

Regulatory Modernization of Special Foods for Dietary Use and Infant Foods

**UNICEF Canada Submission: Health Canada
Consultation**

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Introduction

UNICEF Canada applauds Health Canada for initiating the modernization of Divisions 24 and 25 of the *Food and Drug Regulations* (FDR), which govern foods for special dietary use and foods for infants in Canada. This is an important and timely initiative. The following comments are intended to support Health Canada in this work, by providing an evidence- and rights-based perspective that focuses on issues related to infant and young child feeding and nutrition. We encourage Health Canada to continue with this critical work, and to centre the health and rights of children and women as it proceeds.

Recommendations

1. **The modernized regulations should comprehensively implement the International Code of Marketing of Breast-milk Substitutes.**

Health Canada has appropriately recognized that “[a]s a signatory of the WHO Code, Canada has an obligation to support and promote breastfeeding, facilitate breastfeeding by mothers through legislative and social action, and prevent inappropriate sales promotion of infant foods that can be used to replace human milk.” **UNICEF Canada commends Health Canada for taking action to fulfill its obligation to implement the Code, and emphasizes the importance of including the full scope of the Code in the modernized regulations.**

Children need appropriate foods at the right time to grow and develop to their full potential. UNICEF and the World Health Organization (WHO) recommend that infants begin breastfeeding within one hour of birth, be exclusively breastfed for the first six months, and continue breastfeeding until 2 years of age or beyond.¹ In Canada in 2020, 91% of all mothers initiated breastfeeding, but more than 50% stopped by six months. Only about one in three infants is breastfed exclusively for six months,² with lower rates among socially and economically vulnerable women. This rate is lower than the 2030 Sustainable Development Goals target of 70% to which Canada has pledged. At the age of 6 months, children need to begin eating their first foods, often referred to as “complementary foods”. Currently, many infants and young children are not receiving the nutrition they need to survive and thrive, and are increasingly being fed sweet drinks and ultra-processed packaged snacks high in salt, sugar and fat³[OBJ].

Canada lags behind most high-income countries in implementing the International Code of Marketing of Breast-milk Substitutes, reported in the 2022 status report UNICEF/WHO/IBFAN Marketing of breast-milk substitutes: national implementation of the international Code. Full implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent resolutions by the World Health Assembly (WHA), along with the 2016 WHO Guidance on ending the inappropriate promotion

¹ UNICEF, Early childhood nutrition, <https://www.unicef.org/nutrition/early-childhood-nutrition>.

² Statistics Canada. Health characteristics, two-year period estimates. Table 13-10-0113-01, release date 1022-04-19: <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310011301> (Accessed April 26, 2022).

³ *Id.*

of foods for infants and young children (hereafter collectively referred to as ‘the Code’), is crucial for the protection and promotion of breastfeeding and proper nutrition for infants and young children. It is important to recognize that ‘the Code’ is used as an umbrella term. It incorporates subsequent WHA resolutions and the WHO Guidance on ending the inappropriate promotion of foods for infants and young children, which have kept the Code up to date since it was first adopted in 1981. These documents have accounted for advances in research on the risks of not breastfeeding, changes in marketing techniques, the development of new and often unnecessary products, and loopholes that needed to be closed.⁴

The Code protects the health and rights of children and women by prohibiting the inappropriate marketing of breast-milk substitutes (BMS), feeding bottles and teats, and complementary foods, along with other key provisions. These include requirements regarding information and educational materials on infant and young child feeding, preventing the health care system from being used to promote BMS and foods for infants and young children (FIYC), product labels, composition and quality of products, and emergency contexts. All these categories of requirements should be included in Health Canada’s regulatory modernization effort for BMS and FIYC. To ensure that Health Canada modernizes its regulations according to best practices for BMS and FIYC, UNICEF Canada underscores the importance of implementing the full scope of the Code. Some elements required for full implementation are discussed below.

2. The modernized regulations’ provisions on BMS and FIYC should include digital environments.

Health Canada’s regulatory modernization effort offers a key opportunity to address the current and growing issue of digital marketing of BMS and FIYC. In 2023, the WHO published the Guidance on regulatory measures aimed at restricting digital marketing of breast-milk substitutes (the ‘WHO 2023 Guidance’)⁵ to support Member States in developing and implementing Code regulations that apply to digital environments. The WHO 2023 Guidance explains that “digital environments are fast becoming the predominant source of exposure to promotion of breast-milk substitutes globally”.⁶ It highlights the importance of Code regulations applying in digital environments, and the need for them to be mandatory, comprehensive and include carefully crafted monitoring and enforcement provisions to ensure their efficacy. **UNICEF Canada strongly encourages Health Canada to take up the WHO 2023 Guidance’s recommendations and develop strong regulations that apply the Code in digital environments.**

The proliferation and harmful impacts of digital marketing of BMS and FIYC is extensively documented. For example:

- The WHO report, *Scope and impact of digital marketing strategies for promoting breast-milk substitutes*, explains that “manufacturers and distributors of breast-milk substitutes commonly

⁴ UNICEF has developed a resource, *What I Should Know About ‘the Code’: A guide to implementation, compliance and identifying violations*,⁴ which consolidates the Code’s various obligations and explains how they apply to governments, along with other key audiences. United Nations Children’s Fund (UNICEF), *What I Should Know About ‘the Code’: A Guide to Implementation, Compliance and Identifying Violations*, 2023.

⁵ World Health Organization, *Guidance on regulatory measures aimed at restricting digital marketing of breast-milk substitutes*. WHO, Geneva, 2023, (<http://www.who.int/publications/i/item/9789240084490>).

⁶ *Id.*

use digital marketing strategies across a wide range of online channels and social media platforms and that the use of digital marketing strategies dramatically increases the reach and impact of breast-milk substitutes promotions”.⁷ It further explains, “[d]igital technologies offer advertisers new marketing tools that are powerfully persuasive, extremely cost effective and often not easily recognizable as breast-milk substitutes promotions”.⁸

- The 2023 Lancet series on breastfeeding highlights the issue of digital marketing, noting that “[a]ll predictions show digital marketing will continue to grow. We cannot stop it, but regulations can protect consumers and more vulnerable groups”.⁹
- The WHO report, *Restricting digital marketing in the context of tobacco, alcohol, food and beverages, and breast-milk substitutes: existing approaches and policy options*, explains that through digital media, consumers are “more frequently and intensively exposed to advertisements than through marketing in traditional media”.¹⁰

The need for BMS and FIYC regulations to apply in digital environments is clear, and this pressing issue should not be delayed. Thus, UNICEF Canada encourages Health Canada to incorporate digital environments in its regulatory modernization initiative for BMS and FIYC at this critical time.

3. Protections against industry interference and conflicts of interest are essential throughout the regulatory development and implementation processes.

UNICEF Canada encourages Health Canada to ensure that strong protections against industry interference and conflicts of interest (COI) are used throughout the process of developing and implementing the modernized regulations for BMS and FIYC. There is robust documentation from around the world that the BMS and baby food industry goes to great lengths to limit progress on Code implementation, and has often succeeded in stalling, stopping or weakening such regulations.¹¹

The 2023 Lancet Series on Breastfeeding outlines the industry’s multifaceted and highly effective strategies to target policy-makers, parents and health-care professionals.¹² It describes how the industry engages in many tactics – including the lobbying of governments, both directly and covertly via trade and professional associations and front groups – to oppose strengthening breastfeeding protection laws and challenge food standard regulations. These activities are highly sophisticated and

⁷ Scope and impact of digital marketing strategies for promoting breast-milk substitutes. Geneva: World Health Organization 2022 (<https://apps.who.int/iris/handle/10665/353604>).

⁸ *Id.*

⁹ Rollins, N., Piwoz, E., Baker, P. et al. Marketing of commercial milk formula: a system to capture parents, communities, science, and policy. *Lancet* 2023; 401: 486-502; published online 7 February 2022 (second in a series of three paper about breastfeeding; all papers in the series available at <https://www.thelancet.com/series/Breastfeeding-2023>).

¹⁰ Restricting digital marketing in the context of tobacco, alcohol, food and beverages, and breast-milk substitutes: existing approaches and policy options. Geneva: World Health Organization; 2023 (<https://iris.who.int/handle/10665/373130>).

¹¹ Baker P, et al. Globalization, first-foods systems transformations and corporate power: a synthesis of literature and data on the market and political practices of the transnational baby food industry. *Global Health*. 2021 May 21;17(1):58.

¹² Series from the Lancet journals: Breastfeeding 2023, *The Lancet*, 7 February 2023

(<https://www.thelancet.com/series/Breastfeeding-2023>).

are coordinated on a global scale.¹³ Marketing intelligence reports show that the industry is “fighting a rearguard action against regulation on a country-by-country basis”.¹⁴

Many WHA resolutions that are part of the Code specifically address COI, including WHA 49.15, WHA 58.32, WHA 61.20, WHA 65.60 and WHA 69.9.¹⁵ They call on governments to develop processes and tools to safeguard against possible COI in policy development and implementation of nutrition programs. Additionally, the 2016 WHO Guidance on ending the inappropriate promotion of foods for infants and young children confirms that the involvement of baby food manufacturers and distributors during the drafting process is inappropriate, as it would represent a COI.¹⁶

Three critical components of protecting against industry interference and COI when developing and implementing the modernized regulations for BMS and FIYC include:

- a) **BMS and baby food companies should not be involved in the regulatory development and drafting processes.** Inspiration from Article 5.3 of the World Health Organization Framework Convention on Tobacco Control, which aims to protect strong tobacco control policies from the harmful influence of the tobacco industry, may be useful. It requires Parties to the treaty “to protect their public health policies related to tobacco control from commercial and other vested interests of the tobacco industry”. The history of Code implementation suggests that it requires the same level of protection.
- b) **The regulatory process should remain transparent and open to public scrutiny.** Health Canada should continue to follow all procedural requirements and give interested parties the opportunity to comment on draft regulations and publish submissions that are received. Closed door meetings with the BMS and baby food industry, or any other regulated entity or party representing their interests, should be prohibited. Mechanisms should be put in place – or if they already exist, used rigorously – to prevent such interactions.
- c) **The executive process should be protected against conflicts of interest.** Regulations to implement the Code generally provide for the establishment of an intersectoral coordinating committee or advisory board to oversee their implementation.¹⁷ Companies involved in the manufacture or distribution of BMS or FIYC, or anyone with a current or recent direct or indirect financial or other interest in any such company, should be prohibited from serving on such an executive body. Otherwise, this would result in a COI that compromises the independence, integrity and credibility of the body that advises the government on the implementation and enforcement of the regulations.

¹³ Rollins, N., Piwoz, E., Baker, P. et al. Marketing of commercial milk formula: a system to capture parents, communities, science, and policy. *Lancet* 2023; 401: 486-502; published online 7 February 2022 (second in a series of three paper about breastfeeding; all papers in the series available at <https://www.thelancet.com/series/Breastfeeding-2023>).

¹⁴ Global Packaged Food: Market Opportunities for Baby Food to 2013. Euromonitor International; September 2008.

¹⁵ United Nations Children’s Fund (UNICEF), *Protecting Infant and Young Child Nutrition from Industry Interference and Conflicts of Interest*, 2023.

¹⁶ Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual. Geneva: World Health Organization; 2017 (<https://apps.who.int/iris/bitstream/handle/10665/260137/9789241513470-eng.pdf>).

¹⁷ Code Essentials 2: Guidelines for Policy Makers on Implementing the International Code of Marketing of Breastmilk Substitutes and subsequent WHA resolutions. International Baby Food Action Network and International Code Documentation Centre; 2018 (<https://www.babymilkaction.org/wp-content/uploads/2023/05/201802-CE2-2nd-Edition-Final.pdf>).

- d) The proposed regulations should specify that health professionals working in infant and young child health in roles noted in the regulations must be independent of industry related conflicts of interest, consistent with WHA58.32, WHA65.6, WHA Guidance A69/7 Add.1, Global Strategy for Infant and Young Child Feeding endorsed at the WHA 55.25.

To protect the legitimacy and efficacy of the process of developing and implementing modernized regulations for BMS and FIYC, UNICEF Canada encourages Health Canada to use strong protections against industry interference and COI.

4. Details regarding implementation, monitoring and enforcement should be considered from the initial stages of planning the modernized regulations.

When developing provisions on BMS and FIYC for the modernized regulations, it is imperative that implementation, monitoring and enforcement are considered from the outset. The 2023 Global Breastfeeding Scorecard notes that “[m]onitoring and enforcement mechanisms are key to ensure Code implementation”, yet “[o]nly 25% of countries have clearly defined governmental authorities responsible for monitoring the Code and have continuous monitoring systems in place”.¹⁸ Implementation, monitoring and enforcement are often not fully considered until too late in the process, such as the regulatory drafting stage or after measures are passed. **UNICEF Canada encourages Health Canada to closely consider, from the outset, how the modernized regulations for BMS and FIYC will be implemented, monitored and enforced, to ensure that they will not only appear strong on paper but be effective in practice.**

An important factor to consider is whether appropriate government bodies have sufficient powers and coordination mechanisms for all relevant provisions of the regulations. This includes identifying which government bodies are going to implement, monitor and enforce the various components of the regulations, and the scope of their powers. Health Canada may have the power to pass these regulations, but potentially will not monitor and enforce all aspects of the law. For example, it may have the power to pass regulations prohibiting inappropriate marketing of BMS and FIYC, while potentially lacking the power to monitor and enforce them across the entire media spectrum – including everything from a national broadcasting campaign, to an advertisement on a local bus, to a wide-reaching digital campaign. It is therefore important for Health Canada to coordinate with any agencies that will have responsibilities for monitoring and enforcing the regulations, to ensure they have the necessary powers.

A second key factor is ensuring that there will be sufficient and sustainable resources for monitoring and enforcement. Funding sources should be determined from the outset, so that they can be written into the measure or included in a related budget bill, to the extent possible. Additional resources or expertise may be needed to enforce the modernized regulations, so where these resources come from and how they will be appropriated should be determined upfront. Relevant considerations include which government bodies will need funding; what mechanisms, activities, personnel, training, equipment, evaluation tools, etc. will be funded; and how much funding will be required. If possible, it can be beneficial to allocate funds generated from enforcement of the law’s monetary penalties to future monitoring and enforcement efforts.

¹⁸ Global Breastfeeding Scorecard 2023. Global Breastfeeding Collective, UNICEF and WHO (2023).

A third important factor is assessing whether all existing agencies that have been identified to implement, monitor and enforce the law have the political will to do so. Relevant inquiries include whether they have been consulted, are they vulnerable to COI, and how any potential COI risks can be managed.

A final key factor is whether there is a clear plan for how compliance will be monitored. Considerations include whether there are already inspectors or other existing mechanisms available to monitor the Code regulations; whether civil society organizations and/or the public will be able to submit complaints to the monitoring mechanism; what sanctions would be appropriate and effectively deter violating behavior, including for large companies; and for monitoring of digital violations, whether other regulated products such as pharmaceuticals are effectively monitored, and if any of the mechanisms used for such products can be applied or adapted for these modernized regulations.

Based on the experience of countries around the world, it is clear that regulations implementing the Code are most effective when issues related to implementation, monitoring and enforcement are accounted for early on in the regulatory development process. Therefore, UNICEF Canada recommends that Health Canada fully consider these important topics from the outset.

5. Health Canada should continue and expand its use of a rights-based approach when developing the modernized regulations for BMS and FIYC.

Health Canada has importantly recognized that as a signatory to the Code, it has an obligation “to support and promote breastfeeding, facilitate breastfeeding by mothers through legislative and social action, and prevent inappropriate sales promotion of infant foods that can be used to replace human milk”. **UNICEF Canada encourages Health Canada to maintain and expand its use of a rights-based approach when developing the modernized regulations for BMS and FIYC.** This includes but is not limited to incorporating a rights-based approach into the stated aims of the regulatory modernization proposal.

Code implementation is a human rights obligation under the Convention on the Rights of the Child (CRC) and other relevant human rights instruments to respect, protect, and fulfill children's rights to health and to nutritious foods, and women's rights to be protected from harmful interference by non-State actors, particularly the business sector, and to have skilled support to enable them to breastfeed.¹⁹

The CRC requires governments to “take all necessary measures to protect, promote, and support breastfeeding and end the inappropriate promotion of breast-milk substitutes and other foods intended for infants and young children up to the age of three years”.²⁰ The Code is considered a

¹⁹ Guidance on ending the inappropriate promotion of foods for infants and young children: implementation manual. Geneva: World Health Organization; 2017 (<https://www.who.int/publications/i/item/9789241513470>).

²⁰ United Nations, Joint statement by the UN Special Rapporteurs on the Right to Food, Right to Health, the Working Group on Discrimination against Women in law and in practice, and the Committee on the Rights of the Child in support of increased efforts to promote, support and protect breast-feeding, United Nations Office of the High Commissioner for Human Rights, Geneva, 17 November 2016, (www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=20871&LangID=E).

“necessary measure” that all governments are obliged to implement to comply with their obligations under international human rights law.²¹

Government action to protect against industry interference and COI when developing and implementing regulations for BMS and FIYC is also part of their obligations under the CRC. According to the UN Special Rapporteur on the Right to Health, “[t]he responsibility to protect the enjoyment of the right to health warrants State intervention in situations when third parties, such as food companies, use their position to influence dietary habits by directly or indirectly encouraging unhealthy diets, which negatively affect people’s health.”²²

The best interests of children must be the primary lens for the development of the regulations. The federal Department of Justice released a Child Rights Impact Assessment (CRIA) process in 2023 which should be applied to the proposed regulations. This tool would support fulsome, children’s rights-based consideration of the commercialization and sale of human breast milk banking to ensure that the human rights of recipients, donors and the infant children of donors are fully respected.

UNICEF Canada supports Health Canada’s recognition of its obligation to implement the Code, and encourages it to expand its use of a rights-based approach as it develops the modernized regulations for BMS and FIYC.

Conclusion

UNICEF Canada applauds Health Canada for beginning the work of modernizing regulations that pertain to BMS and FIYC. With these comments, we intend to communicate support for this effort and provide suggestions to improve the development of strong and effective regulations for BMS and FIYC. UNICEF Canada encourages Health Canada to continue with this critical work, and to center the health and rights of children and women as it proceeds.

About UNICEF Canada

UNICEF stands for every child, everywhere. UNICEF is the world’s farthest-reaching humanitarian organization for children. Across 190 countries and territories, and in the world’s toughest places, we work day in and day out to defend children’s human rights and a fair chance to fulfil their potential, guided by the 1989 Convention on the Rights of the Child. UNICEF Canada was founded in 1955 to fundraise for UNICEF’s highest priorities and to secure the human rights of children in Canada. As part of the UN family, our ability to work neutrally with to work neutrally with governments, civil society, the private sector and young people generates results on a scale that is unparalleled. Our mission has always been for children as the highest priority – regardless of race, religion or politics – and has always relied on voluntary contributions.

²¹ United Nations, Committee on the Rights of the Child, General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), para. 44, UN Doc. CRC/C/GC/15, (www.crcasia.org/wp-content/uploads/2016/11/CRC-GC15-Highest-Standard-of-Health.pdf).

²² United Nations, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, UN Doc. A/HRC/26/31, 1 April 2014, ([A-HRC-26-31 en.doc](http://www.unhcr.org/refugees/doc/54000000.html)).

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