

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF APRIL 7, 2004

SCHEDULE NO. 1344 (DIFENOCONAZOLE)

P.C. 2004-260 OF MARCH 23, 2004

SOR/2004-51 OF MARCH 23, 2004

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 (1344 — Difenoconazole)*.

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1344 -
DIFENOCONAZOLE)

AMENDMENT

1. The portion of item D.14 of Table II to Division 15 of Part B of the *Food and Drug Regulations*¹ in columns II to IV is replaced by the following:

Item No.	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
D.14	1-[2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-ylmethyl]-1H-1,2,4-triazole	0.1	Wheat
		0.05	Eggs, meat and meat by-products of cattle, goats, hogs, poultry and sheep, mustard seed
		0.03	Rapeseed (canola)
		0.01	Barley, milk

COMING INTO FORCE

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

¹C.R.C., c. 870

REGULATORY IMPACT ANALYSIS STATEMENT
(This statement is not part of the Regulation)

Description

Difenoconazole is registered under the *Pest Control Products Act* as a fungicide for the control of seed-borne Septoria, seedling blight (caused by seed- and soil-borne Fusarium), general seed rots (caused by Penicillium and Aspergillus), covered smut, false loose smut, and Pythium damping-off; and for suppression of common root rot (*Cochliobolus* spp.), Fusarium crown rot, Fusarium foot rot, and take-all on wheat as a seed treatment. A Maximum Residue Limit (MRL) has been established under the *Food and Drugs Act* for residues of difenoconazole resulting from this use at 0.1 parts per million (ppm) in wheat. MRLs have also been established at 0.05 ppm in eggs and meat and meat by-products of cattle, goats, hogs, poultry and sheep and at 0.01 ppm in milk to cover residues in food derived from animals fed with crops treated with difenoconazole. 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 difenoconazole in order to allow its use for the control of seed-borne Septoria, seedling blight, general seed rots, covered smut, false loose smut, and Pythium damping-off; and for suppression of common root rot, Fusarium crown rot, Fusarium foot rot, and take-all on barley, rapeseed (canola) and mustard as a seed treatment. This regulatory amendment will establish MRLs for residues of difenoconazole resulting from this use in barley, mustard seed and rapeseed (canola) 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 (ARD) 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.

PDI's 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 ARD 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 MRLs for difenoconazole of 0.05 ppm in mustard seed, 0.03 ppm in rapeseed (canola) and 0.01 ppm in barley would not pose an unacceptable health risk to the public. This regulatory amendment will also amend the chemical name of difenoconazole in order to comply with international nomenclature conventions.

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 difenoconazole, establishment of MRLs for barley, mustard seed and rapeseed (canola) is necessary to support the additional 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 difenoconazole on barley, mustard seed and rapeseed (canola) 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 difenoconazole 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 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.

This schedule of amendment was published in the *Canada Gazette*, Part I, on May 3, 2003. Interested parties were invited to make representations concerning the proposed amendment. One comment was received indicating that the proposed MRL for barley of 0.01 ppm was lower than the MRL of 0.1 ppm in the United States.

The MRL of 0.01 ppm for difenoconazole in barley being established through this regulatory amendment is based on approved application rates for difenoconazole in Canada. Any exporter to Canada who uses a pesticide at application rates and with agricultural practices that would result in residues exceeding a Canadian MRL can petition the PMRA to establish a different MRL so that higher residue levels would be permitted. The petitioner must submit the necessary information, including a description of the use of the pesticide and relevant data on residue chemistry and levels. To date, no such petition has been received.

The comment also requested the data and scientific justification for establishing the MRL in Canada. The confidential test data cannot be provided, as they are protected from disclosure under the *Access to Information Act*. Risk assessment methodology used by the PMRA is described in the document Science Policy Notice SPN2000-01, *A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency*, which is available on the PMRA web site (www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf).

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the MRLs for difenoconazole are adopted.

Contact

Geraldine Graham, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9. (Tel.: (613) 736-3692; Fax: (613) 736-3659; E-mail: geraldine_graham@hc-sc.gc.ca)

January 27, 2004