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Vol. 138, No. 39 — September 25, 2004

Regulations Amending the Food and Drug Regulations (1367 — Imidacloprid)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health



REGULATORY IMPACT ANALYSIS STATEMENT

Description

Imidacloprid is registered under the *Pest Control Products Act* as an insecticide for the control of aphids, Colorado potato beetles, flea beetles, fruit flies and other insect pests on apples, blueberries, sweet and sour cherries, greenhouse cucumbers, lettuce, potatoes and tomatoes as a post-emergent treatment. It is also registered for use as a seed treatment for mustard and rapeseed (canola). Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of imidacloprid and its metabolites containing the 6-chloropicolyl moiety resulting from these uses at 6 parts per million (p.p.m.) in tomato paste, 3.5 p.p.m. in lettuce, 3 p.p.m. in sour cherries, sweet cherries and tomato purée, 1 p.p.m. in blueberries and

tomatoes, 0.5 p.p.m. in apples and cucumbers, 0.3 p.p.m. in potatoes, and 0.05 p.p.m. in mustard seed and rapeseed (canola), and at 3.5 p.p.m. in brassica crops, 1.5 p.p.m. in grapes, 1 p.p.m. in citrus fruits and peppers, 0.6 p.p.m. in pears, 0.2 p.p.m. in mangoes, and 0.05 p.p.m. in cottonseed oil and pecans imported into Canada. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 p.p.m.

The Pest Management Regulatory Agency (PMRA), of Health Canada, has recently approved applications to amend the registration of imidacloprid in order to allow its use for the control of Colorado potato beetle on eggplants as a preplant soil incorporated treatment or as a foliar treatment; and for the control of corn flea beetle and wireworms on field corn and sweet corn as a seed treatment. This proposed regulatory amendment would establish MRLs for residues of imidacloprid and its metabolites containing the 6-chloropicolyl moiety resulting from these uses in eggplants, field corn grain (the kernels of field corn) and sweet corn kernel plus cob with husks removed, 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 imidacloprid and its metabolites containing the 6-chloropicolyl moiety of 0.08 p.p.m. in eggplants, and 0.05 p.p.m. in field corn grain and sweet corn kernel plus cob with husks removed would not pose an unacceptable health risk to the public.

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 p.p.m. is permitted unless a lower MRL has been established in Table II, Division 15, of the *Food and Drug Regulations*. In the case of imidacloprid, establishment of MRLs for eggplants, field corn grain and sweet corn kernel plus cob with husks removed is necessary to support the additional use of a pest control product which has been shown to be both safe and effective, while at the same time preventing the sale of food with unacceptable residues.

Benefits and costs

The use of imidacloprid on eggplants, field corn and sweet corn 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 the analysis of imidacloprid and its metabolites containing the 6-chloropicolyl moiety 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 imidacloprid are 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 (1367 — Imidacloprid)*.

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 (1367 — IMIDACLOPRID)**

AMENDMENT

1. The portion of item I.2.1 of Table II to Division 15 of Part B of the *Food and Drug Regulations* ([see footnote 1](#)) in columns III and IV is replaced by the following:

| | III | IV |
|--------------|-------------------------------------|--|
| | Maximum Residue Limit p.p.m. | Foods |
| I.2.1 | 6 | Tomato paste |
| | 3.5 | Brassica crops, lettuce |
| | 3 | Sour cherries, sweet cherries, tomato purée |
| | 1.5 | Grapes |
| | 1 | Blueberries, citrus fruits, peppers, tomatoes |
| | 0.6 | Pears |
| | 0.5 | Apples, cucumbers |
| | 0.3 | Potatoes |
| | 0.2 | Mangoes |
| | 0.08 | Eggplants |
| | 0.05 | Cottonseed oil, field corn grain, mustard seed, pecans, rapeseed (canola), sweet corn kernel plus cob with husks removed |

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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