



Voluntary Report – Voluntary - Public Distribution **Date:** December 05, 2023

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Report Name: Canada Proposes Modernized Regulations for Foods for

Special Dietary Use and for Infant Foods

Country: Canada

Post: Ottawa

Report Category: FAIRS Subject Report

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Report Highlights:

Health Canada opened pre-consultations on a proposed new regulatory framework for foods for special dietary use and infant foods, which include categories such as infant formula, prepackaged human milk, medical foods, gluten-free foods, formulated nutritional foods, and foods for use in weight reduction diets. Stakeholders may provide comments until February 6, 2024.

The federal government <u>seeks input</u> on a proposal to modernize Divisions 24 and 25 of the <u>Food and Drug Regulations</u> (FDR), which cover foods for special dietary use, and foods for infants in Canada. The regulatory modernization <u>proposal</u> is intended as a comprehensive restructuring of the regulatory requirements for these types of foods.

An essential element of the proposal is the introduction of a new category of foods called **Foods for a Special Dietary Purpose** (FSDP). The regulatory initiative would establish a clear differentiation between products that meet the definition of FSDP and those that do not, so that FSDP become subject to enhanced regulatory oversight, including premarket authorization for most infant FSDP, and stop-sale provisions for public health reasons.

Additionally, compositional requirements - both for products that are FSDP and those that are not - would be updated to reflect the latest Dietary Reference Intakes. The proposal also aims to improve product labelling by requiring detailed information on FSDP labels for safe use, and differentiation from products that are not FSDP.

Please refer to the Infographic on the next page for a comparison between the current and proposed regulatory frameworks.

Interested stakeholders are strongly encouraged to review Canada's new proposed regulatory framework and to provide comments, **before February 6, 2024**, at the following coordinates:

Bureau of Nutritional Sciences, Food Directorate Health Products and Food Branch, Health Canada 251 Sir Frederick Banting Driveway Mail stop 2203E Ottawa, ON K1A 0K9

Email: bns-bsn@hc-sc.gc.ca

Attachments:

No Attachments.

Infographic: Health Canada's Current Regulatory and Proposed Modernized Regulatory Frameworks (Divisions 24 and 25 refer to sections in Canada's Food and Drug Regulations)

Current regulatory framework Proposed modernized framework Division 24 - Foods for Special Dietary Use Division for Foods for a Special Dietary Purpose • Foods that are • Formulated liquid Meal replacements • Infant formula free/low in diets Nutritional supplements • Prepackaged human milk · Foods for proteinenergy, free/low Gluten-free foods Medical foods in sodium, or free restricted or low amino • Foods for use in weight • For infants, including HMF reduction diets: of sugars acid diets • For ages one or more • Foods for very low Meal replacements • Total diet replacements for weight reduction[±] • Prepackaged meals energy diets* · Foods sold by weight [±]Total diet replacements for weight reduction may also be represented for use *Foods for very low energy diets reduction clinics in weight reduction diets. may also be represented for use in weight reduction diets. **Division for other foods Division 25 - Infant Foods** • Other infant foods · Gluten-free foods Foods containing Human milk fortifier infant formula as an (HMF) Conventional infant foods ingredient · Infant formula · Formulated nutritional foods • For children ages 1 to 13 • For ages 14 or more, including formulated meal replacements (FMR) · Foods for use in weight reduction diets: • FMR Prepackaged meals · Foods sold by weight reduction clinics Legend Foods that will be removed from proposed framework, Foods that would not be carried over in Foods for a Special Dietary Foods that are not FSDP but claims can still be made, per Division 1, FDR the modernized framework Purpose (FSDP)

Source: Health Canada's consultation document