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REGIONAL OFFICE FOR Europe

EFFECTIVE REGULATORY FRAMEWORKS FOR

ENDING INAPPROPRIATE MARKETING OF BREAST-MILK SUBSTITUTES AND FOODS FOR INFANTS AND YOUNG CHILDREN

in the WHO European Region

ABSTRACT

This Policy Brief is intended to guide Member States in the WHO European Region as they embark on the vital task of safeguarding parents and caregivers from all forms of promotion of breastmilk substitutes (BMS) and the inappropriate promotion of foods for infants and young children (FIYC). Such promotion undermines optimal infant and young child feeding practices, including breastfeeding and safe and appropriate complementary feeding, placing a child's survival, growth and development at risk. It can also contribute to the growing public health problem of childhood overweight and obesity, which can lead not only to premature mortality from non-communicable diseases (NCDs), but also to adverse health outcomes throughout life. In Eastern Europe and Central Asia, the number of children under five with overweight has increased from 1.6 million in 2000 to 4.5 million in 2016.

United Nations human rights experts have reminded States of their obligations under human rights treaties 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 3 years".

The International Code of Marketing of Breastmilk Substitutes and subsequent Resolutions by the World Health Assembly, along with the 2016 WHO Guidance on ending the inappropriate promotion of foods for infants and young children provide the regulatory framework to put an end to unethical marketing practices. This policy brief provides step-by-step guidance on how to review the current level of national implementation of these instruments and then proceed to strengthen measures and establish effective systems for implementation and enforcement. This includes the use of a "model law" developed specifically for the Region to demonstrate what effective regulations should look like

KEYWORDS

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POLICY BRIEF

INTRODUCTION

Over the past few decades, public health experts on infant and early-life nutrition have tended to focus on stunting and wasting (undernutrition) in children and the importance of the protection, promotion and support of breastfeeding as one of the most effective ways to ensure child health and survival (1,2).¹ The adoption of the International Code of Marketing of Breast-milk Substitutes (3) by the World Health Assembly in 1981 was an important milestone in protecting parents and caregivers from one of the major obstacles to successful breastfeeding: the unethical and aggressive promotion of breast-milk substitutes (BMS) by the baby food industry. Since then, the World Health Assembly has adopted a series of subsequent resolutions to update the Code and address new forms of promotion or clarify ambiguities in the original Code. (References to the Code in this policy brief refer to the Code and subsequent relevant World Health Assembly resolutions.) As of 2020, 136 countries around the world have adopted some form of regulation to implement the Code, which includes 51 of the 53 Member States in the WHO European Region (4).

Greater attention has been paid more recently to the problem of childhood overweight and obesity as an equally worrying form of malnutrition, contributing not only to premature mortality from noncommunicable diseases (NCDs) but also to adverse health outcomes throughout the life course (5). Globally in 2019, an estimated 38.2 million children aged 5 years and younger were overweight or obese (6). In eastern Europe and central Asia, the number of children under 5 years with overweight had increased from 1.6 million in 2000 to 4.5 million in 2016 (7).

It is important to emphasize that when manufacturers of BMS target mothers with promotional material intended to persuade them to give up breastfeeding and switch to inferior and expensive substitutes, they are violating the human rights of both the mother and her child. This was perhaps best expressed by a former UNICEF Deputy Director Stephen Lewis when addressing a meeting in Geneva in 1999, where he announced that such companies “are not to be regarded as clever entrepreneurs just doing their job, but as human rights violators of the worst sort” (8). More recently, United Nations experts have agreed that “Breastfeeding is a human rights issue for both the child and the mother.” They went on to remind States of “their obligation under relevant human rights treaties to provide all necessary support and protection to mothers and their infants and young children to facilitate optimal feeding practices ... [and 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 3 years” (9).

As is the case with the promotion of BMS, the inappropriate promotion of complementary foods can undermine optimal infant and young child feeding. It can lead to the premature cessation of exclusive breastfeeding, displacement of breast-milk after the age of 6 months, or to the consumption of food products for infants and young children (FIYC) with insufficient nutritional value as well as foods with high levels of free sugars, salt, and saturated fat. FIYC refers to any manufactured food or drink other than a BMS that is marketed as suitable for infants and young children. Inappropriate promotion of FIYC may also displace more affordable, nutrient-dense, home-prepared and locally available foods. This could give parents and caregivers the false impression that FIYC are superior to home-prepared meals, or foster an overreliance on FIYC as a convenient substitute (10).

¹ According to the World Health Assembly, the global public health recommendation is for exclusive breastfeeding for six months, and thereafter the provision of safe and appropriate complementary foods, with continued breastfeeding up to two years of age or beyond (11).

While breastfeeding can also contribute to a reduction in the risk of overweight and obesity in children, improved complementary feeding practices are necessary not only to address undernutrition but also to attain the United Nations global target for a 25% reduction in premature mortality from NCDs by 2025 (10).

In 2010, the World Health Assembly emphasized the need to address “the double burden of malnutrition”, which includes both under- and overnutrition, calling on Member States to put an end to the inappropriate promotion of FIYC while strengthening the implementation and enforcement of the Code. While the Code provided clear guidance on regulating the marketing of BMS, most Member States were unclear as to what was considered appropriate or inappropriate in the marketing of complementary foods. Therefore, in 2012 the World Health Assembly requested that guidance be developed by WHO, the official secretariat of the World Health Assembly, which resulted in the 2016 Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children (the Guidance) (11). This was welcomed by the World Health Assembly, together with a call on Member States to implement recommendations from the Guidance, while continuing to implement the Code (12). In the WHO European Region, Member States reaffirmed the need to promote appropriate complementary feeding practices through the WHO European Food and Nutrition Action Plan 2015–2020 (13), notably by establishing standards for the marketing of FIYC.

REGULATING THE MARKETING OF FOODS FOR INFANTS AND YOUNG CHILDREN

In 2019 the WHO Regional Office for Europe carried out a study of the availability, composition and marketing of FIYC in four Member States of the Region (14) to help Member States to understand the range of FIYC currently in the market, and to support implementation of the Guidance at the regional level. This study found evidence of widespread inappropriate promotion of FIYC and concluded that, despite globally agreed rules on the promotion of foods for infants and children and the elapse of nearly 40 years since the introduction of the Code, many companies were failing to adhere to these rules. According to the Report, action is required by Member States, with the support of the WHO Regional Office for Europe, to ensure effective implementation of the Code and the Guidance and to end the inappropriate promotion of FIYC.

Additionally, a discussion paper in 2019 outlined the first steps in developing a nutrient profile model to drive changes to product composition and labelling and promotion practices in the WHO European Region (15) as a basis for discussion and consultation with Member States. Nutrient profiling is the science of classifying or ranking foods according to their nutritional composition for reasons related to preventing disease and promoting health (16) and a guiding principles and framework manual for the development or adaptation of nutrient profile models is currently in development.

This Policy Brief is intended to guide Member States as they embark on safeguarding parents and caregivers from all forms of promotion of BMS and the inappropriate promotion of FIYC through the effective implementation, monitoring and enforcement of the Code and the Guidance.

INAPPROPRIATE PROMOTION OF FIYC AND ADVERSE EFFECTS OVER THE LIFE COURSE

Safeguarding caregivers from the inappropriate promotion of FIYC should be seen as part of a continuum of protection from harmful marketing required throughout the life of a child (a child being understood to

mean someone below 18 years of age in accordance with the United Nations Convention on the Rights of the Child (17)) to promote health and prevent disease. This begins with implementation of the Code in order to protect pregnant and breastfeeding women, their family members and the health workers who counsel them from the unethical marketing of formula milks, bottles and teats; it moves on to safeguarding caregivers from the inappropriate promotion of FIYC through implementation of the Guidance and then to the protection of children themselves from the harmful effects of the promotion of foods targeted directly at them through implementation of the Set of recommendations on the marketing of foods and non-alcoholic beverages to children (18,19). This Policy Brief focuses on the first two forms of promotion, which are aimed at pregnant women, parents and caregivers. Ideally, this would be addressed in a single regulatory instrument incorporating all of the provisions of the Code and the Guidance. Member States should also be aware of additional regulatory requirements as part of efforts to prevent overweight and obesity in childhood and adolescence in relation to the marketing of foods and beverages; labelling; reformulation; fiscal measures (such as sugar taxes); and policies and standards around food and beverages provided in schools. UNICEF has a number of documents that support measures for prevention of overweight and obesity in children and adolescents (5,20).

THE GUIDANCE

Following the 2012 request from the World Health Assembly to the WHO Director-General for clarification and guidance on the inappropriate promotion of foods for infants and young children, a Scientific and Technical Advisory Group was established in 2013. The Group developed a discussion paper containing a set of recommendations that were made available for public scrutiny and comment (15). Informal dialogues were subsequently convened with nongovernmental organizations (NGOs) and private sector entities, as well as an informal consultation with Member States and with other United Nations bodies.

The WHO Secretariat submitted the guidance document for consideration by the 69th World Health Assembly in May 2016, with the Assembly declaring, in resolution WHA69.9, that it “WELCOMES with appreciation the technical guidance on ending the inappropriate promotion of foods for infants and young children” (12). However, there were concerns that the World Health Assembly did not adopt or endorse the guidance as it had in the past with other policy recommendations. The use of this wording does not undermine the fact that the World Health Assembly went on to urge Member States, in accordance with their national context, “to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children, including, in particular, implementation of the guidance recommendations”. Clearly, the guidance can be regarded as a World Health Assembly-supported policy recommendation with similar status to the Code itself.

Whereas the Code applies to the marketing of BMS, feeding bottles and teats, the Guidance applies to all commercially produced foods that are marketed as being suitable for infants and young children aged 6–36 months. Products are considered to be marketed as being suitable for this age group if they:

- are labelled with the words “baby”, “infant,” “toddler” or “young child”;
- are recommended for introduction at an age below 3 years;
- have a label with an image of a child who appears to be below the age of 3 years or feeding with a bottle; or
- are in any other way presented as being suitable for children below the age of 3 years.

The Guidance Implementation Manual explains that this “does not include infant formula, as this product is covered by the International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly resolutions... However, follow-up formula (or follow-on milks) and so-called growing up milks are covered” (10).

With regard to the types of manufacturer covered by the Guidance, particularly in relation to recommendation 6, which deals with avoiding conflicts of interest in the health-care system, this includes all companies that market foods for infants and young children. As “foods for infants and young children” are defined in the Guidance as “commercially produced food or beverage products that are specifically marketed as suitable for feeding children up to 36 months of age” (11), this would include manufacturers and distributors of all BMS, including infant formulas, and FIYC intended for consumption by children up to the age of 36 months.

The six recommendations that Member States are urged to implement are as follows.

- 1. Promote optimal infant and young child feeding** based on the guiding principles for complementary feeding of the breastfed child (21) and for feeding non-breastfed children aged 6–24 months (22). It is important to ensure an emphasis on the use of suitable, nutrient-rich, home-prepared and locally available foods that are prepared and fed safely, avoiding an overreliance on commercially produced products, which may be more costly but still inferior in terms of nutritional value.
- 2. Prohibit all promotion of products that function as BMS** and clearly define which milks are to be considered as BMS: meaning any milk, or product that could be used to replace milk, marketed for feeding infants and young children up to the age of 3 years. This would include follow-up or follow-on milks or any growing-up or toddler milks, irrespective of the product name, if they are marketed as suitable for use by children younger than 3 years of age. In many countries, this will require updating of national Code regulations to ensure the coverage of all BMS products.
- 3. Apply and develop standards for foods for infants and young children** that do not function as BMS (the complementary food products). Promotion of such products should only be permitted if they meet relevant national, regional and global standards in relation to nutrient composition, safety and quality, and are in line with national dietary guidelines. This recommendation does present considerable challenges, as noted in the Guidance Implementation Manual (10): “national nutrition standards are generally lacking”, and “limited nutritional guidelines exist for products promoted to infants and young children. This is of particular concern for added sugars, salt or fats, in foods that contribute to obesity and noncommunicable diseases in later life.” The Implementation Manual also notes that “the Guidance recognizes that current Codex standards on nutrient values, particularly for added sugars and salt, are inadequate ... as such, application of current Codex standards would be insufficient for defining whether a particular food is appropriate for promotion for infants and young children.”

It is important to remember that in the absence of adequate standards, promotion of foods for infants and young children should not be permitted, and governments should focus on developing and adopting the necessary standards.

- 4. Define appropriate messages that are permitted for use in the promotion of foods for infants and young children and prohibit inappropriate ones.** Promotion can take many forms, including advertisements, sponsorship, brochures, online information and labelling. Appropriate messages should always:
 - include a statement on the importance of continued breastfeeding for up to 2 years or beyond and the importance of not introducing complementary feeding before 6 months of age;

- include the appropriate age of introduction of the food (this must not be less than 6 months); and
- be easily understood by parents and caregivers, with all required label information being visible and legible.

Messages should not:

- include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages);
- include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast milk or suggests that the product is nearly equivalent or superior to breast milk;
- recommend or promote bottle feeding; or
- convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

These requirements need to be incorporated into national, legally enforceable regulations, and this can be achieved in many countries by updating and strengthening national Code legislation, as explained below.

- 5. Prohibit cross-promotion of BMS** when promoting foods for infants and young children. Cross-promotion is defined in the Guidance as a form of marketing where customers of one product or service are targeted with the promotion of a related product. This often involves similar packaging in terms of the use of the same or similar brand names, logos and/or designs such that one product closely resembles the other. Often companies that manufacture BMS and complementary foods will use a common mascot, such as a teddy bear or animal on the packaging of both products. In order to prohibit cross-promotion:

- the packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for BMS so that they cannot be used in a way that also promotes BMS (for example, different colour schemes, designs, names, slogans and mascots other than the official company name and logo should be used); and
- companies that market BMS should refrain from engaging in the direct or indirect promotion of their other FIYC by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).

Again, such requirements should be incorporated into national regulations, preferably by amending and strengthening national Code regulations.

- 6. Eliminate conflict of interest in the health-care system.** The Code, as adopted in 1981, failed to deal adequately with conflict of interest, and manufacturers of BMS were permitted to make contributions to health workers for fellowships, study tours, research grants, attendance at professional conferences and the like. The only condition was that both the manufacturer and recipient should disclose the support to the institution to which the health worker was affiliated. Over the years there was growing recognition and concern that such sponsorship often creates a sense of obligation on the part of the health worker to reciprocate in kind, resulting in an unconscious bias in favour of the manufacturer and its products [23]. Recommendation 6 addresses this problem by describing behaviours that are considered conflicts of interest and should not be permitted in an attempt to distance the baby food industry from the health-care system and caregivers. Recommendation 6 applies not only to companies

that market foods for infants and young children, but also to health workers, health systems, health professional associations and NGOs, who should also avoid such conflicts of interest. Companies, or their representatives, should not:

- provide free products, samples or reduced-price foods for infants or young children to families through health workers or health facilities, except as supplies distributed through officially sanctioned health programmes (and in this case, products should not display company brands);
- donate or distribute equipment or services to health facilities;
- give gifts or incentives to health-care staff;
- use health facilities to host events, contests or campaigns;
- give any gifts or coupons to parents, caregivers and families;
- directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities;
- provide any information for health workers other than that which is scientific and factual; or
- sponsor meetings of health professionals and scientific meetings.

Likewise, health workers, health systems, health professional associations and NGOs should not accept or allow any of the above.

It is worth noting that it is not always easy to identify or categorize companies that market foods for infants and young children in terms of the inclusion of subsidiary or parent companies. In the United States of America, for example, all of the major brands of jarred baby food experienced changes in ownership between 2000 and 2008 (24). Member States need to consider the development of criteria for identifying companies that should be subject to the conflict-of-interest prohibitions.

These important prohibitions need to be included in national regulations, which can be achieved by amending and strengthening national Code regulations.

METHODS TO REVIEW NATIONAL CODE REGULATIONS TO IDENTIFY WEAKNESSES AND LOOPHOLES

It is important to have methods to assess strengths and weaknesses in national Code regulations, particularly with regard to the incorporation of the recommendations from the Guidance. Not all Member States in the WHO European Region are starting from the beginning when it comes to adopting national regulations to implement the Code or, to a lesser extent, the Guidance; all have some form of legal measure in place to implement the Code, with the exception of Israel and Montenegro.

Since 2016, the International Baby Food Action Network (IBFAN) UNICEF and WHO and have issued biennial status reports on national implementation of the Code. So far, each report has highlighted a specific aspect of Code implementation, beginning in 2016 with a focus on monitoring and enforcement mechanisms (25). The 2018 report contains a preliminary analysis of selected legal provisions in those countries where complementary foods are listed as designated products in their Code-related legislation (26). This was done to provide a baseline assessment of the 2016 Guidance and to provide a useful starting point to assess the extent to which the current legal and regulatory landscape in countries is supportive of effective implementation of the recommendations of the Guidance.

The 2020 Status Report highlights specific provisions considered to be particularly instrumental in addressing and eliminating the promotion of BMS, feeding bottles and teats to health workers and in health facilities (4). In the 2020 Status Report, a new scoring algorithm was used to classify national Code regulations based on a checklist developed to facilitate a systematic and objective classification of countries according to their alignment with the Code. For the first time, this included several of the recommendations from the Guidance. The report provides an excellent, ready-made analysis of all existing national measures, enabling governments, policy-makers or advocates to pinpoint legislative strengths, weaknesses and loopholes in their country. Armenia, for example, scores an enviable 90/100, ranking as “substantially aligned with the Code”. Annex 4 in the 2020 Report shows that Armenia’s regulations cover all BMS products up to the age of 36 months, as well as complementary foods, in line with the Code and WHO Guidance.

However, for the Member States of the European Union (EU), where national regulations are determined by European Commission delegated regulation 2016/127 (27), we see that these countries only score 39/100, and Annex 4 reveals that, among other weaknesses, regulations only cover BMS for children up to the age of 12 months, and do not cover complementary foods at all. Several non-EU Member States in the Region also scored poorly, some having scores as low as 14, 16 or 18 out of 100.

The algorithm developed for the 2020 Status Report classified national legal measures as shown in Table 1.

Table 1. Scoring algorithm to classify national legal measures on the Code

Measure	Total points possible
Scope	20
Monitoring and enforcement	10
Informational/educational materials on IYCF	10
Promotion to general public	20
Promotion in health-care facilities	10
Engagement with health workers and systems	15
Labelling	15
Total	100

Source: WHO, 2020 (4).

Annex 1 of the report then provides details of the number of points provided for each Code/Guidance provision included in the analysis, Annex 2 outlines the legal status of each country’s national regulations and Annex 3 shows how these regulations scored for each category of Code provisions analysed.

As an example, In Tables 2-4, Armenia, a non-EU Member State, is compared with EU Member States whose national regulations follow Regulation 609/2013 as supplemented by EU Commission Delegated Regulation 2016/127.

Table 2. Entry in Annex 2 in the 2020 Status Report for the legal status in Armenia and EU Member States

Country	Region	Date of legal measure	Legal status of the Code (category)
Armenia	European	2014	Substantially aligned with the Code
EU Member States	European	2013, 2016	Moderately aligned with the Code

Adapted from: WHO, 2020 (4).

Table 3. Regulation scores for Code categories in Annex 3 of the 2020 Status Report for Armenia and EU Member States

Measure	Armenia	EU Member States
Scope (out of 20)	20	8
Monitoring and enforcement (out of 10)	8	0
Informational/educational materials on IYCF (out of 10)	9	3
Promotion to general public (out of 20)	17	17
Promotion in health-care facilities (out of 10)	10	0
Engagement with health workers and systems (out of 15)	14	0
Labelling (out of 15)	12	11
Total (possible score of 100)	90	39

Source: WHO, 2020 (4).

Table 4. Scores for scope and for monitoring and enforcement requirements in Annex 4 of the 2020 Status Report for Armenia and EU Member States

Country	Scope				Monitoring and enforcement	
	BMS products covered up to age (months)	Complementary foods	Bottles and teats	Identifies who is responsible for monitoring compliance	Defines sanctions for violations	Requires that monitoring and enforcement should be independent, transparent and free from commercial influence
Armenia	36	+	+	+	+	-
EU Member States	12	-	-	-	-	-

Adapted from: WHO, 2020 (4).

So while Armenia may need to adjust its regulations a little for monitoring and enforcement or labelling, the scores for EU Member States indicate that in EU Member States the regulations need to be strengthened considerably, particularly in the areas of scope (products covered), informational and educational materials, promotion in health-care facilities and engagement with health workers and health systems. The reviews in Annexes 4–9 of the 2020 Status Report provide further detailed information on where the strengths and weaknesses are in relation to each of these categories (4). For example, Annex 4 provides an indication of the products covered or not covered under the scope of the national regulations and monitoring and enforcement requirements using a tick or cross system. Table 4 shows that while Armenia needs only to work on ensuring that monitoring and enforcement are independent, transparent and free from commercial influence, EU Member States have much work to do in expanding the scope of their regulations to cover

all BMS products up to the age of 36 months, complementary foods, and bottles and teats, as well as identifying independent monitoring mechanisms and defining sanctions for violations of their regulations.

Annexes 5–9 provide similar checklists:

Annex 5: provisions on informational and educational materials

Annex 6: provisions on promotion to the general public

Annex 7: provisions on promotion in health-care facilities

Annex 8: provisions on engagement with health-care workers and health systems

Annex 9: provisions on labelling.

While the 2020 Status Report did not include the existence of national or regional standards or nutrient profile models as part of the scoring of national regulations, as per recommendation 3 of the Guidance, Annex 3 of the 2018 Status Report indicated that there is not a single instance of a country incorporating or referencing such standards in national Code regulations (26). This highlights the need for governments to prioritize the development of nutrient profiles and standards for foods for infants and young children (28) based on the draft nutrient profile model proposed in the WHO Regional Office for Europe's discussion paper (15).

THE MODEL LAW AS A TOOL TO HELP TO STRENGTHEN NATIONAL REGULATORY FRAMEWORKS

The Model Law is a tool that has been developed to help to strengthen national regulatory frameworks to protect infants and young children from the harmful effects of food marketing. Having analysed national measures and identified weaknesses and loopholes that need to be addressed, policy-makers can turn to a Model Law for assistance in finding appropriate legal language to strengthen their national Code regulations, ensuring they incorporate all of the provisions of the Code, including the Guidance.

The Model Law was developed by the International Code Documentation Centre, which is part of IBFAN, with input from a variety of international Code and legal experts. It has been updated regularly as new resolutions have been adopted by the World Health Assembly and is contained in Annex 4 of Code Essentials 2 (29). For many years, IBFAN, UNICEF and WHO have advocated for the use of the Model Law as a tool to assist in drafting national Code regulations in workshops and capacity-development endeavours at international, regional and national levels. The Model Law has been used as the basis for the drafting of some of the highest-scoring national regulations in the 2020 Status Report, including those adopted in Armenia, and has been further adapted for this Policy Brief to incorporate additional requirements on packaging and labelling proposed by the WHO Regional Office for Europe.

Contents of the Model Law

The Model Law sets out to be the foundation for regulations or laws “to ensure safe and adequate nutrition for infants and young children by protecting breastfeeding and by regulating the marketing of food products manufactured for infants and young children and of feeding bottles, teats and pacifiers” (29). The whole content of the Model Law revised for European Countries is given in Annex 1 of this Policy Brief and an overview of it is given here.

Chapter I: the introductory chapter

This chapter includes the definitions (Section 2). National regulations must be clear and concise and ensure that all parties understand which products are covered by the regulations, and what sorts of behaviour are or are not permitted. This requires agreed-upon definitions, and the Model Law includes definitions that incorporate the requirements of the Guidance, such as the need to cover all milk products marketed for children up to the age of 3 years within the scope, and to prohibit cross-promotion.

Chapter II: prohibitions

Section 4 of this chapter provides language to effectively prohibit:

- promotion to the public, including at the retail level;
- promotion through the health-care system and contact with health workers and health systems, including those activities considered to constitute a conflict of interest under the 2016 Guidance;
- behaviour by health workers or their associations that would constitute a conflict of interest;
- the use of health or nutrition claims;
- cross-promotion; and
- the use of inappropriate messages in the promotion of complementary foods, while requiring statements that support breastfeeding and reinforce the appropriate age of introduction of complementary feeding.

Sections 5–11 of Chapter II provide prohibitions and requirements for labels of all products covered by the Code, as well as specific requirements for different categories of products: infant formula, follow-on formula and young child formula (Section 6), complementary foods (Section 7), feeding bottles and teats (Section 10) and pacifiers (Section 11).

In addition to the model provisions contained in Section 7, the proposed requirements on packaging and labelling from Ending Inappropriate Promotion of Food Products for Infants and Young Children Between 6 and 26 months in Europe (15) should also be incorporated into national regulations:

- Other products on the market targeted at older children over 36 months that are unsuitable for infants and young children up to 36 months (those that are not intended for infants and young children, do not comply with the nutrient profile model and/or do not meet other regulatory requirements for FIYC) should clearly state a minimum age of 36 months/3 years on packs (including sweet breakfast cereals, energy drinks and children's snack foods).
- All FIYC containing fruit (fresh or processed in any way) should state the percentage of this product in the ingredient list
- All FIYC should state the percentage of added water in the ingredients list.
- Food packaging with a spout should state clearly, "Infants and young children must not be allowed to suck directly from the pouch/pack/container".
- If the total sugar content exceeds specified limits, the front of pack must show the percentage of energy from total sugar. Limits for different foods are set at 30% energy for dry cereals and fruit/vegetable purées, 40% for dairy-based foods, 20% for vegetable purées with cereals or milk, and 15% for savoury and meal-type foods.
- Front-of-pack product names should better reflect the ingredients in descending order of content to

ensure they do not mislead parents and caregivers. They must state the name of the largest ingredient, when appropriate, as the first listed food in the front-of-pack product name and possibly with the amount expressed as a percentage of total weight or in grams or other measures (according to country customs) in the ingredient list.

Chapter III: health worker responsibilities

Health worker responsibilities include their duty to encourage, support and protect breastfeeding and to know the provisions of national regulations.

Chapter IV: information and education

Chapter IV aims to ensure that all information and education received by the public on the topic of infant and young child feeding is up to date, evidence based and does not undermine breastfeeding or encourage bottle feeding. Materials must not mention the brand name or logo of any product or manufacturer. Materials should also emphasize the importance of introducing complementary foods from the age of 6 months, while reassuring caregivers that complementary foods can easily be prepared at home using local ingredients (Section 13). When it comes to providing information about the use of BMS, Section 14 requires that caregivers receive adequate instructions on the use of the products, along with warnings on the risks of their use, including the fact that powdered formula is not sterile and may be contaminated with pathogenic microorganisms and needs to be prepared carefully in accordance with the instructions. While manufacturers and distributors may provide information to health professionals on their products, these materials must be restricted to scientific and factual matters, backed up by reference to published and peer-reviewed studies (Section 15).

Chapters V and VI: administration, sanctions and procedure

Chapters V and VI are intended to provide an example of the types of bodies/systems and mechanisms that need to be established to implement, monitor and enforce national regulations. However, since the Model Law was adopted, UNICEF and WHO have established the Network for Global Monitoring and Support for Implementation of the International Code of Marketing of Breast-milk Substitutes and Subsequent Relevant World Health Assembly Resolutions (NetCode) with the goal of strengthening Member States' and civil society capacity to monitor the Code, and to facilitate the development, monitoring and enforcement of national Code legislation by Member States. The NetCode Toolkit for Ongoing Monitoring and Periodic Assessment of the Code (30) will assist in establishing effective and sustainable systems that will:

- detect violations of national regulations;
- document and report such violations;
- investigate and validate whether the reported activities are indeed violations;
- activate an enforcement mechanism that would stop such violations and deter future violations; and
- hold manufacturers, distributors, retail outlets, the health-care system and health-care workers to account for their breaches of national regulations.

Using the model law to strengthen weaknesses in current regulations

Returning to the review of national Code regulations carried out in accordance with the information provided in the 2020 Status Report, those involved in strengthening measures can turn to the appropriate sections of the Model Law to correct weaknesses and loopholes identified in the national regulatory measures. For example, in EU Member States, where the analysis showed a poor score in terms of the scope of their regulations (Tables 2–4), drafters should turn to Chapter I of the Model Law, and more specifically Section 2 (10) which provides the following definition of “designated” products that should be covered:

“**Designated product**” means

- (a) infant formula;
- (b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;
- (c) follow-up formula;
- (d) young child formula;
- (e) ready-to-use therapeutic food;
- (f) complementary food product;
- (g) feeding bottles, teats, pacifiers; and
- (h) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a “designated product” for the purposes of this Act.

By incorporating this wording into their revised regulations, they can be sure that they are aligning their regulations with the Code and international public health policy.

Similarly, EU Member States (Tables 2–4) that lack elements of the required labelling information for infant and follow-up formulae, should turn to Section 6 of the Model Law for specific wording on required warnings, notices and instructions (as well as the proposed requirements on packaging and labelling from Ending Inappropriate Promotion of Food Products for Infants and Young Children Between 6 and 36 months in Europe (15)).

ADOPTING, IMPLEMENTING, MONITORING AND ENFORCING EFFECTIVE NATIONAL REGULATIONS

Having identified weaknesses in the national regulatory framework and knowing where to find appropriate legal language to rectify these are small parts of the drafting and legislative process. Unfortunately, many countries reach this stage and develop a draft that then goes no further. Some of the general principles and steps that should be followed to ensure the successful adoption, implementation and enforcement of the Code legislation are to:

- use a human right-based approach, recalling that Code implementation is the fulfilment of legal obligations under relevant human rights treaties 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” (9);

- remember that implementation of the Code and the Guidance is part of a comprehensive and consistent approach for promoting healthy diets and preventing overweight and obesity in children, and that alignment between measures is desirable to increase public health impact;
- ensure the process is government led, leading to the adoption of *mandatory* measures accompanied by monitoring and enforcement measures, rather than utilizing voluntary actions such as industry-led self-regulatory codes, or co-regulatory public–private partnerships; and
- ensure there is multisector engagement involving the necessary range of government departments and agencies, including those representing health, business and commerce, trade and investment, food and agriculture, media and communications, consumer affairs, education, and relevant enforcement agencies.

The Guidance Implementation Manual (10) provides useful tips on managing the legislative process, including the involvement of:

- legal experts with experience, skills and knowledge in law making, government powers and procedures, and constitutional issues, to work alongside public health practitioners with knowledge of the issues around the marketing of foods, and infant and young child health and nutrition;
- other key experts, including members of the legislative body who will ultimately have to enact legislation and, therefore, need to understand why it is important and how to advocate for it; and
- supporters and champions of legislation, including civil society organizations, political figures, academic experts, religious leaders and celebrities.

The Implementation Manual points out that the involvement of food manufacturers and distributors during the drafting process is inappropriate as it would represent a conflict of interest. Companies should be given an opportunity to comment on the draft regulations along with other interested parties, preferably through a public process where objections and comments are submitted in writing and placed on public record.

IBFAN, UNICEF and WHO have successfully organized and promoted capacity-building workshops at international, regional and national levels in order to bring the relevant parties together to create a shared understanding of the urgent need for and rationale behind effective Code implementation. These workshops can also assist in the drafting of appropriate regulations and the development of a strategy for their adoption, application, monitoring and enforcement. UNICEF and WHO remain available to provide such support.

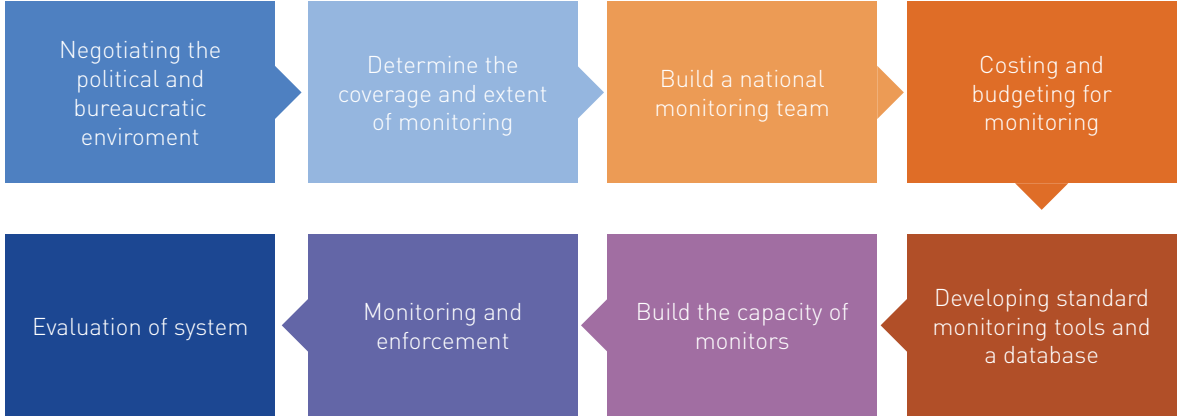
Monitoring and enforcement of national Code regulations is essential to the effective protection of caregivers and infants and young children from inappropriate and harmful promotion. Yet the 2016 Status Report (25) highlighted that only 32 countries in the world reported having a monitoring mechanism in place, and of those, few were fully functional. It was with this in mind that NetCode was established and the NetCode Toolkit for Ongoing Monitoring and Periodic Assessment of the Code was developed (30). The Toolkit is intended to assist governments in establishing a sustainable system that will monitor, detect and report violations of national regulations, enabling relevant enforcement actions to be taken so that violators can be held accountable for behaviour and practices that undermine breastfeeding and place the health of infants and young children at risk. Governments should view the establishment of the monitoring system as an integral part of the implementation of the Code and Guidance, and the protocol provides a user-friendly, step-by-step guide on how to achieve that goal and how to establish and operationalize an ongoing system (Fig. 1).

Fig. 1. A step-by-step guide to setting up a national monitoring system

The establishment of an effective and sustainable monitoring system requires the following steps:

A	Negotiate the political and bureaucratic environment;
B	Determine the coverage and extent of monitoring activities based on provision of national laws (what and where and when to monitor);
C	Build a national monitoring team to monitor, report and act upon violations of national laws (who should monitor, including through identified existing monitoring mechanisms);
D	Determine the cost of establishing and maintaining a national monitoring system, and budget for, and allocate resources, accordingly (including identification of existing resources, where possible);
E	Develop standard monitoring tools and a database, based on the NetCode universal monitoring form;
F	Build the capacity of monitors;
G	Monitor and enforce to capture and act upon violations of national laws; and
H	Evaluate and assess effectiveness of monitoring system.

Establishing and operationalizing an ongoing national monitoring system



The Toolkit guides the reader through each of the eight steps and provides templates for data entry forms and reporting as well as instructions for data entry and the development of central databases and suggested modules for building capacity of monitors. Again, UNICEF and WHO have developed resources to assist governments in the use of the Toolkit to establish an effective, sustainable ongoing monitoring system.

CONCLUSIONS

In order to protect the human rights of mothers, caregivers, infants and young children in the WHO European Region, through effective implementation and enforcement of the Code, the Guidance and the European Food and Nutrition Action Plan 2015–2020, Member States should:

- review their national Code regulations to identify weaknesses and loopholes, particularly with regard to the incorporation of the recommendations from the Guidance, using the 2020 Status Report to create a table/list of matters requiring revision and strengthening;
- as part of the drafting process, refer to the Model Law for Europe – which includes the WHO Regional Office for Europe’s proposed requirements on packaging and labelling for complementary foods for language to be included in strengthened regulations;
- manage the legislative process in accordance with the Guidance Implementation Manual;
- ensure that the establishment of a sustainable ongoing monitoring system is an integral part of the legislative process, following the NetCode Toolkit to ensure effective monitoring of the marketing of all BMS and foods for infants and young children; and
- request support from UNICEF and WHO, including the provision of technical support through the organization of capacity-building and drafting workshops.

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ANNEX 1.

MODEL LAW FOR THE WHO EUROPEAN REGION

An Act¹ to ensure safe and adequate nutrition for infants and young children by protecting breastfeeding and by regulating the marketing of food products manufactured for infants and young children and of feeding bottles, teats and pacifiers.

It is hereby enacted as follows:

CHAPTER I INTRODUCTORY

Section 1. Short Title and Commencement

- (1) This Act may be called the *[Marketing of Foods and Related Products for Infants and Young Children Act or Protection of Breastfeeding Act]*.²
- (2) This Act shall come into effect 60 days after the date of enactment.
- (3) This act extends to the whole of *[Anyland]*.

Section 2. Definitions

For purposes of this Act

- (1) “**Advertise**” means to make any communication or representation by any means whatsoever for the purpose of promoting the sale or use of a designated product, including but not limited to:
 - (a) written publication, television, radio, film, electronic transmission including the Internet, social media, video, telephone or mobile application;
 - (b) display of signs, billboards, or notices; or
 - (c) exhibition of pictures or models.
- (2) “**Advisory Board**” means a Board set up under Section 18.
- (3) “**Artificial feeding**” means feeding with any manufactured food product which replaces breastmilk either partially or totally.
- (4) “**Brand name**” means a name given by the manufacturer to a product or range of products.
- (5) “**Bottle feeding**” means feeding liquid or semi-solid food from a bottle with a teat.

¹ In common law jurisdictions, a law adopted in parliament is known as an ‘Act’ and this is the approach taken in CE2. Each distinct article in an Act is called a ‘section’. If the Code is implemented as subsidiary legislation under an existing Act, it is usually referred to as a set of ‘Regulations’. In civil law jurisdictions, the terminology used and the drafting convention may differ but the substance of legal provisions should be the same.

² Text in [] brackets can be replaced with different wording that is more appropriate to national circumstances.

- (6) “**Complementary food**” means any food suitable or represented as suitable as an addition to breastmilk, infant formula or follow-up formula for infants from the age of six months (180 days) up to the age of 36 months.³”
- (7) “**Container**” means any form of packaging of a designated product for sale as a retail unit, including wrappers.
- (8) “**Cross-promotion**” means the use of similar brand names, packaging designs, labels, text, images, colour schemes, symbols or slogans or other means for the purpose of promoting another product.
- (9) “**Designated product**”⁴ means
- (a) infant formula;
 - (b) any other product marketed or otherwise represented as suitable for feeding infants up to the age of six months;
 - (c) follow-up formula;
 - (d) young child formula;
 - (e) ready-to-use therapeutic food;
 - (f) food product for infants and young children;
 - (g) feeding bottles, teats, pacifiers; and
 - (h) such other product as the Minister of Health may, by Notice in the Official Gazette, declare to be a “designated product” for the purposes of this Act.
- (10) “**Distributor**” means a person, corporation or other entity engaged in the business of marketing any designated product, whether wholesale or retail.
- (11) “**Follow-up formula**” means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country’s standard for follow-up formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Follow-up Formula*] and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age. It is also referred to as “follow-on formula” or “follow-on milk”. For the purposes of this Act, the term ‘follow-up formula’ includes any follow up formula for special medical purposes or dietary requirements and any follow-up therapeutic milk product for acutely malnourished infants and young children.
- (12) “**Food product for infants and young children**” means a manufactured food or drink other than a breastmilk substitute, that is marketed as suitable for feeding infants and young children.
- (13) “**Health care facility**” means a public or private institution or organisation or private practice engaged directly or indirectly in the provision of health care or in health care education. It also includes a day-care centre, a nursery or other infant and young child-care facility.

3 The definition of “complementary food”, in particular its age range, will determine which complementary food product falls within the definition of “designated product”. The upper age limit for “complementary food” can be adjusted if a country chooses to limit the ban on promotion of complementary food products to say, infants or young children up to 12 or 24 months. Such discretion on age range cannot be exercised for formulaproducts. See also Subsections 4(4) and 4(5) and footnote 6.

4 By introducing this collective term, one can avoid the use of the term “breastmilk substitute”, the meaning of which is a subject of long drawn controversy. If a full range of products is listed as being covered by the term “designated product” like in this Model Law, there will be no room for dispute about the scope of the law. Text in the substantive parts of the law will be neater and easier to read as well.

(14) "Health claim" means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. A health claim includes but is not limited to the following:

- (a)** a nutrient function claim that describes the physiological role of the nutrient in growth, development and normal functions of the body;
- (b)** any other function claim concerning specific beneficial effects of the consumption of foods or their constituents that relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health; and
- (c)** a reduction of disease risk claim relating to the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

In this context, health means a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.

(15) "Health professional" means a health worker with a professional degree, diploma or licence, such as a medical practitioner, a registered nurse or midwife or such other person as may be specified by the Minister of Health by a Notice in the Official Gazette.

(16) "Health worker" means a person providing or in training to provide health care services in a health care facility, whether professional or non-professional, including voluntary unpaid workers.

(17) "Infant" means a child from birth up to the age of 12 months.

(18) "Infant formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with [*citation to the country's standard for infant formula or, in the absence of such standard, citation to the Codex Alimentarius Standard for Infant Formula*] and intended to satisfy, by itself, the nutritional requirements of infants from birth and/or during the first six months and includes products that continue to meet part of an infant's nutritional requirements after the first six months. For the purposes of this Act, the term 'infant formula' includes any formula for special medical purposes or dietary requirements and any therapeutic milk product for acutely malnourished children.

(19) "Inspector" means an inspector appointed under Section 22.

(20) "Label" means a tag, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, attached or otherwise appearing on a container of a designated product. For the purposes of Sections 5(1), 5(3), 10 and 11, the term "label" includes packaging and inserts.

(21) "Labelling" includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

(22) "Logo" means an emblem, picture or symbol by means of which a company or a product is identified.

(23) "Manufacturer" means a person, corporation or other entity engaged in the business of manufacturing a designated product whether directly, through an agent, or through a person controlled by or under an agreement with it.

(24) "Market" means to promote, distribute, sell, or advertise a designated product and includes product public relations and information services.

(25) "Minister" means Minister of Health of [*Anyland*].

- (26) **“Nutrient profile model”** means a tool used to classify foods and non-alcoholic beverages based on their nutritional characteristics. Such tools are generally used to differentiate between foods and non-alcoholic beverages that are more likely to be part of a healthy diet from those that are less likely (notably those that may contribute to excess consumption of energy, saturated fats, trans fats, sugar or salt).
- (27) **“Nutrition claim”** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute a nutrition claim:
- (a) the mention of substances in the list of ingredients;
 - (b) the mention of nutrients as a mandatory part of nutrition labelling;
 - (c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.
- (28) **“Pacifier”** means an artificial teat for babies to suck, also referred to as a “dummy”.
- (29) **“Prescribed”** or “as prescribed” means prescribed or as prescribed by rules or written decision made pursuant to this Act.
- (30) **“Promote”** means to employ any method of directly or indirectly encouraging a person, a health facility or any other entity to purchase or use a designated product whether or not there is reference to a brand name.
- (31) **“Ready-to-use therapeutic food”** means an energy-dense, vitamin- and mineral-enriched food specifically designed to treat severe acute malnutrition in children above 6 months.
- (32) **“Sample”** means a single or small quantity of a designated product provided without cost.
- (33) **“Sponsorship”** means any financial or in-kind assistance to a person or a group of persons or an entity, whether public or private, and sponsor has a corresponding meaning.
- (34) **“Young child”** means a child from the age of 12 months up to the age of three years (36 months).
- (35) **“Young child formula”** means an industrially formulated milk or milk-like product of animal or vegetable origin that is marketed or otherwise represented as suitable for feeding young children from 12 months of age. It is also referred to as “growing up milk”, “formulated milk” or “toddler milk” (note: There is as yet no international quality standard for young child formula).

CHAPTER II PROHIBITIONS

Section 3. Sale of a designated product

A person shall not distribute for sale, sell, stock or exhibit for sale any designated product that

- (a) is not registered according to Section 21 of this Act or is not in accordance with the conditions of its registration; or
- (b) has exceeded its date of minimum durability.

Section 4. Promotion

- (1) [Except as provided in Subsections 4(4) and 4(5)]⁵, a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote any designated product. Prohibited promotional practices include but are not limited to:
- (a) advertising;
 - (b) sales devices such as special displays, discount coupons, premiums, rebates, special sales, loss-leaders, tie-in sales, prizes or gifts;
 - (c) giving of one or more samples of a designated product to any person;
 - (d) donation or distribution of information or education material referring to infant or young child feeding or performance of educational functions related to infant or young child feeding, except as provided in Section 15;
 - (e) the use of health or nutrition claims on labels of designated products or in any information and education materials referring to infant and young child feeding, except as provided in Section 15; and
 - (f) cross-promotion of a designated product.
- (2) A manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf
- (a) donate, waive payment through any means or provide at lower than the published wholesale price where one exists, and in its absence, lower than 80 per cent of the retail price, any quantity of a designated product to a health worker or a health care facility;
 - (b) donate to or distribute within a health care facility equipment, services or materials such as pens, calendars, posters, note pads, growth charts and toys or any other materials;
 - (c) offer or give any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value to a health worker or to an association of health workers engaged in maternal and child health, including but not limited to fellowships, research grants or funding for meetings, seminars, continuing education courses or conferences;
 - (d) sponsor events, telephone counselling lines, campaigns or programmes related to reproductive health, pregnancy, childbirth, infant or young child feeding or related topics;

⁵ Delete as appropriate. See footnote 6 below.

- (e) directly or indirectly establish relationships with parents and other caregivers through baby clubs, social media groups, childcare classes, contests and any other means; or
 - (f) include the volume of sales of designated products in the calculation of its employee remuneration or bonuses, nor set quotas for sales of designated products.
- (3) A health worker or an association of health workers engaged in maternal and child health shall not:
- (a) accept any gift, contribution, sponsorship, benefit, financial or otherwise, of whatever value, from a manufacturer or distributor or any person on his or her behalf;
 - (b) accept or give samples of designated products to any person; or
 - (c) demonstrate the use of infant formula, except to individual mothers or members of their families in very special cases of need, and in such cases, shall give a clear explanation of the risks of the use of infant formula as well as the other information required by Chapter IV.
- (4)⁶ A manufacturer or distributor may promote a food product for infants and young children provided that:
- (a) it meets the requirements of the national nutrition profile model (and those of other relevant national standards for composition, safety and quality)
 - (b) such promotional practice does not take place in a health care facility;
 - (c) any material promoting a food product for infants and young children must include a statement in characters *[insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"]* on:
 - i. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
 - ii. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
- (5)⁷ Notwithstanding Subsection 4(4), a manufacturer or distributor shall not him or herself, or by any other person or entity on his or her behalf, promote a food product for infants and young children through the use of messages in any form or media that are prohibited by Subsection 7 (1) (a) – (f).

Section 5. Prohibitions related to labelling of designated products

- (1) Except as provided in Subsection 7(1), a manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto includes a photograph, drawing or other graphic representation other than for illustrating methods of preparation.
- (2) A manufacturer or distributor shall not offer for sale or sell a designated product, other than a feeding bottle, teat or pacifier, unless the labelling thereto indicates in a clear, conspicuous and easily readable manner, in [insert appropriate language(s)], the following particulars:
- (a) instructions for appropriate preparation and use in words and in easily understood graphics;
 - (b) the age in numeric figures after which the product is recommended;

⁶ Subsections 4(4) and 4(5), based on the Guidance on ending the inappropriate promotion of foods for infants and young children (69/7 Add.1), are only applicable to countries that choose to permit certain types of promotion for food products for infants and young children, e.g. in retail outlets. Countries that choose to prohibit ALL promotion of food products for infants and young children should delete these Subsections. Otherwise, there will be a contradiction with preceding Subsections 4(1), 4(2) and 4(3) which ban the promotion of ALL designated products. See also footnote 3.

⁷ Delete as appropriate; see footnote 6 above

- (c) a warning about the health risks of improper use, preparation or storage and of introducing the product prior to the recommended age;
 - (d) the list of ingredients and the declaration of nutritional value in accordance with relevant national standards or, in the absence of such standard, with the relevant Codex Alimentarius Standard;
 - (e) the required storage conditions both before and after opening, taking into account climatic conditions;
 - (f) the batch number, date of manufacture and date before which the product is to be consumed, taking into account climatic and storage conditions;
 - (g) the name and national address of the manufacturer or distributor; and
 - (h) such other particulars as may be prescribed.
- (3) A manufacturer or distributor shall not offer for sale or sell a designated product if the labelling thereto contains any health or nutrition claim or any representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development and normal functions of the body.

Section 6. Prohibitions related to labelling of infant formula, follow-up formula and young child formula.

- (1) A manufacturer or distributor shall not offer for sale or sell infant formula or follow-up formula unless the container or label affixed thereto, in addition to the requirements of Section 5, conforms to the following:
- (a) contains the words, "IMPORTANT NOTICE" in capital letters and indicated thereunder, the statement "Breastfeeding is the normal and optimal way to feed infants and young children. Breastmilk is important for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses" in characters *[insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 2mm in height"]*;
 - (b) contains the word, "WARNING" and indicated thereunder, the statement, "Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional. It is important for your baby's health that you follow all preparation instructions carefully. If you use a feeding bottle, your baby may refuse to feed from the breast. It is more hygienic to feed from a cup" in characters *[insert particulars relating to character size, placement, appearance, etc. For example, "no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height"]*;
 - (c) has preparation instructions for infant or follow-up formula in powdered form that state that:
 - i. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;
 - ii. it is necessary for formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
 - iii. any unused milk must be discarded immediately after every feed.
 - (d) includes a feeding chart in the preparation instructions;
 - (e) does not use the terms "maternalised", "humanised" or terms similar thereto or any comparison with breastmilk;

- (f) does not use text that may tend to discourage breastfeeding;
 - (g) specifies the source of the protein; and
 - (h) in the case of follow-up formula, states that the product shall not be used for infants less than six months old or used as the sole source of nutrition of infants in characters *[insert particulars relating to character size, placement, appearance, etc.]*
- (2) A manufacturer or distributor shall not offer for sale or sell young child formula unless the container or label affixed thereto, in addition to the requirements of Subsections 5 and 6(1)(c) – (g), states that the product shall not be used to feed infants below 12 months or used as the sole source of nutrition for young children” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

Section 7. Prohibitions related to labelling of ready-to-feed therapeutic food and food products for infants and young children.

- (1) In addition to the requirements of Subsections 5(2) and 5(3), a manufacturer or distributor shall not offer for sale or sell a ready-to-feed therapeutic food or a food product for infants and young children if the container or label affixed thereto contains:
- (a) any text, image or other representation that suggests the suitability of the product for infants under six months including but not limited to references to development milestones clearly reached before six months, the use of pictures of infants appearing to be younger than six months;
 - (b) any text, image or other representation that idealises the product or is likely to undermine or discourage breastfeeding or create a belief that the product is equivalent or superior to breastmilk;
 - (c) any text, image or representation that undermines or discourages appropriate complementary feeding or that may suggest that the product is inherently superior to home prepared complementary foods;
 - (d) any recommendation to feed the product in a bottle or otherwise promote the use of bottle feeding;
 - (e) any endorsement, or anything that may be conveyed or construed as an endorsement by a health professional, an association of health professional or other body; and
 - (f) any element that allows for cross-promotion of any other designated product.
- (2) In addition to the requirements of Subsection (1), the label of a ready-to-feed therapeutic food or a food product for infants and young children shall include:
- (a) A statement in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]* on:
 - i. the importance of exclusive breastfeeding for the first six months and of continued breastfeeding up to two years or beyond; and
 - ii. the recommended age of introduction which is not less than six months (180 days) and a statement that early introduction of complementary foods negatively affects breastfeeding.
 - (b) instructions for preparation, storage, handling and use; and
 - (c) a feeding chart showing the appropriate ration/serving size consistent with guiding principles issued by the World Health Organization.

(3) In addition to the requirements of Subsections (1) and (2):

- All food products for infants and young children containing fruit (fresh or processed in any way) shall include the percentage of fruit in the ingredient list on the label
- the label of a food product for infants and young children shall display the percentage of added water in the ingredients list.
- The label of a food product for infants and young children package containing a spout shall include a warning that “Infants and young children must not be allowed to suck directly from the pouch/pack/container”.
- A food product for infants and young children that has a total sugar content that exceeds specified limits, shall display, on the front of the package, the percentage of energy from total sugar. Limits for different foods are set at 30% energy for dry cereals and fruit/vegetable purées, 40% for dairy-based foods, 20% for vegetable purées with cereals or milk, and 15% for savoury and meal-type foods.
- A product name appearing on the front of package of a food product for infants and young children shall reflect the ingredients in descending order of quantity to ensure they do not mislead parents and caregivers. They must state the name of the ingredient highest in quantity as the first listed ingredient in the product name, and state the names of remaining ingredients in descending order of content. The amount of each ingredient should also be expressed as a percentage of total weight in the ingredient list.

Section 8. Prohibitions related to labelling of skimmed or condensed milk.

A manufacturer or distributor shall not offer for sale or sell skimmed or condensed milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used to feed infants” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

Section 9. Prohibitions related to labelling of low-fat and standard milk

A manufacturer or distributor shall not offer for sale or sell low-fat or standard milk in powder or liquid form, unless the container or label affixed thereto contains the words, “This product should not be used as an infant’s sole source of nourishment” in characters *[insert particulars relating to character size, placement, appearance, etc.]*

[Note: The milks in Sections 8 and 9 do not fall within the scope of this Act unless they are marketed or otherwise represented as suitable for infants. It is recommended that these labelling provisions be incorporated into the country’s food labelling laws. In addition, Sections 8 and 9 will require revision according to the types of milk products available in individual countries.]

Section 10. Prohibitions related to labelling of feeding bottles and teats

A manufacturer or distributor shall not offer for sale or sell a feeding bottle or teat unless the package or label affixed thereto, in addition to the requirements of Section 5(1), indicates in a clear, conspicuous and easily readable manner, in *[insert appropriate language(s)]*, the following particulars:

- (a)** the words, “IMPORTANT NOTICE” in capital letters and indicated thereunder, the statement, “Breastfeeding is best. Breastmilk is the ideal food for the healthy growth and development of infants and young children. It protects against diarrhoea and other illnesses” in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]*;
- (b)** the statement, “Warning: It is important for your baby’s health that you follow the cleaning and sterilisation instructions very carefully. If you use a feeding bottle, your baby may no longer want to feed from the breast” in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 2mm in height”]*;
- (c)** instructions for cleaning and sterilisation in words and graphics;
- (d)** a statement explaining that feeding with a cup is more hygienic than bottle feeding;
- (e)** a warning that children should not be left to self-feed for long periods of time because extended contact with sweetened liquids, including infant formula, may cause severe tooth decay; and
- (f)** the name and national address of the manufacturer or the distributor.

Section 11. Prohibitions related to labelling of pacifiers (dummies)

A manufacturer or distributor shall not offer for sale or sell a pacifier unless, in addition to the requirements of Section 5(1), it is labelled with the words, “Warning: Use of a pacifier can interfere with breastfeeding” in characters *[insert particulars relating to character size, placement, appearance, etc. For example, “no less than one-third the size of the characters in the product name, and in no case less than 1.5mm in height”]*.

CHAPTER III

HEALTH WORKER RESPONSIBILITIES

Section 12. Health worker responsibilities

1. Heads of health care facilities and national and local health authorities shall take measures to encourage and protect breastfeeding and to implement this Act, and shall give information and advice to health workers regarding their responsibilities and particularly ensure that health workers are familiar with all of the information specified in Chapter IV.
2. Health workers shall encourage, support and protect breastfeeding. They are expected to know the provisions of this Act, particularly the information specified in Chapter IV.
3. Health workers shall work to eliminate practices that directly or indirectly impede the initiation and continuation of breastfeeding, such as prelacteal feeds.
4. Health workers shall make in writing a report to the head of their work place, who shall in turn report to the Advisory Board, on any offer a health worker receives for a sample or gift or other benefit from a manufacturer or distributor or on any other contravention of the provisions of this Act.

CHAPTER IV

INFORMATION AND EDUCATION

Section 13. Information and education materials about infant and young child feeding

Information and education materials, whether written, audio or visual, which refer to infant and young child feeding shall:

- (1) contain only correct and current information and shall not use any pictures or text that encourage artificial feeding, or the use of feeding bottles or that discourage breastfeeding;
- (2) be written in [insert appropriate language(s)];
- (3) not give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or to breastfeeding;
- (4) not contain the brand name or logo of any designated product nor of any manufacturer or distributor of a designated product; provided that this clause shall not be applicable to information about designated products intended for health professionals as authorised by Section 15 of this Act; and
- (5) clearly and conspicuously explain each of the following points:
 - (a) the benefits and superiority of breastfeeding;
 - (b) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond;
 - (c) how to initiate and maintain exclusive and sustained breastfeeding;
 - (d) why it is difficult to reverse a decision not to breastfeed;
 - (e) the importance of introducing complementary foods from the age of six months;
 - (f) how and why any introduction of artificial feeding, the use of a feeding bottle or the early introduction of complementary foods negatively affects breastfeeding; and
 - (g) that complementary foods can easily be prepared at home using local ingredients.

Section 14. Information and education materials about artificial feeding or feeding bottles.

- (1) If the material referred to in Section 13 includes the topic of artificial feeding or the use of a feeding bottle, it must also include the following points:
 - (a) instructions for the proper preparation, storage and use of the product including cleaning and sterilisation of feeding utensils;
 - (b) how to feed infants with a cup;
 - (c) the health risks of artificial feeding, the use of a feeding bottle and improper preparation of the product;
 - (d) explain that
 - i. powdered formula is not sterile and may be contaminated with pathogenic microorganisms during the manufacturing process or may become contaminated during preparation;

- ii. it is necessary for powdered formula to be prepared one feed at a time using water first boiled and then cooled to not less than 70 °C; and
 - iii. any unused milk must be discarded immediately after every feed.
 - (e) the approximate financial cost of feeding an infant or a young child with such a product in the recommended quantities and
 - (f) that the practice of providing follow-up formula and young child formula is not necessary.
- (2) Except as provided in Section 15 concerning product information for health professionals, materials that include the topic of artificial feeding shall not contain any health or nutrition claims or other representation that states or suggests that a relationship exists between the product or constituent thereof and health, including the physiological role of a nutrient in growth, development or normal functions of the body.

Section 15. Product information for health professionals

Manufacturers and distributors may give materials about designated products to health professionals if such materials

- (1) are restricted to scientific and factual matters regarding the technical aspects and methods of use of the product;
- (2) provide references to published and peer-reviewed studies to support any representation or claim that states or suggests that a relationship exists between the product or a constituent thereof and health, growth or development; and
- (3) are otherwise in accordance with Sections 13 and 14 of this Act.

Section 16. Submission of materials to Advisory Board (OPTIONAL)

Any person who produces or distributes any materials referred to in this Chapter shall submit copies to the Advisory Board according to procedures as shall be prescribed⁸.

⁸ Consider whether Government has the capacity and resources to review and approve materials prior to their distribution

CHAPTER V ADMINISTRATION

Section 17. Implementation

- (1) The Ministry of Health is principally responsible for the implementation of this Act.
- (2) The Minister of Health shall, when necessary, call upon other ministries to ensure the implementation of this Act.
- (3) For the purpose of implementing this Act, the Minister of Health shall have the following powers and functions:
 - (a) to promulgate such rules as are necessary or proper for the implementation of this Act and the accomplishment of its purposes and objectives;
 - (b) to call for consultations with government agencies and other interested parties to ensure implementation and strict compliance with the provisions of this Act and the rules promulgated hereunder;
 - (c) to cause the enforcement of this Act and to appoint an official within the Ministry of Health to carry out this function on his or her behalf; and
 - (d) to exercise such other powers and functions that may be necessary for or incidental to the attainment of the purposes and objectives of this Act.

Section 18. National Advisory Board for the Promotion and Protection of Breastfeeding

- (1) There shall be a National Advisory Board for the Promotion and Protection of Breastfeeding to be composed of the following members:

[In this section, list the members to be included in this inter-disciplinary committee. Countries usually include representatives of relevant ministries such as Health, Education, Communications and Trade, and representatives of organisations of health professionals, consumers, breastfeeding support groups as well as experts in relevant fields. The proviso excludes manufacturers and distributors of designated products from the committee because their involvement would create conflicts of interest. Such conflicts would compromise independence, integrity and credibility of a committee that advises the government on enforcement of the law.]

- (a) The Minister of Health or his representative who shall be its ex officio Chairman;
 - (b)
 - (c) . . .
 - (x) Such other persons as the Minister may, by Notice in the Official Gazette, appoint as members of the Advisory Board; provided that no person shall be appointed who has any direct or indirect financial interest in any designated product.
- (2) The Minister shall appoint the members of the Advisory Board within 90 days of the date of enactment.
- (3) The members of the Advisory Board shall hold office for a term of 3 years and shall be eligible for re-nomination.

- (4) Any member of the Advisory Board may, at any time, resign his or her office by writing to the Minister or shall vacate his or her office if the Minister so directs. A vacancy shall be filled in the same manner as the original appointment for the balance of the unexpired term.
- (5) The Advisory Board may invite national or foreign experts to take part in the meetings as observers and may constitute committees or appoint experts for the purpose of detailed study of any matter set before it.
- (6) The Minister may, by Notice published in the Official Gazette, change the size and composition of the Advisory Board.

Section 19. Administration of the Advisory Board

- (1) The Minister shall appoint the Secretary of the Advisory Board and such other officers as he or she deems necessary to carry out the purposes of this Act.
- (2) The Advisory Board shall hire permanent staff necessary to carry out its functions, subject to the budgetary approval of the Minister.
- (3) The Advisory Board shall meet as often as it deems necessary, but not less than once every month at such time and place as the Secretary shall indicate.
- (4) The Secretary shall call meetings at the direction of the Chairman; shall maintain minutes of the meetings and shall perform such other duties as may be directed by the Advisory Board.
- (5) Two-thirds of the members of the Advisory Board shall constitute a quorum for a meeting.
- (6) A majority vote of the members present shall be sufficient to approve any business presented in a meeting of the Advisory Board.
- (7) Decisions of the Advisory Board shall be certified by the Secretary.
- (8) The Advisory Board may make such other administrative rules as may be required for its proper functioning.

Section 20. Powers and functions of the Advisory Board

- (1) The Advisory Board shall have the following powers and functions:
 - (a) to advise the *[insert Head of State]* and the Minister on national policy for the promotion and protection of breastfeeding;
 - (b) to create regional committees to carry out the functions of the Advisory Board at the regional level, as may be prescribed;
 - (c) to advise the Minister on designing a national strategy for developing communication and public education programmes for the promotion of breastfeeding; information and educational materials on the topics of infant and young child feeding; continuing education for health workers on lactation management and the requirements of this Act; curricula for students in the health professions that include lactation management and to ensure widespread distribution of and publicity concerning this Act, in a method as may be prescribed;
 - (d) to review reports of violations or other matters concerning this Act;
 - (e) to issue instructions to inspectors as to actions to be taken, or take such other actions as the case may be, against any person found to be violating the provisions of this Act or the Rules promulgated pursuant thereto;

- (f) to scrutinize materials submitted in accordance with Section 16 and recommend appropriate actions to be taken in the case of a violation of Chapter IV; and
- (g) such other powers and functions, including the powers of an Inspector, as are conferred by the provisions of this Act and as may be prescribed.

Section 21. Registration of designated products

- (1) The Minister of Health shall cause all designated products to be registered in accordance with such conditions and procedures as may be prescribed.
- (2) The Minister of Health shall, by notification in the Official Gazette, fix the date after which no designated product that is not registered may be imported, manufactured or sold.
- (3) A person applying for registration of a designated product shall furnish such information and samples as may be prescribed.
- (4) Once the registration of a designated product has been approved, a Certificate of Registration shall be issued.
- (5) No Certificate of Registration shall be granted unless the designated product is in accordance with the [insert applicable Food Quality Standards] and has a label which is in accordance with the requirements contained in Chapter II of this Act.

Section 22. Inspectors

The Minister shall appoint such persons as he or she sees fit having the prescribed qualifications to be Inspectors for purposes of this Act within such local limits as he or she may assign to them respectively, provided that no person who has any direct or indirect financial interest in any designated product shall be so appointed.

Section 23. Powers of inspectors

- (1) An inspector may, within the local limits for which he or she is appointed:
 - (a) inspect any premises where any designated product is imported, manufactured, sold, stocked, exhibited for sale, advertised or otherwise promoted and all relevant records;
 - (b) institute prosecution with respect to violations of this Act and the Rules made pursuant thereto; and
 - (c) exercise such other powers as may be prescribed.

Section 24. Procedure for inspectors

- (1) Inspectors shall inspect, not less than the number of times as may be prescribed, the premises as may be prescribed.
- (2) After each inspection, the inspector shall submit a report including any finding of a violation of this Act and the Rules made pursuant thereto, to the Advisory Board and seek instructions as to the action to be taken in respect of such contravention.
- (3) Institute enforcement, where applicable.

CHAPTER VI SANCTIONS, PROCEDURE

Section 25. Penalties

- (1) Any person who him or herself or on behalf of any other person contravenes Sections 3 and 4 shall be punishable with imprisonment for a term which shall not be less than *[time]* or a fine which shall not be less than *[amount]* or both.
- (2) Any person having been convicted of an offence under Subsection (1) and who is again convicted of an offence under that Subsection, shall be punishable with imprisonment for a term which shall not be less than *[time]* or with a fine that shall not be less than *[amount]*.
- (3) Any person who contravenes any other provision of this Act or the Rules made pursuant thereto may be subject to a fine of up to *[amount]* or a period of imprisonment of up to *[time]*.

Section 26. Improvement Notices, Cease and desist orders, etc.

- (1) If the Minister or any official appointed by the Minister has reasonable grounds for believing that any person is failing to comply with the provisions of this Act or the Rules promulgated thereto, he or she may, by a notice served on that person (in this Act referred to as an “improvement notice”):
 - (a) state the grounds for believing that the person is failing to comply with this Act or the Rules promulgated thereto;
 - (b) specify the matters which constitute the person’s failure so to comply;
 - (c) specify the measures which the person must take in order to secure compliance; and
 - (d) require the person to take those measures, or measures which are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.
- (2) In addition to the powers conferred under Subsection (1), the Minister or any official appointed by the Minister shall have the power to make cease and desist orders upon receiving a report from an inspector or the Advisory Board of a violation of the provisions of this Act or the Rules promulgated pursuant thereto.
- (3) Any person who fails to comply with an improvement notice or cease and desist order under Subsection (1) or (2) shall, after notice and an opportunity to be heard have been given, be guilty of an offence.

Section 27. Suspension or revocation of certificate of registration

Where any person has been found to have contravened any of the provisions of this Act, or the Rules pursuant thereto, the Minister, upon written recommendation of the Advisory Board, and after notice and an opportunity to be heard have been given, may suspend or revoke any Certificate of Registration that has been issued to that person pursuant to this Act.

Section 28. Suspension or revocation of professional licence

Where any health professional has been found to have contravened any provision of this Act, or the Rules pursuant thereto, the Minister may recommend to the relevant authority the suspension or revocation of any licence for the practice of that person’s profession.

Section 29. Suspension or revocation of licence, permit or authority

[Note: If a licence to manufacture, import or sell is required, give the Minister the power to suspend or revoke that licence.]

Section 30. Appeal

There shall be a right of appeal to the [insert higher court] within 35 days of the judgment.

Section 31. Strict liability for officers, directors, etc.

When the person guilty of an offence under this Act is a corporation, company, partnership, firm or other association, every director, officer, partner, and employee of the corporation, company, partnership, firm or other association, shall also be liable for that offence unless he or she proves that the offence was committed without his or her knowledge or consent.

Section 32. Institution of prosecution

- (1) Prosecution under this Act may be instituted only by:
 - (a) an Inspector appointed pursuant to Section 22;
 - (b) a member of the Advisory Board; or
 - (c) a representative of such voluntary organisation engaged in the field of child welfare and development or child nutrition as the Minister, by notification in the Official Gazette, may authorise in this behalf

Section 33. Public enforcement

- (1) Any person has the right to lodge a formal complaint to the Advisory Board, which may recommend that proceedings be instituted against any person relating to a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.
- (2) Any person has the right to commence an action for damages in [a court of law] against any manufacturer or distributor or other person for any harm suffered as a result of a violation of any provision that constitutes an offence under this Act or Rules made pursuant thereto.

Section 34. Power to make Rules

- (1) The Ministry of Health may, by notification in the Official Gazette, make Rules for carrying out the purposes of this Act.
- (2) In particular but notwithstanding the generality of the foregoing provision, such Rules may prescribe:
 - (a) the functions of the Advisory Board;
 - (b) conditions and procedures for the registration of designated products;
 - (c) qualifications and powers of and procedures for Inspectors appointed pursuant to this Act; and
 - (d) procedures for submitting educational or informational materials to the Advisory Board.

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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