CANADIAN HEALTH FOOD ASSOCIATION
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February 26, 2024

Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch
Health Canada

Submitted via email: bns-bsn@hc-sc.gc.ca

Re: Feedback on proposal to modernize the regulations for foods for special dietary use, FDR Division 24

On behalf of the Canadian Health Food Association ("**CHFA**"), we are writing to provide comments on the consultation for the *proposed Regulatory Modernization of Foods for Special Dietary Use.* CHFA appreciates the opportunity to provide feedback. As Canada's largest trade association dedicated to natural health, organic, and wellness products, CHFA is committed to representing our members and the industry on proposed regulatory changes that will directly influence their business operations. Our membership base consists of hundreds of businesses across Canada, including manufacturers, retailers, wholesalers, distributors and importers of food and natural health products. These businesses produce a variety of pre-packaged foods and would be affected by these proposed amendments.

Regulatory Modernization encourages growth and innovation within the food sector by becoming more agile, transparent, and responsive to new and emerging science, technology, market innovation and risk to health. Applying an outcome-based approach to regulation ensures that the focus is not just on the processes, but on the actual results achieved in terms of food safety, quality, and consumer protection.

Applying a modern and flexible approach to the regulatory framework, by aligning with international jurisdictions will both decrease existing regulatory burden, and attract more interest internationally, supporting diversity in the Canadian market and meeting the needs of Canada's consumers and industry. This shift towards outcome-based regulation emphasizes the importance of measurable results, efficiency, and effectiveness, ensuring that regulations are not only robust but also adaptable to the evolving landscape of the food industry.

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THE PROPOSED MODERNIZED FRAMEWORK

General

CHFA supports Health Canada's efforts to modernize Division 24 of the *Food and Drug Regulations* concerning *Foods for Special Dietary Use*. Our alignment lies in the restructuring of Division 24 and 25, aimed at redefining product categories based on product risk profiles and the vulnerability of the specific sub-population. This restructuring includes the separation of products requiring enhanced regulatory oversight from those that do not. Specifically, we advocate for the decoupling of "other foods" from higher-risk nutrition products, defined as *Foods for Special Dietary Purposed (FSDP)* which are intended for use with medical supervision or as the main source of nutrition. By implementing this separation, lower-risk foods would be liberated from previous advertising restrictions, fostering a shift towards a self-care framework that empowers consumers to actively participate in their healthcare decisions. In essence, we support the proposed risk-based approach, which entails enhanced regulatory oversight, such as pre-market authorizations, for certain FSDPs, while exempting "other foods" from such requirements by creating a separate division for these foods. CHFA supports the proposal for less restrictive and burdensome regulatory requirements. In theory this should allow for Canadian innovation and harmonization of nutrient levels with international jurisdictions.

Terminology

We support the proposal to eliminate the term "*Foods for Special Dietary Use" (FSDU)* to alleviate confusion and prevent its conflation with "*Foods for Special Dietary Purposes" (FSDP), which was* introduced into the *Food and Drug Act* in 2019 for these higher risk nutrition products.

We suggest considering one of the following titles for the Division representing "other foods":

- Nutrient Targeted Foods
- Nutrient Specific Foods

- Customized Dietary Foods
- Dietary Tailored Foods
- Tailored Foods
- Targeted Foods
- Specialty Foods

We foresee potential confusion arising from the classification of various meal replacement style products. Therefore, we propose the introduction of new term specifically for formulated meal replacements designed for weight reduction diets. For instance, we suggest considering the term *Weight Reduction Meal Replacement (WRMR)*. This new designation would facilitate clear differentiation both from and between *Total Diet Replacements (TDR) and Formulated Meal Replacements (FMR), the former being a FSDP and the latter being a meal replacement not intended for weight reduction purposes*.

Labelling

While we support the idea of harmonizing labelling practices with the general labelling requirements for prepackaged where it makes sense, such as Nutritional Facts table (NFt) labeling, we express reservations about implementing Front-of-Pack (FOP) labeling on Formulated Meal Replacements and Formulated Meal Replacements for weight reduction. These products adhere to rigorous composition standards with specific macronutrient content requirements, including energy limitations for meal replacements designed for weight reduction purposes. Consequently, there is minimal flexibility for incorporating nutrients of concern into these products and representing them on FOP labeling, such as sugar. In reality, much of the sugar content in meal replacement beverages derives from their mixing liquid, such as milk (lactose), when prepared according to instructions. Subjecting these products to the same 15% Daily Value (DV) sugar rule applied to general prepackaged foods could have adverse effects on the product category. This approach may confuse and mislead consumers regarding the efficacy of meal replacement products for weight reduction benefits if their labels are evaluated using FOP labeling criteria intended for snack foods or foods lacking a specific dietary purpose.

Furthermore, it is essential to evaluate a meal replacement product based on its comprehensive nutritional profile. FOP symbols might erroneously imply that the absence of three antinutrients is the primary consideration for a balanced meal, disregarding the importance of beneficial nutrients. This skewed perspective fails to accurately represent the factors for evaluating a balanced meal. Therefore, we propose exempting formulated meal replacements from FOP labeling requirements, similar to the approach proposed for conventional infant foods within the same division. Requiring FOP labelling on these products would contradict the principles of outcome-based regulation, as it might oversimplify complex nutritional considerations and deter consumers away from products with actual benefits for weight management or dietary needs.

While we oppose FOP labeling for formulated meal replacements, we fully support the mandate for these products to feature a Nutrition Facts table (NFt) and label statements specifying the intended use. This provision ensures that consumers have access to essential information for assessing product nutrient profiles, and fosters fairness across industry.

THE PROPOSED REQUIREMENTS FOR GLUTEN-FREE FOODS

CHFA supports the proposed modernized framework for gluten-free foods. Specifically, we endorse the suggestion to classify gluten-free within the category of "other foods" rather than under Foods for Special Dietary Purposes (FSDP). This adjustment aligns with international standards, encompassing foods that are inherently or naturally gluten-free within the definition.

Furthermore, we advocate for the consideration of fortification and the removal of advertising restrictions on fortified gluten-free products. These restrictions previously disincentivized manufacturers from fortifying gluten-free alternatives, hindering efforts to address nutrient deficiencies in populations requiring a gluten-free diet.

CHFA also stands in alignment with maintaining the gluten-free claims threshold (< 20 ppm gluten) and loosening restrictions to allow inherently gluten-free foods to carry gluten-free claims, even if they were

not specifically formulated as such. We believe that gluten-free claims should not be confined to specific food categories. If an absence claim, such as "gluten-free," is factually accurate, it should be permitted, similar to other "free from" claims.

Any concerns regarding potential misconceptions or a "health halo" associated with gluten-free claims should be addressed through public health education, rather than by suppressing factual information. It is imperative to ensure transparency and accuracy in labeling, empowering consumers to make informed choices about their dietary needs.

THE PROPOSED REQUIREMENTS FOR FORUMULATED NUTRITIONAL FOODS AND FOR USE IN WEIGHT REDUCTION DIETS

As you have pointed out, an existing challenge with the current regulatory frameworks is that the compositional requirements in Division 24 are outdated and do not align with the latest recommendations from NASEM and standards in other jurisdictions. While Health Canada states that the outdated requirements force manufacturers to develop separate formulations exclusively for the Canadian market, the Department is not aligning its compositional requirements with that of other national regulations or international standards. Codex published the *Standard for Formula Foods for Use in Weight Control Diets* (CODEX Stan 181-1991). Following Codex standard, Australia (2000), Korea, Brazil (1998), Chile (2006), Indonesia (2011), and European Union (1996 and 2016) published compositional requirements for meal replacements prescribed in their food regulation. In fact, European Union went through a similar process of removing meal replacement category from the “Food for Specific Groups,” which includes infant formula, baby food, food for special medical purposes, and total dietary replacement for weight control. In 2016, the European Commission updated the nutritional composition requirements for partial meal replacements, which allowed products meeting these requirements to bear permitted health claims on weight control.

We encourage Health Canada to consider aligning with existing international nutritional composition

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requirements. Since EU has 27 member states, fully aligning with the EU nutrition composition requirement will significantly help with concerns around shortages and allow companies to streamline their formulations, reducing regulatory burden. Aligning with the EU partial meal replacement composition will require changes to Health Canada's proposed regulation on energy content, macro-nutrient content, amino acid requirement, and micro-nutrient content.

While the proposed framework offers some modernization, the proposal contains gaps in alignment with international jurisdictions which would hinder the intended outcome of the modernization to prevent shortages and establish permanent solutions. These concerns must be addressed in the final development of regulations to truly modernize the framework.

In conclusion, to foster innovation and encourage growth within the food industry, Canada must address outdated compositional requirements for formulated nutritional foods that are holding back and unnecessarily burdening the food sector. It will be important to meet the needs of Canada's consumers and industry stakeholders. By reducing the regulatory burden faced by Canadian food business and aligning more with international trading partners, the modernization of Canada's regulatory framework for food is contributing to efficient business practices and economic growth in the country.

Thank you for considering our feedback as part of your outreach. As a dedicated and forward-looking stakeholder, we are hopeful that our comments are given due consideration and used to inform the development of the regulations for these foods. We stand ready to lend our expertise and support.

Sincerely,

Ashley Cornell
Directory of Regulatory Affairs and Policy
Canadian Health Food Association