

- PREPUBLICATION NOTICE -

TB MEETING OF OCTOBER 31, 2005

WILL APPEAR IN THE PART I - CANADA GAZETTE - OF NOVEMBER 5, 2005

FOOD AND DRUG REGULATIONS - PROPOSED AMENDMENT

SCHEDULE NO. 1438 (ACIBENZOLAR-S-METHYL)

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulation)

Description

The pest control product (pesticide) acibenzolar-S-methyl is a plant defence mechanism activator to provide protection against certain bacterial and fungal diseases on a wide variety of crops as pre-harvest management. This proposed regulatory amendment would establish Maximum Residue Limits (MRLs) under the *Food and Drugs Act* for residues of acibenzolar-S-methyl and its metabolite in amaranth, arugula, bananas, bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cardoon, cauliflower, celery, celtuce, Chinese broccoli, Chinese celery, Chinese mustard cabbage, collards, corn salad, dandelion leaves, dock, edible leaved chrysanthemum, eggplants, endives, fresh chervil leaves, fresh Florence fennel leaves and stalks, garden cress, garden purslane, garland chrysanthemum, groundcherries, head lettuce, kale, kohlrabi, leaf lettuce, mustard greens, mustard spinach, Napa Chinese cabbage, New Zealand spinach, orach leaves, parsley leaves, pepinos, peppers, radicchio, rape greens, rhubarb, sea kale, spinach, Swiss chard, tomatillos, tomatoes, tomato paste, upland cress, vine spinach and winter purslane, 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 (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

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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 acibenzolar-S-methyl, including its metabolite, of 3 ppm in tomato paste, 1 ppm in bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, collards, eggplants, groundcherries, kale, kohlrabi, mustard greens, mustard spinach, Napa Chinese cabbage, New Zealand spinach, pepinos, peppers, rape greens, spinach, tomatillos, tomatoes and vine spinach, 0.25 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, orach leaves, parsley leaves, radicchio, rhubarb, sea kale, Swiss chard, upland cress and winter purslane, and 0.1 ppm in bananas would not pose an unacceptable health risk to the public. These new MRLs harmonize with those established by the United States Environmental Protection Agency.

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 acibenzolar-S-methyl establishment of MRLs for amaranth, arugula, bok choy Chinese cabbage, broccoli, broccoli raab, Brussels sprouts, cabbage, cauliflower, cardoon, celery, celtuce, Chinese broccoli, Chinese celery, Chinese mustard cabbage, collards, corn salad, dandelion leaves, dock, edible leaved chrysanthemum, eggplants, endives, fresh chervil leaves, fresh Florence fennel leaves and stalks, garden cress, garden purslane, garland chrysanthemum, groundcherries, head lettuce, kale, kohlrabi, leaf lettuce, mustard greens, mustard spinach, Napa Chinese cabbage, New Zealand spinach, orach leaves, parsley leaves, pepinos, peppers, radicchio, rape greens, rhubarb, sea kale, spinach, Swiss chard, tomatillos, tomatoes, tomato paste, upland cress, vine spinach and winter purslane 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.

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 acibenzolar-S-methyl in bananas 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 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 acibenzolar-S-methyl and its metabolite in the foods 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.

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 acibenzolar-S-methyl 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: pmra_regulatory_affairs-affaires_réglementaires_arla@hc-sc.gc.ca)

July 25, 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 (1438 - Acibenzolar-S-methyl)*.

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

Diane Labelle
Acting Assistant Clerk of the Privy
Council

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1438 - ACIBENZOLAR-S-METHYL)

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:

Item No.	Common Chemical Name	Chemical Name of Substance	Maximum Residue Limit p.p.m.	Foods
A.001.1	acibenzolar-S-methyl	1,2,3-benzothiadiazole-7-carbothioic acid S-methyl ester, including the metabolite 1,2,3-benzothiadiazole-7-carboxylic acid	3	Tomato paste
			1	Broccoli, broccoli raab, bok choy Chinese cabbage, Brussels sprouts, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, collards, eggplants, groundcherries, kale, kohlrabi, mustard greens, mustard spinach, Napa Chinese cabbage, New Zealand spinach, pepinos, peppers, rape greens, spinach, tomatillos, tomatoes, vine spinach
			0.25	Amaranth, argula, cardoon, celery,

¹ C.R.C., c. 870

celtuce, Chinese
celery, corn salad,
dandelion leaves, dock,
edible leaved
chrysanthemum, endives,
fresh chervil leaves,
fresh Florence fennel
leaves and stock,
garden cress, garden
purslane, garland
chrysanthemum, head
lettuce, leaf lettuce,
orach leaves, parsley
leaves, radicchio,
rhubarb, sea kale,
Swiss chard, upland
cress, winter purslane

Bananas

0.1

COMING INTO FORCE

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