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Vol. 138, No. 39 — September 25, 2004

## Regulations Amending the Food and Drug Regulations (1383 — Clothianidin)

*Statutory authority*

*Food and Drugs Act*

*Sponsoring department*

Department of Health

### REGULATORY IMPACT ANALYSIS STATEMENT

*Description*

Under the 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) clothianidin as an insecticide for the control of flea beetles, corn rootworm, corn flea beetles, black cutworm, seed corn maggot, wireworm and whitegrub in corn and rapeseed (canola) as a pre-plant seed treatment. This proposed regulatory amendment would establish a Maximum Residue Limit (MRL) under the *Food and Drugs Act* for residues of clothianidin resulting from this use in field corn grain (the kernels of field corn), popcorn grain, rapeseed (canola), and sweet corn kernel plus cob with husks removed, in order to



permit the sale of food containing these residues. This proposed amendment would also establish an MRL in milk to cover residues in food derived from animals fed with crops treated with clothianidin.

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 clothianidin of 0.01 parts per million (p.p.m.) in field corn grain, milk, popcorn grain, rapeseed (canola), and sweet corn kernel plus cob with husks removed would not pose an unacceptable health risk to the public. These new MRLs harmonize with those established by the United States Environmental Protection Agency.

### *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 p.p.m. is permitted unless a lower MRL has been established in Table II, Division 15, of the *Food and Drug Regulations*. In the case of clothianidin, establishment of an MRL for field corn grain, milk, popcorn grain, rapeseed (canola), and sweet corn kernel plus cob with husks removed 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 above-listed uses of clothianidin 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.

The review of the application for registration of clothianidin was conducted jointly by the PMRA and the United States Environmental Protection Agency. Registration of this pest control product and establishment of an MRL in Canada will benefit the Canadian agricultural industry and will prevent interruption of trade in food commodities between the two countries.

Some costs may be incurred related to the implementation of analytical methods for the analysis of clothianidin in the foods 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 proposed MRL for clothianidin is adopted.

### *Contact*

Mr. Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, 2720 Riverside Drive, Address Locator 6607D1, Ottawa, Ontario K1A 0K9, (613) 736-3665 (telephone), (613) 736-3659 (facsimile), [cameron\\_laing@hc-sc.gc.ca](mailto:cameron_laing@hc-sc.gc.ca) (electronic mail).

## **PROPOSED REGULATORY TEXT**

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1383 — Clothianidin)*.

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](mailto: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, September 22, 2004

EILEEN BOYD  
Assistant Clerk of the Privy Council

**REGULATIONS AMENDING THE FOOD AND DRUG  
REGULATIONS (1383 — CLOTHIANIDIN)**

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations* ([see footnote 1](#)) is amended by adding the following after item C.10.5:

	I	II	III	IV
Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
C.10.6	clothianidin	[C(E)]-N-[(2-chloro-5-thiazolyl)methyl]-N'-methyl-N''-nitroguanidine	0.01	Field corn grain, milk, popcorn grain, rapeseed (canola), sweet corn kernel plus cob with husks removed

COMING INTO FORCE

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

[39-1-o]

[Footnote a](#)

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

[Footnote 1](#)

C.R.C., c. 870

**NOTICE:**

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



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