- PREPUBLICATION NOTICE -

TB MEETING OF MARCH 21, 2005

WILL APPEAR IN THE PART I - CANADA GAZETTE - OF MARCH 26, 2005

FOOD AND DRUG REGULATIONS - PROPOSED AMENDMENT

SCHEDULE NO. 1423 (TEPRALOXYDIM)

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

Description

Under authority of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA), of Health Canada, has approved an application for the registration of the pest control product tepraloxydim as a herbicide for the control of a variety of annual and perennial grasses in dry peas, flax and lentils as a post-emergent treatment. This proposed regulatory amendment would establish a Maximum Residue Limit (MRL) under the *Food and Drugs Act* for residues of tepraloxydim and its metabolites resulting from this use in dry peas, flax and lentils, in order to permit the sale of food containing these residues. This proposed amendment would also establish MRLs for residues of tepraloxydim and its metabolites in eggs; meat and meat by-products of cattle, hogs, horses, poultry and sheep; and milk to cover residues in food derived from animals fed with crops treated with tepraloxydim.

Before making a registration decision regarding a new pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. Pest control products will be registered 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

.../2

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 tepraloxydim, including its metabolites, of 0.15 parts per million (ppm) in eggs; and, meat and meat by-products of cattle, hogs, horses, poultry and sheep, 0.1 ppm in dry peas, flax and lentils, and 0.03 ppm in milk 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 tepraloxydim, establishment of MRLs for eggs; meat and meat by-products of cattle, hogs, horses, poultry and sheep; and milk are 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 tepraloxydim in dry peas, flax and lentils 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 above listed uses of tepraloxydim will provide joint benefits to consumers and the agricultural industry as a result of improved management of pests. In addition, this proposed 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 tepraloxydim and its metabolites 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 Organisation for Economic Co-operation 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.

Compliance and Enforcement

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

Contact

Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario, K1A 0K9. (Tel.: (613) 736-3665; Fax: (613) 736-3659; E-mail: cameron_laing@hc-sc.gc.ca)

.../4

November 23, 2004

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Notice is hereby given that the Governor in Council, pursuant to subsection 30(1)[a] of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1423 — Tepraloxydim)*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Cameron Laing, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Department of Health, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario K1A 0K9 (tel.: (613) 736-3665; fax: (613) 736-3659; e-mail: cameron_laing@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, , 2004

Eileen Boyd
Assistant Clerk of the Privy Council

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

.../6

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS
(1423 —— TEPRALOXYDIM)

AMENDMENT

1. Table II to Division 15 of Part B of the *Food and Drug Regulations*[1] is amended by adding the following after item T.1:

I	II	III	IV
Item No.	**Common Chemical Name**	**Chemical Name of Substance**	**Maximum Residue Limit p.p.m.**	**Foods**
T.1.01	tepraloxydim	(*EZ*)-(*RS*)-2-{1-[(2*E*)-3-chloroallyloxyimino]propyl}-3-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one including its metabolites convertible to dimethyl 3-(perhydropyran-4-yl)glutarate, dimethyl 3-hydroxy-3-(perhydropyran-4-yl)glutarate and dimethyl 3-(pentan-5-olid-3-yl)glutarate, expressed as parent equivalent	0.15	Eggs; meat and meat by-products of cattle, hogs, horses, poultry and sheep
		0.03	Milk

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

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Item No.	**Common Chemical Name**	**Chemical Name of Substance**	**Maximum Residue Limit p.p.m.**	**Foods**
		(*EZ*)-(*RS*)-2-{1-[(2*E*)-3-chloroallyloxyimino]propyl}-3-hydroxy-5-perhydropyran-4-ylcyclohex-2-en-1-one including its metabolites convertible to 3-perhydropyran-4-ylglutaric acid and 3-hydroxy-3-perhydropyran-4-ylglutaric acid, expressed as parent equivalent	0.1	Dry peas, flax, lentils

COMING INTO FORCE

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