

CANADA GAZETTE, PART II

FOOD AND DRUG REGULATIONS - AMENDMENTS

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SCHEDULE NO. 1425 (CLOPYRALID)

P.C. 2005-502 OF APRIL 5, 2005

SOR/2005-96 OF APRIL 5, 2005

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 (1425 - Clopyralid)*.

¹S.C. 1999, c. 33, s. 347

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1425 - CLOPYRALID)

AMENDMENT

1. The portion of item C.10.4 of Table II to Division 15 of Part B of the *Food and Drug Regulations*² 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.10.4	3,6-dichloro-2-pyridinecarboxylic acid	7	Barley, oats and wheat milling fractions, excluding flour
		2	Barley, oats, wheat
		1	Broccoli, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, kohlrabi, Napa Chinese cabbage, strawberries
		0.36	Kidney of cattle, goats, horses and sheep
		0.2	Flax, kidney of poultry
		0.05	Eggs; fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep; kidney of hogs
		0.01	Milk

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

Clopyralid is registered under the *Pest Control Products Act* as a herbicide for the control of a wide variety of broadleaf weeds and grasses in apples, barley, broccoli, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, Chinese radish, cranberry, field corn, flax, highbush blueberries, kohlrabi, Napa Chinese cabbage, oats, rapeseed (canola), strawberries, sugar beets and wheat as a pre-plant incorporated, pre-emergent, post-emergent or post-harvest treatment. Maximum Residue Limits (MRLs) have been established under the *Food and Drugs Act* for residues of clopyralid resulting from these uses at 7 parts per million (ppm) in barley, oats and wheat milling fractions, excluding flour, 2 ppm in barley, oats and wheat, 1 ppm in broccoli, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, kohlrabi, Napa Chinese cabbage and strawberries, and 0.2 ppm in flax. 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 clopyralid in order to allow its use for the control of broadleaf weeds and Canada thistle in timothy grass for forage and hay production as a post-emergent treatment. This regulatory amendment will establish MRLs for residues of clopyralid in eggs; fat, kidney, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep; and milk to cover residues in food derived from animals fed with crops treated with clopyralid.

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 MRLs for clopyralid of 0.36 ppm in kidney of cattle, goats, horses and sheep, 0.2 ppm in kidney of poultry, 0.05 ppm in eggs; fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep; and kidney of hogs, and 0.01 ppm in milk would not pose an unacceptable health risk to the public. This regulatory amendment will also amend the chemical name of clopyralid in order to comply with international nomenclature conventions.

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

Benefits and Costs

The above listed use of clopyralid 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 clopyralid 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 November 20, 2004. 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 clopyralid are adopted.

Contact

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