USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** July 27, 2022

Report Number: CA2022-0024

Report Name: Canada Publishes New Regulations for Supplemented Foods

Country: Canada

Post: Ottawa

Report Category: FAIRS Subject Report

Prepared By: Tyler Babcock

Approved By: Tyler Babcock

Report Highlights:

On July 20, 2022, Canada announced final regulations to amend the Food and Drug Regulations (FDR) to establish detailed conditions for the use of supplemental ingredients in food. The amendments will also establish additional requirements on the labelling of supplemented foods beyond the general requirements in the FDR for prepackaged foods. Supplemented foods will now be required to carry a Supplemented Food Facts table (SFFt) that provides information on each of the supplemental ingredients added to them. These regulations came into force on the date they were published in the Canada Gazette, Part II on July 20, 2022. Supplemented foods that are already on the market with a Temporary Market Authorization (TMA), or for which a company has submitted an application for a TMA before July 21, 2022 that is subsequently approved by Health Canada, will have until December 31, 2025, to comply. New supplemented foods will need to comply immediately.

On July 20, 2022, Health Canada published Regulations Amending the Food and Drug Regulations and the Cannabis Regulations (Supplemented Foods): SOR/2022-169 (referred to as the Supplemented Foods Regulations) in the Canada Gazette, Part II (CGII). These regulations amend the Food and Drug Regulations (FDR) to provide a regulatory framework for supplemented foods.

Supplemented foods are prepackaged foods containing one or more added supplemental ingredients, such as vitamins, minerals, amino acids, caffeine, and herbal ingredients, which have historically been marketed as providing specific physiological or health effects. This includes beverages with added minerals marketed for hydration, caffeinated energy drinks (CEDs) marketed for temporarily restoring mental alertness, and snack bars with added vitamins marketed for the maintenance of good health. Before the issuance of these final regulations, there was no regulatory framework for supplemented foods in the FDR. As an interim measure, Health Canada was using Temporary Marketing Authorizations (TMAs) to permit the sale of supplemented foods on a case-by-case basis and under specific conditions.

The Supplemented Foods Regulations will establish detailed conditions for the use of supplemental ingredients in food. For each supplemental ingredient, the conditions of use will include the categories of food to which it may be added, the maximum amount allowed in a supplemented food, and the cautionary statements that may be required on the product label.

The regulations will also establish additional requirements on the labelling of supplemented foods beyond the general requirements in the FDR for prepackaged foods. Supplemented foods will be required to carry a Supplemented Food Facts table (SFFt) that provides information on each of the supplemental ingredients added to them. When a supplemented food is required to carry a list of cautionary statements, it will also be required to display a supplemented food caution identifier (SFCI) on the principal display panel of its label, and certain representations (e.g., health claims on the label or in an advertisement) will be restricted.

The Supplemented Foods Regulations should be read in conjunction with other provisions of the FDR applicable to pre-packaged products as well as the FDA and the documents incorporated by reference into the FDR (List of Permitted Supplemental Ingredients, List of Permitted Supplemented Food Categories, Directory of Supplemented Food Facts Table Formats, and Directory of Supplemented Food Caution Identifier Specifications).

Health Canada's webpage on Supplemented Foods provides information and resources related to the requirements for supplemented foods.

The new Supplemented Foods Regulations came into force on July 21, 2022. Prior to the publication of the Supplemented Foods Regulations, supplemented foods were able to gain market access if the manufacturers or distributors received a TMA for their products. The TMAs are no longer valid. However, manufacturers or distributors of supplemented foods that held a valid TMA for their products at coming into force of the regulations are given until December 31, 2025, to come into compliance with the Supplemented Foods Regulations, subject to applicable conditions in the transitional provisions. The same transition period is provided to manufacturers or distributors of foods that submitted a request for a TMA prior to coming into force and that receive a written notification from the Minister of Health authorizing the sale of the food. For more on the transition period, please visit here.

Attachments:

No Attachments.