

- PREPUBLICATION NOTICE -

TB MEETING OF JUNE 27, 2005

WILL APPEAR IN THE PART I - CANADA GAZETTE - OF JULY 9, 2005

FOOD AND DRUG REGULATIONS - PROPOSED AMENDMENT

SCHEDULE NO. 1334 (ACETAMIPRID)

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulation)

Description

Under authority of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA), of Health Canada, has approved an application for the registration of the pest control product (pesticide) acetamiprid as an insecticide for the control of numerous insect pests on a variety of crops. This proposed regulatory amendment would establish Maximum Residue Limits (MRLs) under the *Food and Drugs Act* for residues of acetamiprid resulting from its use in Canada and other countries in amaranth, apples, arugula, bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cardoon, cauliflower, celery, celtuce, Chinese broccoli, Chinese celery, Chinese mustard cabbage, citrus fruits, collards, corn salad, crabapples, dandelion leaves, dock, dried citrus fruit pulp, edible leaved chrysanthemum, eggplants, endives, fresh chervil leaves, fresh Florence fennel leaves and stalks, garden cress, garden purslane, garland chrysanthemum, grapes, groundcherries, head lettuce, loquats, kale, kohlrabi, leaf lettuce, mayhaws, mustard greens, mustard seed, mustard spinach, Napa Chinese cabbage, New Zealand spinach, orach leaves, oriental pears, parsley leaves, pears, pepinos, peppers, potatoes, quinces, radicchio, rape greens, rapeseed (canola), rhubarb, spinach, Swiss chard, tomatillos, tomatoes, tomato paste, undelinted cotton seed, upland cress, vine spinach and winter purslane, in order to permit the sale of food containing these residues. This proposed amendment would also establish MRLs for acetamiprid and its metabolite in eggs; fat, liver and meat of poultry; fat, meat and meat by-products of cattle, goats, hogs, horses and sheep; and milk to cover residues in food derived from animals fed with crops treated with acetamiprid.

Before making a registration decision regarding a new pest control product, the PMRA conducts the appropriate assessment of

the risks and value of the product specific to its proposed use. Pest control products will be registered 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. In order to establish an MRL for a crop group, representative data from residue studies conducted for sentinel crops are used. 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 acetamiprid, including its metabolite, of 3 parts per million (ppm) in amaranth, arugula, cardoon, celery, celtuce, Chinese celery, corn salad, dandelion leaves, dock, edible leaved chrysanthemum, endives, fresh chervil leaves, fresh Florence fennel leaves and stalks, garden cress, garden purslane, garland chrysanthemum, head lettuce, leaf lettuce, New Zealand spinach, orach leaves, parsley leaves, radicchio, rhubarb, spinach, Swiss chard, upland cress, vine spinach and winter purslane, 1.2 ppm in bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, collards, dried citrus fruit pulp, kale, kohlrabi, mustard greens, mustard spinach, Napa Chinese cabbage and rape greens, 1 ppm in apples, crabapples, loquats, mayhaws, oriental pears, pears and quinces, 0.6 ppm in undelinted cotton seed, 0.5 ppm in citrus fruits, 0.4 ppm in

tomato paste, 0.3 ppm in meat by-products of cattle, goats, hogs, horses and sheep, 0.2 ppm in eggplants, grapes, groundcherries, pepinos, peppers, tomatillos and tomatoes, 0.1 ppm in fat and meat of cattle, goats, hogs, horses and sheep; and milk, 0.05 ppm in liver of poultry, and 0.01 ppm in eggs; fat and meat of poultry; mustard seed; potatoes; and rapeseed (canola) would not pose an unacceptable health risk to the public. A summary of the data reviewed and risk assessment for acetamiprid can be found in Regulatory Note REG2002-05 available on the PMRA website at www.hc-sc.gc.ca/pmra-arla/english/pdf/reg/reg2002-05-e.pdf.

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*. Also 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 acetamiprid, establishment of MRLs for acetamiprid in amaranth, apples, arugula, bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cardoon, cauliflower, celery, celtuce, Chinese broccoli, Chinese celery, Chinese mustard cabbage, citrus fruits, collards, corn salad, crabapples, dandelion leaves, dock, dried citrus fruit pulp, edible leaved chrysanthemum, eggplants, eggs, endives, fat of poultry, fresh chervil leaves, fresh Florence fennel leaves and stalks, garden cress, garden purslane, garland chrysanthemum, grapes, groundcherries, head lettuce, loquats, kale, kohlrabi, leaf lettuce, liver of poultry, mayhaws, meat by-products of cattle, goats, hogs, horses and sheep, meat of poultry, mustard greens, mustard seed, mustard spinach, Napa Chinese cabbage, New Zealand spinach, orach leaves, oriental pears, parsley leaves, pears, pepinos, peppers, potatoes, quinces, radicchio, rape greens, rapeseed (canola), rhubarb, spinach, Swiss chard, tomatillos, tomatoes, tomato paste, undelinted cotton seed, upland cress, vine spinach and winter purslane, is necessary to support the 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.

Even though the sale of food containing residues of pest control products at a level greater than 0.1 ppm would already be prohibited by virtue of subsection B.15.002(1) of the *Food and*

Drug Regulations, the establishment of an MRL of 0.1 ppm in Table II, Division 15, of the Regulations, for residues of acetamiprid in fat and meat of cattle, goats, hogs, horses and sheep; and milk would provide more clarity regarding the applicable MRL and would clearly indicate that the appropriate risk assessment has been completed. This is in keeping with current trends towards increased openness and transparency of regulatory processes and is consistent with current practices of most pesticide regulatory agencies throughout the world.

Benefits and Costs

This proposed regulatory amendment would provide joint benefits to consumers, the agricultural industry and importers of agricultural products as a result of improved management of pests and would contribute to a safe, abundant and affordable food supply by allowing the importation and sale of food commodities containing acceptable levels of pesticide residues.

The review of the application for registration of acetamiprid was conducted jointly by the PMRA and the United States Environmental Protection Agency. The registration decision for acetamiprid was announced in Canada in January 2003. MRLs for acetamiprid have been established in the United States and the proposed Canadian MRLs would be the same. Registration of this pest control product and establishment of MRLs in Canada will benefit the Canadian agricultural industry, facilitate trade, and protect the health of consumers.

Some costs may be incurred related to the implementation of analytical methods for analysis of acetamiprid and its metabolite 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 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.

Compliance and Enforcement

Compliance would be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the proposed MRLs for acetamiprid are adopted.

Contact

Francine Brunet, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9. (Tel.: (613) 736-3678; Fax: (613) 736-3659; E-mail: francine_brunet@hc-sc.gc.ca)

March 18, 2005

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1)^a of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1334 - Acetamiprid)*.

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 Francine Brunet, 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) 736-3678; fax: (613) 736-3659; e-mail: francine_brunet@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,

, 2005

Eileen Boyd
Assistant Clerk of the Privy Council

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1334 -
ACETAMIPRID)

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 A.001:

I	II	III	IV
Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m. Foods
A.002	acetamiprid	<i>(E)</i> - <i>N</i> -[(6-chloro-3-pyridinyl)methyl]- <i>N'</i> -cyano- <i>N</i> -methylethanamide	3 Amaranth, arugula, cardoon, celery, celtuce, Chinese celery, corn salad, dandelion leaves, dock, edible leaved chrysanthemum, endives, fresh chervil leaves, fresh Florence fennel leaves and stalks, garden cress, garden purslane, garland chrysanthemum, head lettuce, leaf lettuce, New Zealand spinach, orach leaves, parsley leaves, radicchio, rhubarb, spinach, Swiss chard, upland cress, vine spinach, winter purslane

¹ C.R.C., c. 870

Item No.	I Common Chemical Name	II Chemical Name of Substance	III Maximum Residue Limit p.p.m.	IV Foods
			1.2	Bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cauliflower, Chinese broccoli, collards, Chinese mustard cabbage, dried citrus fruit pulp, kale, kohlrabi, mustard greens, mustard spinach, Napa Chinese cabbage, rape greens
			1	Apples, crabapples, loquats, mayhaws, oriental pears, pears, quinces
			0.6	Undelinted cotton seed
			0.5	Citrus fruits
			0.4	Tomato paste
			0.2	Eggplants, grapes, groundcherries, pepinos, peppers, tomatillos, tomatoes
			0.01	Mustard seed, potatoes, rapeseed (canola)

Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	IV Foods
		(E)-N-[(6-chloro-3-pyridinyl)methyl]-N'-cyano-N-methylethanamide, including the metabolite	0.3	Meat by-products of cattle, goats, hogs, horses and sheep
		(E)-N-[(6-chloro-3-pyridinyl)methyl]-N'-cyanoethanimidamide	0.1	Fat and meat of cattle, goats, hogs, horses and sheep; milk
			0.05	Liver of poultry
			0.01	Eggs; fat and meat of poultry

COMING INTO FORCE

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