

- PREPUBLICATION NOTICE -

TB MEETING OF MARCH 21, 2005

WILL APPEAR IN THE PART I - CANADA GAZETTE - OF MARCH 26, 2005

FOOD AND DRUG REGULATIONS - PROPOSED AMENDMENT

SCHEDULE NO. 1396 (FENHEXAMID)

**REGULATORY IMPACT ANALYSIS STATEMENT**

(This statement is not part of the Regulation)

**Description**

Fenhexamid is registered under the *Pest Control Products Act* as a fungicide for the control of *Botrytis* diseases on blackberries, grapes, loganberries, raspberries and strawberries. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of fenhexamid resulting from this use at 20 parts per million (ppm) in blackberries, loganberries and raspberries, 6 ppm in raisins, 4 ppm in grapes and 3 ppm in strawberries, and at 6 ppm in apricots, cherries and peaches/nectarines, 0.5 ppm in plums and 0.02 ppm in almonds imported into Canada, in order to permit the 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 ppm.

The Pest Management Regulatory Agency (PMRA), of Health Canada, has recently approved applications to amend the registration of fenhexamid in order to allow its use for the control of *Botrytis* diseases on blueberries, currants, elderberries, gooseberries, huckleberries, lettuce and tomatoes. This proposed regulatory amendment would establish MRLs for residues of fenhexamid resulting from this use in blueberries, currants, elderberries, gooseberries, huckleberries, lettuce and tomatoes, 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 (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 MRLs for fenhexamid of 23 ppm in lettuce, 4 ppm in blueberries, currants, elderberries, gooseberries and huckleberries, and 1 ppm in tomatoes would not pose an unacceptable health risk to the public.

### **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 fenhexamid, establishment of MRLs for blueberries, currants, elderberries, gooseberries, huckleberries, lettuce and tomatoes is necessary to support additional uses of a pest control product which have been shown to be both safe and effective, while at the same time preventing the sale of food with unacceptable residues.

As a means to improve responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) was issued on October 18, 2003, to permit the immediate sale of tomatoes containing residues

of fenhexamid with an MRL of 1 ppm while the regulatory process to formally amend the regulations is undertaken. A second IMA was issued on February 7, 2004 to permit the immediate sale of lettuce containing residues of fenhexamid with an MRL of 23 ppm and the immediate sale of blueberries, currants, elderberries, gooseberries and huckleberries containing residues of fenhexamid with an MRL of 4 ppm while the regulatory process to formally amend the regulations is undertaken.

### **Benefits and Costs**

The use of fenhexamid on the above mentioned crops 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.

Some costs may be incurred related to the implementation of analytical methods for analysis of fenhexamid 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 MRLs for fenhexamid are adopted.

### **Contact**

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Division, Pest Management Regulatory Agency, Health Canada, Address  
Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9.  
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January 4, 2005

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1)<sup>a</sup> of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1396 — Fenhexamid)*.

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).

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,

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Eileen Boyd  
Assistant Clerk of the Privy Council

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1396 - FENHEXAMID)

AMENDMENT

1. The portion of item F.1.001 of Table II to Division 15 of Part B of the *Food and Drug Regulations*<sup>1</sup> in columns III and IV is replaced by the following:

	III	IV
Item No.	Maximum Residue Limit p.p.m.	Foods
F.1.001	23	Lettuce
	20	Blackberries, loganberries, raspberries
	6	Apricots, cherries, peaches/nectarines, raisins
	4	Blueberries, currants, elderberries, gooseberries, grapes, huckleberries
	3	Strawberries
	1	Tomatoes
	0.5	Plums
	0.02	Almonds

COMING INTO FORCE

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

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