



Modernization of Divisions 24 and 25 of the Food and Drug Regulations

Response to Health Canada's
Cost-Benefit Analysis Consultation

Submitted by

**Mouvement allaitement
du Québec**

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1. Introduction

This document constitutes the response of the Mouvement allaitement du Québec (MAQ) to Health Canada's consultation entitled Survey on the Cost-Benefit Analysis for the Modernization of Divisions 24 and 25 of Part B of the Food and Drug Regulations.

MAQ recognizes the significant work undertaken by Health Canada to modernize a regulatory framework that has not kept pace with the rapid evolution of the marketing, promotion, advertising and commercialization of breastmilk substitutes and other products intended for infants and young children. Several of the proposed measures move toward stronger oversight of these products and reflect a commitment to improving consumer information, reducing problematic promotional practices and better protecting families.

At the same time, MAQ is concerned by important limitations in the current cost-benefit analysis process. As discussed throughout this submission, the consultation questionnaire places considerable emphasis on industry compliance costs while providing no opportunity to document expected public health costs and benefits related to breastfeeding, infant and young child nutrition, health equity, environmental impacts and health system costs. This approach appears difficult to reconcile with the requirements of the *Policy on Cost-Benefit Analysis* and the *Canadian Cost-Benefit Analysis Guide of the Treasury Board of Canada Secretariat*, both of which call for a balanced assessment of the full range of regulatory costs and benefits.

The modernization of Divisions 24 and 25 must also be considered in accordance with Canada's international obligations and commitments. Canada has ratified the *Convention on the Rights of the Child*, endorsed the *International Code of Marketing of breast-milk Substitutes (the Code)* and participates in the work of the Codex Alimentarius. Together, these instruments recognize the importance of protecting maternal and child health, nutrition and development, supporting, promoting and protecting breastfeeding, and appropriately regulating the marketing of products that may influence infant and young child feeding practices.

Despite the fact that several of the proposed measures appear intended to support, promote and protect breastfeeding, these objectives remain largely implicit in the consultation documents and are not assessed as expected regulatory benefits.

In this context, the present submission is intended as a constructive contribution to Health Canada's work. It seeks to support the modernization of Divisions 24 and 25 by bringing forward considerations related to public health, breastfeeding, infant and young child nutrition, international guidance and Canada's obligations toward children. MAQ views itself as an ally in this modernization process and hopes to contribute to the development of a regulatory framework that effectively protects breastfeeding, promotes optimal infant and young child feeding practices and safeguards the health and well-being of infants, young children and their families.

2. Liste des acronymes

BMS	Breastmilk substitutes
CBA	Cost-Benefit Analysis
CCFL	Codex Committee on Food Labelling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
Codex	Codex Alimentarius
CRC	Convention on the Rights of the Child
FDR	Food and Drug Regulations
FNF	Formulated Nutritional Food
FSMP	Foods for Special Medical Purposes
FSDU	Foods for Special Dietary Use
HMF	Human Milk Fortifier
MAQ	Mouvement allaitement du Québec
PHM	Pre-packaged Human Milk
TBS	Treasury Board of Canada Secretariat
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization

3. A cost-benefit analysis that provides limited documentation of expected public health impacts

3.1 Requirements of the Cost-Benefit Analysis Policy

The current survey supporting the cost-benefit analysis of the proposed modernization of Divisions 24 and 25 is largely focused on collecting information regarding costs and impacts on the Canadian industry. **This focus contrasts with the approach recommended by the *Policy on Cost-Benefit Analysis* and the *Canadian Cost-Benefit Analysis Guide* issued by the Treasury Board of Canada Secretariat (TBS), which call for the assessment of all costs and benefits associated with a regulatory measure, including health, social and environmental impacts.**

Based on the questionnaire, it remains difficult to understand how many of these dimensions will be reflected in the final analysis.

The *Policy on Cost-Benefit Analysis* specifies that a regulatory analysis should assess the economic, environmental and social impacts of a regulatory proposal and consider both positive and negative effects in order to inform public decision-making. In contrast, the questionnaire used in this consultation indicates that questions relating to costs and benefits are primarily intended to measure impacts on Canadian industry and that responses should be framed from that perspective.

This focus raises questions regarding how other categories of impacts associated with the proposed measures will be documented, including those related to public health, health systems, families, the environment and particularly vulnerable populations.

The *Canadian Cost-Benefit Analysis Guide* further states that a regulatory analysis should identify and assess all direct and indirect costs and benefits associated with a proposal, including health, social, environmental and distributional impacts. The guide also notes that effects that cannot be monetized remain relevant and should be assessed qualitatively.

In the absence of questions that would allow respondents to document potential impacts on breastfeeding, the health of mothers and breastfeeding parents, child health and development, health care costs, environmental impacts or effects on families, it is difficult to understand how Health Canada intends to satisfy these methodological requirements when conducting its cost-benefit analysis.

A review of the questionnaire indicates that respondents are asked to estimate reformulation costs, labelling costs, administrative costs, costs associated with pre-market authorizations, costs related to sales restrictions, costs associated with shortages, as well as potential savings resulting from regulatory flexibilities.

Conversely, no questions seek information on expected costs or benefits related to public health, breastfeeding protection, health systems, Canadian families or the environment. This imbalance in data collection creates a significant risk that the cost-benefit analysis will rely on detailed information concerning compliance costs while having very limited information regarding the public health benefits sought through the proposed regulatory measures.

In the specific context of breastmilk substitutes and foods intended for infants and young children, this omission is particularly concerning and should be addressed in order to ensure that the analysis adequately captures the full range of public health impacts associated with the proposed regulatory measures.

3.2 Costs and benefits for women, children and Canadian families

The Treasury Board guidance and Cabinet Directive also recognize that broader impacts should be considered and documented as part of the cost-benefit analysis. Applied to the subject of this analysis, it should include:

- impacts on breastfeeding, including exclusive breastfeeding rates;
- health and nutritional outcomes for infants, children and breastfeeding persons;
- costs incurred by provincial and territorial health systems;
- costs incurred by families;
- health inequities that may be exacerbated or reduced by regulatory measures;
- environmental impacts associated with the production (including water consumption), packaging, transportation and use of breastmilk substitutes.

These categories of impact correspond directly to the social, health and environmental dimensions that the *Policy on Cost-Benefit Analysis* requires regulators to assess.

Furthermore, since a significant portion of the modernization of Divisions 24 and 25 directly affects infant formula, human milk fortifiers, formulated supplementary foods, conventional foods marketed for children aged 1 to 3 years and medical foods for infant, the absence of questions relating to expected public health benefits is particularly problematic.

Potential benefits associated with stronger controls on the marketing of breastmilk substitutes, enhanced protection of breastfeeding and more objective information for families and health professionals should form an integral part of the data collection process supporting the regulatory analysis.

By focusing on potential costs to industry while omitting potential benefits for population health, possible savings for health systems, social impacts and environmental effects, the survey risks producing an incomplete and biased picture of the impacts of the proposed regulatory modernization. Such an approach appears difficult to reconcile with the requirements of the *Policy on Cost-Benefit Analysis* and the TBS Guide, both of which call for a balanced and comprehensive assessment of the costs and benefits of regulatory proposals.

3.3 Omission of expected benefits related to the protection, promotion and support of Breastfeeding

In its current form, the cost-benefit analysis does not appear to provide an adequate mechanism for assessing the expected benefits associated with the protection, promotion and support of breastfeeding. This methodological limitation is particularly concerning given Canada's endorsement of the Code. **While Canada has endorsed the Code, its provisions have yet to be incorporated into Canadian legislation. In this context, opportunities to assess and document the public health benefits associated with the protection, promotion and support of breastfeeding are especially important.**

The Code was adopted specifically to:

“contribute to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.” (Code, Article 1)

A foundational principle of the Code is the recognition that the marketing of breastmilk substitutes can have significant consequences for the health and nutrition of infants and young children and that appropriate regulatory controls constitute a public health measure.

In this context, an assessment of the costs and benefits associated with the modernization of Divisions 24 and 25 cannot be limited to industry compliance costs. An analysis consistent with the provisions of the Code should also examine the potential effects of the proposed measures on infant feeding practices, breastfeeding protection, families' exposure to promotional activities and the quality of information made available to them.

These are precisely the public health outcomes sought by the international instruments to which Canada has committed, including the Code and the Convention on the Rights of the Child.¹

In fact, the modernization of Divisions 24 and 25 must also be considered in light of Canada's international obligations regarding children's rights. Canada ratified the Convention on the Rights of the Child in 1991, following its adoption by the United Nations General Assembly in 1989.

By ratifying this Convention, Canada committed to undertaking all legislative, administrative and other measures necessary to implement the rights recognized therein. Article 24 explicitly recognizes the right of the child to the enjoyment of the highest attainable standard of health and requires States Parties to take appropriate measures to combat disease and malnutrition, ensure access to adequate nutrition and provide parents with the information necessary for the health and nutrition of children, including the advantages of breastfeeding.

Extract from the Convention on the Rights of the Child

« Article 24

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:

- (a) To diminish infant and child mortality;
- (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
- (c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;
- (d) To ensure appropriate pre-natal and post-natal health care for mothers;

¹ United Nations. (1989). Convention on the Rights of the Child. United Nations.
<https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-child>

(e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;

(f) To develop preventive health care, guidance for parents and family planning education and services.

3. States Parties shall take all effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children.

4. States Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries. »

The Convention also provides that the best interests of the child shall be a primary consideration in all actions concerning children.

In this context, Canada has more than a moral responsibility to protect the health and nutrition of infants and young children; it has made a solemn public political commitment to the United Nations to protect children in this way (by ratifying the Convention) that it has simply not realized with binding legal commitments at home. The federal Department of Justice has even formally acknowledged the importance of children's rights in law-making in an [online course for public servants and the public](#). Regulatory decisions affecting foods intended for infants and young children should therefore be assessed in light of their ability to protect, promote and support children's health, nutrition and development, consistent with Canada's international commitments.

3.4 Omission of the economic and health costs associated with not breastfeeding

The scientific literature demonstrates that the consequences of not breastfeeding, or of suboptimal breastfeeding, extend well beyond individual choices and can have significant impacts on health systems, families, employers and the broader economy.^{2,3} Research published in *The Lancet Breastfeeding Series* has highlighted that many of the social, economic and environmental costs associated with replacing breastfeeding with commercial infant formula remain largely invisible within conventional financing systems and are rarely incorporated into economic or regulatory analyses.

In this context, the absence of questions relating to the health-related costs and benefits associated with infant feeding practices raises concerns regarding the ability of the cost-benefit analysis to adequately capture the potential costs and savings for Canadian health systems associated with the regulatory options under consideration.

Economic tools are now available to estimate the economic losses, health care costs and deaths attributable to suboptimal breastfeeding practices. For example, the *Cost of Not Breastfeeding Tool* developed by Walters and colleagues allows countries to estimate health care costs, mortality and economic losses attributable to not breastfeeding.⁴ Such tools illustrate that the costs and benefits associated with infant feeding practices can be quantified and incorporated into policy analyses when relevant evidence is collected. More recently, a study conducted in Ontario concluded that suboptimal breastfeeding rates generate significant costs for the health care system due to increased rates of childhood illnesses, including respiratory infections, gastrointestinal infections, ear infections, childhood obesity and certain serious diseases.⁵ The authors further note that the consequences of not breastfeeding affect not only the health of children and mothers, but also the environment and society as a whole.

² Walters, D. D., Phan, L. T. H., & Mathisen, R. (2019). The cost of not breastfeeding: Global results from a new tool. *Health Policy and Planning*, 34(6), 407–417. <https://doi.org/10.1093/heapol/czz050>

³ United Nations Children's Fund (UNICEF), World Health Organization (WHO), & Global Breastfeeding Collective. (2017). *Nurturing the health and wealth of nations: The investment case for breastfeeding*. <https://www.globalbreastfeedingcollective.org/media/426/file/The%20investment%20case%20for%20breastfeeding.pdf>

⁴ Walters, Phan et Mathisen, *The Cost of Not Breastfeeding*.

⁵ Onah, N. M., Hoy, S., & Slofstra, K. (2023). The costs of suboptimal breastfeeding in Ontario, Canada and potential economic impacts from improving rates: A health system costing analysis. Research Square. <https://doi.org/10.21203/rs.3.rs-3220814/v1>

3.5 Recommendation 1: Compliance with the Policy on Cost-Benefit Analysis and the Canadian Cost-Benefit Analysis Guide

The considerations outlined above suggest the value of expanding data collection efforts to better document the full range of impacts associated with the proposed measures, including those affecting public health, families and other dimensions of the public interest.

Recommendation 1: Conduct a cost-benefit analysis consistent with applicable public health and children's rights requirements

MAQ recommends that Health Canada revise its analytical approach to ensure that expected public health costs and benefits are documented with the same level of rigour as industry compliance costs. In light of the requirements set out in the *Policy on cost-benefit analysis*, the *Canadian cost-benefit analysis guide*, the *International Code of Marketing of breastmilk Substitutes* and the obligations arising from the *Convention on the Rights of the Child*, the analysis should explicitly assess the effects of the proposed measures on:

- the health, nutrition and development of infants and young children;
- the protection, promotion and support of breastfeeding; and
- environmental impacts associated with infant and young child feeding practices.

In addition, the analysis should document the expected costs and benefits of the proposed measures for families, health systems and society as a whole, in order to provide a comprehensive assessment of their public health implications.

4. Risk-Based Approach: Public Health Considerations That Should Be Documented

The proposed modernization would introduce several changes to the authorization, notification and oversight requirements applicable to certain products intended for infants and young children. These changes include a greater reliance on risk-based mechanisms as well as certain reductions in pre-market authorization and notification requirements. Such changes raise issues that extend beyond administrative considerations, as they also affect public health protection and the prevention of risks among particularly vulnerable populations.

During the previous consultation on the proposed risk-based approach for the authorization of foods for special dietary use intended for infants, MAQ and several other stakeholders raised concerns related to the precautionary principle, the limitations of scientific risk assessment, the particular vulnerability of infants and the potential public health impacts of certain regulatory options.

These considerations remain relevant in the context of the present cost-benefit analysis because they directly affect the benefits, risks and uncertainties associated with the regulatory approaches under consideration. A better understanding of these dimensions would contribute to a more complete assessment of the potential impacts of the proposed options on the health and well-being of infants and young children.

4.1 The Precautionary Principle

In its submission to the previous consultation, MAQ emphasized that infants constitute a particularly vulnerable population and that regulatory decisions affecting infant feeding should be guided by the precautionary principle.

This approach is consistent with the public health objectives underlying the regulatory framework for infant formula and other foods intended for infants and young children.

However, the current questionnaire contains no questions aimed at documenting the benefits associated with preventive oversight mechanisms or pre-market review processes, nor does it seek to assess the risks associated with their removal.

A cost-benefit analysis of a health-related regulatory proposal should also account for the preventive value of regulatory measures, particularly when the products involved may represent the primary and in some cases the sole, source of nutrition for an infant.

4.2 Scientific Limitations of Risk Assessment

MAQ's previous submission also noted that assessing the safety of certain ingredients or formulations intended for infants remains complex. The scientific literature cited in that submission suggested that traditional risk assessment methodologies have limitations when applied to certain bioactive ingredients and that long-term effects on infant development may be difficult to measure with certainty.

In this context of recognized scientific uncertainty, the cost-benefit analysis questionnaire does not appear to collect information that would help assess how such uncertainties may be considered in evaluating the regulatory options under consideration.

Yet the Treasury Board of Canada Secretariat's *Canadian Cost-Benefit Analysis Guide* states that particular attention should be paid to uncertainty whenever it may influence the outcomes of a cost-benefit analysis.

In the case of foods intended for infants, the recognized limitations of scientific risk assessment, together with uncertainties surrounding certain long-term outcomes, constitute relevant considerations that should form part of the evaluation of regulatory options.

4.3 Best Interests of the Child

Finally, MAQ recommended that the best interests of the child be treated as a primary consideration in regulatory decisions relating to foods intended for infants.

This recommendation is based on the fact that infants constitute a particularly vulnerable population whose growth, development and health status depend directly on the nutritional quality and safety of the foods they consume.

Once again, no questions seek to document the potential public health costs or benefits associated with the proposed regulatory measures based on the risk-based approach.

Overall, the issues raised during the previous consultation on the risk-based approach related primarily to public health protection, infant vulnerability, the scientific limitations of risk assessment and the application of the precautionary principle. Yet these considerations appear to be absent from the information that the questionnaire seeks to collect as part of the current cost-benefit analysis. As a result, the exercise may not fully capture the potential impacts of the regulatory options under consideration. This omission is concerning because infants are the very population that the regulatory framework is intended to protect.

Recommendation 2: Document the public health costs associated with the risk-based approach

We recommend that Health Canada specifically include in its data collection:

1. the benefits associated with maintaining rigorous pre-market review and oversight mechanisms, as well as the costs associated with their removal;
2. the potential impacts of scientific uncertainties on the health of infants and young children;
3. the potential costs to health systems resulting from the implementation of regulatory measures based on a risk-based approach; and
4. the expected effects of the various regulatory options on the health, nutrition, development and well-being of infants and young children

5. Labelling requirements for products covered by the Code: a measure to protect breastfeeding and infant nutrition

During its 2023 - 2024 consultation on the modernization of Divisions 24 and 25 of the *Food and Drug Regulations* (FDR), Health Canada proposed several changes to labelling requirements applicable to infant formula and other products intended for infants and young children. These included the addition of a breastfeeding statement, restrictions on certain images and text that could idealize infant formula and measures aimed at preventing cross-promotion.

These proposals recognize that labelling serves a function that extends beyond the simple communication of information needed for the safe use of a product.

5.1 Labelling is not a neutral information tool

For products intended for infants and young children, labelling also serves as a marketing strategy.

The text, illustrations, symbols, logos, nutrition claims and graphic elements displayed on product packaging help shape consumer perceptions and influence decisions related to infant and young child feeding.

This reality has been recognized since the adoption of the *Code*, which includes specific provisions relating to labelling aimed at preventing the idealization of breastmilk substitutes and protecting breastfeeding.

The Code is based on the principle that the way a product is presented to families can significantly influence decisions regarding infant and young child feeding.

5.2 Packaging as a vehicle for commercial promotion

Research conducted by WHO, UNICEF and the NetCode network demonstrate that packaging has become one of the primary promotional tools used for breastmilk substitutes and related products.

Where certain forms of advertising are restricted, packaging remains a powerful means of maintaining brand visibility and conveying promotional messages to families.

5.3 Labelling elements may be used to:

- enhance the appeal of certain brands;
- create an impression of product superiority;
- establish associations with child development, health or nutrition;
- strengthen loyalty to a product line; and
- influence parental perceptions regarding the feeding of their child.

In this context, labelling requirements do not function solely as consumer information measures. They also serve as mechanisms for regulating promotional practices within the infant and young child feeding market.

5.4 Cross-Promotion

Perhaps the clearest example of this promotional function is cross-branding or cross-promotion.

WHO and UNICEF have noted that the use of similar visual elements across product categories, including colours, logos, characters, brand names and other visual identity elements, can indirectly promote breastmilk substitutes to families.

This strategy helps maintain brand recognition and circumvent certain restrictions on the promotion of products intended for infants and young children.

Health Canada's proposal to specifically address this practice reflects an acknowledgement of the role that labelling can play in the marketing of products intended for infants and young children.

5.5 A public health objective distinct from compositional requirements

Health Canada's consultations on the modernization of Divisions 24 and 25, as well as on compositional requirements, have focused primarily on product safety, nutritional quality and appropriate use.

Labelling requirements pursue an additional objective. They help shape the commercial and informational environment in which families make decisions about feeding their children. As such, they contribute to the protection of breastfeeding, the prevention of inappropriate promotion of breastmilk substitutes and the protection of infant nutrition.

For this reason, labelling requirements applicable to products intended for infants and young children should be considered public health measures in their own right and assessed in light of their potential effects on infant and young child feeding practices, alongside the other measures proposed as part of the regulatory modernization.

5.6 General principle arising from the Code and subsequent resolutions

Labelling of products intended for infants and young children is not merely a mechanism for providing consumers with information. The provisions of the Code recognize that it may also serve as a channel for commercial promotion capable of influencing infant feeding decisions.

Labelling requirements therefore pursue a public health objective aimed at protecting and supporting breastfeeding, ensuring objective information and preventing promotional practices that may undermine optimal infant and young child feeding.

Recommendation 3: Document the public health benefits associated with labelling requirements

We recommend that Health Canada explicitly document the potential benefits associated with the proposed labelling requirements and their effects on:

- the protection, promotion and support of breastfeeding;
- the quality, objectivity and comprehension of information provided to families;
- perceptions and decision-making related to infant and young child feeding;
- reducing the influence of promotional practices that are inconsistent with the objectives of the Code;
- preventing cross-promotion and the idealization of breastmilk substitutes;
- infant and young child feeding practices; and
- the contribution of labelling requirements to the public health objectives pursued through the proposed regulatory modernization.

6. Sales restrictions and stop-sale provisions: public health measures whose expected benefits should be considered

The cost-benefit analysis questionnaire includes several questions aimed at documenting the impacts of proposed sales restrictions and stop-sale provisions on the Canadian industry for certain categories of foods for special dietary use. Once again, however, the questionnaire does not appear to seek equivalent information regarding the potential costs and benefits of these mechanisms for public health, breastfeeding protection, or Canadian health systems.

Sales restrictions and stop-sale provisions are public health tools intended to promote the appropriate use of regulated products while preventing and correcting situations of non-compliance.

6.1 Sales restrictions: promoting use consistent with the intended purpose of the product

The sales restrictions proposed by Health Canada are based on the principle that certain products intended for infants and young children should be accessible under conditions that promote their use in accordance with their nutritional or medical indication. This approach is consistent with the principles of the *International Code of Marketing of breastmilk Substitutes* (the *Code*), which recognizes that breastmilk substitutes and related products should be used when necessary and on the basis of adequate information.

The degree of oversight applicable to a given product category should reflect both the degree of product specialization and the vulnerability of the population for which it is intended. Accordingly, the more specialized a product is in addressing a particular nutritional or medical need, the more justified it is that access to that product be linked to its intended use and, where appropriate, to professional assessment or follow-up.

Similarly, when Health Canada recognizes that the risk of inappropriate use justifies restrictions for one category of products, it is reasonable to consider whether the same rationale should also apply to other products that address comparable nutritional needs.

6.2 Standard infant formula and infant formulas for special medical purposes

MAQ supports Health Canada's proposal not to impose sales restrictions on standard infant formula.

Rationale:

- infant formula may constitute an infant's sole source of nutrition;
- access should not be unnecessarily restricted;
- the Code was never intended to limit access to breastmilk substitutes when they are needed;
- rather, the objective of the Code is to regulate their marketing and appropriate use.

MAQ supports partially the alternative option proposing certain sales restrictions for infant formulas for special medical purposes. We agree that formulas intended for severe allergies, malabsorption disorders, metabolic diseases and other clearly defined medical conditions should not necessarily be treated in the same manner as products intended for the general feeding of healthy infants.

“Alternatively, Health Canada is considering an option that could result in sales restrictions for medical infant formula. It is being considered that sale would only allow for use by a person for which the food is appropriate from:

- **Manufacturers and distributors, with appropriate safeguards in place to ensure products are only sold to intended consumers**
- Healthcare institutions
- Pharmacists (i.e. pharmacies, behind the counter)
- Physician, nurse practitioner or dietitian.”

Rationale:

- **these products address specific medical needs;**
- **their use is generally associated with a clearly defined clinical condition;**
- **access should remain linked to professional assessment;**
- **this approach aligns product use more closely with its actual clinical indication;**
- **it is consistent with the principle of the Code that breastmilk substitutes should be used when necessary.**

However, MAQ has reservations regarding the proposed distribution channel relying on manufacturers and distributors with "appropriate safeguards" in place to ensure that products are sold only to intended consumers.

The consultation document does not specify:

- the nature of these safeguards;
- how their effectiveness would be assessed;
- how Health Canada would verify their implementation;
- or what oversight mechanisms would ensure ongoing compliance.

Given that the rationale for these restrictions is to ensure that products remain available only to infants with specific medical or nutritional needs, MAQ believes that the corresponding control mechanisms should be clearly defined, objectively verifiable and subject to adequate regulatory oversight.

Access channels involving health care institutions, pharmacists (behind the counter only) and qualified health professionals appear to provide a clearer framework for verification and accountability than mechanisms administered directly by manufacturers or distributors.

We further believe that access channels involving health care institutions or qualified health professionals provide a clearer framework for verification and accountability than mechanisms administered directly by manufacturers or distributors. Accordingly, any approach that relies on industry-administered controls or undefined safeguards should be supported by a much clearer justification and a more robust regulatory framework.

Recommendation 4: Restrict access to infant formulas for special medical purposes through mechanisms that are independently verifiable

MAQ recommends that sales restrictions applicable to infant formulas intended for special medical purposes be implemented through access channels that provide a clear, independent and verifiable mechanism for confirming that products are used by infants for whom they are medically or nutritionally indicated.

Given the absence of clearly defined safeguards, MAQ does not support relying primarily on manufacturer- or distributor-administered controls to determine eligibility for access to these products. Health Canada should instead prioritize mechanisms involving healthcare institutions and qualified health professionals, where accountability, verification and regulatory oversight can be more readily ensured.

6.3 Medical Foods for Infants and Human Milk Fortifiers

MAQ does not support Health Canada's proposal nor support the alternative option for medical foods for infants and human milk fortifiers (HMFs).

We do not support the sale of infant formulas for special medical purposes, medical foods for infants or human milk fortifiers directly to individual consumers by manufacturers or distributors, even where such sales are accompanied by a written request from a hospital or by manufacturer-administered safeguards. These products are intended for infants with specific medical or nutritional needs and their use is generally associated with clinical assessment, professional follow-up and, in many cases, ongoing monitoring. In this context, access should occur through health care institutions, pharmacists or other qualified health professionals who are subject to professional obligations, accountability mechanisms and regulatory oversight.

MAQ is concerned that manufacturer- or distributor-administered safeguards do not provide the same level of independence, verification and accountability. The consultation document does not specify how such safeguards would be implemented, monitored or enforced. In the absence of clearly defined and independently verifiable mechanisms, it is difficult to determine how Health Canada could ensure that these products are consistently restricted to the populations for whom they are intended.

Recommendation 5: Apply sales restrictions to specialized infant products through independently accountable channels

MAQ recommends that products subject to sales restrictions remain available to individual consumers only through health care institutions, pharmacists (behind the counter) and other authorized health professionals.

Note: MAQ notes that the term “*enriched medical foods for infants*” used in the consultation materials does not appear to be defined. Clarification of this terminology would assist stakeholders in understanding the scope of the proposed options.

Medical foods for infants and HMFs:

- are intended for particularly vulnerable infants;
- are generally used in specialized clinical settings;
- address nutritional needs that exceed those of the general population;
- often require professional assessment and follow-up.

In this context, extending to medical foods for infants the same restrictions currently applied to HMFs appears appropriate. It would also promote regulatory consistency among products intended for infants with particularly complex nutritional needs.

6.4 Medical foods for individuals aged one year and older

MAQ partially supports Health Canada's alternative proposal for medical foods intended for individuals aged one year and older.

We welcome Health Canada's recognition of the risk of inappropriate use associated with enriched medical foods for individuals aged one year and older, as well as the introduction of sales restrictions for these products.

The consultation document proposes sales restrictions for enriched medical foods intended for individuals aged one year and older, while maintaining unrestricted access for non-enriched medical foods. However, the distinction between these two categories is not clearly justified from a public health perspective. Both categories are intended to address specific nutritional or medical needs and are not designed for the general population. The rationale supporting restricted access to enriched medical foods would therefore appear equally applicable to non-enriched medical foods intended for individuals with specialized nutritional requirements.

MAQ therefore believes that non-enriched medical foods for individuals aged one year and older should be subject to a comparable level of oversight in order to ensure that access remains linked to their intended use and to the needs of the populations for whom they are intended.

Drafting Observations

MAQ would also like to draw attention to two apparent drafting errors in the consultation document:

- The expression "medical infant formulas" would benefit from clarification and greater alignment with internationally recognized terminology, such as "infant formulas for special medical purposes" or "formulas for special medical purposes intended for infants", as used in Codex standards.
- in the section on medical foods for individuals aged one year and older, the phrase "*non-enriched medical foods for an age or older*" appears intended to read "*non-enriched medical foods for one year of age and older.*"

Recommendation 6: Apply comparable sales restrictions to enriched and non-enriched medical foods intended for individuals aged one year and older

MAQ recommends that Health Canada apply comparable sales restrictions to both enriched and non-enriched medical foods intended for individuals aged one year and older, given that both categories are designed to address specific nutritional or medical needs and are not intended for use by the general population. Access to these products should remain linked to their intended use and target population.

Table 1.

Summary of MAQ's Positions on Health Canada's Proposed Sales Restrictions

Product Category	Health Canada Proposal	MAQ Position	Main Rationale
Infant formula	No sales restrictions	Support	These products must remain accessible when needed. The Code is intended to regulate marketing and appropriate use, not restrict access.
Infant formulas for special medical purposes	No restrictions (preferred option) / sales restrictions (alternative option)	Support for alternative option with sales restrictions	These products address specific medical needs and should remain linked to a defined clinical or nutritional indication and, where appropriate, professional assessment.
Medical foods for infants and human milk fortifiers (HMFs)	Apply current HMF restrictions to all medical foods for infants subject to pre-market authorization	Support preferred option	These products are intended for particularly vulnerable infants and are used in specialized clinical settings. A high degree of oversight is justified.
Medical foods for infants and human milk fortifiers (HMFs)	Alternative option: less restrictive sales conditions	Oppose	The products in question have characteristics comparable to HMFs and should benefit from a similar level of oversight.
Enriched medical foods for individuals aged one year and older	No sales restrictions	Oppose	These products also address specific nutritional needs and their use is linked to a particular nutritional or medical indication. Comparable oversight is warranted.
Enriched medical foods for individuals aged one year and older	Alternative option: sales restrictions	Support and extend to non-enriched medical foods	Health Canada recognizes that these products present a risk of inappropriate use that justifies restricted access.

6.5 Stop-sale provisions: an essential mechanism for regulatory enforcement

The proposed modernization of Divisions 24 and 25 would expand the scope of existing stop-sale provisions, which currently apply to certain product categories, including infant formula and human milk fortifiers (HMFs), to all foods for special dietary use (FSDU).

Stop-sale provisions form part of a broader set of monitoring and enforcement mechanisms that support the implementation of the *International Code of Marketing of breastmilk Substitutes* (the Code).

WHO and UNICEF's work on Code implementation demonstrates that the effectiveness of a regulatory framework depends not only on the requirements it establishes, but also on its ability to ensure compliance and enforcement in practice. Countries that have implemented the Code more comprehensively generally provide for monitoring, investigation and enforcement mechanisms that allow authorities to intervene when non-compliance is identified. Depending on the jurisdiction, these mechanisms may include inspections, corrective actions, product or advertising withdrawals, suspension of authorizations and administrative or financial sanctions. Although their form varies from one country to another, they pursue a common objective: ensuring the effective implementation of measures designed to protect breastfeeding, prevent inappropriate promotional practices and safeguard the health of infants and young children.

6.6 The importance of measuring the costs and benefits of stop-sale provisions

In this context, the stop-sale provisions proposed by Health Canada appear first and foremost to serve as a mechanism to verify and maintain compliance of products intended for particularly vulnerable populations. They contribute to the effectiveness of requirements related to composition, labelling, marketing and the appropriate use of products regulated under Divisions 24 and 25.

Potential benefits associated with these mechanisms may include:

- improved compliance with regulatory requirements;
- more timely intervention when concerns are raised about a product;
- enhanced protection of infants and young children;
- increased credibility and effectiveness of the regulatory oversight system; and
- greater effectiveness of measures designed to protect breastfeeding and infant nutrition.

As with other measures discussed in this submission, the potential benefits associated with these mechanisms appear to be largely absent from the information that the questionnaire seeks to collect. Yet these benefits constitute an important component of the intended outcomes of stop-sale provisions and should be considered alongside the administrative and operational costs associated with their implementation.

6.7 Evidence requested from industry

Health Canada proposed provision:

“The evidence requested would primarily concern demonstrating that the product is nutritionally appropriate for the target population when consumed according to the conditions of use and that such nutritional adequacy is maintained until the stated expiration date.”

MAQ welcomes Health Canada's intention to require manufacturers to demonstrate the continuing nutritional adequacy of products intended for vulnerable populations. However, we note that the proposed provisions appear to focus primarily on issues of nutritional adequacy.

We emphasize that the objectives of the modernization of Divisions 24 and 25 also include labelling, advertising, marketing, the appropriate use of products and the protection of breastfeeding and infant nutrition.

From this perspective, MAQ believes that monitoring and enforcement mechanisms should permit intervention whenever non-compliance compromises any of these public health objectives, rather than only in situations where the nutritional adequacy of a product can no longer be demonstrated. Accordingly, stop-sale provisions should not be limited to circumstances in which nutritional adequacy cannot be demonstrated. They should also be available, through a rigorous and proportionate process, when significant non-compliance is identified with respect to labelling, marketing, advertising, or other requirements intended to protect breastfeeding and infant nutrition.

6.8 Stop-sale provisions should not be limited to FSDUs

MAQ welcomes the proposal to extend stop-sale provisions to all foods for special dietary use (FSDUs). However, we question the exclusion of foods that are not regulated as FSDUs, particularly conventional foods for infants and formulated supplementary foods intended for children aged 1 to 3 years.

Many of the objectives pursued through the regulatory modernization also apply to these product categories. Proposed measures regarding labelling, advertising, claims and breastfeeding-related statements recognize that these products may influence infant feeding practices and family decision-making regarding the feeding of infants and young children.

WHO guidance on ending the inappropriate promotion of foods for infants and young children emphasizes that the protection of breastfeeding and the promotion of optimal feeding practices are not limited to breastmilk substitutes or foods for special medical purposes. They also apply to products marketed for children under 36 months of age when those products may influence infant and young child feeding practices.

It therefore appears necessary that stop-sale mechanisms not be limited solely to FSDUs. They should also be available, through a rigorous and proportionate process, for conventional infant foods and formulated supplementary foods intended for children aged 1 to 3 years when non-compliance is identified with respect to composition, labelling, advertising or marketing practices.

6.9 Compliance Period

MAQ welcomes the possibility of immediate intervention when there is a serious and imminent risk to human health. However, in the case of products intended for infants and young children, the determination of the level of risk that justifies rapid intervention should take into account the particular vulnerability of the target population. The potential consequences of non-compliance affecting safety, food safety, nutritional adequacy or the appropriate use of a product may be significantly greater for infants than for the general population.

MAQ therefore believes that compliance verification, food safety and regulatory oversight mechanisms applicable to products intended for infants and young children should be applied rigorously and consistently. Where non-compliance may compromise the health, nutrition or appropriate feeding of the intended population, regulatory intervention should be prompt and proportionate to the potential risk involved. Furthermore, the Code and subsequent World Health Assembly resolutions are based on the principle that infants constitute a particularly vulnerable population and that governments must implement the measures necessary to protect their health and nutrition. The Code specifically aims to ensure safe and adequate infant nutrition and the proper use of breastmilk substitutes when they are necessary.

Accordingly, the threshold for intervention should be interpreted with particular caution when products are intended for:

- infants;
- preterm infants;
- children with special nutritional needs; or
- populations whose nutrition depends substantially on these products.

When a product is intended for a vulnerable population, the consequences of an error can be significant even when the risk initially appears limited.

Examples include:

- microbiological contamination;
- formulation errors;
- defects affecting nutritional stability;
- inaccurate information that may influence product use; and
- labelling deficiencies related to a particular medical condition.

In many of these situations, the potential consequences may be far greater for an infant than for the general population.

Recommendation 7: Extend stop-sale provisions to foods intended for infants and young children that are not regulated as foods for special dietary use (FSDUs)

MAQ recommends that Health Canada extend stop-sale provisions to foods intended for infants and young children that are not regulated as foods for special dietary use (FSDUs), including conventional foods for infants and formulated supplementary foods intended for children aged 1 to 3 years, when a significant non-compliance compromises the public health objectives pursued by the regulatory framework.

Recommendation 8 : Expand the scope of stop-sale provisions

MAQ recommends that stop-sale provisions be available whenever a significant non-compliance compromises the achievement of the public health objectives pursued by the regulatory framework, including where such non-compliance relates to labelling, marketing practices, or any other requirement intended to protect breastfeeding and infant nutrition.

MAQ further recommends that Health Canada assess the application of these provisions to conventional foods for infants and formulated supplementary foods intended for children aged 1 to 3 years.

Recommandation 9 : Better document the effects of sales restrictions and stop-sale provisions

MAQ recommends that the cost-benefit analysis take into account the expected effects of sales restrictions and stop-sale provisions on:

- the health, nutrition and development of infants, young children and other populations targeted by the regulated products;
- the use of products in accordance with their nutritional or medical indication;
- the protection, promotion and support of breastfeeding, as well as the maintenance of environments that support optimal infant and young child feeding;
- the effectiveness of measures relating to product composition, labelling, advertising, product presentation and marketing; and
- the prevention and correction of situations of non-compliance that may compromise the public health objectives pursued through Divisions 24 and 25.

7. Advertising Restrictions: an opportunity to bring Canada closer to international standards

The International Code of Marketing of breastmilk Substitutes is founded on a fundamental principle: products that function as breastmilk substitutes should not be promoted. This interpretation was reaffirmed in the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children and supported through World Health Assembly Resolution WHA 69.9. According to this guidance, breastmilk substitutes include milks and milk replacement products specifically marketed for feeding infants and young children up to three years of age, including follow-up formulas and growing-up milks.

At present, however, the Canadian regulatory framework remains far from this objective. Products covered by the Code continue to be subject to various forms of advertising, promotion and marketing. In this context, MAQ believes that the modernization of Divisions 24 and 25 represents an important opportunity to move Canada toward stronger protection of infant feeding and breastfeeding.

7.1 Better documentation of marketing practices

One of the challenges facing Canada is the lack of systematic data on current marketing practices affecting products covered by the Code.

Advertising and promotion of these products now occur simultaneously across multiple environments:

- social media and digital platforms;
- influencer marketing;
- targeted online advertising;
- corporate websites;
- healthcare settings;
- activities directed at health professionals;
- events, partnerships and sponsorships;
- retail settings and the broader commercial environment.

Recent work by WHO, UNICEF and the *Lancet Breastfeeding Series* demonstrates that digital strategies now play a central role in the marketing of breastmilk substitutes and allow brands to maintain a constant presence in the lives of families.

7.2 A progressive approach toward the implementation of international standards

MAQ recognizes that achieving a framework fully consistent with the Code will likely require a gradual approach in Canada. As a first step, Canada could document current advertising, promotion and marketing practices affecting products covered by the Code. Such work would improve understanding of the extent to which families are exposed to promotional messages and would help inform the development of future regulatory measures adapted to contemporary marketing environments.

Canada could thereby position itself as a leader among OECD countries in the development of modern systems for monitoring and regulating the marketing of products intended for infants and young children.

MAQ also believes that it can contribute to this effort by mobilizing its networks of experts, research partners and accumulated expertise in the fields of infant feeding protection and Code implementation.

7.3 The high-income country paradox

It might be assumed that high-income countries naturally provide the most favourable environments for breastfeeding. Yet several of these countries report breastfeeding rates that are lower than those observed in some low- and middle-income regions.

Access to safe drinking water, healthcare services and commercial infant formula reduces the immediate risks associated with artificial feeding and contributes to the social normalization of breastmilk substitutes. In this context, marketing practices can exert a significant influence on family decisions regarding infant and young child feeding.

This reality reinforces the importance of adopting regulatory measures that are adapted to contemporary advertising and marketing environments in order to effectively protect breastfeeding and support optimal infant and young child feeding practices.

Recommendation 10: document and monitor the marketing of products covered by the Code

MAQ recommends that Health Canada develop a national strategy to document, monitor and publicly report on advertising, promotion and marketing practices targeting products covered by the Code, including products marketed for children under 36 months of age.

This strategy should include both digital and non-digital environments and serve as a foundation for the progressive implementation of stronger measures to protect breastfeeding and infant and young child nutrition.

8. Formulated nutritional foods for children: a distinct category with particular public health considerations

8.1 International guidance on products marketed for children under 36 months

Products marketed for infants and young children have been the subject of sustained attention from the World Health Assembly, the World Health Organization and the Codex Alimentarius for several decades.

As early as 1986, World Health Assembly Resolution WHA 39.28 explicitly stated that the practice of providing infants with specially formulated milks, referred to as “follow-up milks”, was not necessary. The resolution also recognized that foods and drinks provided before they are nutritionally required may interfere with the initiation and maintenance of breastfeeding.⁶

In 2016, WHO published the *WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children*. Recommendation 2 of the guidance states that products functioning as breastmilk substitutes should not be promoted and clarifies that **breastmilk substitutes include any milks or milk replacement products specifically marketed for feeding infants and young children up to three years of age, including follow-up formulas and growing-up milks.**⁷

RECOMMENDATION 2

Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products.

The same year, the World Health Assembly adopted Resolution WHA 69.9 on ending the inappropriate promotion of foods for infants and young children. Through this resolution, **Member States welcomed the WHO guidance and were urged to take all necessary measures, in accordance with national circumstances, to implement its recommendations and end inappropriate promotional practices targeting infants and young children.**⁸

In 2018, WHO issued *Information Note: Clarification on the Classification of Follow-Up Formulas for Children 6–36 Months as breastmilk Substitutes*, further clarifying that follow-up formulas and growing-up milks marketed for children up to 36 months fall within the scope of the Code.⁹

⁶ World Health Organization. (1986). Infant and young child feeding (WHA39.28). In Thirty-ninth World Health Assembly, Geneva, 5–16 May 1986: Resolutions and decisions, annexes (pp. 15–17).

⁷ World Health Organization. (2016). Guidance on ending the inappropriate promotion of foods for infants and young children: Implementation manual. World Health Organization. <https://iris.who.int/handle/10665/260137>

⁸ World Health Organization. (2016). Ending inappropriate promotion of foods for infants and young children (WHA69.9). In Sixty-ninth World Health Assembly, Geneva, 23–28 May 2016: Resolutions and decisions, annexes.

⁹ World Health Organization. (2018). Information note: Clarification on the classification of follow-up formulas for children 6–36 months as breastmilk substitutes (WHO/NMH/NHD/18.11). <https://www.who.int/publications/i/item/WHO-NMH-NHD-18.11>

Importantly, whether a product functions as a breastmilk substitute is not determined by its composition or nutritional suitability. Article 3 of the Code defines a breastmilk substitute as “Any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose.”¹⁰

As a result, differences in composition between infant formula and products marketed for children aged 6 to 36 months do not prevent such products from being considered breastmilk substitutes.

Taken together, the Code, WHA Resolution 39.28, the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, WHA Resolution 69.9 and the 2018 WHO Information Note establish a consistent international framework recognizing that products marketed for children under 36 months may influence breastfeeding, complementary feeding and young child nutrition and therefore require specific regulatory consideration.

8.1.1 Codex requirements applicable to products intended for young children

The Codex includes several provisions intended to protect and support breastfeeding.

- It requires products intended for young children to carry a statement indicating that breastfeeding is recommended up to two years of age and beyond.
- It also requires a statement encouraging parents and caregivers to seek advice from a health care professional regarding the feeding of young children. These provisions reflect the recognition that feeding practices among children aged 12 to 36 months raise specific public health considerations.
- The Codex also prohibits representations that may undermine or discourage breastfeeding.
- Products intended for young children must not be presented in a manner that compares them with breast milk or suggests that they are similar, equivalent or superior to it.
- The standard further requires products intended for young children to be clearly distinguished from infant formula, follow-up formula and formulas for special medical purposes intended for infants. This distinction must be apparent in the text, images and colours used on product packaging. This means that products intended for children aged 1 to 3 years should not be presented as part of the same

¹⁰ World Health Organization. (1981). International Code of Marketing of breastmilk Substitutes. <https://www.who.int/publications/i/item/924154160>

product line as infant formula, should not use sequential numbering systems that create a direct association with infant formula products, should not promote or depict other products intended for infants and should not encourage progression from infant formula to products intended for young children.

- The Codex also prohibits references to infant formula, follow-up formula and formulas for special medical purposes intended for infants on labels intended for young children. These provisions help prevent the creation of direct marketing links between product categories and reduce the potential for cross-promotion across products intended for different age groups. These requirements reflect a broader objective of ensuring that products intended for young children are marketed as distinct products and are not used to maintain brand recognition, extend promotional claims or create associations with products intended for infants. In this respect, the Codex provisions can be understood as measures designed to help prevent cross-promotion and reduce confusion between product categories.
- The Codex further recognizes that, in some jurisdictions, products intended for young children are regulated as breastmilk substitutes. This acknowledgement illustrates that a number of authorities consider these products to have implications for young child feeding practices and the continuation of breastfeeding.

8.2 Health Canada's proposals and areas of alignment with international guidance

Health Canada's proposals relating to Formulated Nutritional Food (FNF) intended for children introduce new product subcategories, specific compositional requirements, particular labelling requirements and various restrictions regarding product presentation and marketing.

MAQ considers that these proposals reflect the recognition of an important reality: FNF intended for children cannot be viewed solely as ordinary food products. Their marketing and use occur within a context in which family decisions may influence young child feeding practices and, in some cases, the continuation of breastfeeding.

Several proposed measures appear consistent with concerns identified in international guidance and standards.

Health Canada proposes that FNF intended for children should not be represented as:

- a meal replacement;
- a product intended for weight-loss purposes;
- a substitute for human milk;
- a fortified plant-based beverage or a substitute for cow's milk.

Health Canada is also considering the addition of statements indicating that:

- the product is not intended to be used as a sole source of nutrition;
- breastfeeding is recommended up to two years of age for products intended for children aged 1 to 2 years;
- consumption should not exceed specified daily quantities.

These measures reflect a recognition that products intended for young children may influence parental perceptions and feeding practices and therefore require a level of oversight that goes beyond conventional food regulation.

Several of these proposals are consistent with international guidance, including provisions contained in the Codex Standard for Follow-up Formula for Older Infants and Product for Young Children (CXS 156-1987)¹¹, which requires breastfeeding-related statements and recognizes the need to clearly distinguish products intended for young children from other product categories.

8.3 Remaining gaps between the proposed framework and international standards

Despite these positive elements, important gaps remain between the proposed framework and international guidance.

8.3.1 Gap 1: The primary categorization proposal does not adequately recognize the distinct considerations associated with products intended for children aged 12–36 months

The Codex Standard for Follow-up Formula for Older Infants and Product for Young Children (CXS 156-1987) explicitly recognizes products intended for children aged 12 to 36 months as a distinct category. Similarly, the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children, WHO's 2018

¹¹ Codex Alimentarius Commission. (2023). Standard for follow-up formula for older infants and product for young children (CXS 156-1987). In Codex Alimentarius. Food and Agriculture Organization of the United Nations (FAO) & World Health Organization (WHO).

clarification on follow-up formulas and subsequent World Health Assembly resolutions all identify specific public health considerations associated with products marketed for children under 36 months of age.

Health Canada's primary proposal groups products intended for children aged 1 to 13 years within a single category. This approach risks obscuring issues that are unique to the 12-36 month age group, including continued breastfeeding, complementary feeding and the marketing of products intended for very young children.

At the same time, Health Canada has identified an alternative categorization approach that includes a distinct category for products intended for children aged 1 to 3 years. MAQ considers that this alternative approach is the only one consistent with the international framework established by the Code, the WHO Guidance, WHA Resolution 69.9, the 2018 WHO clarification and the Codex Standard.

Recommendation 10: Retain a Distinct 1–3-Year Category

MAQ recommends that Health Canada retain the alternative proposal establishing a distinct category for products intended for children aged 1 to 3 years in order to align the modernization of Divisions 24 and 25 with the Code, WHO guidance and the Codex framework applicable to products marketed for children under 36 months of age.

8.3.2 Gap 2: Limited measures addressing cross-promotion

The Codex standard contains several provisions intended to prevent cross-promotion between products intended for different age groups.

It requires products intended for young children to be clearly distinguished from infant formula, follow-up formula and formulas for special medical purposes intended for infants through the use of distinct text, images and colours. It also prohibits references to these categories on labels intended for young children.

The current proposals include measures intended to reduce confusion between products, but they do not appear to address several practices commonly associated with cross-promotion, such as:

- cross-promotion practices based on shared branding, packaging and product-line continuity;
- stage-based numbering systems linking products intended for different age groups;
- brand-extension strategies;
- indirect references to infant formula and related products.

Recent work by WHO, UNICEF and the *Lancet Breastfeeding Series* has highlighted that products marketed for children under 36 months of age may influence young child feeding practices and contribute to the persistence of promotional strategies targeting families.

The same body of work identifies cross-promotion as one of the primary mechanisms used to maintain brand visibility and influence consumer behaviour across product categories.

While several proposed measures move in the direction of addressing these concerns, **additional measures would be required to fully align the framework with international guidance on the prevention of cross-promotion and the protection of breastfeeding.**

Recommendation 11: Strengthen measures to prevent cross-promotion between products intended for infants and young children

MAQ recommends that Health Canada strengthen the proposed framework to explicitly address cross-promotion between products intended for different age groups, particularly products marketed for children under 36 months of age.

To ensure greater alignment with *the International Code of Marketing of breastmilk Substitutes*, WHO guidance, WHA Resolution 69.9 and the Codex Standard for Follow-up Formula for Older Infants and Product for Young Children (CXS 156-1987), Health Canada should incorporate these measures into the regulatory framework :

- prohibiting the use of shared branding, logos, colours and visual identities across product categories intended for different age groups;
- prohibiting stage-based numbering systems and other marketing practices that create continuity between products intended for infants and those intended for young children;

- prohibiting references, whether direct or indirect, to infant formula, follow-up formula or formulas for special medical purposes intended for infants on products marketed for young children;
- requiring product packaging and labelling to be clearly distinguishable from infant formula and follow-up formula;
- restricting product-line extension strategies that maintain brand recognition across products intended for different age groups;
- prohibiting promotional practices that encourage progression from infant formula to products marketed for children aged 1 to 3 years;
- ensuring that products intended for young children are not marketed in a manner that may undermine, discourage or compete with continued breastfeeding; and
- recognizing and addressing cross-promotion as a distinct regulatory concern within the modernization of divisions 24 and 25.

8.3.3 Gap 3: Limited recognition that products marketed for children under 36 months may function as breastmilk substitutes

WHO guidance and the *2018 WHO Information Note* explicitly recognize that follow-up formulas and growing-up milks marketed for children up to 36 months may function as breastmilk substitutes and should be considered within the scope of the Code. This perspective does not appear to be fully reflected in the proposed modernization, which continues to approach these products primarily from a compositional and nutritional perspective.

Recommendation 12 : Recognize products marketed for children under 36 months as breastmilk substitutes

MAQ recommends that Health Canada explicitly recognize that follow-up formulas, growing-up milks and other milk-based products marketed for children under 36 months may function as breastmilk substitutes and should therefore be assessed in a manner consistent with the objectives of the International Code of Marketing of breastmilk Substitutes, the WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children and the 2018 WHO clarification on follow-up formulas.

This recognition should be reflected in the development of labelling, marketing and promotional requirements applicable to products intended for children under 36 months of age.

8.3.4 Gap 4: Insufficient consideration of the necessity of follow-up products

The World Health Assembly has questioned the necessity of follow-up milks since 1986. WHA Resolution 39.28 explicitly stated that the practice of providing infants with specially formulated milks, referred to as “follow-up milks”, was not necessary.

In this context, any regulatory category established for products intended for infants and young children should be supported by clearly demonstrated public health benefits rather than by the existence of the products themselves.

Recommendation 13 : Assess the necessity of follow-up products

MAQ recommends that Health Canada explicitly assess and document the public health need and expected benefits associated with regulatory categories for follow-up formulas and related products intended for infants and young children.

Given that the World Health Assembly has questioned the necessity of follow-up milks since 1986, the continued recognition of such products within the regulatory framework should be supported by a clear public health justification.

8.4 Flavourings and highly processed products marketed to young children

Health Canada’s proposed requirements focus primarily on nutritional composition, safety and suitability. However, the use of flavourings and other non-essential ingredients also warrants consideration from a public health perspective.

Children aged 1 to 3 years are in a critical period of dietary development during which food preferences and eating habits are being established. Flavourings and other ingredients intended to enhance palatability may influence food acceptance and contribute to the establishment of lasting preferences.

The role of flavourings in FNF intended for young children may therefore extend beyond nutritional considerations alone and influence:

- food preferences and taste development;
- product acceptability and consumption patterns;
- parental perceptions regarding product necessity;
- young child feeding practices.

Recommendation 14 : Document the public health impact of flavouring in products intended for children aged 1 to 3 years

MAQ recommends that, where flavourings do not serve a demonstrated nutritional purpose, the expected public health benefits associated with their inclusion in products intended for children aged 1 to 3 years be explicitly documented and considered as part of the cost-benefit analysis.

8.5 Ultra-processed products and young child feeding

Many products marketed for children aged 1 to 3 years are highly processed commercial products that may contain added sugars, flavourings and other ingredients intended to enhance palatability.¹² From a public health perspective, questions remain regarding the role of these products within a diversified diet based primarily on family foods.

Recent research has drawn attention to the growing availability of ultra-processed foods and beverages marketed to infants and young children, including products intended for children aged 12 to 36 months. Researchers have raised concerns regarding the sugar content, level of processing and marketing of many of these products, as well as their potential influence on caregiver perceptions and feeding practices during a critical period of dietary development.¹³

In addition, several public health authorities and researchers have questioned the necessity of toddler milks for most healthy children and have highlighted concerns related to their sugar content, flavourings and marketing practices.¹⁴

Given these considerations, the expected public health benefits associated with the use of flavourings and other non-essential ingredients in products intended for children aged 1 to 3 years should be explicitly assessed and documented as part of the cost-benefit analysis.

¹² Dunford, E. K., & Popkin, B. M. (2023). Ultra-processed food for infants and toddlers; dynamics of supply and demand. *Bulletin of the World Health Organization*, 101(5), 358-360.

¹³ Richter, A. P. C., Grummon, A. H., Falbe, J., Taillie, L. S., Wallace, D. D., Lazard, A. J., Golden, S. D., & Hall, M. G. (2024). Toddler milk: A scoping review of research on consumption, perceptions and marketing practices. *Nutrition Reviews*, 82(3), 425-438. <https://doi.org/10.1093/nutrit/nuad061>

¹⁴ Fuchs, G. J., III, Abrams, S. A., Amevor, A. A., & Committee on Nutrition. (2023). Older infant-young child “formulas”. *Pediatrics*, 152(5), e2023064050. <https://doi.org/10.1542/peds.2023-064050>

Recommandation 15 : Assess the public health implications of highly processed products marketed to young children

MAQ recommends that Health Canada explicitly assess and document the public health costs and benefits associated with the use of highly processed products and other non-essential ingredients in products intended for children aged 1 to 3 years.

9. Pre-packaged human milk : distinct public health, ethical and governance issues

In November 2023, as part of its consultation on the modernization of the regulatory framework for foods for special dietary use and foods for infants, Health Canada proposed the creation of a new regulatory category for pre-packaged human milk (PPHM). In its comments submitted to Health Canada in February 2024, MAQ expressed its opposition to this proposal.

More recently, WHO published the *Standards for Donor Human Milk Banking in 2026*.¹⁵ These standards recognize donor human milk as an important intervention for vulnerable infants when mother's own milk is unavailable or insufficient. The standards place particular emphasis on the protection and support of breastfeeding, equitable access, donor and recipient safety, ethical sourcing of donor milk and the integration of milk banks within maternal, newborn and child health programmes. They also stress that donor human milk should serve as a bridge that helps mothers establish or restore lactation rather than replace breastfeeding. **These standards provide an important international reference for the development of the Canadian regulatory framework applicable to pre-packaged human milk.**

9.1 Opposition to the commercialization of human milk by private interests

MAQ recognizes the clinical value of donor human milk for particularly vulnerable infants, including very preterm infants and infants with specific medical conditions. In these contexts, public human milk banks play an essential role in supporting

¹⁵ World Health Organization. (2026). Standards for donor human milk banking. <https://www.who.int/publications/i/item/9789240122307>

neonatal care and improving access to a product whose benefits are well documented.

However, MAQ believes that the proposed category of “pre-packaged human milk” combines two fundamentally different realities: on the one hand, human milk collected and distributed by public human milk banks for public health purposes and, on the other hand, human milk collected, processed and commercialized by private companies. These models pursue different objectives, rely on different sourcing mechanisms and raise distinct regulatory, ethical and public health concerns that should not be treated interchangeably.

International experience demonstrates that the commercialization of human milk raises complex issues related to sourcing, compensation of donors and equity. In several jurisdictions, the emergence of private companies purchasing human milk has generated concerns regarding the economic exploitation of women in vulnerable situations, the creation of financial incentives that may influence breastfeeding decisions and competition with public donor milk systems.

The 2026 WHO standards furthermore emphasize that donor recruitment should be based on the availability of surplus milk beyond the needs of the donor's own child. This principle reflects the importance of ensuring that milk donation does not compromise the health, nutrition or feeding of the donor's infant. Public human milk banks are specifically encouraged to recruit only mothers who can safely donate milk in excess of their infants' needs.

These standards reinforce concerns regarding commercial models that depend on a continuous supply of human milk as a raw material. A commercial market may create incentives that differ from those guiding public milk banking systems and may increase pressure on donor recruitment in ways that are not aligned with the public health objectives identified by WHO.

The case of Cambodia illustrates these concerns particularly well. In 2017, the Cambodian government prohibited the commercial export of human milk following concerns raised by UNICEF regarding the sourcing of milk from women living in economically precarious circumstances. This situation highlighted the risks associated with creating an international market for human milk that relies on economic disparities between populations.

The commercialization of human milk also raises important equity concerns. While public milk banks distribute human milk based on the clinical needs of the most vulnerable infants, a commercial market necessarily relies on the purchasing power

of families or health care institutions. This logic differs fundamentally from a needs-based public health approach.

MAQ believes that the modernization of Divisions 24 and 25 is the occasion to clearly prohibit commercialization of human milk by private interests. The recent WHO standards further reinforce the distinction between donor human milk used within public health systems and human milk treated as a commercial product. Throughout the document, donor human milk is considered within a framework of equitable access, ethical governance, breastfeeding protection and integration into health services. The standards do not approach donor human milk primarily as a market commodity, but rather as a specialized health intervention intended for vulnerable infants.

Supporting public human milk banks is consistent with public health, equity and infant protection objectives. By contrast, the commercialization of human milk raises concerns that warrant a distinct and much more comprehensive assessment before being incorporated into the Canadian regulatory framework.

Recommendation 16 : Prohibit the commercialization of human milk and support public human milk banks

MAQ recommends that Health Canada prohibit the commercialization of human milk by private interests in Canada and exclude commercially sourced human milk from the regulatory framework applicable to pre-packaged human milk.

MAQ further recommends that Health Canada use the 2026 WHO Standards for Donor Human Milk Banking as a primary reference in the development of the Canadian regulatory framework governing donor human milk, including provisions related to ethical sourcing, donor protection, equitable access, breastfeeding protection and governance.

MAQ also recommends that federal and provincial governments support the development and long-term sustainability of public human milk banks in order to ensure equitable access to donor human milk for infants with the greatest clinical need.

10. Compositionnal requirements

MAQ believes that compositional requirements applicable to products intended for infants should be evaluated through the lens of the precautionary principle. Infants constitute a particularly vulnerable population, and products intended for them may represent their primary, or even sole, source of nutrition during critical periods of growth and development.

Recent international contamination events involving arachidonic acid (ARA) oil illustrate the importance of maintaining a cautious approach to ingredients used in products intended for infants. In 2026, WHO reported a multi-country food safety event that led to recalls of infant formula and other nutritional products in 99 countries and territories following contamination of ARA oil with cereulide toxin.¹⁶ WHO highlighted the particular vulnerability of infants to such events, as well as the importance of traceability, surveillance and risk-management mechanisms associated with ingredients used in products intended for this population.

This event serves as a reminder that the evaluation of compositional requirements should not be limited to the expected benefits of proposed ingredients or formulations. It should also take into account scientific uncertainties, potential risks and the consequences that failures in ingredient supply chains may have for a particularly vulnerable population.

Recommandation 17 : Apply the precautionary principle to compositional requirements and monitor emerging food safety risks

MAQ recommends that Health Canada apply the precautionary principle when establishing and revising compositional requirements for products intended for infants and young children.

MAQ further recommends that Health Canada actively monitor and assess emerging scientific and food safety concerns related to ingredients used in infant nutrition products, including the recent international food safety event involving arachidonic acid (ARA) oil contamination, and update regulatory requirements when new evidence indicates potential risks to infant health.

¹⁶ World Health Organization. (2026, March 13). International food safety event: Infant formula and products containing arachidonic acid oil contaminated with cereulide toxin – Multi-country (DON596). <https://www.who.int/emergencies/disease-outbreak-news/item/2026-DON596>

11. Conclusion: towards a modernization aligned with international standards

Taken together, the *International Code of Marketing of breastmilk Substitutes*, the *WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children*, the *WHA Resolutions 39.28 and 69.9*, the *2018 WHO Information Note*, and the *Codex Standard for Follow-up Formula for Older Infants and Product for Young Children (CXS 156-1987)* support a regulatory approach in which products marketed for children under 36 months receive distinct consideration because of their potential influence on breastfeeding, complementary feeding and young child nutrition.

While several elements of Health Canada's proposals move in this direction, important gaps remain with respect to product categorization, cross-promotion, the treatment of products that function as breastmilk substitutes and the public health rationale underlying certain product categories and ingredients. Addressing these gaps would strengthen the alignment of the modernization of Divisions 24 and 25 with internationally recognized standards and contribute to a regulatory framework that better protects breastfeeding and supports optimal infant and young child feeding practices.