

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF APRIL 20, 2005

SCHEDULE NO. 1395 (TRIFLUMIZOLE)

P.C. 2005-499 OF APRIL 5, 2005

SOR/2005-93 OF APRIL 5, 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 (1395 - Triflumizole)*.

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1395 - TRIFLUMIZOLE)

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 T.7.1:

I	II	III	IV
Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m. Foods
T.7.2	triflumizole	1-[1-[[4-chloro-2-(trifluoromethyl)phenyl]imino]-2-propoxyethyl]-1H-imidazole, including metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, expressed as triflumizole	2.5 Grapes 1.5 Sour cherries, sweet cherries 0.5 Apples, pears

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

The pest control product (pesticide) triflumizole is a fungicide for the control of powdery mildew and scab on apples, grapes, pears, sour cherries and sweet cherries. This regulatory amendment will establish Maximum Residue Limits (MRLs) under the *Food and Drugs Act* for residues of triflumizole and its metabolites in apples, grapes, pears, sour cherries and sweet cherries, in order to permit the import and sale of food containing these residues. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 parts per million (ppm).

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 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 MRLs for triflumizole, including its metabolites, of 2.5 ppm in grapes, 1.5 ppm in sour cherries and sweet cherries, and 0.5 ppm in apples and pears 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*, 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 triflumizole, establishment of MRLs for apples, grapes, pears, sour cherries and sweet cherries is necessary

to support the import of food containing residues that have been shown to be safe, while at the same time preventing the sale of food with unacceptable residues.

Benefits and Costs

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 triflumizole and its metabolites in the foods 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 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 October 2, 2004. Interested parties were invited to make representations concerning the proposed amendment. One comment was received which requested the scientific evidence on which the MRL of 0.1 ppm for all other foods is based.

Regulation B.15.002(1) of the *Food and Drugs Regulations* establishes 0.1 ppm as the "General Maximum Residue Limit". This regulation states that a food is adulterated if it contains residues of a pesticide at a level greater than 0.1 ppm unless a specific MRL has been established in Table II, Division 15 of the *Food and Drug Regulations*. For triflumizole, since specific MRLs have not been set on all food crops, the 0.1 ppm MRL will apply to all foods not listed in Table II of the *Food and Drug Regulations*.

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 triflumizole are adopted.

Contact

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