

- PREPUBLICATION NOTICE -

TB MEETING OF MARCH 21, 2005

WILL APPEAR IN THE PART I - CANADA GAZETTE - OF MARCH 26, 2005

FOOD AND DRUG REGULATIONS - PROPOSED AMENDMENT

SCHEDULE NO. 1435 (S-METOLACHLOR)

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulation)

Description

S-metolachlor is registered under the *Pest Control Products Act* as a herbicide for the control or suppression of annual grasses and broadleaf weeds in a variety of crops as a pre-plant surface, pre-plant incorporated, pre-emergent or early post-emergent treatment. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of S-metolachlor and its metabolites resulting from these uses at 0.3 parts per million (ppm) in dry beans, lima beans, peas and snap beans, 0.2 ppm in potatoes and soybeans, and 0.1 ppm in apples, apricots, cherries, corn, peaches/nectarines, pears, plums, rutabagas, sugar beets and tomatoes. MRLs have also been established at 0.2 ppm in kidney of cattle; 0.05 ppm in liver of cattle and poultry; and 0.02 ppm in eggs; meat of cattle, goats, hogs, poultry and sheep; and milk to cover residues in food derived from animals fed with crops treated with S-metolachlor. 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 S-metolachlor in order to allow its use for the control of annual grasses and broadleaf weeds in sugar beets as a post-emergent treatment. Following the review of data submitted in connection with this application, this proposed regulatory amendment would increase the MRL for residues of S-metolachlor and its metabolites resulting from this use in sugar beets, in order to permit the sale of food containing these residues.

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 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 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 S-metolachlor, including its metabolites, of 0.3 ppm in sugar beets 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 S-metolachlor, increasing the MRL for sugar beets 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 S-metolachlor on sugar beets 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 S-metolachlor and its

metabolites 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.

Compliance and Enforcement

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

Contact

Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9. (Tel.: (613) 736-3665; Fax: (613) 736-3659; E-mail: cameron_laing@hc-sc.gc.ca)

November 23, 2004

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 (1435 - S-metolachlor)*.

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 Cameron Laing, 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) 736-3665; fax: (613) 736-3659; e-mail: cameron_laing@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,

, 2004

Eileen Boyd
Assistant Clerk of the Privy Council

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1435 - S-METOLACHLOR)

AMENDMENT

1. The portion of item M.7.2 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
	Maximum Residue	
Item No.	Limit p.p.m.	Foods
M.7.2	0.3	Dry beans, lima beans, peas, snap beans, sugar beets
	0.2	Kidney of cattle; potatoes; soybeans
	0.1	Apples, apricots, cherries, corn, peaches/nectarines, pears, plums, rutabagas, tomatoes
	0.05	Liver of cattle and poultry
	0.02	Eggs; meat of cattle, goats, hogs, poultry and sheep; milk

COMING INTO FORCE

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

¹ C.R.C., c. 870