CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1378 (FLUAZIFOP-BUTYL)

P.C. 2004-1331 OF NOVEMBER 15, 2004

SOR/2004-247 OF NOVEMBER 15, 2004

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)[1] of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1378 — Fluazifop-butyl)*.

[1] S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1378 — FLUAZIFOP-BUTYL)

AMENDMENTS

1. (1) The portion of item F.1.1.1 of Table II to Division 15 of Part B of the English version of the *Food and Drug Regulations*[2] in column II is replaced by the following:

	II
Item No.	**Chemical Name of Substance**
F.1.1.1	butyl(±)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate

(2) The portion of item F.1.1.1 of Table II to Division 15 of Part B of the Regulations in columns III and IV is replaced by the following:

	III	IV
Item No.	**Maximum Residue Limit p.p.m.**	**Foods**
F.1.1.1	1 (calculated as acid)	Soybeans, strawberries
	0.3 (calculated as acid)	Mustard
	0.2 (calculated as acid)	Flax, solin
	0.1 (calculated as acid)	Blueberries
	0.05 (calculated as acid)	Eggs; fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep
	0.01 (calculated as acid)	Milk

COMING INTO FORCE

[2] C.R.C., c. 870

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

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulation)

Description

Fluazifop-butyl is registered under the *Pest Control Products Act* as a herbicide for the control of grasses in various broadleaf crops as a post-emergent treatment. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of fluazifop-butyl resulting from this use at 1 part per million (ppm) in soybeans and strawberries, 0.3 ppm in mustard and 0.2 ppm in flax and solin. MRLs have also been established at 0.05 ppm in eggs, and fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep, and 0.01 ppm in milk to cover residues in food derived from animals fed with crops treated with fluazifop-butyl. 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 an application to amend the registration of fluazifop-butyl in order to allow its use for the control of quackgrass in blueberries as a post-emergent treatment. This regulatory amendment will establish an MRL for residues of fluazifop-butyl resulting from this use in blueberries, 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 an MRL for fluazifop-butyl of 0.1 ppm in blueberries would not pose an unacceptable health risk to the public. This regulatory amendment will also amend the English chemical name of fluazifop-butyl in order to comply with international nomenclature conventions.

Alternatives

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 fluazifop-butyl in blueberries 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

The use of fluazifop-butyl in blueberries will provide joint benefits to consumers and the agricultural industry as a result of improved management of pests. In addition, this 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 fluazifop-butyl in the food 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.

This schedule of amendment was published in the *Canada Gazette*, Part I, on March 27, 2004. Interested parties were invited to make

representation concerning the proposed amendment. No responses were recieved.

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the MRL for fluazifop-butyl is adopted.

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