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Vol. 138, No. 39 — September 25, 2004

Regulations Amending the Food and Drug Regulations (1422 — Iprovalicarb)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health



REGULATORY IMPACT ANALYSIS STATEMENT

Description

The pest control product iprovalicarb is a fungicide for the control of downy mildew on grapes as a foliar treatment. This proposed regulatory amendment would establish a Maximum Residue Limit (MRL) under the *Food and Drugs Act* for residues of iprovalicarb in grapes, 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 (p.p.m.).

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 iprovalicarb of 2 p.p.m. in grapes 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 p.p.m. unless a higher MRL has been established in Table II, Division 15, of the *Food and Drug Regulations*. In the case of iprovalicarb, establishment of an MRL for grapes 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 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 iprovalicarb in grapes. 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.

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 MRL for iprovalicarb is adopted.

Contact

Mr. Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, 2720 Riverside Drive, Address Locator 6607D1, Ottawa, Ontario K1A 0K9, (613) 736-3665 (telephone); (613) 736-3659 (facsimile); cameron_laing@hc-sc.gc.ca (electronic mail).

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1422 — Iprovalicarb)*.

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, September 22, 2004

EILEEN BOYD
Assistant Clerk of the Privy Council

**REGULATIONS AMENDING THE FOOD AND DRUG
REGULATIONS (1422 — IPROVALICARB)**

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations* ([see footnote 1](#)) is amended by adding the following after item I.2.1:

	I	II	III	IV
Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
I.2.2	iprovalicarb	[2-methyl-1[[[(1S)-(4-methylphenyl)ethyl]amino]carbonyl]propyl] carbamic acid methylethylester	2	Grapes

COMING INTO FORCE

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

[39-1-o]

[Footnote a](#)

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

[Footnote 1](#)

C.R.C., c. 870

NOTICE:

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.


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