**CANADA GAZETTE, PART II**

**FOOD AND DRUG REGULATIONS - AMENDMENTS**

**WILL BE PUBLISHED IN CANADA GAZETTE, PART II OF DECEMBER 1, 2004**

**SCHEDULE NO. 1372 (Trimethylsulfonium Cation)**

**P.C. 2004-1329 OF NOVEMBER 15, 2004**

**SOR/2004-246 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 (1372 — Trimethylsulfonium Cation)*.

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

.../2

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1372 — TRIMETHYLSULFONIUM CATION)

AMENDMENT

**1. The portion of item T.9 of Table II to Division 15 of Part B of the *Food and Drug Regulations*[2] in columns III and IV is replaced by the following:**

| | III | IV |
|---|---|---|
| **Item No.** | **Maximum Residue Limit p.p.m.** | **Foods** |
| **T.9** | 15 | Barley, oat milling fractions, excluding flour |
| | 13 | Soybeans |
| | 10 | Oats, rapeseed (canola) |
| | 3 | Flax, peas, wheat |
| | 1.5 | Lentils |
| | 1 | Beans; kidney of cattle, goats, hogs, horses and sheep |
| | 0.5 | Liver of cattle, goats, hogs and sheep; meat and meat by-products of cattle, goats, hogs, horses and sheep; milk |
| | 0.1 | Kidney and liver of poultry |
| | 0.05 | Meat of poultry |
| | 0.02 | Eggs |

COMING INTO FORCE

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

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

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

## Description

Glyphosate, formulated as trimethylsulfonium salt, is registered under the *Pest Control Products Act* as a herbicide for the control of annual and perennial grasses, and broadleaf weeds in a wide variety of crops as pre-plant incorporated, pre-emergent and post-emergent treatments, and for pre-harvest management. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of trimethylsulfonium cation resulting from this use at 15 parts per million (ppm) in barley and oat milling fractions, excluding flour, 10 ppm in oats and rapeseed (canola), 3 ppm in flax, peas and wheat, 1 ppm in beans and 0.5 ppm in lentils. An MRL has also been established at 0.5 ppm in kidney and liver of cattle, goats, hogs, poultry and sheep to cover residues in food derived from animals fed with crops treated with glyphosate, formulated as trimethylsulfonium salt. 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 glyphosate, formulated as trimethylsulfonium salt, in order to allow its use for the control of annual and perennial grasses, and broadleaf weeds in soybeans as pre-plant incorporated, pre-emergent and post-emergent treatments, and for pre-harvest management. This regulatory amendment will establish MRLs for residues of trimethylsulfonium cation resulting from this use in soybeans in order to permit the sale of food containing these residues. The regulatory amendment will also establish MRLs in eggs; kidney of horses; meat and meat by-products of cattle, goats, hogs, horses and sheep; meat of poultry; and milk to cover residues in food derived from animals fed with crops treated with glyphosate, formulated as trimethylsulfonium salt. The regulatory amendment will also increase the MRL for lentils from 0.5 ppm to 1.5 ppm, increase the MRL for kidney of cattle, goats, hogs and sheep from 0.5 ppm to 1 ppm, and decrease the MRL for kidney and liver of poultry from 0.5 ppm to 0.1 ppm as a result of the evaluation of additional data submitted in connection with this application.

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.

.../4

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 residues of trimethylsulfonium cation of 13 ppm in soybeans, 1.5 ppm in lentils, 1 ppm in kidney of cattle, goats, hogs, horses and sheep, 0.5 ppm in meat and meat by-products of cattle, goats, hogs, horses and sheep; and milk, 0.1 ppm in kidney and liver of poultry, 0.05 ppm in meat of poultry and 0.02 ppm in eggs would not pose an unacceptable health risk to the public.

## 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 trimethylsulfonium

.../5

cation establishment of MRLs for eggs; kidney, meat and meat by-products of cattle, goats, hogs, horses and sheep; lentils; meat of poultry; milk; and soybeans 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.

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 trimethylsulfonium cation in kidney and liver of poultry 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 glyphosate, formulated as trimethylsulfonium salt, on soybeans 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 trimethylsulfonium cation 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.

.../6

This schedule of amendment was published in the *Canada Gazette*, Part I, on November 22, 2003. Interested parties were invited to make representations concerning the proposed amendment. No responses 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 trimethylsulfonium cation are adopted.

## Contact

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