CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1419 (GLUFOSINATE-AMMONIUM)

P.C. 2005-2223 OF NOVEMBER 28, 2005

SOR/2005-398 OF NOVEMBER 28, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1)[a] of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1419 – Glufosinate-ammonium)*.

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

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1419 — GLUFOSINATE-AMMONIUM)

AMENDMENT

1. The portion of item G.1 of Table II to Division 15 of Part B of the *Food and Drug Regulations*[1] in columns II to IV is replaced by the following:

	II	III	IV
Item No.	**Chemical Name of Substance**	**Maximum Residue Limit p.p.m.**	**Foods**
G.1	ammonium(±)-2-amino-4-(hydroxymethyl phosphinyl)butanoate, including the metabolite propanoic acid, 3-(hydroxymethyl phosphinyl)	6	Lentils
		3.5	Cottonseed oil
		3	Dry Peas, rapeseed (canola)
		2	Soybeans
		1	Liver and kidney of cattle, goats, hogs, poultry and sheep; rice
		0.5	Dry white beans
		0.4	Potatoes
		0.2	Corn, wheat
		0.1	Eggs; fat, meat and meat by-products of cattle, goats, hogs, poultry and sheep
		0.04	Milk

COMING INTO FORCE

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

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

REGULATORY IMPACT ANALYSIS STATEMENT
(This statement is not part of the Regulation)

Description

Glufosinate-ammonium is registered under the *Pest Control Products Act* as a herbicide for the control of a wide variety of broadleaf weeds and grasses, and as a dessicant in apples, asparagus, carrots, dry beans, flax, grapes, lentils, lettuce, onions, peaches, pears, peas, plums, potatoes, rapeseed (canola), raspberries, soybeans and wheat as a pre-plant incorporated, pre-emergent or post-emergent treatment or for pre-harvest management. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of glufosinate-ammonium and its metabolite resulting from these uses at 6 parts per million (ppm) in lentils, 3 ppm in dry peas and rapeseed (canola), 0.5 ppm in dry white beans, 0.4 ppm in potatoes, and 0.2 ppm in corn and wheat. An MRL has also been established at 1 ppm in liver and kidney of cattle, goats, hogs, poultry and sheep to cover residues in food derived from animals fed with crops treated with glufosinate-ammonium. By virtue of subsection B.15.002(1) of the *Food and Drug Regulations*, the MRL for other foods is 0.1 ppm.

This regulatory amendment will establish MRLs for residues of glufosinate-ammonium and its metabolite in imported cottonseed oil and rice, and amend the MRL for soybeans, in order to permit the import and sale of food containing these residues. The amendment will also establish MRLs in eggs; fat, meat and meat by-products of cattle, goats, hogs, poultry and sheep; and milk to cover residues in food derived from animals fed with crops treated with glufosinate-ammonium.

In order to determine whether proposed MRLs are safe, Health Canada's Pest Management Regulatory Agency (PMRA) 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 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 glufosinate-ammonium, including its metabolite, of 3.5 ppm in

cottonseed oil, 2 ppm in soybeans, 1 ppm in rice, 0.1 ppm in eggs and fat, meat and meat by-products of cattle, goats, hogs, poultry and sheep, and 0.04 ppm in milk would not pose an unacceptable health risk to the public. This regulatory ammendment will also amend the the chemical name of glufosinate-ammonium in order to comply with international nomenclature conventions.

International Situation and Trade Implications

The Canadian MRLs proposed in this regulatory amendment differ from tolerances established in the United States (U.S.) (http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr180_04.html) and Codex MRLs (http://www.mrldatabase.com). These differences are outlined in the following table:

Foods	**Canada**	**U.S.**	**Codex***
Cottonseed oil	3.5	4**	none established
Eggs, meat of cattle, goats, hogs, poultry and sheep	0.1	0.15	none established
Fat of cattle, goats, hogs and sheep	0.1	0.4	none established
Meat by-products of cattle, goats, hogs and sheep	0.1	6.0	none established
Milk	0.04	0.15	none established
Poultry fat	0.1	0.15	none established
Poultry meat by-products	0.1	0.6	none established

*Codex is an international organization under the auspices of the United Nations which develops international food standards, including MRLs.

** The U.S. EPA has not set a tolerance for cottonseed oil. Residues in the oil are covered by the tolerance on cottonseed.

MRLs may vary from one country to another for a number reasons including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Under the North American Free Trade Agreement (NAFTA), Canada, the United States and Mexico are committed to resolving MRL discrepancies to the broadest extent possible. MRL/tolerance harmonization will standardize the protection of human health across North America and promote the free trade of safe food products. Until harmonization is achieved, the Canadian MRLs proposed in this regulatory amendment are necessary. The differences in MRLs/tolerances outlined above are not

expected to negatively impact businesses or adversely affect international competitiveness of Canadian firms or to negatively affect any regions of Canada.

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 glufosinate-ammonium, the establishment of MRLs 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 glufosinate-ammonium in eggs and fat, meat and meat by-products of cattle, goats, hogs, poultry and sheep 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 regulatory amendment will provide joint benefits to consumers, the agricultural industry and importers of agricultural products as a result of improved management of pests and 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 glufosinate-ammonium 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.

This schedule of amendment was published in the *Canada Gazette*, Part I, on December 18, 2004. Interested parties were invited to make representations concerning the proposed amendment. No comments were received.

Compliance and Enforcement

Compliance will be monitored through ongoing domestic and/or import inspection programs conducted by the Canadian Food Inspection Agency when the MRLs for glufosinate-ammonium are adopted.

Contact

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