

Santé Canada

Health Products and Food Branch

Direction générale des produits de santé et des aliments

> Tunney's Pasture A.L. 0701A5 Ottawa, Ontario K1A 0L2

September 27, 2004

Mr. Jan Westcott
President
Association of Canadian Distillers
Suite 1203, 275 Slater Street
Ottawa, Ontario K1P 5H9

Dear Mr. Westcott:

The Food Directorate would like to inform you of changes to the original proposal that was the subject of the letter of February 19, 2004 from Mr. Paul Mayers, A/Director General, Food Directorate on regulatory amendments to enhance labelling requirements for added specific priority allergens, gluten sources and sulphites in prepackaged foods sold in Canada.

The Directorate has considered issues raised by stakeholders in reaction to the February 19, 2004, proposal, more specifically in relation to the labelling requirements applicable to alcoholic beverages subject to standards of composition in Division 2 of the Food and Drug Regulations, (e.g., wine, beer). Based on the nature of these products and their manufacturing processes, it will now be proposed that fining agents derived from milk, egg and fish used during the manufacture of standardized alcoholic beverages be exempted from the regulatory requirements to declare the presence of added protein-containing substances from these three sources on product labels. These ingredients have been used for many years in the preparation of certain standardized alcoholic beverages, and to date, we are not aware of documented clinical evidence of allergenic reactions from the consumption of these products.

Health Canada laboratories will continue to conduct research on the potential presence of protein-containing residues of priority allergens resulting from the use of fining agents derived from milk, egg or fish in alcoholic beverages. The exemption of fining agents from these three sources from the requirements for labelling of allergens will be reconsidered when the data from all research conducted by Health Canada, provincial authorities and other countries become available.

The proposed regulatory requirements for the declaration of added protein-containing substances from the other specified sources, gluten sources and sulphites would still apply to these alcoholic beverages. While the original proposal indicated that this declaration would be required on the principal display panel, it is now proposed that the declaration would be allowed anywhere on the label.

Thank you again for your interest and cooperation on this important initiative.

Yours truly,

Ron Burke

Director

Bureau of Food Regulatory, International and Interagency Affairs

cc. John Salminen, HC Greg Orniss, CFIA



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> Food Directorate Tunney's Pasture A.L. 0702C1 Ottawa, Ontario K1A 0L2

March 18, 2004

Mr. Jan H. Westcott President & CEO Association of Canadian Distillers 21 Four Seasons Place, Suite 602 Toronto, Ontario M9B 6J8

Dear Mr. Westcott:

Thank you for your letter dated March 17, 2004, with regard to the proposed allergen labelling requirements under the *Food and Drugs Act* for prepared foods sold in Canada.

I am pleased to advise that your understanding of the labelling requirements for gluten (or other identified priority allergen) in the proposal is correct: labelling would not be required if no gluten or associated protein - containing derivative is present in the final product.

If you wish any further clarification, please feel free to contact me again.

Best regards.

Yours truly,

Ron Burke

Director

Bureau of Food Regulatory

International and Interagency Affairs

cc. John Salminen

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March 17, 2004

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Mr. Ronald Burke
Director
Bureau of Food Regulatory, International and Interagency Affairs
Health Canada
Tunney's Pasture
Ottawa, Ontario
K1A 0L2

Dear Mr. Burke:

We appreciated receiving Health Canada's March 2, 2004 correspondence containing information in regards to proposed allergen labeling requirements for prepackaged foods sold in Canada.

We would appreciate clarification on one critical issue. It is our understanding that, under the proposal, no label declaration will be required for glutens (or other identified priority allergens) used as an ingredient in products where no gluten or associated protein-containing derivative is present in the final product.

As you may be aware, we have previously provided medical and scientific evidence to Health Canada demonstrating that the distillation process used in the production of spirit products removes all traces of gluten and that whisky and other spirits may be consumed safely even by celiac sufferers.

We would appreciate confirmation of our understanding of the proposals in this regard.

Sincerely,

Jan H. Westcott President & CEO

