CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1341 (CHLORPYRIFOS)

P.C. 2005-15-21 OF SEPTEMBER 14, 2005

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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 (1341 — Chlorpyrifos)*.

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

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REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS
(1341 — CHLORPYRIFOS)

AMENDMENT

1. The portion of item C.10.1 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**
C.10.1	0,0-diethyl-0-(3,5,6-trichloro-2-pyridyl) phosphorothioate	2	Kiwi fruit
		1 (calculated on the fat content)	Meat and meat by-products of cattle, other than fat, liver and kidney
		1	Citrus fruits, fat, kidney and liver of cattle, peppers
		0.5	Rutabagas
		0.01	Apples, grapes, tomatoes

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

Chlorpyrifos is an active ingredient in pest control products (pesticides) that have been registered under the *Pest Control Products Act* as insecticides for the control of various insect pests on barley, beans, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, celery, Chinese cabbage, corn, cucumbers, filberts, flax, garlic, lentils, oats, onions, peaches/nectarines, peas, peppers, potatoes, radishes (including Asian radishes), rapeseed (canola), rutabagas, strawberries, sugar beets, sunflowers, tomatoes and wheat. Maximum Residue Limits (MRLs) were, previously, established under the *Food and Drugs Act* for residues of chlorpyrifos and its metabolite resulting from this use at 1 part per million (ppm) in peppers and 0.5 ppm in rutabagas, and at 2 ppm in kiwi fruit, 1.5 ppm in apples and 1 ppm in citrus fruits imported into Canada. An MRL has also been established at 1 ppm in fat, kidney, liver and meat and meat by-products of cattle to cover residues in food derived from animals fed with crops treated with chlorpyrifos. 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 initiated a process to re-evaluate and to determine the conditions of acceptability for pesticide active ingredients that were registered in Canada before 1995, along with their currently registered end-use products. Re-evaluation is the review of pesticide active ingredients and their end-use products on the basis of updated data and information to determine whether, and under what conditions, their continued registration is acceptable.

Before making a decision regarding the continued registration of a pest control product, the PMRA conducts an assessment of the risks of the product specific to currently registered uses. The existing registration of the pest control product will be maintained if the re-evaluation indicates that the product has merit and value and that the human health and environmental risks associated with its continued use are acceptable.

The human health risk assessment includes a review of extensive toxicological and residue studies to assess the dietary risks posed by the pest control product in imported and domestic food. An acceptable daily intake (ADI) and/or acute reference dose (ARfD) is calculated by applying a margin of safety 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. Additional margins of safety are used to account for possible increased sensitivity of subpopulations. The potential residue intake from food is calculated taking into account dietary preferences of various subpopulations (including infants,

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toddlers, children, adolescents, adults and seniors) and the average residue levels found on these foods. The residues are considered acceptable if the potential residue intake from food is less than the ADI, taking into account time exposure scenarios and exposure from all other non-occupational sources.

Based on all currently registered uses and known imports for chlorpyrifos, the PMRA has determined that the chronic dietary risk posed by chlorpyrifos is acceptable for all subpopulations, including infants and children.

However, when age-related dietary preferences and daily consumption patterns were taken into account, the expected residue levels of chlorpyrifos were higher than the acceptable one-day intake for the most highly exposed subgroup, children 1-6 years old. The major contributors to this acute dietary risk were tomatoes, imported apples, and imported grapes.

Therefore, as a result of this first stage of the re-evaluation of chlorpyrifos, it was decided that products containing chlorpyrifos could not be used in Canada on tomatoes after December 31, 2003. Chlorpyrifos is not registered for use on apples or grapes in Canada. The PMRA will also address acute dietary risk concerns by decreasing the MRLs for chlorpyrifos in apples, grapes and tomatoes to 0.01 ppm. After the review of all available data, the PMRA has determined that following this amendment, both the acute dietary risk and the chronic or lifetime risk from foods treated with chlorpyrifos will not be a concern for the general Canadian population or any population subgroup, including infants and children. Since chlorpyrifos is still registered for use on other commodities in Canada, this MRL is being established to cover residues as a result of the misuse of chlorpyrifos and residues found in imported commodities.

The residue data reviewed also indicate that the dietary risk following use of chlorpyrifos is adequately described by naming only the parent compound, as the metabolite is not of toxicological concern. Therefore, this regulatory amendment will redefine the chemical name of chlorpyrifos for apples, grapes and tomatoes in order to remove the metabolite.

These amendments harmonize with changes proposed by the United States Environmental Protection Agency (U.S. EPA) with respect to MRLs for chlorpyrifos and the description of the residue of concern.

Alternatives

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 chlorpyrifos, decreasing the MRLs for apples, grapes and tomatoes is

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necessary to prevent the import and sale of food with unacceptable residues.

Benefits and Costs

The Canadian public will derive significant benefit from this regulatory amendment through the strengthened health protection that it affords. In determining the MRLs, modern risk assessment methods have been applied including additional safety factors to protect infants and children. The regulatory amendment will protect the health of Canadians, and particularly Canadian children, by preventing the sale of food with unacceptable residues.

There are no additional costs to the agricultural industry as a result of this regulatory amendment as the use of chlorpyrifos on apples, grapes and tomatoes is not currently permitted in either Canada or the U.S. Costs to industry with respect to future decisions regarding chlorpyrifos will be minimized by retaining the most critical uses in Canada, provided the health and environmental risks of these uses are determined to be acceptable, and by harmonizing registration decisions and MRLs with those of the U.S. to the extent possible.

Some costs to the government may be incurred related to the analysis of chlorpyrifos in the foods mentioned above. However, it is anticipated that no additional funding above the current level will be required by 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 re-evaluations conducted by the PMRA include a review of the assessments conducted by the U.S. EPA, as well as MRLs adopted by other national health/regulatory agencies.

Canadians were consulted on the PMRA's approach to re-evaluation through a Regulatory Proposal published in 1999. The finalized program was published in 2001 as Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*.

With respect to the re-evaluation of chlorpyrifos, Re-evaluation Note REV2000-01, *Update on the Re-evaluation of Chlorpyrifos in Canada*, was published in June 2000 to inform registrants of chlorpyrifos that the new approaches to risk management adopted by the PMRA and the U.S. EPA, including the additional safety factor to protect infants and children, might lead to regulatory action to restrict the use of chlorpyrifos in Canada. A second Re-evaluation Note, REV2000-05, *Chlorpyrifos*, was published in September 2000 to announce the changes to registrations and

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MRLs described above. Since then, a consultation document entitled Proposed Acceptability for Continuing Registration PACR2003-03, *Phase 2 of the Re-evaluation of Chlorpyrifos*, was published in March 2003 to propose further regulatory action with respect to chlorpyrifos.

Regulatory Directives, Re-evaluation Notes, and Proposed Acceptability for Continuing Registration documents may be found under Publications on the PMRA website at http://www.pmra-arla.gc.ca.

This schedule of amendment was published in the *Canada Gazette*, Part I, on January 15, 2005. Interested parties were invited to make representation 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 chlorpyrifos are adopted.

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