

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF NOVEMBER 17, 2004

SCHEDULE NO. 1382 (PYRIMETHANIL)

P.C. 2004-1236 OF OCTOBER 25, 2004

SOR/2004-236 OF OCTOBER 25, 2004

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)<sup>a</sup> of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1382 — Pyrimethanil)*.

---

<sup>a</sup> S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1382 —  
PYRIMETHANIL)

AMENDMENTS

1. (1) The portion of item P.8.1 of Table II to Division 15 of Part B of the English version of the *Food and Drug Regulations*<sup>1</sup> in column II is replaced by the following:

---

---

II	
Item No.	Chemical Name of Substance
P.8.1	4,6-dimethyl-N-phenyl-2-pyrimidinamine

---

(2) The portion of item P.8.1 of Table II to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:

---

---

III		IV
Item No.	Maximum Residue Limit p.p.m.	Foods
P.8.1	8	Raisins
	5	Grapes
	0.05	Bananas

---

COMING INTO FORCE

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

---

<sup>1</sup> C.R.C., c. 870

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

**Description**

The pest control product (pesticide) pyrimethanil is a fungicide for the control of black and yellow sigatoka on bananas as a foliar treatment. This regulatory amendment will establish a Maximum Residue Limit (MRL) under the *Food and Drugs Act* for residues of pyrimethanil in bananas, in order to permit the import and sale of food containing these residues. MRLs for pyrimethanil at 8 parts per million (ppm) in raisins and 5 ppm in grapes have previously been established. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 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 an MRL for pyrimethanil of 0.05 ppm in bananas would not pose an unacceptable health risk to the public. This regulatory amendment will also amend the English chemical name of pyrimethanil 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 pyrimethanil, establishment of an MRL for bananas 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 pyrimethanil 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 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 November 22, 2003. 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 pyrimethanil 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)

October 25, 2004