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February 26, 2024

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

**Re: Regulatory Modernization of Foods for Special Dietary Use and Infant Foods**

Dear Sir/Madam:

Thank you for the opportunity to provide feedback on the [proposed restructured framework regarding Foods for Special Dietary Use \(FSDU\) and infant foods](#), currently regulated within Divisions 24 and 25 of Canada's Food and Drug Regulations (FDR).

Ontario Dietitians in Public Health (ODPH) is the official voice of Registered Dietitians working in Ontario's Public Health System. Our mission is to advance public health nutrition through member and partner collaboration to improve population health and health equity locally and provincially.

ODPH supports Health Canada's efforts to apply a risk-based approach in developing the proposed regulatory amendments and is pleased with improved regulatory oversight of food products that strive to meet a variety of nutritional needs for Canadians.

While there are advantages to the proposed regulations, ODPH has provided feedback below to Health Canada's consultation questions regarding regulatory changes for products and processes applicable to infants and young children. These products include infant formula, prepackaged human milk, conventional infant foods, and formulated nutritional food for children. ODPH supports evidence-informed decision making as it relates to infant feeding and we endorse the tenets of the World Health Organization's Baby-Friendly Initiative to protect and promote breastfeeding.

We acknowledge that all individuals, regardless of sex and/or gender identity or expression may be in a feeding relationship with their baby/child. The term parent is used throughout this document and refers to a parent or caregiver who is involved in the child's care.

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***Q 1 - Do you support the proposal to restructure Divisions 24 and 25 of the FDR into a division for Food for Special Dietary Purpose (FSDP) and one for foods that are not FSDP?***

**Yes.** We recognize that a streamlined framework for regulating infant formula and foods reduces duplication across the regulatory divisions and has advantages both for the federal government as the body responsible for market approval of such products, and for the food industry to expedite entry of products into the Canadian market.

***Q 2 - Do you support the proposal for infant formula?***

**Partially.** ODPH applauds Health Canada's efforts to better align Canada's policies with the *International Code of Marketing of Breastmilk Substitutes* (WHO Code) and *Codex Alimentarius Commission* standards (Codex). We also support improved clarity with respect to labelling requirements and stronger legislative oversight of advertising restrictions. However, ODPH presents the following considerations:

**1) The proposed regulatory framework falls short in meeting Canada's obligation as a signatory to the WHO Code to support and promote breastfeeding.**

[The WHO Code](#) prohibits:

- *Donations of free or subsidized supplies of infant formula or other products in any part of the health care system.* As written, proposed restrictions will not address aggressive marketing of infant formula to new parents within hospital settings through hospital donations.
- *All forms of promotion of infant formula.*

Below are some of the examples that ODPH has been made aware of regarding infant formula product promotion. Examples such as these would not be addressed through the proposed regulations.

WHO Code prohibition	Examples of existing prohibited promotional activities in Canada
Manufacturers and distributors shall not “perform educational functions” (Article 8.2)	<ul style="list-style-type: none"> <li>• <a href="#">Register   Coupons &amp; Parental Support   Nestlé Baby &amp; me (nestlebaby.ca)</a>.</li> </ul>
Manufacturers and distributors shall not give away “samples or...discount coupons” (Article 5.3)	<ul style="list-style-type: none"> <li>• <a href="#">Register   Coupons &amp; Parental Support   Nestlé Baby &amp; me (nestlebaby.ca)</a></li> <li>• <a href="#">Similac® Club   Free Baby Formula Samples, Coupons &amp; More</a>.</li> <li>• <a href="#">How to Get Enfamil Baby Formula Coupons &amp; Offers   Enfamil A+ Canada</a></li> </ul>
“There shall be no advertising or other form of promotion to the general public of products within the scope of this Code.” (Article 5.1)	<ul style="list-style-type: none"> <li>• <a href="#">Meet Baby Nyles!   Nestlé Baby &amp; me (nestlebaby.ca)</a> – This website is announcing the winner of the Canadian 2023 photo search who is titled the “2023 Gerber Spokesbaby &amp; Chief Growing Officer”</li> </ul>
“Sponsor meetings of health professionals and scientific meetings” ( <a href="#">UNICEF, 2023</a> )	<ul style="list-style-type: none"> <li>• <a href="#">Dietitians of Canada National Conference 2023</a></li> <li>• <a href="#">Children's Healthcare Canada - A Bright Future for Child Health in Canada Conference 2022</a></li> <li>• <a href="#">Canadian Paediatric Society - Annual Conference 2023</a></li> </ul>

**Therefore, it is recommended that:**

- i) To better align with the WHO code and to further protect breastfeeding, updated regulations include enhanced language to prohibit any advertisement or promotion of infant formula in Canada. Advertising restrictions should be extended to ensure enforcement of regulations across all communication platforms including online and social media.

- ii) *Unless medically required*, legislation should include mechanisms to regulate, monitor and enforce the prohibition of donations of free or subsidized supplies of infant formula within Canadian health systems.

**2) The labelling changes proposed within the regulatory framework will not adequately ensure that manufacturers meet Article 9 of the WHO Code requiring that infant formula labelling provides “clear, conspicuous, easily readable and understandable messages.”**

Proposed mandatory information regarding infant formula products will improve caregivers’ ability to make informed product selection decisions. However, proposed formats and language lack all necessary instructions crucial for diverse and vulnerable Canadian populations needing more complete information to properly use infant formula. Notably, principal display panels on infant formula packaging currently available for sale contain small and crowded text of varying font sizes, symbols, and images. As is, critical information regarding appropriate use of formula is often overlooked, disregarded (such as guidance to ‘use on advice of a health professional’) or misinterpreted and may result in unsafe consumption. There is room for improvement to clarify and enhance proposed label messaging details.

**Therefore, it is recommended that:**

- i) Infant formula container sizes and shapes, as well as *all* mandatory statements including formula preparation, storage, and disposal, are standardized across all infant formula products with regard to colour, size, and location of mandatory label statements on product display panels.
- ii) The proposed label messaging is improved to strengthen clarity and consistency. Suggested revisions include:
  - Addition of a symbol instructing user *not to add water* for ready-to-feed infant formula instructions. This is to parallel the proposed symbol instructing users to *add water* for liquid concentrated infant formula instructions.
  - Directions to boil infant formula equipment to include time limit (i.e., 2 minutes).
  - Literacy-friendly language when communicating instructions and cautioning consumers. For example, use
    - “Do not add water or other liquids” instead of “do not dilute,” and
    - “amounts” instead of “proportions.”
  - A definition of “safe water.”
  - Advice that formula can be offered cold depending on preference. Formula does not need to be served at body temperature as the proposed instructions suggest.
  - Instructions on safe storage of pre-boiled water.
  - Instructions to clean bottles before sterilization. This step is absent from the proposed regulations.

***Q 3 - Do you support the proposal for prepackaged human milk?***

**Partially.** ODPH supports enhanced regulatory oversight with respect to safety and quality concerning prepackaged human milk (PPHM).

ODPH recommends that Health Canada considers the results of [the World Health Organization's systematic reviews on donor human milk banking processes](#) anticipated in May 2024, before finalizing regulations for this food category.

***Q 7 - Do you support the proposal for shortage provisions applicable to all FSDP?***

**Partially.** ODPH supports the addition of these provisions to require infant formula manufacturers to report shortages and to imbed emergency importation policies within the FDR to accommodate shortages. It is uncertain however, given the lack of Canadian infant formula manufacturing, that these strategies alone will protect Canada's vulnerable reliance on support from US and international markets during supply chain disruptions.

With respect to infant formula, human milk fortifiers (HMF), and dietary products for the treatment of inborn errors of metabolism (metabolic products), and human milk, ODPH recommends that regulations:

- i) ensure safeguards for equitable distribution of products intended for infants most at-risk.
- ii) require a freeze on cost increases of all formulas, HMF and metabolic products during periods of shortages.
- iii) require manufacturers to report discontinued products.
- iv) prohibit the promotion of homemade infant formulas.

It is also recommended that Health Canada develop a plan to increase manufacturing of infant formula within Canada's borders for availability to Canadians.

***Q 8 - Do you support the proposal for stop-sale provisions applicable to all FSDP?***

**Partially.** ODPH agrees that the Minister be given authority to quickly halt the sale of all FSDP products sold. This would be particularly important for infants and vulnerable populations for whom stop-sale provisions may be crucial to matters of nutritional adequacy, and product and food safety.

**It is also recommended that** regarding product safety, the stop-sale provisions should also be applied to all products related to FSDP. For example, regarding infant formula these products would include bottles, nipples, utensils, preparation equipment and formula dispensers.

**Q 10 – Do you support the proposal for conventional infant food?**

**Partially.** ODPH supports the addition of this important food category to the FDR. We also present the following recommendations to enhance the regulations regarding package labelling of conventional infant foods.

- 1) The prohibition of inappropriate promotion of commercially produced foods for infants and young children aged 6–36 months as per the [WHO Code](#) is not adequately addressed in the proposed regulations.**

Inappropriate labelling of products currently available are a health risk to infants.

For example, [Cerelac](#) is a cereal product intended for children older than 12 months. While “Infant” is defined in the FDR, “baby” is not. This product, inappropriately labeled as a “baby” cereal, contains powdered honey. [Health Canada](#) advises that parents and caregivers not give honey to a child under 12 months of age to prevent infant botulism. The label reference to “baby” is confusing for parents and caregivers who have purchased these for their infants and may inadvertently feed their infants a potentially harmful ingredient.

Below are other examples of inappropriate staged labelling of foods intended for different ages:

- [“Stage 1 – Supported Sitter” Rice Baby Cereal](#)
- [“Crawler” Mild Cheddar Lil’ Crunchies® | Gerber](#)
- [“Junior” Alphabet Beef Baby Food](#)

Finally, examples of product labelling for [infant snacks](#) include text and images suggestive that contents predominately contain vegetables and fruit when in fact the product contains negligent amounts of these foods. In working with the public, ODPH members have identified that parents typically purchase these items to replace whole vegetables and fruit. This type of product labelling may mislead many parents to believe that the nutritional contents of these products are superior than they actually are.

- 2) Limits within the proposed regulations to address intake of nutrients of concern among small children will not adequately address chronic disease risk.**

Health Canada’s [Nutrition for Healthy Term Infants](#) recommends that children one year of age and older are offered foods prepared with little or no added salt or sugar. Although Statistics Canada collects limited data on consumption of sugar and sodium in young Canadian children, practice-based anecdotal information indicates that sodium and sugar consumption is above these recommendations. ODPH members who support families with young children report that caregivers often provide infant snack type foods multiple times per day, and often with a meal (e.g., rice rusks, puffs, dehydrated snacks).

**Therefore, it is recommended that:**

- i) In addition to the proposed labelling requirement to include the age range of the intended user of the product, Health Canada should prohibit ambiguous product-label referencing, such as “baby,” “junior,” “crawler,” “sitter” etc.
- ii) The FDR prohibit the addition of sodium chloride or added sugars in any infant foods including infant “snack” type foods that are increasingly popular.
- iii) Regulations prohibit false promotion of vegetable and fruit content.

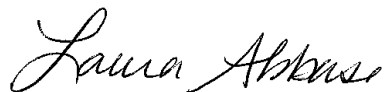
***Q 12 - Do you support the proposal for formulated nutritional food for children?***

**Yes.** ODPH supports the proposed mandatory labelling requirements for formulated nutritional foods for children and that staged product labelling of infant formula products for children beyond 12 months of age (i.e., Stage 3 or 4) be prohibited (Ref: 5.3.1).

Given that these products are not recommended by health care professionals, this will help parents and caregivers to differentiate these from infant formula which is intended as the sole source of nutrition for infants.

Thank you again for providing the opportunity to participate in this stakeholder consultation. We ask that you continue to engage and consult with health officials at various levels of government on this matter, including public health professionals to ensure that the health and safety of the population is protected and promoted.

Sincerely,



Laura Abbasi, RD, MHSc  
Ontario Dietitians in Public Health Chair



Paula Ross, RD, MAN  
Family Health Advisory Group Chair