WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures Original: English

TRANSITION PROCESS FOR FOODS MARKETED AS NATURAL HEALTH PRODUCTS TO THE FOOD REGULATORY FRAMEWORK

Communication from Canada

The following communication, received on 6 July 2012, is being circulated at the request of the Delegation of Canada.

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1. Some products with added vitamins, minerals or amino acids that appear to be foods, as well as foods making certain health claims, have previously been able to gain market access as Natural Health Products (NHPs). Canada is undertaking a transition process for food products marketed as NHPs to the food regulatory framework. As such, these products will be required to meet all food-related requirements. Examples of food products that are currently marketed as NHPs include energy drinks, waters and juices with added vitamins and minerals, and yogurts and bars with specific health claims. These food products currently marketed as NHPs represent a very small portion (2 per cent) of the approximately 50,000 NHPs currently in the Canadian marketplace.

2. The Department of Health has determined, based on consumption patterns, history of use, representation to consumers, and in accordance with its guidance document "Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats" ("http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php"), that most of these food products currently marketed as NHPs fit the definition of a food. The Department of Health, therefore, intends to classify and transition most of these products to the food regulatory framework. This is consistent with the policy intent of the NHPR, as outlined in the regulatory impact analysis statement (http://www.gazette.gc.ca/archives/p2/2003/2003-06-18/pdf/g2-13713.pdf), as well as the outcomes of the Natural Health Product Regulatory review, conducted in 2007, which re-iterated that foods are excluded from the scope of the NHP Regulations.

3. As of 17 April 2012 Canada is no longer accepting NHP applications for products that are represented, packaged and sold as foods. For those products already on the market as NHPs, the Department of Health has put in place a transition process to minimize the disruption to market, as long as the products are safe to be consumed as foods. Products that are captured under the transition are those where a Product Licence Application has been received by the Department of Health's Natural Health Products Directorate (NHPD) and have been issued either a natural product number, an exemption number or are considered an application in progress.

4. The transition of eligible food products marketed as NHPs to the food regulatory framework will be facilitated through the issuance of a Temporary Marketing Authorization Letter (TMAL) (http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/food-market-author-marche-aliment-eng.php). Submissions for a Temporary Marketing Authorization (TMA) are only needed for new products for which there is a regulatory impediment to the legal marketing of a safe food in Canada. New products

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that comply with the *Food and Drug Regulations* are not subject to pre-market scrutiny and do not require TMAs.

5. The end goal of this transition process is to ensure that products that look like foods and are consumed as foods are regulated as foods.

6. This serves to inform Members of how Canada is proceeding with the transition process. This information has also been provided in G/TBT/N/CAN/25/Add.1. When ready, Canada will notify the WTO to provide Members the opportunity to comment on the proposed regulatory changes to the *Food and Drug Regulations* that would allow the sale of these products.

More information on the transition process and other relevant documents can be found on Health Canada's website:
http://www.hc-sc.gc.ca/fn-an/prodnatur/transit-process-food-aliment-eng.php (English)
http://www.hc-sc.gc.ca/fn-an/prodnatur/transit-process-food-aliment-fra.php (French)