc.ca)

February 9, 2006

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1)[a] of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1454 — Imazethapyr)*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Francine Brunet, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Department of Health, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario K1A 0K9 (tel.: (613) 736-3678; fax: (613) 736-3659; e-mail: pmra_regulatory_affairs-affairs_reglementaires_arla@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, , 2006

Eileen Boyd
Assistant Clerk of the Privy Council

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1454 — 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, peas, 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