CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1392 (ISOXADIFEN-ETHYL)

P.C. 2005-391 OF MARCH 21, 2005

SOR/2005-68 OF MARCH 21, 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 (1392 — Isoxadifen-ethyl)*.

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

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REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1392 — ISOXADIFEN-ETHYL)

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations*[1] is amended by adding the following after item I.3:

	I	II	III	IV
Item No.	**Common Chemical Name**	**Chemical Name of Substance**	**Maximum Residue Limit p.p.m.**	**Foods**
I.3.1	isoxadifen-ethyl	ethyl 4,5-dihydro-5,5-diphenyl-3-isoxazolecarboxylate	0.08	Field corn grain

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

Isoxadifen-ethyl is a safener used as a formulant in certain pest control products (pesticides) that are used as herbicides for the control of annual and perennial grasses, and broadleaf weeds in field corn. A safener is added to the formulation of a pesticide in order to prevent adverse effects on the crops on which the pesticide is used. This regulatory amendment will establish a Maximum Residue Limit (MRL) under the *Food and Drugs Act* for residues of isoxadifen-ethyl in field corn grain (the kernels of field corn), in order to permit the sale of food containing these residues.

In order to determine whether proposed MRLs are safe, the Pest Management Regulatory Agency (PMRA), of Health Canada, 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 substance may be added in the future.

After the review of all available data, the PMRA has determined that an MRL for isoxadifen-ethyl of 0.08 parts per million (ppm) in field corn grain would not pose an unacceptable health risk to the public.

Alternatives

Under the *Food and Drugs Act*, the sale of food containing

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residues of agricultural chemicals 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 isoxadifen-ethyl, establishment of an MRL for field corn grain is necessary to support the use of pesticides that have been shown to be safe and effective, while at the same time preventing the sale of food with unacceptable residues.

Benefits and Costs

The use of herbicides containing isoxadifen-ethyl on field corn 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 residues.

Some costs may be incurred related to the implementation of analytical methods for analysis of isoxadifen-ethyl in the food mentioned above. Resources required are not expected to result in significant costs to the government.

Consultation

Dietary risk assessments conducted 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.

This schedule of amendment was published in the *Canada Gazette*, Part I, on October 2, 2004. Interested parties were invited to make representations concerning the proposed amendment. No responses were received.

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 isoxadifen-ethyl is adopted.

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