WORLD TRADE ORGANIZATION

G/TBT/N/CAN/8/Add.2
2 August 2005

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Committee on Technical Barriers to Trade Original: English

NOTIFICATION

Addendum

The following communication, dated 29 July 2005, is being circulated at the request of the Delegation of Canada.

Labelling Requirements for Nutrition Labelling, Nutrient Content Claims and Diet-Related Health Claims

Further to Canada's earlier communications (G/TBT/N/CAN/8 and G/TBT/N/CAN/8/Add.1) on the Proposed Amendment to the Food and Drug Regulations regarding nutrition labelling, nutrient content claims and diet-related health claims, the present communication serves to advise WTO Members that the adopted regulations, which were published in the Canada Gazette Part II on 1 January 2003, give manufacturers until 12 December 2005 (or for small manufacturers until 12 December 2007) to comply.

The amended Food and Drug Regulations:

- Require mandatory nutrition labelling on most pre-packaged foods;
- Set out labelling and compositional criteria for nutrient content claims; and
- Set out labelling and compositional criteria for diet-related health claims.

The amendments are intended to protect and enhance human health by providing clear and uniform information to support consumers in making informed food choices toward healthy eating goals.

Immediate compliance with the amended regulations is required when the label or advertisement for a food displays the phrase "nutrition facts", "valeur nutritive" or "valeurs nutritives" or one of the new nutrient content or diet-related health claims.

The Food and Drug Regulations apply equally to domestically produced and imported food products.

The Compliance Test to Assess the Accuracy of Nutrient Values, communicated by Canada in G/TBT/N/CAN/8/Add.1 has been finalized and is available at:

http://www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml (English)
http://www.inspection.gc.ca/francais/fssa/labeti/nutricon/nutriconf.shtml (French)

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The electronic version of the amendments to the Food and Drug Regulations is available at:

http://canadagazette.gc.ca/partII/2003/20030101/html/sor11-e.html (English)
http://canadagazette.gc.ca/partII/2003/20030101/html/sor11-f.html (French)

The above-mentioned documents can also be requested from:

Canadian Enquiry Point
Standards Council of Canada
200-270 Albert Street
Ottawa, Ontario
K1P 6N7

Tel.: (+613) 238 3222
Fax.: (+613) 569 7808
E-mail: info@scc.ca

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Canadian Food Inspection Agency
Food Safety Directorate
Bureau of Food Safety and Consumer Protection
Fair Labelling Practices Program

Nutrition Labelling Compliance Test

Nutrition Labelling, Nutrient Content Claims and Health Claims: CFIA Compliance Test to Assess the Accuracy of Nutrient Values

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Summary

On January 1, 2003, Health Canada published, in Canada Gazette, Part II, amendments to the *Food and Drug Regulations* to require most prepackaged foods to bear a Nutrition Facts table, listing 13 nutrients and Calories, as well as new and updated regulations for nutrient content claims and diet-related health claims. These amendments will provide Canadians with information to prevent injury to their health by helping them make appropriate food choices.

The Canadian Food Inspection Agency (CFIA) is responsible for enforcing the food requirements of the *Food and Drugs Act and Regulations.* While industry is responsible for complying with the new regulations within three years (five years for small business), Health Canada and the CFIA are committed to facilitating their implementation in a manner that will retain the confidence of consumers and health professionals in the reliability of the nutrition information. During the transition phase, the CFIA will be training staff and updating inspection tools, such as the *2003 Guide to Food Labelling and Advertising* and the Nutrition Labelling Compliance Test (Compliance Test).

The challenges for industry in generating product-specific nutrient data for nutrition labelling are recognized. Industry is responsible for ensuring the accuracy of label values and may choose the risk management strategy best suited to the food(s) to be labelled.

The purpose of the CFIA Compliance Test is to provide a transparent, science-based system for verifying the accuracy of nutrient values on labels and in advertising via laboratory analysis as part of assessing compliance with the *Food*

and Drug Regulations. A consultation document, Nutrition Labelling, Nutrient Content Claims and Health Claims, a Proposed Compliance Test to Assess the Accuracy of Nutrient Values, was issued November 28, 2002, soliciting comments on proposed changes to section 6.3, the *Guide to Food Labelling and Advertising* (the *Guide*), titled: Compliance for Nutrient Content Claims and Declarations. The intent was to revise the system to be simpler yet as effective as possible in promoting accurate nutrition information. The document assessed various sampling plans and tolerances using a statistical framework, while considering criteria of public health, consumer protection, fair treatment of manufacturers and efficiency and effectiveness of the inspection system. The comments of stakeholders on compliance issues during the Health Canada consultations were also considered.

The CFIA received responses to the Consultation Document from sixteen stakeholders, including the Consumers' Association of Canada, eight major national associations representing either producers, manufacturers or retailers, a number of individual manufacturers, a commercial laboratory and a university professor of nutritional sciences. The respondents generally supported the science-based approach to minimizing the consumer's risk and producer's risk considering multiple sources of variation. The sampling plan and the acceptance criteria involving a 20% tolerance for the Nutrition Facts table were supported; however, there was less support for some of the more restrictive criteria, for example, those for nutrient content claims. A number of respondents expressed concern that the approach did not provide for the use or development of nationally representative data base values for raw single ingredient foods, such as fruits, vegetables, meat and fish.

The resultant Compliance Test constitutes the CFIA methodology for assessing the accuracy of nutrition labelling and claims. It is based on the laboratory analysis of the nutrient content of three composite samples of four consumer units each, randomly selected from a lot and the results of analysis subjected to three acceptance criteria. The principal acceptance criterion would require accuracy within 20% of declared value for the average of three composite samples for naturally occurring nutrients in the Nutrition Facts table, i.e., the analyzed nutrient content would have to be at least 80% of declared value for protein, carbohydrate, fibre, vitamins and minerals and not more than 120% of declared value for Calories, fat, saturated fat, *trans* fat, cholesterol, sugars and sodium. For added vitamins, mineral nutrients and amino acids in claims or in the Nutrition Facts table, the amount found in the sample must be at least equal to the label value. In addition, adjustments are made for rounding in accordance with rounding rules in the *Food and Drug Regulations*. Acceptance criteria for overall variability of nutrient levels also apply.

This test does not apply to a human milk substitute, a food represented as containing a human milk substitute, a formulated liquid diet, a meal replacement, a nutritional supplement, a food represented for use in a very low energy diet, or minimum or maximum requirement for added nutrients, which are not part of the nutrition labelling and claims amendments but subject to their own regulations. Section 6.3 of the *Guide* will continue to apply to these foods.

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Important Notices